MASSETER MUSCLE ADAPTATION FOLLOWING ORTHOGNATHIC SURGERY

FERNANDO DUARTE

DMD, MSc (OMFS), MSc (Laser), Oral Surgeon Specialist (OMD)

European Board of Oral Surgery (EBOS)

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ABSTRACT

After facial deformity surgery, long-term skeletal stability relies heavily on the structural and functional adaptation of the facial muscles. If these muscles, particularly the pterygo-masseteric sling comprising the masseter and medial pterygoid, cannot adjust to post-surgical changes in length or orientation, they may exert undesirable forces on their attachments. This failure to adapt can cause skeletal instability and compromise surgical outcomes. While treatment options have expanded to include myofunctional appliances for children and orthognathic surgery for adults, a fundamental principle of adult surgery is avoiding the stretching of the pterygomasseteric sling, which increases the risk of relapse. If muscles revert to their original functioning length faster than they can adapt organically, or if their attachments migrate, bone resorption can occur due to inadequate muscle support. Consequently, capturing functional adaptation accurately requires multiple sophisticated assessment measures.

Academic support from UCL Eastman Dental Institute helped identify the project topic, structure the four developments presented, define repeatability tests, and conduct pilot studies. Technical support from CEiiA supervised the construction of two devices used in Phase 1: the Occlusal Force Diagnostic System and the Bite Training Machine. The development of the MRI protocol at the John Radcliffe Hospital - MRI Centre, presented in Phase 3, enabled the identification and visualisation of muscle fibres and their orientation. The Medical, Dental, and Surgical Center – Clitrofa, Portugal provided clinical support by selecting patients, performing surgical interventions, and conducting follow-ups for the four phases presented.

The selected patients for the pilot and follow-up studies underwent a bimaxillary osteotomy, combining a maxillary Le Fort I impaction procedure and a sagittal split advancement of the mandible.

Future studies with larger patient cohorts are actively assessing surgical efficacy further. These evaluations will increasingly employ ultrasonography, a portable, radiation-free method that provides real-time, cross-sectional assessment of soft-tissue thickness and adaptation.

ACKNOWLEDGEMENTS

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A particular thanks goes to Professor João Neves da Silva for his help with the statistics; his contribution gave order and organisation to my studies.

To Manuel Oliveira, for his help in developing the machines we built —a good friend always ready to help —this work is also yours.

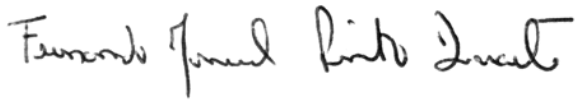
To my family for keeping my spirits and hopes always above ground and for being there when I needed them.

This thesis is dedicated to my beloved wife Carina Ramos and to my two children Henrique Mar and Bruna Mar; together, they are the reason for my life.

DECLARATION

I declare that whilst registered as a candidate for the above degree, I have not been registered for any other research award. The results and conclusions embodied in this thesis are the work of the named candidate and have not been submitted for any other academic award.

The work undertaken for this degree has not been submitted elsewhere for any other award. The work contained within this submission is my work and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due acknowledgement has been made in the text.



Fernando Duarte

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LIST OF ABBREVIATIONS

MRI: Magnetic Resonance Imaging

PDL: Periodontal Ligament

TMJ: Temporomandibular Joint

MyHC: Myosin Heavy Chain

LFS: Long Face Syndrome

SFS: Short Face Syndrome

VDO: Vertical Dimension of Occlusion

EMG: Electromyographic

VFD: Vertical Facial Deformity

MMF: Maxillomandibular Fixation

CL/P: Cleft Lip and Palate

PREFACE

My journey in Oral and Maxillofacial Surgery began over twenty-seven years ago when I had the opportunity to train in this field. I earned a Master of Science degree in Oral and Maxillofacial Surgery from the Eastman Dental Institute at University College London (UK). The clinical and research experience gained during my studies amplified my interest in orthognathic surgery and its surgical management.

In pursuit of innovation, I expanded my professional horizons by completing a Master's in Laser Dentistry at the Laser & Health Academy in Ljubljana (Slovenia) and a second Master of Science degree in Laser Dentistry at the Catholic University of Sacred Heart in Rome (Italy).

As Clinical Director and Oral Surgeon Specialist recognised by the Portuguese Dental Association (OMD), I lead a private clinic in Trofa (Portugal), specialised in Oral and Maxillofacial Surgery and Oral Implantology.

Recently, I had the opportunity to participate in a research project that explored advanced methods for measuring muscle structure and function. This project specifically focused on the importance of muscle adaptation for the effectiveness of therapeutic approaches in orthognathic surgery. I believe that assessing masticatory function requires multiple evaluation methods; therefore, it is essential to take simultaneous measurements whenever possible.

The studies conducted over the past ten years have afforded me the opportunity to deserve recognition and obtain some awards, examples of which are: In 2019, "Portuguese of Value" prize by Lusopress, a company based in Paris that aims to recognise and reward Portuguese personalities who stand out in various areas of professional activity. In 2022, "Honorary Academic" of the Brazilian Academy of Dentistry and in 2023, "Personality of the Year" by the Brazilian Society of Dentistry and Integrative Health.

This thesis presents new insights from 12 publications that focus on evidence-based findings in the diagnosis, therapy, and prognosis of orthognathic surgery. The commentary is organised into an introduction and a literature review, followed by four chapters that explore studies on the structure (occlusal force and occlusal pressure) and

function (area/volume and biomodelling) of the masseter muscle following orthognathic surgery. The thesis concludes with an integrated discussion, conclusion, and summary. At the end of each chapter, all peer-reviewed research articles included in this thesis are presented, along with my contributions to each article and their citation metrics.

I believe that this body of published work, entitled “Masseter Muscle Adaptation Following Orthognathic Surgery”, contributes to knowledge in this field and raising the profile and status of clinical evidence-based research.

LIST OF PUBLISHED ARTICLES

Duarte F., Silva JN., Hopper C., Hunt N. The importance of Occlusal Force Measurement in Orthognathic Surgery - A pilot study. Journal of Surgery, Periodontology and Implant Research 2020; 2:13-26.doi:https://doi.org/10.35252/jspir.2020.1.002.1.02

Duarte F., Silva JN., Ramos C., Hopper C. Measurement of Occlusal Force in Orthognathic Surgery using Force Sensing Sensors. Int J of Dent & Ora Hea 2021; 7(8):94-108

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Duarte F., Silva JN., Ramos C., Hopper C. Evaluation of Occlusal Force Changes in Orthognathic Surgery using Force Sensing Sensors in 3 Years of Follow-up. Annals of Medicine & Surgery 2024; 86(9):5199-5205

Duarte F., Silva JN., Hopper C., Hunt N. The Importance of Pressure Measurement in Orthognathic Surgery. Scientific Archives of Dental Sciences 2020; 3(9):01-11

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INTRODUCTION & LITERATURE REVIEW

INTRODUCTION

Orthodontic and surgical technical advances in the last 10 years have created treatment opportunities for a wide range of craniofacial skeletal disorders, in both adolescent and adult patients. In growing children, interventions may include myofunctional orthodontic appliance therapy or distraction osteogenesis procedures, whereas in adults, the mainstay approach typically involves orthognathic surgery.

The literature agrees that, for a change in craniofacial morphology to remain stable, the muscles acting on the facial skeleton must be capable of adapting their structure and, therefore, their function (Noden, 2006). Failure of the muscles to adapt to the change in their length or orientation will place undesirable forces on the muscle attachments, leading to potential instability of the skeleton. Adaptation can occur through various processes, including those within the neuromuscular feedback mechanism, through changes within muscle structure, through altered muscle physiology, and changes at the muscle/bone interface.

Post-surgical stability is a key measure of a surgical procedure's effectiveness, as it directly reflects the ability to maintain desired outcomes over time, whether in the short term or long term following surgery. During the first post-surgical year, the surgical movements can be placed in four groups, ranging from highly stable to problematic. The procedures typically used to treat Class II/long face problems are quite stable in the first year; the procedures typically used to treat Class III problems are less so. A surprisingly large number of patients experience skeletal changes from one to five years post-surgery, when healing is complete, and in that time frame, clinically relevant (>2 mm) changes are more likely in Class II/long face patients than in Class III patients. Fewer patients exhibit long-term changes in dental occlusion than in skeletal structures because adaptive changes often occur in the dentition as skeletal changes occur. In both the post-surgical and post-treatment periods, most changes occur in a minority of patients, so it is better to consider the percentage of patients with clinically significant changes than the mean change. The database makes it clear that clinically satisfactory results can be obtained and maintained long-term in the great majority of orthognathic surgery patients, but the

differences among various directions of movement must be considered when treatment is planned (Proffit *et al.*, 2007).

It is now accepted that because there is no single method for assessing masticatory function, several measures should be taken, and whenever possible, simultaneously (Hunt *et al.*, 2006). However, the literature lacks studies that simultaneously evaluate masticatory function using multiple methods, thereby justifying this project.

This research project was designed to apply several newly developed, more sophisticated methods for measuring muscle structure and function to a situation in which muscle adaptation is pivotal to the success of a therapeutic approach.

This pilot investigation was subdivided into 4 phases:

Phase 1: Measurement of occlusal force

One of the primary objectives of orthognathic treatment for patients with dentofacial deformities is to enhance masticatory function and aesthetics. Numerous studies have documented masticatory function, including bite force, occlusal contact and masticatory efficiency, in patients with mandibular prognathism before and after orthognathic surgery (Harada *et al*., 2000; Nagai *et al*., 2001), but few reports compared the results with those in controls with normal occlusion (Nagai *et al*., 2001). There have also been a few studies that involved the evaluation of these parameters at the initial medical consultation for patients undergoing orthognathic surgery (Thomas *et al.*, 1995). However, no reports have simultaneously assessed the relationships between bite force, occlusal contact, and masticatory efficiency in patients with mandibular retrognathia compared to controls with normal occlusion.

Phase 2: Measurement of occlusal pressure

Despite its importance, pressure often receives very scant attention. Bite force has been used to evaluate masticatory function in patients before and after orthognathic surgery (Ellis *et al.*, 1996). Usually, it has been measured using a custom bite-force transducer, however tactile pressure-sensor films are an accurate, efficient, and inexpensive method to determine pressure. These films offer the converting industry an opportunity to determine both the distribution and the magnitude of most operations in which pressure is important (Ellis *et al.*, 1996).

Phase 3: Use of Magnetic Resonance Imaging (MRI) to individualise the masseter muscle and measure its area and volume

MRI is increasingly used to study the structure of human skeletal muscle in health and disease (Clague *et al*., 1995). MRI offers information on the muscular system in vivo, by directly measuring muscle structure with non-ionising radiation. Computer-based image analysis systems can quantify the composition of contractile and noncontractile (fat or connective tissue) components of human muscles (Clague *et al*., 1995). As various clinical conditions can alter the relative proportions of contractile and noncontractile tissue components in human muscle, quantifying these components is of great value (Holmbäck *et al.*, 2002).

The MRI machine used was a Sigma MR/I Twinspeed from GE Medical Systems. To standardise the scanning process, a scanning protocol was developed and applied that describes the preferred imaging parameters and provides the imaging technician with an area to note specifics. Specifications of the applied protocol: T1-FSE (Fast Spin Echo) is a rapid type of image contrast that highlights fat, weighted images and is excellent for showing anatomical details and, with contrast agents, detecting inflammation or tumors. 3D Cor T1 Se (3D Coronal T1 Spin Echo): A three-dimensional scan taken from a front-to-back perspective (coronal) using spin echo, which provides high-resolution anatomical detail. The patient must remain completely still during the scan; if the patient moves during the scan, it will need to be repeated. Only the original fine slice data must be used in the software; reformats will not be accepted. Fine overlapping slices must be used, with a thickness of 1 mm (or nearest to) and a spacing of 0.8 mm. The objective was to extract the muscle from the image (margin identification, extract the muscle across the 3 spatial planes, and calculation of area and volume). For the results, the image with the largest muscle area was used. The software allows the correction of limits at any time, which gives the observer the capacity of double-check the entire process.

Phase 4: Analysis of Bio-modelling of the masseter muscle

Bio-modelling is the generic term describing the ability to replicate the morphology of a biological structure in a solid substance. Specifically, bio-modelling has been defined as “the process of using radiant energy to capture morphological data on a biological structure and the processing of such data by a computer to generate the code

required to manufacture the structure by rapid prototyping apparatus". A biomodel is the product of this process, and virtual reality is the generic term coined for the visualisation medium (D'Urso *et al.*, 1999). The goal was to develop the system and software to produce accurate and reproducible data for masticatory muscles, which not only provided data for muscle area and volume, but also was of sufficient detail to enable analysis of muscle fibre orientation of masseter muscle. The masseter muscle displays a penniform structure typically characterised by the presence of alternating muscular/aponeurotic layers. The anatomical sections and the MRI section in the same plane allowed the appearance of the intramuscular aponeurotic layers on the MRI to be defined.

A study group of 10 patients attending the combined orthodontic/orthognathic surgery outpatient clinic of Medical, Dental and Surgical Center - Clitrofa, in Trofa, Portugal, were selected for the present study by a convenience non-probability sampling method. All the selected patients present skeletal class III malocclusion characterised by a concave facial profile with lower lip protrusion or upper lip retrusion or a combination of the two. The most consistent characteristics of skeletal class III malocclusion seem to be the dental Angle's class III canines and molars, the presence of anterior cross-bite, and retroclined mandibular incisors.

Patients scheduled for a bimaxillary osteotomy, combining a maxillary Le Fort I impaction procedure with sagittal split advancement of the mandible were selected to form the study group. Vertical moves of 2 mm for minor, 4 mm for intermediate, and 6 mm for major impactions are appropriate for all cases. These three categories also simplify the decision-making process. Before surgery, all patients signed their informed consent form. The inclusion criteria were as follows: All patients presenting the joint orthodontic/orthognathic clinic for orthognathic surgery and who accepted the treatment. Diabetic patients were included but noted. The exclusion criteria were as follows: Patients who gave a history of myopathies, endocrine disorders, connective tissue disorders, autoimmune diseases, bone disease, bleeding disorders, and regular use of prescribed drugs were excluded from the study.

Ethical approval: This project has approval from the Joint Research & Ethics Committee of UCL Hospitals NHS Trust, Reference No.03/E012.

Data registration: This project is covered by the UCL Data Protection Registration Reference No. Z6364106, Section 19, Research: Health Research.

LITERATURE REVIEW

Muscle Structure and Organisation

From infancy to old age, significant changes occur in both the quality and quantity of the skeletal muscles (Jones & Round, 1990). The skeletal muscle is developed from myoblasts, and the number of fibres in each human muscle is more or less, set at birth (Saltin & Gollnick, 1983). Muscle fibres, also called muscle cells, are the individual cells that make up skeletal muscle tissue, while myofibrils are the smaller contractile units within these fibres, composed of repeating sarcomeres that facilitate muscle contraction (Goldspink, 1976). Neural influences are necessary for the differentiation and postnatal growth of the muscle fibres. As the muscles grow in size and strength, there is an increase in the diameter and length of the individual muscle fibres (Schmalbruch, 1985). The circumferential growth occurs due to the addition of myofibrils (Saltin & Gollnick, 1983), while longitudinal growth and adaptation primarily happen through the addition of sarcomeres (a structural unit of a myofibril in striated muscle, consisting of a dark band and the nearer half of each adjacent pale band) in series at the ends of the myofibrils (Goldspink, 1976). During puberty, the increase in muscle bulk is particularly rapid; thereafter, adult muscle fibre cross-sectional areas are reached, with generally larger sizes seen in men compared to women (Jones & Round, 1990).

Sex steroids, growth hormones, and physical activity all play important roles in maintaining muscle mass throughout life (Shahid *et al.*, 2024). Inactivity can lead to muscle atrophy, while regular training promotes muscle hypertrophy by increasing the diameter of individual muscle fibres (Dons *et al.*, 1979; Saltin & Gollnick, 1983; Schmalbruch, 1985). The muscle enzymes responsible for energy are released during anaerobic and aerobic muscular effort and the number of capillaries adapt to the prevailing level of activity (Howald, 1982; Saltin & Gollnick, 1983). However, excessive use of muscles, characterised by prolonged activity and high-intensity contractions without adequate rest, can result in local ischemia, increased cell membrane permeability, oedema, and ultimately cellular damage (Astrand & Rodahl, 1986; Edwards, 1988; Sjøgaard *et al.*, 1988). With necrosis of muscle tissue, fibrosis may take place, as well as regeneration of muscle fibres from satellite cells, i.e., resting myoblasts (Schmalbruch, 1985), which also contribute to the muscle growth (Goldspink, 1976).

Muscle mass and overall strength gradually decline during and after the fifth decade of life (Grimby & Saltin, 1983). This decline is particularly pronounced in women following menopause, while men experience a less severe reduction until around the age of 60, after which the decrease may be even more significant than in women (Grimby & Saltin, 1983; Jones & Round, 1990). The age-related wasting of muscle is partly caused by atrophy of muscle fibres (Grimby & Saltin, 1983; Saltin, 1989). Although ageing processes in muscles are inevitable, they can be mitigated by exercise and physical activity up until the age of 80, which help keep the remaining muscle fibres functionally healthy (Klitgaard *et al*., 1990a). Thus, one condition for maintaining the function of the masticatory muscles is a dentition without significant tooth loss (Feldman *et al*., 1980).

Muscle Fibres (Muscle Cells)

The muscle fibres are cylindrical or spindle-shaped cells with considerable variation in size (10-100 μm) and length (1-200 mm); some fibres such as those in the sartorius muscle of the thigh, can be up to 30 cm long. This variation occurs not only between different muscles in the body but also among individuals, influenced by factors such as hormones (Saltin & Gollnick, 1983; Astrand & Rodahl, 1986; Jones & Round, 1990). The average diameter in adult jaw elevator muscles ranges from 20 to 60 μm (Eriksson & Thornell, 1983), and the length from about 15 to 40 mm (Schumacher, 1961). Between the muscle fibres is the endomysium, a thin connective-tissue matrix, with a supply of capillaries, of which the density in the jaw muscles is considered to be high and uniform (Taylor, 1976). From 10 to more than 100 fibres are bundled in fascicles by a thicker layer of connective tissue, the perimysium, while the entire muscle is encased in the epimysium, a dense connective tissue layer that protects the muscle and merges with the tendinous insertions to the bone (Jones & Round, 1990). The tendinous structure of the jaw-closing muscles is complex and large (Schumacher, 1961).

Based on myosin-ATPase staining of muscle sections at pH 9.4, muscle fibres are classified into two main types (Taylor, 1976; Buchthal & Schmalbruch, 1980). Type I fibres are characterised by lighter staining and low ATPase activity, which are typically associated with longer contraction times (slow twitch) and fatigue resistance. In contrast, Type II fibres exhibit darker staining and higher ATPase activity, correlating with rapid

contraction times (fast twitch) and greater fatigability. Type II fibres can be further subclassified into types IIA, IIB, and IIC (Tuxen *et al*., 1992), and IIB is taken to be more rapidly fatigued than IIA (Buchthal & Schmalbruch, 1980; Schmalbruch, 1985). There is a genetic basis for fibre composition of the muscles in the body (Gollnick & Matoba, 1984), and the main fibre differentiation is completed at about one year of age (Saltin & Gollnick, 1983). However, a training-induced adaptation in the fibre type distribution between subgroups may occur, especially from IIB to IIA (Buchthal & Schmalbruch, 1980; Howald, 1982, Klitgaard *et al.*, 1990b). This is probably due to a shift in the preponderance of one isoform of heavy-chain peptides in the myosin molecule to another with different contractile properties (Saltin, 1989; Klitgaard *et al.*, 1990a; Klitgaard *et al.*, 1990b).

In the jaw-closing muscles, there is a significant difference in the diameters of type I (40-60 μm) and type II fibres. Type II is much smaller (20-30 μm) (Eriksson & Thornell, 1983; Tuxen *et al.*, 1992), and fibres with ATPase activity intermediate to types I and II are frequent. Type I fibres predominate, most markedly in the masseter muscle (70-80%) (Eriksson & Thornell, 1983; Tuxen *et al*., 1992) and to a lesser extent in the temporalis muscle (52-90%) (Eriksson & Thornell, 1983). However, the distribution varies slightly among the masticatory muscles and in different parts of the muscles (Eriksson & Thornell, 1983). The fibre size and distribution seem to influence elevator muscle strength during biting and chewing, as positive correlations have been shown between the diameter of type II fibres and bite force (Ringqvist, 1974), and between the area and diameter of type I fibres and the amplitude of chewing activity (Bakke *et al*., 1993). Histochemical analysis of muscle fibres, demonstrating the activity of the enzyme adenosine triphosphatase, clearly distinguishes between type I and type II fibres. It also indicates the presence of some fibres in an intermediate category, referred to as type IIx fibres. Type IIx fibres or fast-glycolytic fibres are the largest, fastest-twitching skeletal muscle fibres in humans, designed for explosive, high-intensity, short-duration power output. They rely on anaerobic metabolism (glycolysis) rather than oxygen, making them highly fatigable, with low mitochondrial density and high myosin ATPase activity (Ringqvist, 1974; Schiaffino *et al.*, 1989).

Voluntary skeletal muscle requires innervation for contraction. A single nerve may innervate a single muscle fibre (fibre control) or, through branching, connect to as

many as 160 or more muscle fibres. Regardless of the pattern, this arrangement is known as a motor unit. Innervation happens at a structure called the motor end plate. At the site of innervation, the nerve loses its myelin sheath, although the Schwann cell covering remains intact. The nerve terminal forms a dilated ending that fits into a corresponding depression on the muscle fibre surface, creating the neuromuscular junction. Between the nerve ending and the sarcolemma lies the synaptic cleft, across which neurotransmitters are released to initiate muscle contraction. The sarcolemmal surface at this junction is organised into junctional folds, which increase the surface area for receptor density and enhance signal transmission efficiency. Each motor unit innervates muscle fibres of a single type, ensuring coordinated contraction (Wheater *et al*., 1985).

Two important neuronal structures associated with the muscle need to be described: the muscle spindle and the Golgi tendon organ. Muscle spindles and Golgi tendon organs are both sensory receptors involved in proprioception, which is the sense of the position and movement of the body. They monitor different aspects of muscle function and provide feedback to the nervous system (Zarb *et al*., 1994; Price *et al.,* 1998).

The muscle spindle is an encapsulated proprioceptor that detects changes in muscle length. It consists of a connective tissue sac approximately 5 mm long and 0.2 mm in diameter, containing 2 to 12 specially adapted muscle fibres known as intrafusal fibres. These intrafusal fibres are narrower than the extrafusal fibres and come in two forms. The first type is called a nuclear bag fibre, so named because many nuclei are concentrated in the fibre. The second type is called a nuclear chain fibre, as the nuclei are aligned in a single row. The nuclear bag fibre receives afferent innervation from a nerve that spirals around it, known as the primary afferent. The nuclear chain receives afferent innervation from two sources: the primary afferent, which supplies the central regions of the chain fibres, and a secondary supply that terminates on each side of the primary ending. It is believed that the primary ending is responsible for detecting both the degree and rate of stretch, while the secondary afferent responds only to the degree of stretch. Additionally, the intrafusal fibres of the muscle spindle retain their afferent nerve supply (Zarb *et al.*, 1994). In contrast, Golgi tendon organs are located at the junction between muscles and their tendons or aponeuroses, where they exert their pulling force. They are about half the size of a muscle spindle and consist of a capsule surrounding a group of collagen fibrils. The afferent nerve breaks up within the capsule, and the terminal fibres

ramify between the collagen bundles. The nerves are stimulated by tension between the collagenous bundles when the tendon is under compression (Zarb *et al.*, 1994; Price *et al.*, 1998). It has been argued that the relatively high proportion of type IIC and IM fibres in the muscles of mastication indicates that such fibres are permanent residents in the masticatory muscle, suggesting special functional characteristics for them. The relationship between fibre character and its innervation is significant and merits further exploration (Zarb *et al.*, 1994; Price *et al.*, 1998). The periodontal ligament (PDL) acts as a crucial sensory organ, containing specialized mechanoreceptors that function as tension and pressure sensors to provide proprioceptive feedback for the masticatory system. These receptors are vital for coordinating jaw movement, providing unique feedback mechanisms that complement, rather than simply mimic, the feedback from the temporomandibular joint (TMJ) capsule (Proske & Gandevia, 2012). The TMJ capsule is a key receptor, providing information on the joint's position (joint position sense). However, the PDL provides immediate, high-resolution feedback on occlusal forces, the pressure exerted on the teeth themselves. While the TMJ capsule provides info on jaw position (joint angle), the PDL tells the brain what is happening to the teeth. This is crucial for regulating the biting force, which is particularly sensitive to PDL health (Proske & Gandevia, 2012).

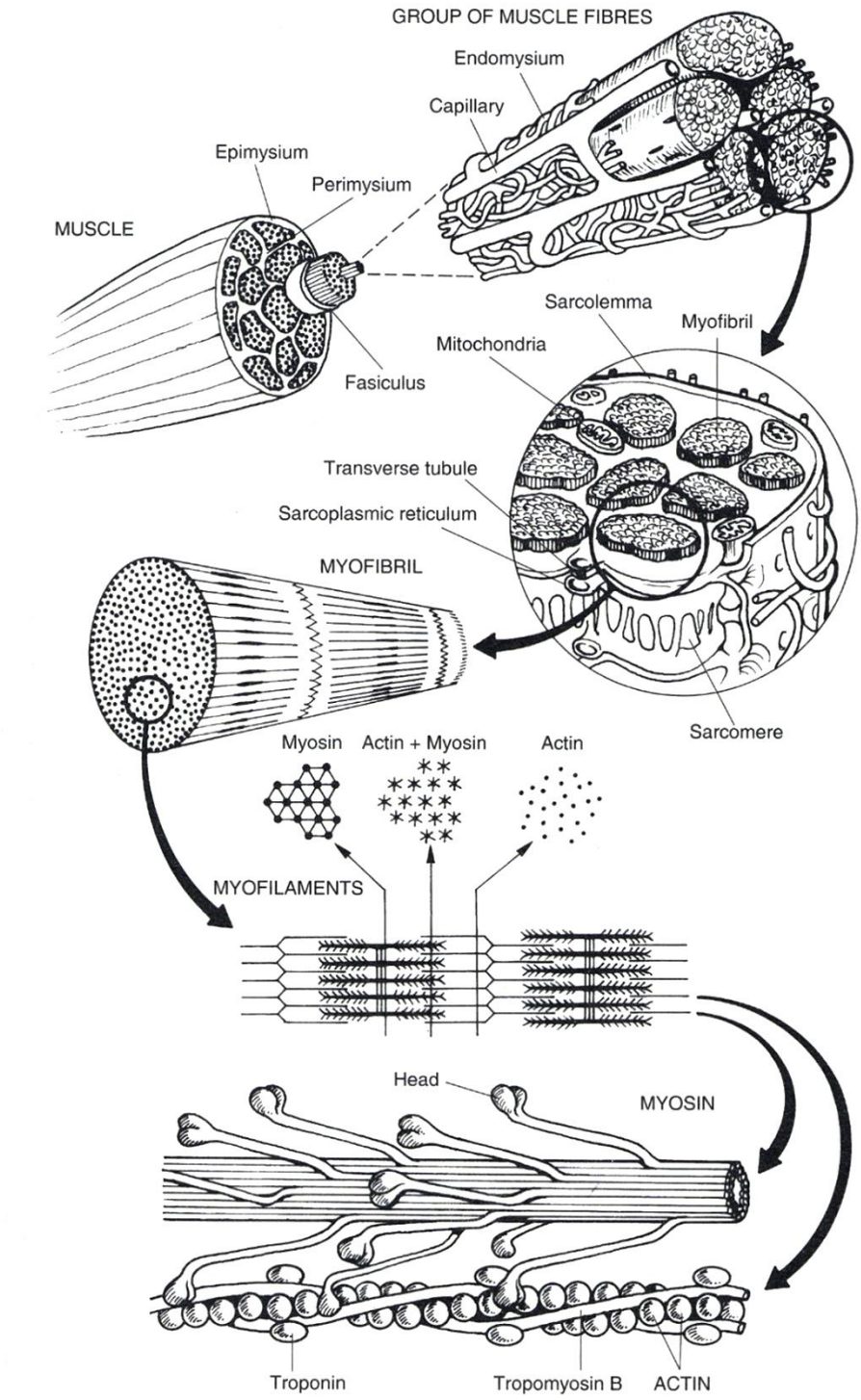


Fig. 1 - Structural levels within a skeletal muscle. The enzyme adenosine triphosphatase is located in the heads of the myosin myofilaments (Hunt, 1998).

Macrostructure of the Masseter Muscle

The mandibular elevators, particularly the temporalis and masseter, are the largest and strongest masticatory muscles (Schumacher, 1961).

The masseter muscle is a quadrilateral muscle, with three layers blended anteriorly, and the fasciculi have a multipennate arrangement with three to five tendinous septa (Schumacher, 1961). The superficial layer is the largest and attached by a thick aponeurosis to the maxillary process of the zygomatic bone and the anterior two-thirds of the inferior border of the zygomatic arch. It descends posteriorly to the mandibular angle and lower posterior half of the lateral surface of its ramus; intramuscular tendinous septa in this layer mark the ramus. The middle layer extends from the medial aspect of the anterior two-thirds of the zygomatic arch and the lower border of its posterior third to the central part of the mandibular ramus. The deep layer arises from the deep surface of the zygomatic arch and extends to the upper part of the mandibular ramus and its coronoid process (Williams *et al*., 1989). Together, the middle and deep layers make up the deep part (MacDougall, 1955).

General Muscle Growth

The dimensions of the muscles in living adults have been assessed by computerised tomography, magnetic resonance imaging and ultrasound scanning. The cross-sectional thickness is just under one cm for the masseter muscle (Raustia *et al*., 1986; Bakke *et al*., 1992) with a 15-50% increase during contraction (Kiliaridis and Kälebo, 1991; Bakke *et al*., 1992). Cross-sectional areas have been determined to be approximately five cm^2 for the temporalis, six cm^2 for the masseter, and about four cm^2 for the medial pterygoid muscle (Weijs & Hillen, 1986; Gionhaku & Lowe, 1989; Hannam & Wood, 1989; van Spronsen *et al*., 1989). Estimates of the physiologic muscular cross sections, i.e., the total cross-sectional area of all fibres, are larger, about 11, 9, and 6.5 cm^2, respectively (Weijs & Hillen, 1986). The corresponding value for the brachial biceps is about 10.5 cm^2 (Saltin & Gollnick, 1983).

The primary factor determining overall muscle strength is the physiological cross-sectional area. Approximately 50% of the intraindividual variation in strength can be

explained by differences in muscle size (Astrand & Rodahl, 1986; Jones & Round, 1990). In jaw-closing muscles, both thickness and area have been linked to strength and activity-related variables. These variables include sex, growth, ageing, bruxism, as well as, skeletal shape and occlusion (Newton *et al.*, 1987; van Spronsen *et al.*, 1989; Sasaki *et al.*, 1989; Kiliaridis & Kalebo, 1991).

Development and Ageing

Generally, muscle fibres attach directly to bone or cylindrical, ovoid, or elongated tendons. Complex skeletal muscles often contain large internal aponeuroses (comprising sheets of compact collagen fibres) to which muscle fibres attach, and it is common for these aponeuroses to differ in orientation and size within the same muscle. Fibres may lie parallel to the line of action of the muscle if it is simple, or at angles to its internal aponeuroses if it is complex. In the latter case, the muscle adopts a feather-like (or "pennate") appearance, with fibres radiating at narrow angles from each aponeurosis. Fibres in parallel-fibred muscles produce only translational motion. Those in pennated muscles must rotate about their attachments, increasing their pennation angle as they shorten, and the attached tendon or tendon sheet translates in the desired direction. When one of the attachments is to a tendon sheet and the other to an area of bone, translation and rotation of both bone and aponeurosis are possible due to the action of an induced force couple (Zarb *et al.*, 1994; Trawitzki *et al.*, 2011).

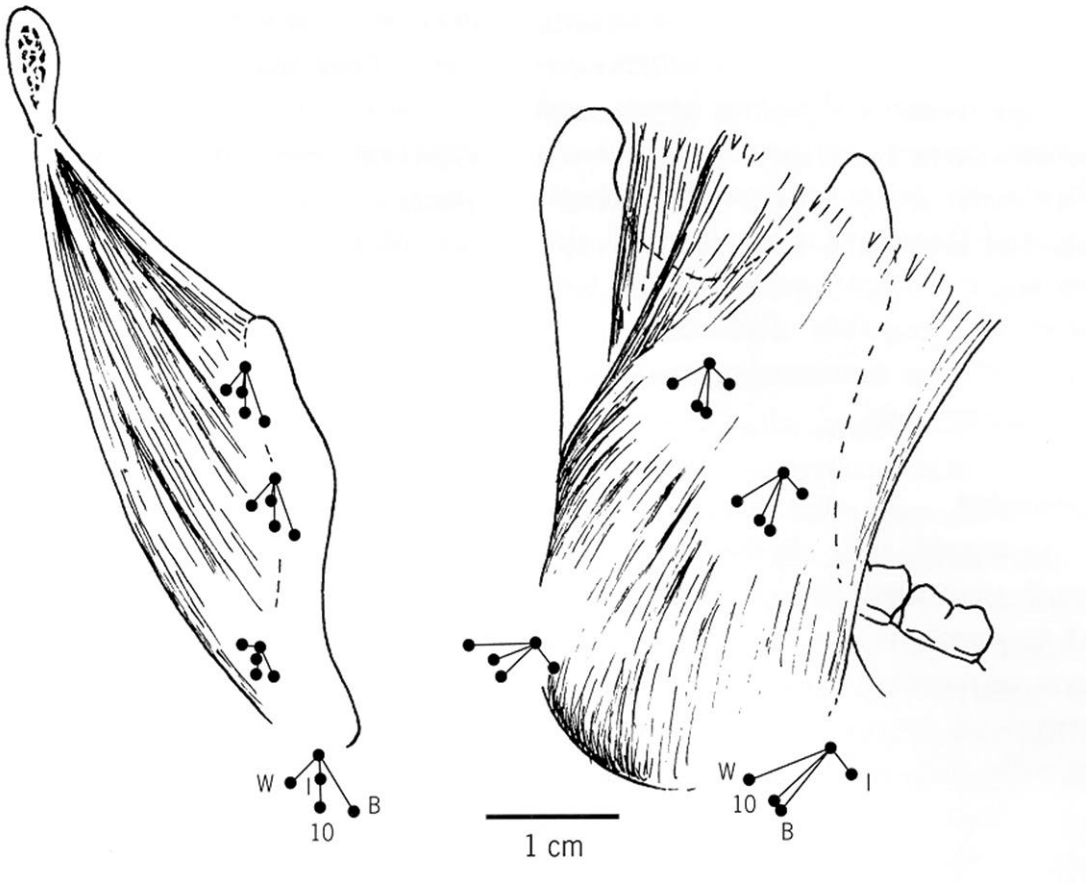


Fig. 2 - Lateral and frontal views of mean displacement trajectories for four attachment sites of the masseter muscle when four jaw movements are made towards the dental intercuspal position. In each case, the initial jaw locations are the turnaround points between jaw opening and closing during chewing when the muscle is on the working (W) and the balancing (B) sides, in edge-to-edge incisal contact (I), and at 10 mm interincisal separation in the midline (10). The apex of each cluster represents the intercuspal position. Different trajectories for the same act are evident in different muscle regions, and each act causes a given attachment site to move differently. The outlines of intramuscular aponeuroses are shown in the frontal projection. From this aspect, jaw muscle fibres are poorly aligned to displace the ramus during working-side movements (W), since they run approximately perpendicular to the line of movement. Nevertheless, they can still contribute to bite force by coactivation with other muscles. The data shown were derived from simulations in 14 adult skulls, and are reproduced from Tonndorf (Zarb *et al*., 1994).

Masseter Muscle Function

Altered muscle function is implicated in the aetiology of vertical facial deformities. The contractile properties of skeletal muscle are largely determined by the expression of various myosin heavy chain (MyHC) isoforms, and the specific pattern of MyHC gene expression serves as an indicator of the muscle's phenotype and functional capacity (Raberin, 2000). Two extremes of vertical facial forms have been described: Long Face Syndrome and Short Face Syndrome (Opdebeeck & Bell, 1978). The Long Face Syndrome (LFS) is characterised by the clinical and radiographic features of

increased lower anterior face height, an increased maxillary/mandibular plane angle, an increased gonial angle, and a tendency toward anterior open bite. The Short Face Syndrome (SFS) exhibits the opposite features, including a reduced lower facial height and a decreased mandibular plane angle. These morphological differences reflect distinct craniofacial growth patterns, where LFS is associated with downward and posterior growth rotation of the mandible, while SFS is linked to anterior growth rotation (Björk, 1969). A significant proportion of the patients presenting with extreme vertical facial discrepancies require surgery to correct their jaw relationship, for both functional and cosmetic reasons. The two are often inextricable, as the severe skeletal deformity causes significant, chronic functional deficits that, if left untreated, lead to long-term health issues and low quality of life, alongside obvious aesthetic concerns (Proffit & White, 1990; Trawitzki *et al.*, 2010). It has been proposed that the muscles of mastication are important determinants of vertical facial growth (Ingervall & Thilander, 1974; Invergall & Helkimo, 1978; Kiliaridis *et al.*, 1985). Studies of masseter muscle function have shown significant differences between LFS and SFS subjects concerning electromyographic (EMG) activity and the magnitude of maximum voluntary bite force; SFS subjects demonstrate higher EMG activity and exert greater bite forces than LFS subjects (Ahlgren, 1966; Sassouni, 1969; Ingervall & Thilander, 1974; Proffit *et al.*, 1983; Ferrario & Sforza, 1996). Whether the observed differences in muscle function are primary causal factors or are secondary to the development of vertical facial form (Proffit, 1978; Kiliaridis *et al.*, 1989). Furthermore, changes in vertical facial form have been induced by either increasing or decreasing the normal activity of the elevator muscles during postnatal growth (Kiliaridis *et al.*, 1985; Ingervall & Bitsanis, 1987).

The molecular motors responsible for muscle contraction are the myosin heavy chains (MyHC), which are found in the myofibrillar apparatus of muscle fibres (Schiaffino & Reggiani, 1996). Muscle fibres serve as the functional and contractile components of muscle, and their physiological properties are largely determined by various MyHC isoforms, distributed among fibres with different contractile characteristics. The masseter muscle differs from other somatic skeletal muscles in the variety of MyHC isoforms expressed in adult muscle (Thornell *et al.*, 1984; Sciote *et al.*, 1994). Myosin heavy chains are encoded by a multigene family, and the principal adult isoforms found in human skeletal muscle include the slow or ß-cardiac, IIa, and IIx

MyHCs, which correspond to type I, type IIa, and type IIb fibres, respectively (Schiaffino & Reggiani, 1996). A human counterpart to the IIb MyHC isoform identified in rats and other species has yet to be discovered (Smerdu *et al*., 1994). Furthermore, the adult human masseter expresses embryonic, perinatal, and α-cardiac MyHCs (Soussi-Yanicostas *et al.*, 1990).

A few studies examining the distribution of fibre type in the muscles of subjects with extremes of vertical facial form suggest that the contribution of different fibre components to the masseter phenotype may vary between normal subjects and those with vertical facial deformity (VFD). Research comparing the distribution of fibre types and cross-sectional areas in biopsies of the anterior deep masseter has shown that individuals with long facial syndrome (LFS) have a reduced proportion of type II fibres in the total cross-sectional area (Boyd *et al*., 1984; Hunt, 1992). In contrast, subjects with short facial syndrome (SFS) either show no significant differences compared to a control group (Hunt, 1992) or exhibit an increased contribution of type II fibres in the same region of the muscle (Boyd *et al.*, 1984).

The differential increase in the anterior and posterior face heights that occurs during surgery may not only stretch the muscle attachments but also alter the orientation of the muscle fibres relative to the occlusal plane. Adaptation is necessary concerning both the resting length and the altered functional activity of these muscles. Research by Hunt and Cunningham (1998) indicated that such adaptation may occur up to 12 months after surgery. In their study, surgical changes in vertical facial height were associated with immediate adaptation of the clinical freeway space, likely mediated by the proprioceptive system. The physiological rest position can be determined by eliminating sensory feedback from the teeth, allowing the mandible to adopt a position based on the resting length of the elevator muscles. This position is partially adjusted to the skeletal changes immediately after the operation but continues to adapt for up to 12 months post-surgery, particularly in patients with vertical excess (Hunt & Cunningham, 1998).

Any increase in posterior vertical facial dimension is prone to relapse in the long term. Three potential mechanisms can explain this phenomenon. Firstly, stretching of the pterygo-masseteric sling may increase pressure at the osteotomy site, leading to bone resorption and a subsequent loss of vertical dimension. The stretching of a muscle beyond its resting length reduces its ability to produce active tension due to decreased actin-

myosin cross-bridge overlap (the sliding filament theory). However, the reason an increased vertical dimension of occlusion (VDO) leads to bone resorption is not solely due to active muscle power, but rather the total tension (active + passive) and, more importantly, the continuous, chronic nature of the loading on the bone (Ferri *et al.*, 2008; Hunt & Cunningham, 1998).

Secondly, condylar remodelling/positioning changes the mechanical alteration of the facial skeleton and can induce remodeling, flattening, or erosion of the mandibular condyles (temporomandibular joint). Additionally, improper or unintentional rotation or displacement of the condyles within the glenoid fossa during fixation can lead to long-term relapse (Ferri *et al.*, 2008; Hunt & Cunningham, 1998).

Thirdly, soft tissue resistance/memory, the soft tissue surrounding the mandible, including the suprahyoid muscles and the facial skin, exerts a "recoil" effect. These tissues resist the new vertical position and attempt to return the mandible to its original, shorter position, leading to skeletal relapse (Ferri *et al.*, 2008; Hunt & Cunningham, 1998).

Regarding the laryngopharyngeal structures, specifically the suprahyoid muscles (digastric, geniohyoid, mylohyoid) hanging off the mandible, they are key contributors to relapse in the following ways: muscle stretching and increased tension, active counter-reaction, mandibular "sling" resistance, airway, and swallowing changes (Van den Bempt *et al.*, 2022).

Stability and Relapse

Skeletal relapse, or a change in the corrected jaw position, is one of the most notable complications following orthognathic surgery. Measurable skeletal relapse occurs after the correction of mandibular retrognathia through ramus surgery, not only after the release of intermaxillary fixation (referred to as later relapse) but also during the fixation period (known as early relapse). During this fixation period, the distal segment of the mandible that has been setback rotates backwards and downward around a fulcrum located at the molars. This rotation increases the steepness of the mandibular plane, characterised by an inferoposterior shift of the symphyseal region and an upward shift of the segment's gonial region. The pharynx and larynx are directly affected and often

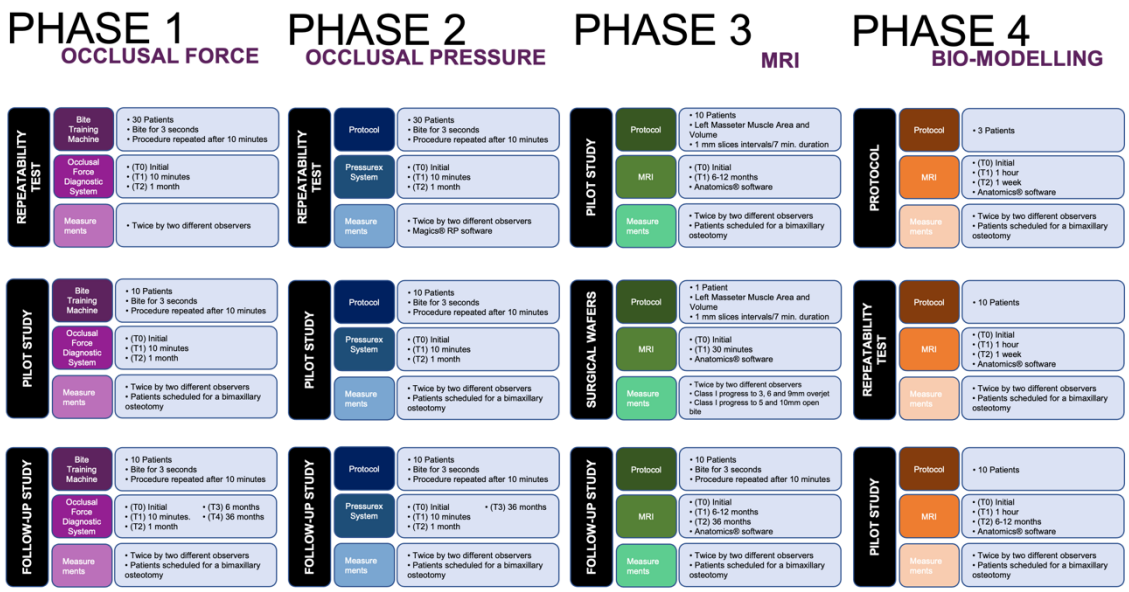
disturbed by the posterior and downward rotation of the distal segment of the mandible during a setback, contrary to the idea that they remain undisturbed (Komori *et al*., 1989; Coclici *et al*., 2019).

Rigid fixation of bony segments has become standard practice in orthognathic surgery. This shift can be attributed to several factors, including shorter hospital stays and increased patient convenience. With minimal or no immobilisation of the jaws, patients can function and resume their daily activities much sooner, leading to an earlier return to work. Improvements in early function and airway management have transformed hospital practices, allowing procedures that were once performed in an inpatient setting to be conducted on an outpatient basis (van Sickels & Richardson, 1996). The results generally show no significant difference in the amount of postsurgical change between maxillomandibular fixation (MMF) and rigid internal fixation (Skoczylas *et al*., 1988; Marchetti *et al*., 1999). Poor treatment planning, compromise of the blood supply to the osteotomy site, inadequate transosseous fixation and condylar distraction are among the factors causing relapse following mandibular advancement. Several factors have been identified as contributors to postsurgical skeletal instability. These include a divergent facial pattern, the direction and amount of correction applied, the displacement of the proximal segment, and the resulting change in facial height. However, specific parameters that reflect the degree of early relapse during the fixation period have not yet been established. Determining these parameters could enhance surgical outcomes and refine the surgical techniques involved (Komori *et al*., 1989; Coclici *et al*., 2019).

The stability and predictability of orthognathic surgical procedures vary with the direction of surgical movement, the type of fixation, and the surgical technique employed, mainly in that order of importance. The most stable orthognathic procedure is superior repositioning of the maxilla, closely followed by mandibular advancement in patients, in whom anterior facial height is maintained or increased (if facial height is decreased by upward rotation of the chin, stability is compromised). Moving the maxilla upward and the mandible forward is significantly more stable when rigid internal fixation is applied to the mandible. The forward movement of the maxilla tends to be reasonably stable, regardless of whether rigid internal fixation is used. However, mandibular setback often lacks stability, and mandibular downward rotation is typically unstable. For mandibular setback surgery, the inclination of the ramus appears to significantly influence stability.

Research suggests that both interpositional synthetic hydroxyapatite grafting and simultaneous ramus osteotomy may enhance the stability of the downward movement of the maxilla, but this has not been thoroughly documented. In two-jaw Class III surgery, the stability of each jaw is comparable to that observed with isolated maxillary advancement or mandibular setback procedures. Among orthognathic procedures, transverse maxillary expansion is the least stable. Although surgically assisted rapid maxillary expansion has been suggested as a more stable alternative to segmental Le Fort I osteotomy, the patterns of movement resulting from the two procedures are different. Rapid maxillary expansion can be made more stable by timing treatment before the pubertal growth spurt, utilising overcorrection, using rigid appliance designs like bone-anchored, and ensuring an adequate retention period to allow for new bone formation (Proffit *et al*., 1996; Marewski *et al.,* 2017).

The publications for this project will be presented following a phased structure, so in Phase 1: Measurement of Occlusal Force using a prototype system, included its description and potential application in orthognathic surgery (Paper 1), repeatability study (Paper 2), the pilot study (Paper 3) and the follow-up study (Paper 4). Phase 2: Measurement of Occlusal Pressure using the Pressurex® system, included the repeatability study (Paper 5), pilot study (Paper 6), and follow-up study (Paper 7). In Phase 3: Magnetic Resonance Imaging, the acquisition and identification protocol for the masseter muscle was published in a pilot study (Paper 8) and in a follow-up study (Paper 9). Finally, in Phase 4: Bio-Modelling, the protocol for superimposing the masseter muscle onto the reference bone structures was published (Paper 10), the repeatability study (Paper 11), and the pilot study (Paper 12). This description is presented schematically.


PHASE 1
OCCLUSAL FORCE
PHASE 2
OCCLUSAL PRESSURE
PHASE 3
MRI
PHASE 4
BIO-MODELLING
REPEATABILITY TEST
Bite Training Machine
• 30 Patients
• Bite for 3 seconds
• Procedure repeated after 10 minutes
Occlusal Force Diagnostic System
• (T0) Initial
• (T1) 10 minutes
• (T2) 1 month
Measure ments
• Twice by two different observers
REPEATABILITY TEST
Protocol
• 30 Patients
• Bite for 3 seconds
• Procedure repeated after 10 minutes
Pressurex System
• (T0) Initial
• (T1) 10 minutes
• (T2) 1 month
Measure ments
• Twice by two different observers
• Magics® RP software
PILOT STUDY
Protocol
• 10 Patients
• Left Masseter Muscle Area and Volume
• 1 mm slices intervals/7 min. duration
MRI
• (T0) Initial
• (T1) 6-12 months
• Anatomics® software
Measure ments
• Twice by two different observers
• Patients scheduled for a bimaxillary osteotomy
PROTOCOL
Protocol
• 3 Patients
MRI
• (T0) Initial
• (T1) 1 hour
• (T2) 1 week
• Anatomics® software
Measure ments
• Twice by two different observers
• Patients scheduled for a bimaxillary osteotomy
PILOT STUDY
Bite Training Machine
• 10 Patients
• Bite for 3 seconds
• Procedure repeated after 10 minutes
Occlusal Force Diagnostic System
• (T0) Initial
• (T1) 10 minutes
• (T2) 1 month
Measure ments
• Twice by two different observers
• Patients scheduled for a bimaxillary osteotomy
PILOT STUDY
Protocol
• 10 Patients
• Bite for 3 seconds
• Procedure repeated after 10 minutes
Pressurex System
• (T0) Initial
• (T1) 10 minutes
• (T2) 1 month
Measure ments
• Twice by two different observers
• Patients scheduled for a bimaxillary osteotomy
SURGICAL WAFERS
Protocol
• 1 Patient
• Left Masseter Muscle Area and Volume
• 1 mm slices intervals/7 min. duration
MRI
• (T0) Initial
• (T1) 30 minutes
• Anatomics® software
Measure ments
• Twice by two different observers
• Class I progress to 3, 6 and 9mm overjet
• Class I progress to 5 and 10mm open bite
REPEATABILITY TEST
Protocol
• 10 Patients
MRI
• (T0) Initial
• (T1) 1 hour
• (T2) 1 week
• Anatomics® software
Measure ments
• Twice by two different observers
• Patients scheduled for a bimaxillary osteotomy
FOLLOW-UP STUDY
Bite Training Machine
• 10 Patients
• Bite for 3 seconds
• Procedure repeated after 10 minutes
Occlusal Force Diagnostic System
• (T0) Initial
• (T1) 10 minutes.
• (T2) 1 month
• (T3) 6 months
• (T4) 36 months
Measure ments
• Twice by two different observers
• Patients scheduled for a bimaxillary osteotomy
FOLLOW-UP STUDY
Protocol
• 10 Patients
• Bite for 3 seconds
• Procedure repeated after 10 minutes
Pressurex System
• (T0) Initial
• (T1) 10 minutes
• (T2) 1 month
• (T3) 36 months
Measure ments
• Twice by two different observers
• Patients scheduled for a bimaxillary osteotomy
FOLLOW-UP STUDY
Protocol
• 10 Patients
• Bite for 3 seconds
• Procedure repeated after 10 minutes
MRI
• (T0) Initial
• (T1) 6-12 months
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Measure ments
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PILOT STUDY
Protocol
• 10 Patients
MRI
• (T0) Initial
• (T1) 1 hour
• (T2) 6-12 months
• Anatomics® software
Measure ments
• Twice by two different observers
• Patients scheduled for a bimaxillary osteotomy

1 OCCLUSAL FORCE MEASUREMENT

ARTICLE 1

Duarte F., Silva JN., Hopper C., Hunt N. The importance of Occlusal Force Measurement in Orthognathic Surgery - A pilot study. Journal of Surgery, Periodontology and Implant Research 2020; 2(1):13-26. doi: https://doi.org/10.35252/jspir.2020.1.002.1.02

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Contribution by F Duarte	Concept Performance of systematic review of literature Appraisal of included studies Development of recurrence risk stratification Manuscript writing & editing
ISSN	2184-4232 (Online Version) e 2184-4208 (Printed Version)
IF	

Post-Viva Addenda:

-The three-region model aligns with the natural arch anatomy, where the posterior teeth are designed for higher vertical loads and the anterior region is designed for lighter, guidance-related forces. The results of this repeatability test demonstrated high reproducibility of the tested system and a high degree of similarity to natural occlusion.

-It was decided to create this system because there was no device available on the market that could be used in this type of clinical situation.

The importance of occlusal force measurement in orthognathic surgery - A pilot study

Duarte F[1], Silva JN[2], Hopper C[3], Hunt N[3]

Affiliations:
1. CEO and Clinical Director of Clitrofa - Trofa, Portugal
2. Instituto Superior de Saúde ISAVE, Portugal
3. UCL Eastman Dental Institute, London, UK

Corresponding author:
Fernando Duarte
fduarte@clitrofa.com

ABSTRACT

Purpose: This pilot investigation was designed to apply several, newly developed and more sophisticated methods of measuring muscle structure and function in a situation where adaptation of muscle is pivotal to the success of a therapeutic approach.

Materials and Methods: Patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the protocol of Bite force and occlusal contact area were simultaneously measured with Bite Training Machine and Occlusal Force Diagnostic System. An Experimental design used for the measurement of occlusal force. The study involved the contribution of two independent examiners that measured the bite pressure (psi) in five different FSS sensors at three different time moments. A combination of different parametric tests has been used to compare the different experimental variables.

Results: Neither the variation of examiner, nor the variations of time have shown to influence the bite pressure (psi). In contrast, the occlusal force measurement system developed has shown a high level of sensitivity due to the distribution of the five FSS sensors in the horseshoe-shaped form. A three-pressure region model fits the experimental data shown in this study, comprising a low-pressure region located in the anterior part of the dental arch, a medium-pressure region in the medial part of the dental arch and an high-pressure region located in the posterior part of the dental arch.

Conclusions: The piezoelectric sensors used in the present study have shown high reproducibility of measurement. Due to the recent miniaturization of FSS sensors, the authors are developing new occlusal force measurement systems comprising a higher number of piezoelectric sensors, with the objective of attaining even higher sensitivity of measurement throughout the different region of the dental arches.

KEYWORDS

Orthognathic surgery, massseter muscle, occlusal force measurement

doi: https://doi.org/10.35252/jspir.2020.1.002.1.02

INTRODUCTION

One of the main purposes of orthognathic treatment in patients with a dentofacial deformity is to improve masticatory function as well as aesthetics. Numerous studies have documented masticatory function, for example: including bite force, occlusal contact and masticatory efficiency, in patients with mandibular prognathism before and after orthognathic surgery[1-13] but few reports compared the results with those in controls with normal occlusion.[1,3,6-9,12,13] There have also been few studies that involved evaluation of these parameters at the initial medical consultation for patients undergoing orthognathic surgery.[14,15] No reports were found that simultaneously evaluated the relationships between bite force, occlusal contact and masticatory efficiency in patients with mandibular prognathism and in controls with normal occlusion. Previously, changes in bite force and occlusal contact before and after orthognathic surgery were investigated and presented using the T-Scan system™ (Tekscan, USA).[3] This system is convenient and simple but is poor regarding reproducibility and quantification. Recently, a simple method for occlusal analysis, the Dental Prescale™ system (Fuji Photo Film Co., Japan), has been developed. This is a computerized system intended to assist occlusal analysis by providing information as to the magnitude of the bite force and the distribution of occlusal contacts. The system is capable of simultaneously measuring these parameters for teeth separated by less than 10mm and has potential for research in centric occlusion. It is a horseshoe-shaped thin film that consists of two layers: a layer of microcapsules containing colour-forming materials and a layer of colour-developing materials. The colour-developing materials, producing a red colour in the contact area when a force is generated, absorb the released colour-forming materials. The Dental Prescale™ system has already been used for analysing occlusion in dentures[16,17], dental implants[18] and orthognathic surgery.[7,8] Many methods for the quantitative measurement of masticatory efficiency have been introduced, but none stands out as ideal. Spectrophotometric methods for the evaluation of masticatory efficiency have been reported, involving measurement of the absorbance of adenosine triphosphate (ATP) granules.[6,7,12] This technique shows accuracy and reproducibility but is complicated. A new chewing-gum system has been developed for the estimation of masticatory function by the Meiji Chewing Gum Corporation. It utilizes a phloxine–sodium bicarbonate reaction and measures a chromatic coordinate as an indicator. This low-adhesive colour developing chewing-gum system has already been used for analysing the masticatory function of dental implants[19] and dentures[20].

The authors decided to build their own Occlusal Force Diagnostic System and test it on a group of patients.

OCCLUSAL FORCE DIAGNOSTIC SYSTEM

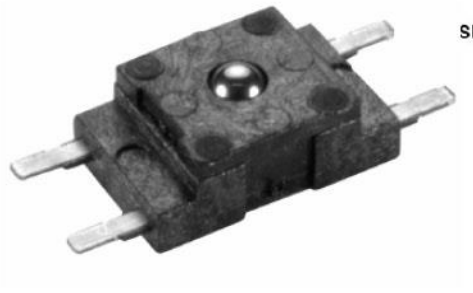
A) Sensors

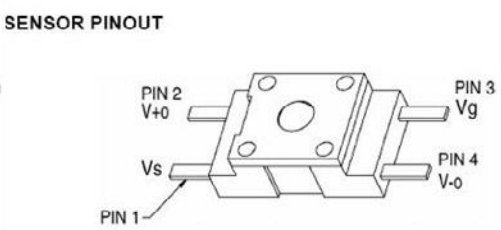
The FS Series sensors provide precise reliable force sensing performance in a compact commercial grade package. The sensor features a proven sensing technology that uses a specialized piezoresistive micromachined silicon sensing element. The low power, unamplified, uncompensated Wheatstone bridge circuit design provides inherently stable mV outputs over the force range.

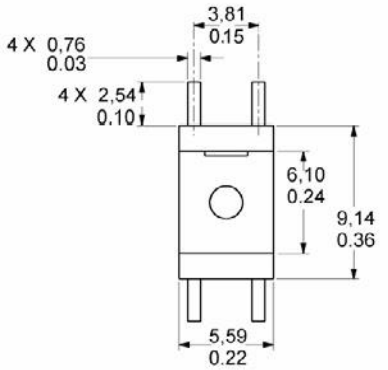
Force sensors operate on the principle that the resistance of silicon-implanted piezoresistors will increase when the resistors flex under any applied force. The sensor concentrates force from the applications, through the stainless-steel ball, directly to the silicon-sensing element. The amount of resistance changes in proportion to the amount of force being applied. This change in circuit resistance results in a corresponding mV output level change.

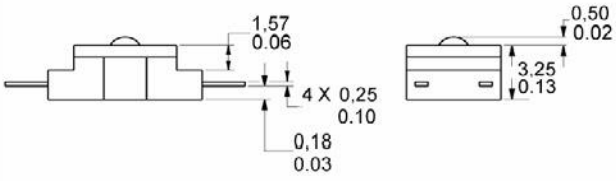
The stainless-steel ball provides mechanical stability and is adaptable to a variety of applications. The FSS sensor delivered 20 million operations in Mean Cycles to Failure (MCTF) reliability testing at 50°C [122°F]. This test determines the number of possible sensor operations at full scale until failure. Various electric interconnects can accept prewired connectors, printed circuit board mounting, and surface mountings. The sensor design also provides a variety of mounting options that include mounting brackets, as well as application specific mounting requirements.

The typical applications of these sensors are medical infusion pumps, ambulatory non-invasive pump pressure, occlusion detection, kidney dialysis machines, load and compression sensing, variable tensions control, robotic end-effectors and wire bonding equipment.









Description of Sensor Circuit:

1. Sensor terminals (pins).
Pin 1 = Supply VS (+), Pin 2 = Output VO (+),
Pin 3 = Ground Vg (-), Pin 4 = Output VO (-)
2. The force sensor may be powered by voltage or current. Maximum supply voltage is not to exceed 12 volts. Maximum supply current is not to exceed 1.6 mA. Power is applied across Pin 1 and Pin 3.
3. The sensor output should be measured as a differential voltage across Pin 2 and Pin 4 (VO = V2 - V4). The output is ratiometric to the supply voltage. Shifts in supply voltage will cause shifts in output. Neither Pin 2 nor Pin 4 should be tied to ground or voltage supply.

Figure 1. Schematic illustration of the FSS Sensor, sensor circuit and mounting

B) Distribution

The occlusal force diagnostic system has been developed between CEiiA - Centre of Engineering and Product Development in Oporto and the UCL, Eastman Dental Institute in London. The first idea was to place seven sensors distributed by the dental arch in a horseshoe-shaped form designated by bite force, but because of the sensors dimensions was decided to place only five. One sensor was for the anterior teeth (central and lateral incisors), two sensors for the canine and first pre-molar and another two sensors for the second pre-molar and first molar. The objective of this sensor's distribution was to make measurements of occlusal contact areas and occlusal pressures individually and in total. The sensors were connected between them, and the cables connected to a transducer that shows the digital reading in kilograms.

During the process of development was felt interesting to have the five sensors reading at the same time. To achieve this several changes were introduced, namely the inclusion of five digital screens, each one corresponding to one sensor, the construction of a portable suitcase able to accommodate all the occlusal diagnostic system and an on-off bottom. Each digital screen works with its own battery placed in the suitcase under a metal foil that cover all the electrical connections.

The dental arch in a horseshoe-shaped form was built by a superior and an inferior 3mm height metal foil covered by a hard resin, with the following intra-oral measures: 63mm total width, 62mm total length, 15mm width in the anterior occlusal contact area, 19mm width in the posterior occlusal contact area, 30mm anterior height and 15mm posterior height. The dental arch dimensions were based on most of the dental arches studied during the improvement process.

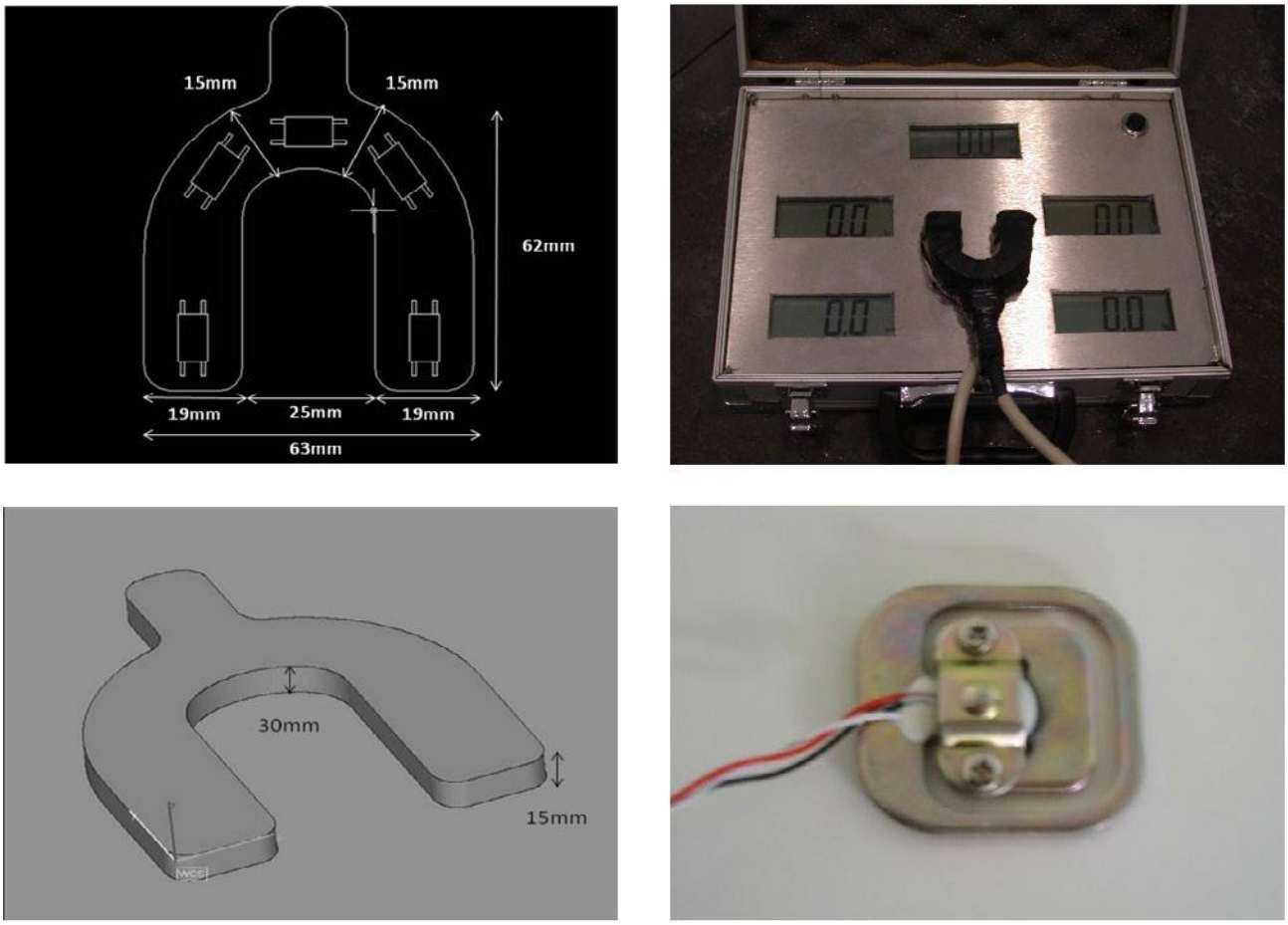


Figure 2. Components of the Occlusal Force Diagnostic System: FSS sensor, Sensors distribution, Occlusal platform dimensions and Digital screens

C) Compatibility

It is very important to ensure compatibility between the pressure or force sensor and the application in which it is used. The following should be considered before a sensor selection is made: (1) material; (2) chemicals; (3) concentration; (4) temperature; (5) exposure time; (6) type of exposure; (7) criteria for failure; and (8) general information such as application environment, protection of the device, and other foreign substances in the area.

D) Repeatability Test

The occlusal force diagnostic system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and after 1 month (T2). In the proposed repeatability test, the bite force and occlusal pressure were measured in 30 consecutive patients twice by two different observers.

The five sensors were distributed in the following order, the readings were in kilograms:

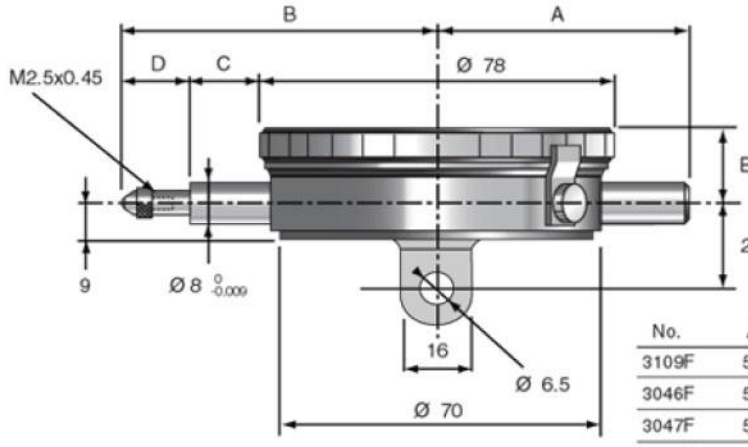
- Sensor A: right maxillary second pre-molar and right maxillary first molar between 1st and 4th quadrants,
- Sensor B: right maxillary canine and right maxillary first pre-molar between 1st and 4th quadrants,
- Sensor C: right and left maxillary central incisors and right and left maxillary lateral incisors area,
- Sensor D: left maxillary second pre-molar and left maxillary first molar between 2nd and 3rd quadrants,
- Sensor E: left maxillary canine and left maxillary first pre-molar between 2nd and 3rd quadrants,

E) Bite Training Machine

In order to provide adequate training to the patients and teach how to bite in the same way during the study a bite training machine was developed. The major components of this new machine were: a dynamometer, a force indicator and an occlusal contact area indicator.

The occlusal contact area was built in a hard-photosensitive resin with a similar strength of the occlusal force diagnostic system, and two springs were placed to allow movement return. The dynamometer was ordered from Mitutoyo™ (Mitutoyo Corporation, USA) and ensure that the patient was biting hard enough to see the reading.

The occlusal contact area indicator was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized in the dynamometer and the procedure was repeated after 10 minutes until the patient felt comfortable.



No.	A	B	C	D	E
3109F	56	79	25	15	17
3046F	56	75.5	15.5	21	16.5
3047F	56	75.5	15.5	21	16.5
3050F	49	93	25	29	16.5
3052F	73	104	25	40	17
3058F	82	142	43	60	17
3060E	112	203	73	91	17
3062E	132	243	94	110	17

Figure 3. Major components of the Bite Training Machine: dynamometer, force indicator and occlusal area

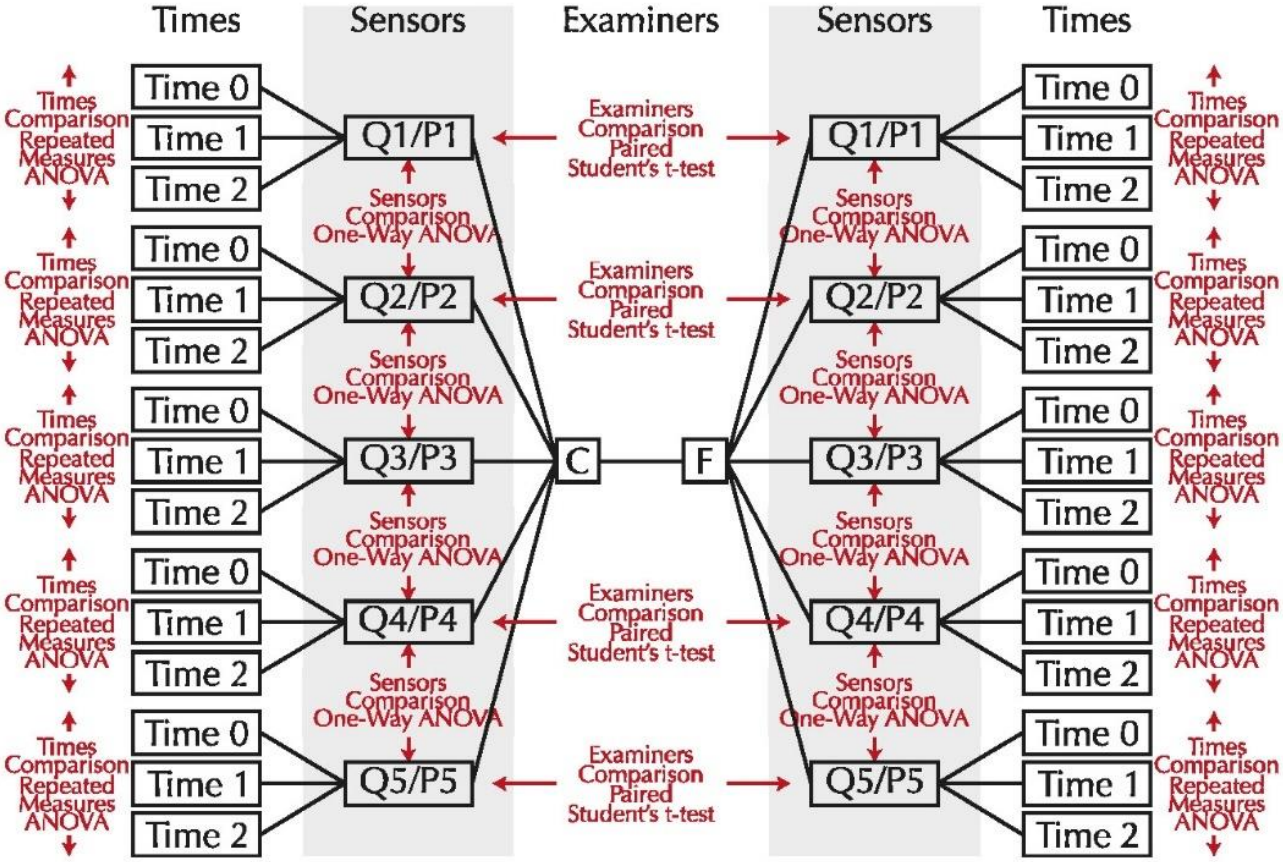


Figure 4. Experimental design used for the measurement of occlusal force. The study involved the contribution of two independent examiners (F and C), that measured the bite pressure (psi) in five different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at three different time moments (Time 0, Time 1 and Time 2).

MATERIALS AND METHODS

Patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol:

a) Bite Training Machine: The occlusal contact area indicator was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized in the dynamometer and the procedure was repeated after 10 minutes until the patient felt comfortable.

b) Occlusal Force Diagnostic System: The system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and after 1 month (T2). In the proposed repeatability test, the bite force and occlusal pressure were measured in 30 consecutive patients twice by two different observers.

A combination of different parametric tests has been used to compare the different experimental variables. The experimental design devised for this study is depicted in Figure 4, comprising a combination of different examiners, sensors and times of measurement.

Comparison A – Testing the Differences between Examiners (F versus C)

Research question: Are there any differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions?

H0: There are no differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions.

H1: There are differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions.

Comparison B – Testing the Differences between Times (T0 versus T1 versus T2)

Research question: Are there any differences in the mean bite pressure (psi) measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions?

H0: There are no differences in the mean bite pressure (psi) measured at moments Time 0, Time 1 and Time 2 in the same experimental conditions.

H1: There are differences in the mean bite pressure (psi) measured at moments Time 0, Time 1 and Time 2 in the same experimental conditions.

Comparison C – Testing the Differences between Sensors (Q1/P1 versus Q2/P2 versus Q3/P3 versus Q4/P4 versus Q5/P5)

Research question: Are there any differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions?

H0: There are no differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions.

H1: There are differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions.

RESULTS

Table 1 presents the experimental data for the measurement of mean bite pressure (psi), as well as its SD and variance values.

Table 1. Values of bite pressure (psi) measured at the different experimental conditions shown in Figure 4.

Variable	Mean (psi)	SD (psi)	Variance
P1_F_T0	52,567	38,264	1464,116
P1_F_T1	53,067	38,224	1461,099
P1_F_T2	54,033	39,063	1525,895
P1_C_T0	53,300	39,034	1523,666
P1_C_T1	53,800	39,284	1543,269
P1_C_T2	53,733	39,559	1564,892
P2_F_T0	36,567	28,877	833,909
P2_F_T1	36,500	28,567	816,052
P2_F_T2	36,967	28,823	830,792
P2_C_T0	36,833	28,666	821,730
P2_C_T1	36,833	28,680	822,557
P2_C_T2	37,133	29,180	851,499
P3_F_T0	0,700	2,667	7,114
P3_F_T1	0,700	2,667	7,114
P3_F_T2	0,667	2,537	6,437
P3_C_T0	0,700	2,667	7,114
P3_C_T1	0,700	2,667	7,114
P3_C_T2	0,667	2,537	6,437
P4_F_T0	28,933	24,996	624,823
P4_F_T1	29,567	25,117	630,875
P4_F_T2	29,433	24,897	619,840
P4_C_T0	29,400	25,125	631,283
P4_C_T1	29,867	24,926	621,283
P4_C_T2	29,600	24,926	619,913
P5_F_T0	67,933	37,300	1391,306
P5_F_T1	65,533	35,586	1266,395
P5_F_T2	66,700	36,174	1308,562
P5_C_T0	66,633	36,480	1330,792
P5_C_T1	66,400	35,953	1292,593
P5_C_T2	66,867	35,509	1260,878

Comparison A – Testing the Differences between Examiners (F versus C)

The statistical comparison between examiners F and C regarding the measurement of mean bite pressure (psi) was performed using a Paired Student's t-test for the five different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at the three different time moments (Time 0, Time 1 and Time 2).

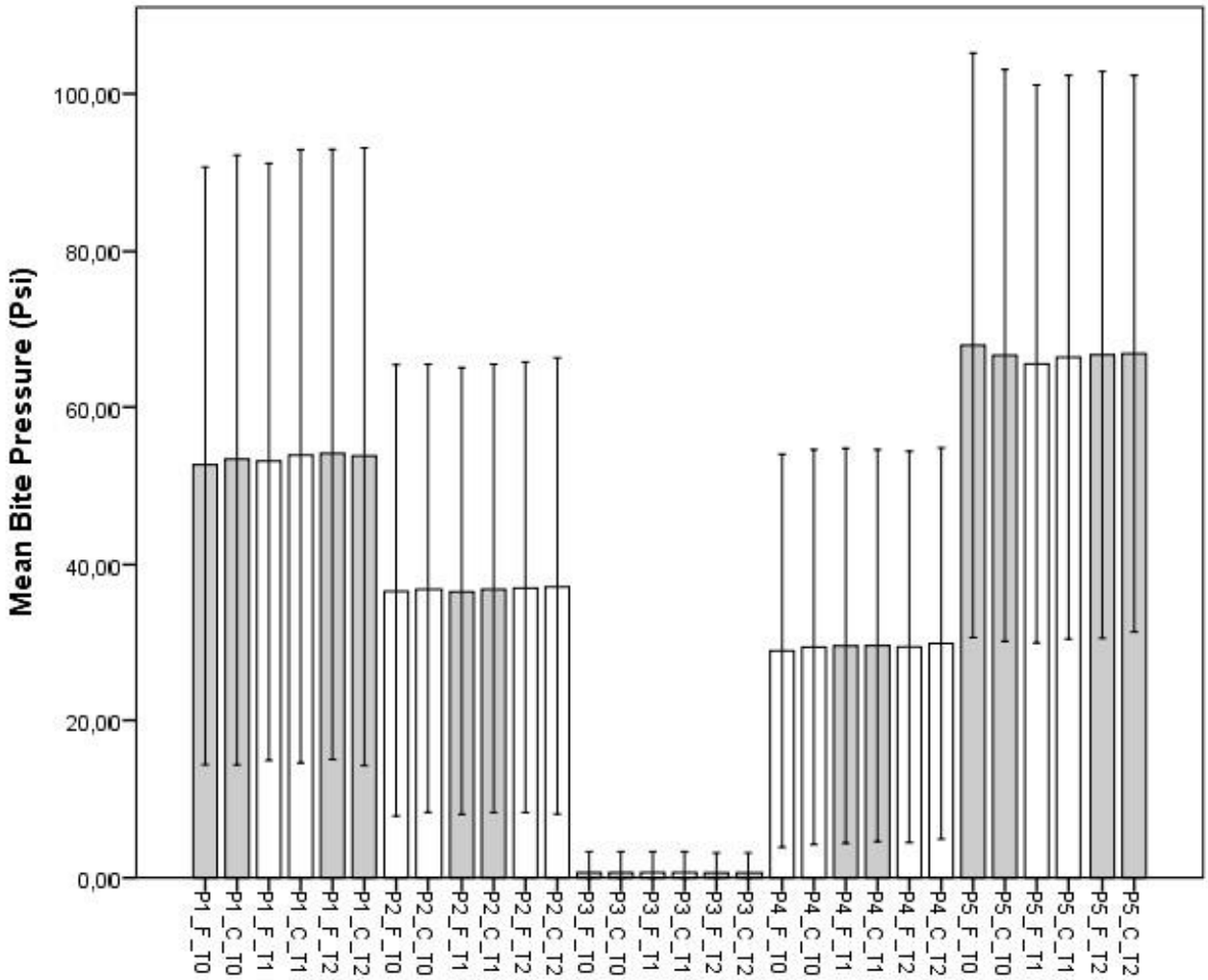


Figure 5. Mean bite pressure (psi) measured by Examiner F and Examiner C in five different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at three different time moments (Time 0, Time 1 and Time 2). Error bars represent standard deviation values.

Table 2. Statistical parameters obtained in the Paired Student's t-test for the comparison of examiners F and C when measuring the mean bite pressure (psi) in different experimental conditions

Examiners Comparison	Mean Difference	Standard Deviation of Differences	Degrees of Freedom *(df)*	Test statistic from Paired *t*-test	P-value from Paired *t*-test
Examiner F versus Examiner C, P1, Time 0	-0,733	4,185	29,000	-0,960	,345
Examiner F versus Examiner C, P1, Time 1	-0,733	2,993	29,000	-1,342	,190
Examiner F versus Examiner C, P1, Time 2	0,300	2,200	29,000	0,747	,461
Examiner F versus Examiner C, P2, Time 0	-0,267	1,437	29,000	-1,017	,318
Examiner F versus Examiner C, P2, Time 1	-0,333	2,040	29,000	-0,895	,378
Examiner F versus Examiner C, P2, Time 2	-0,167	3,302	29,000	-0,276	,784
Examiner F versus Examiner C, P3, Time 0	-0,467	1,961	29,000	-1,304	,203
Examiner F versus Examiner C, P3, Time 1	-0,033	1,426	29,000	-0,128	,899
Examiner F versus Examiner C, P3, Time 2	-0,433	2,944	29,000	-0,806	,427
Examiner F versus Examiner C, P4, Time 0	1,300	3,164	29,000	2,251	,032
Examiner F versus Examiner C, P4, Time 1	-0,867	2,623	29,000	-1,810	,081
Examiner F versus Examiner C, P4, Time 2	-0,167	3,687	29,000	-0,248	,806
Examiner F versus Examiner C, P5, Time 0	-0,733	4,185	29,000	-0,960	,345
Examiner F versus Examiner C, P5, Time 1	-0,733	2,993	29,000	-1,342	,190
Examiner F versus Examiner C, P5, Time 2	0,300	2,200	29,000	0,747	,461

There are no significant differences in the mean bite pressure (psi) measured by Examiner F and Examiner C, when the measurement is made in the same experimental conditions (Figure 5). Almost all experiments reveal p-values above the cut-off value of 0,05 ($p > 0,05$), which means that H0 proposition is valid (Table 2). The results obtained for sensor Q4/P4 at time 0 were not considered significant, as the general trend of data is the absence of statistical differences between examiners. Thus, it is concluded that the choice of examiner is not a variable that affects the mean bite pressure (psi) measured in any of the experimental conditions tested.

Comparison B – Testing the Differences between Times (T0 versus T1 versus T2)

The statistical comparison between the three time moments (Time 0, Time 1 and Time 2) regarding the measurement of mean bite pressure (psi) was performed using a Repeated Measures ANOVA for the five FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) and the different examiners F and C.

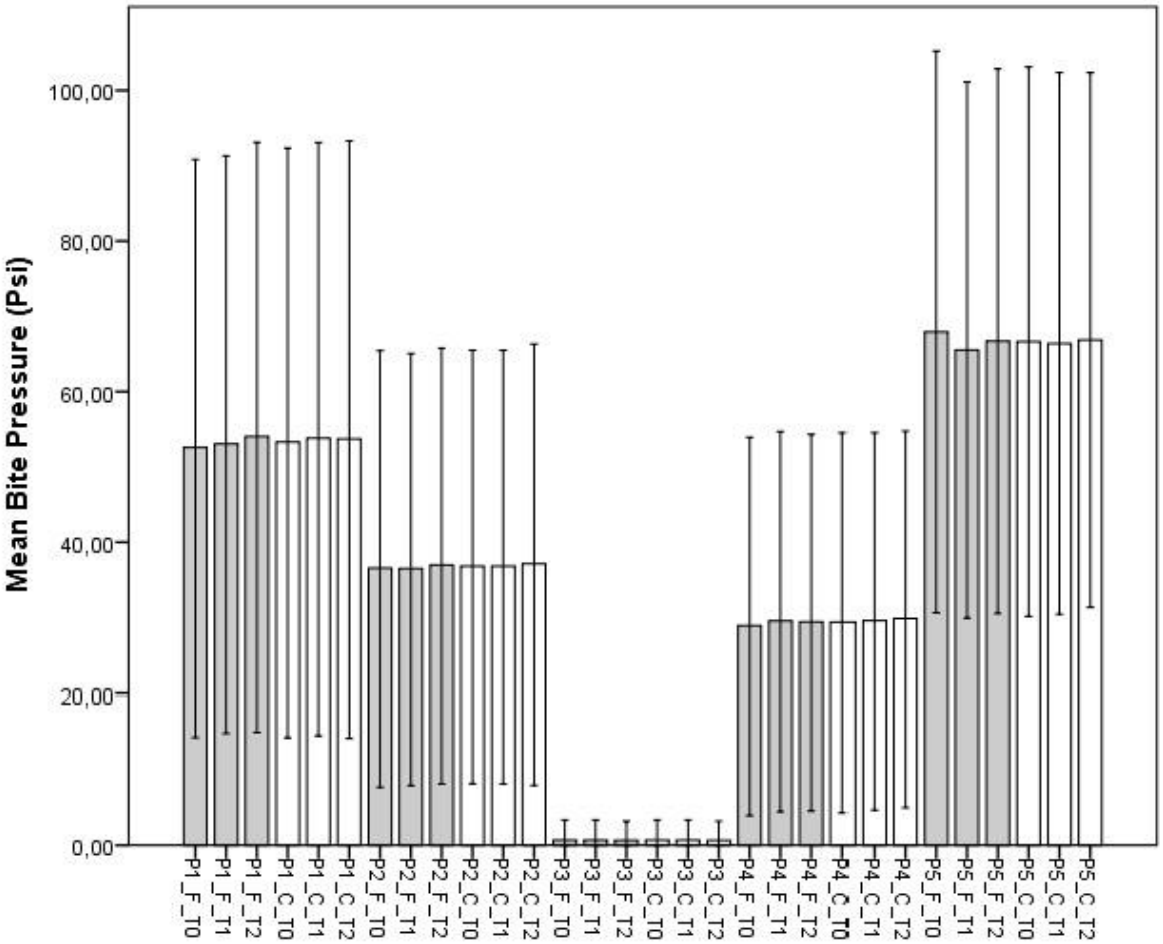


Figure 6. Mean bite pressure (psi) measured in three time moments (Time 0, Time 1 and Time 2) by Examiner F and Examiner C in five different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5). Error bars represent standard deviation values.

Table 3. Statistical parameters obtained in the Repeated Measures ANOVA for the comparison of time moments (Time 0, Time 1 and Time 2) when measuring the mean bite pressure (psi) in different experimental conditions.

Times Comparison	Degrees of Freedom (*df*)	Test statistic (F)	P-value (Sig)
Time 0 vs Time 1 vs Time 2, Examiner F, P1	2,58	3,225(a)	0,047(a)
Time 0 vs Time 1 vs Time 2, Examiner C, P1	2,58	0,714	0,494
Time 0 vs Time 1 vs Time 2, Examiner F, P2	2,58	0,695	0,503
Time 0 vs Time 1 vs Time 2, Examiner C, P2	2,58	0,352	0,705
Time 0 vs Time 1 vs Time 2, Examiner F, P3	2,58	1,000	0,374
Time 0 vs Time 1 vs Time 2, Examiner C, P3	2,58	1,000	0,374
Time 0 vs Time 1 vs Time 2, Examiner F, P4	2,58	1,854	0,166
Time 0 vs Time 1 vs Time 2, Examiner C, P4	2,58	0,488	0,616
Time 0 vs Time 1 vs Time 2, Examiner F, P5	2,58	8,715(a)	0,000(a)
Time 0 vs Time 1 vs Time 2, Examiner C, P5	2,58	0,423	0,657

a) Mauchly's Test of Sphericity ($p < 0,05$) reveals violation of sphericity principle, indicating distortion in the calculation of variance, F-ratio and p-value obtained in these results for the Repeated Measures ANOVA.

There are no significant differences in the mean bite pressure (psi) measured at Time 0, Time 1 or Time 2, for the same Examiner (C or F) and the same Sensor (Q1/P1, Q2/P2, Q3/P3, Q4/P4 or Q5/P5) ($p > 0,05$) (Figure 6). Almost all experiments reveal p-values above the cut-off value of 0,05 ($p > 0,05$), which means that H0 proposition is valid. The results obtained from Examiner F, sensors Q1/P1 and Q5/P5, were not considered significant, as sphericity principle was not verified (Table 3). Thus, it is concluded the mean bite pressure (psi) measured at different time frames is consistently the same, showing the high reproducibility of the measurements.

Comparison C – Testing the Differences between Sensors (Q1/P1 versus Q2/P2 versus Q3/P3 versus Q4/P4 versus Q5/P5)
The statistical comparison between the five FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) regarding the measurement of mean bite pressure (psi) was performed using a One-Way ANOVA for the different examiners F and C at the three different time moments (Time 0, Time 1 and Time 2).

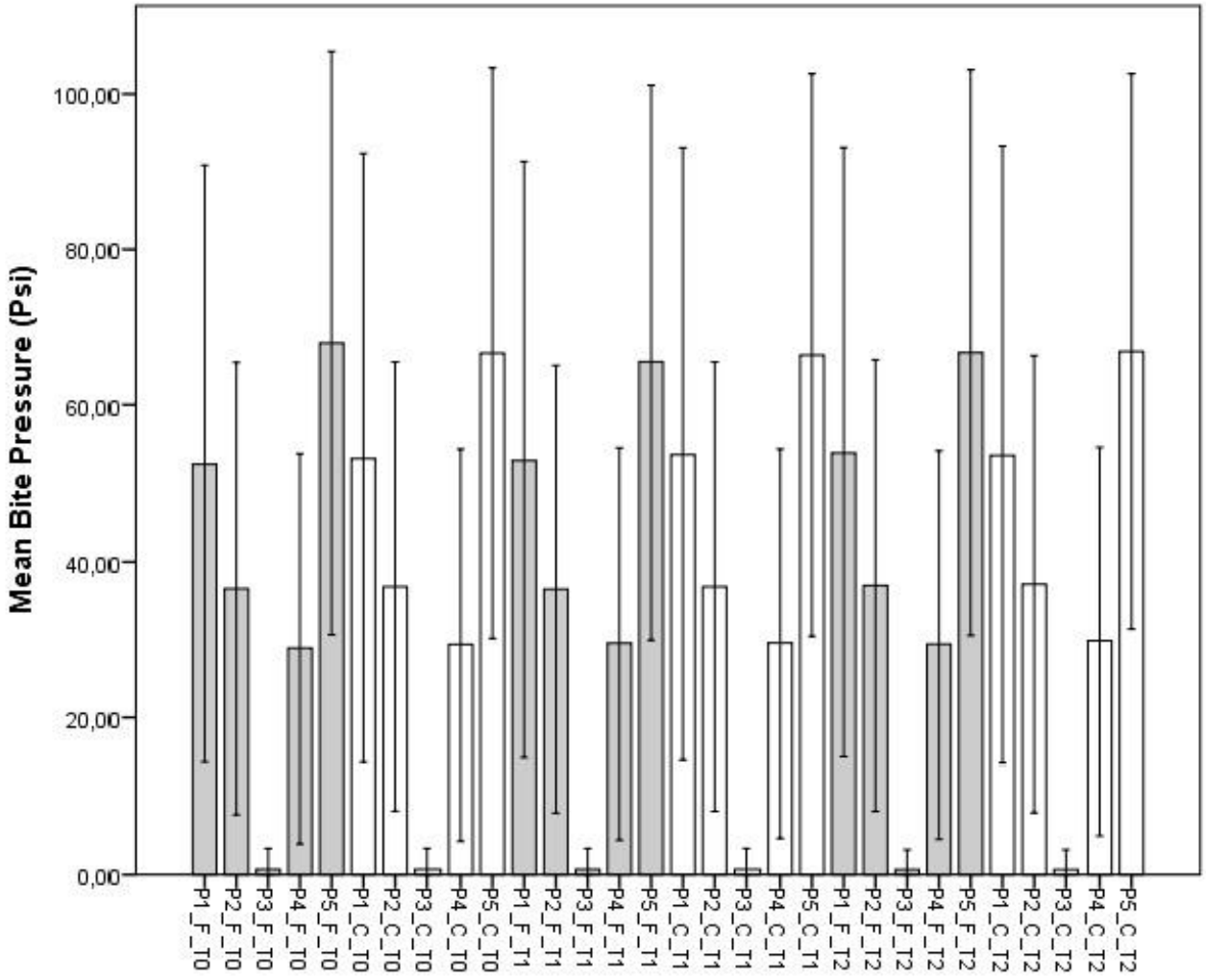


Figure 7. Mean bite pressure (psi) measured in five FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) by Examiner F and Examiner C at three different time moments (Time 0, Time 1 and Time 2). Error bars represent standard deviation values.

Table 4. Statistical parameters obtained in the One-Way ANOVA for the comparison of FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions.

Sensors Comparison		Sum of Squares	Degrees of Freedom *(df)*	Mean Square	Test statistic (F)	P-value (Sig)
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 0	Between Groups	77446,893	4,000	19361,723	22,403	0,000*
	Within Groups	125316,767	145,000	864,254		
	Total	202763,660	149,000	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 1	Between Groups	73363,693	4,000	18340,923	21,931	0,000*
	Within Groups	121264,500	145,000	836,307		
	Total	194628,193	149,000	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 2	Between Groups	76440,693	4,000	19110,173	22,265	0,000*
	Within Groups	124454,267	145,000	858,305		
	Total	200894,960	149,000	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 1	Between Groups	75558,160	4,000	18889,540	21,890	0,000*
	Within Groups	125122,933	145,000	862,917		
	Total	200681,093	149,000	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 2	Between Groups	75539,667	4,000	18884,917	22,027	0,000*
	Within Groups	124317,667	145,000	857,363		
	Total	199857,333	149,000	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 3	Between Groups	76227,040	4,000	19056,760	22,140	0,000*
	Within Groups	124804,933	145,000	860,724		
	Total	201031,973	149,000	-		

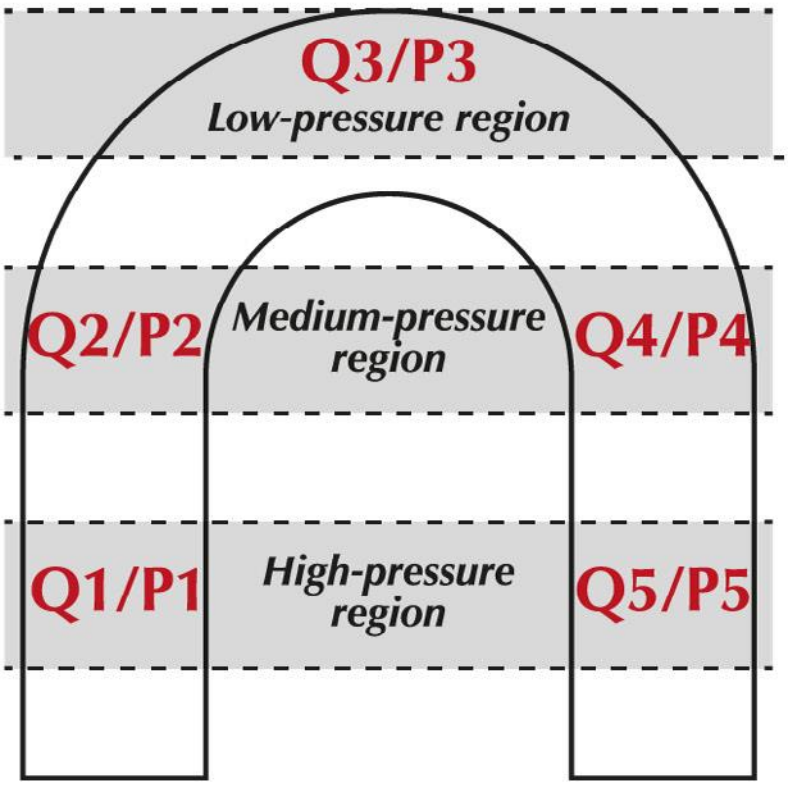


Figure 8. Three-pressure region model for dental occlusion.

Table 5. Statistical parameters obtained in the Post-Hoc Gabriel test for the comparison of FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions.

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
F_T0	Q1/P1	Q2/P2	16,000	7,591	0,308
		Q3/P3	51,867*	7,591	0,000
		Q4/P4	23,633*	7,591	0,022
		Q5/P5	-15,367	7,591	0,363
	Q2/P2	Q1/P1	-16,000	7,591	0,308
		Q3/P3	35,867*	7,591	0,000
		Q4/P4	7,633	7,591	0,976
		Q5/P5	-31,367*	7,591	0,001
	Q3/P3	Q1/P1	-51,867*	7,591	0,000
		Q2/P2	-35,867*	7,591	0,000
		Q4/P4	-28,233*	7,591	0,003
		Q5/P5	-67,233*	7,591	0,000
	Q4/P4	Q1/P1	-23,633*	7,591	0,022
		Q2/P2	-7,633	7,591	0,976
		Q3/P3	28,233*	7,591	0,003
		Q5/P5	-39,000*	7,591	0,000
	Q5/P5	Q1/P1	15,367	7,591	0,363
		Q2/P2	31,367*	7,591	0,001
		Q3/P3	67,233*	7,591	0,000
		Q4/P4	39,000*	7,591	0,000
F_T1	Q1/P1	Q2/P2	16,567	7,467	0,245
		Q3/P3	52,367*	7,467	0,000
		Q4/P4	23,500*	7,467	0,020
		Q5/P5	-12,467	7,467	0,633
	Q2/P2	Q1/P1	-16,567	7,467	0,245
		Q3/P3	35,800*	7,467	0,000
		Q4/P4	6,933	7,467	0,986
		Q5/P5	-29,033*	7,467	0,002
	Q3/P3	Q1/P1	-52,367*	7,467	0,000
		Q2/P2	-35,800*	7,467	0,000
		Q4/P4	-28,867*	7,467	0,002
		Q5/P5	-64,833*	7,467	0,000
	Q4/P4	Q1/P1	-23,500*	7,467	0,020
		Q2/P2	-6,933	7,467	0,986
		Q3/P3	28,867*	7,467	0,002
		Q5/P5	-35,967*	7,467	0,000
	Q5/P5	Q1/P1	12,467	7,467	0,633
		Q2/P2	29,033*	7,467	0,002
		Q3/P3	64,833*	7,467	0,000
		Q4/P4	35,967*	7,467	0,000

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
C_T0	Q1/P1	Q2/P2	16,467	7,585	0,271
		Q3/P3	52,600*	7,585	0,000
		Q4/P4	23,900*	7,585	0,020
		Q5/P5	-13,333	7,585	0,563
	Q2/P2	Q1/P1	-16,467	7,585	0,271
		Q3/P3	36,133*	7,585	0,000
		Q4/P4	7,433	7,585	0,980
		Q5/P5	-29,800*	7,585	0,001
	Q3/P3	Q1/P1	-52,600*	7,585	0,000
		Q2/P2	-36,133*	7,585	0,000
		Q4/P4	-28,700*	7,585	0,002
		Q5/P5	-65,933*	7,585	0,000
	Q4/P4	Q1/P1	-23,900*	7,585	0,020
		Q2/P2	-7,433	7,585	0,980
		Q3/P3	28,700*	7,585	0,002
		Q5/P5	-37,233*	7,585	0,000
	Q5/P5	Q1/P1	13,333	7,585	0,563
		Q2/P2	29,800*	7,585	0,001
		Q3/P3	65,933*	7,585	0,000
		Q4/P4	37,233*	7,585	0,000
C_T1	Q1/P1	Q2/P2	16,967	7,560	0,231
		Q3/P3	53,100*	7,560	0,000
		Q4/P4	24,200*	7,560	0,017
		Q5/P5	-12,600	7,560	0,635
	Q2/P2	Q1/P1	-16,967	7,560	0,231
		Q3/P3	36,133*	7,560	0,000
		Q4/P4	7,233	7,560	0,983
		Q5/P5	-29,567*	7,560	0,001
	Q3/P3	Q1/P1	-53,100*	7,560	0,000
		Q2/P2	-36,133*	7,560	0,000
		Q4/P4	-28,900*	7,560	0,002
		Q5/P5	-65,700*	7,560	0,000
	Q4/P4	Q1/P1	-24,200*	7,560	0,017
		Q2/P2	-7,233	7,560	0,983
		Q3/P3	28,900*	7,560	0,002
		Q5/P5	-36,800*	7,560	0,000
	Q5/P5	Q1/P1	12,600	7,560	0,635
		Q2/P2	29,567*	7,560	0,001
		Q3/P3	65,700*	7,560	0,000
		Q4/P4	36,800*	7,560	0,000

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
F_T2	Q1/P1	Q2/P2	17,067	7,564	0,225
		Q3/P3	53,367*	7,564	0,000
		Q4/P4	24,600*	7,564	0,014
		Q5/P5	-12,667	7,564	0,629
	Q2/P2	Q1/P1	-17,067	7,564	0,225
		Q3/P3	36,300*	7,564	0,000
		Q4/P4	7,533	7,564	0,977
		Q5/P5	-29,733*	7,564	0,001
	Q3/P3	Q1/P1	-53,367*	7,564	0,000
		Q2/P2	-36,300*	7,564	0,000
		Q4/P4	-28,767*	7,564	0,002
		Q5/P5	-66,033*	7,564	0,000
	Q4/P4	Q1/P1	-24,600*	7,564	0,014
		Q2/P2	-7,533	7,564	0,977
		Q3/P3	28,76667*	7,564	0,002
		Q5/P5	-37,26667*	7,564	0,000
	Q5/P5	Q1/P1	12,667	7,564	0,629
		Q2/P2	29,73333*	7,564	0,001
		Q3/P3	66,03333*	7,564	0,000
		Q4/P4	37,26667*	7,564	0,000

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
C_T2	Q1/P1	Q2/P2	16,600	7,575	0,259
		Q3/P3	53,067*	7,575	0,000
		Q4/P4	23,867*	7,575	0,020
		Q5/P5	-13,133	7,575	0,582
	Q2/P2	Q1/P1	-16,600	7,575	0,259
		Q3/P3	36,467*	7,575	0,000
		Q4/P4	7,267	7,575	0,983
		Q5/P5	-29,733*	7,575	0,001
	Q3/P3	Q1/P1	-53,067*	7,575	0,000
		Q2/P2	-36,467*	7,575	0,000
		Q4/P4	-29,200*	7,575	0,002
		Q5/P5	-66,200*	7,575	0,000
	Q4/P4	Q1/P1	-23,867*	7,575	0,020
		Q2/P2	-7,267	7,575	0,983
		Q3/P3	29,20000*	7,575	0,002
		Q5/P5	-37,00000*	7,575	0,000
	Q5/P5	Q1/P1	13,133	7,575	0,582
		Q2/P2	29,73333*	7,575	0,001
		Q3/P3	66,20000*	7,575	0,000
		Q4/P4	37,00000*	7,575	0,000

There are significant differences in the mean bite pressure (psi) measured by the different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5), when the measurement is made in the same experimental conditions (Figure 7 and Table 4). All experiments reveal p-values below the cut-off value of 0,05 ($p < 0,05$), which means that H0 proposition is invalid. Thus, it is concluded that the five FSS sensors detect different mean bite pressures (psi) for the same Examiner (F or C) at the same time moment (Time 0, Time 1 or Time 2).

Because One-Way ANOVA only gives information about the presence of differences, not specifying where these differences are located, a Post-hoc Gabriel test was used to perform pairwise comparisons between the FSS sensors, and these results are represented in Table 5.

Significant differences ($p < 0,05$) have been identified between certain pairs of FSS sensors (Table 5), allowing the definition of a three-pressure region model (Figure 8): 1) low-pressure region located in the anterior part of the dental arch; 2) medium-pressure region in the intermediate part of the dental arch; and 3) high-pressure region located in the posterior part of the dental arch.

Another interesting observation is that, when two FSS sensors are located in the same pressure region (i.e., Q1/P1+Q5/P5 and Q2/P2+Q4/P4), no statistical differences are recognisable within the pairs of FSS sensors, meaning that the pressures detected are statistically identical to one another ($p > 0,05$).

On the opposite side, whenever two FSS sensors are located in different pressure regions, statistically significant differences ($p < 0,05$) have been found between the measured pressures (Figure 8 and Table 5), showing the high sensibility of measurement of the experimental device.

CONCLUSIONS

The piezoelectric sensors used in the present study have shown high reproducibility of measurement. Neither the variation of examiner, nor the variation of time have shown to influence the bite pressure (psi).

In contrast, the occlusal force measurement system developed has shown a high level of sensitivity due to the distribution of the five FSS sensors in the horseshoe-shaped form.

A three-pressure region model fits the experimental data shown in this study, comprising a low-pressure region located in the anterior part of the dental arch, a medium-pressure region in the medial part of the dental arch and an high-pressure region located in the posterior part of the dental arch.

Due to the recent miniaturization of FSS sensors, the authors are developing new occlusal force measurement systems comprising a higher number of piezoelectric sensors, with the objective of attaining even higher sensitivity of measurement throughout the different region of the dental arches.

CONFLICT OF INTEREST

The authors declared that there is no conflict of interest.

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ARTICLE 2

Duarte F., Silva JN., Ramos C., Hopper C. Measurement of Occlusal Force in Orthognathic Surgery using Force Sensing Sensors. Int J of Dent & Ora Hea 2021; 7(8):94-108

Authors	**Duarte F.,** Silva JN., Ramos C., Hopper C.
Journal	International Journal of Dentistry and Oral Health 2021; 7(8):94-108
DOI	
Contribution by F Duarte	Concept Performance of systematic review of literature Appraisal of included studies Development of recurrence risk stratification Manuscript writing & editing
ISSN	2471-657X
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Post-Viva Addenda:

-In conclusion, the distance of the sensor from the occlusal plane means the distance from the fulcrum of motion of the mandible.

-In conclusion, the surgery was successful, and the bilateral contacts are accurate in the new Intercuspal Position, with no discrepancy in the inclination between the maxilla and mandible during the operation.

International Journal of Dentistry and Oral Health

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Research Article

Measurement of Occlusal Force in Orthognathic Surgery using Force Sensing Sensors

Fernando Duarte*[1], João Neves Silva[2], Carina Ramos[3], Colin Hopper[4]

[1]Oral Surgeon Specialist by OMD (Portuguese Dental Association), Master of Science in Oral and Maxillofacial Surgery at Eastman Dental Institute University College of London, PhD student at UCL - University College of London
[2]Professor at ISAVE - Instituto Superior de Saúde - Portugal, Member of the Interdisciplinary Center for Health Sciences (ICHS) - ISAVE -Instituto Superior de Saúde
[3]MSc student in Oral Oncology at Instituto de Ciências Biomédicas Abel Salazar - Oporto University – Portugal
[4] Oral and Maxillofacial Surgery Department at Eastman Dental Institute – University College of London

Corresponding author: Fernando Duarte
Clitrofa - Centro Médico, Dentário e Cirúrgico, Avenida de Paradela 622, 4785-248 Trofa - Portugal
Tel: +351252428960 E-mail: fduarte@clitrofa.com

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Abstract

Purpose: This study was designed to apply alternative and innovative methods of measuring muscle area, volume, structure, function and fibre orientation to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach.
Materials and Methods: Ten patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol:
a) Bite Training Machine: The occlusal contact area indicator was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized in the dynamometer and the procedure was repeated after 10 minutes until the patient felt comfortable.
b) Occlusal Force Diagnostic System: The system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and 1 month after surgery (T2).
In this study, the bite force and occlusal pressure were measured for 10 patients twice by two different observers. These 10 patients were scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible.
Conclusions: When comparing pre-op (Times 0 and 1) and post-op (Time 2) data, significant statistical differences have been found in the mean bite pressure measured by FSS sensor Q3/P3 located in the anterior region of the maxilla/ mandible ($p < 0,05$), those differences being absent in the remaining FSS sensors Q1/P1, Q2/P2, Q4/P4 and Q5/P5 ($p > 0,05$). Significant differences ($p < 0,05$) have been identified between certain pairs of FSS sensors, allowing the definition of a three-pressure region model where the key-factor seems to be the relative distance of the sensors to the occlusion region: the higher the distance to the occlusion region, the lower is the mean bite pressure (psi).

Keywords
Orthognathic Surgery; Masseter Muscle; Occlusal Force Measurement

Declaration of Conflicting Interest
The authors declare that they have no conflict of interest.

Introduction:

One of the main purposes of orthognathic treatment in patients with a dentofacial deformity is to improve masticatory function as well as aesthetics. Numerous studies have documented masticatory function for example: including bite force, occlusal contact and masticatory efficiency, in patients with mandibular prognathism before and after orthognathic surgery[1,2,3,4,5,6,7,8,9,10,11,12,13] but few reports compared the results with those in controls with normal occlusion[1,3,4,7,8,9,12,13]. There have also been few studies that involved evaluation of these parameters at the initial medical consultation for patients undergoing orthognathic surgery[14,15]. No reports were found that simultaneously evaluated the relationships between bite force, occlusal contact and masticatory efficiency in patients with mandibular prognathism and in controls with normal occlusion.

Previously, changes in bite force and occlusal contact before and after orthognathic surgery were investigated and presented using the T-Scan system™ (Tekscan, USA)[3]. This system is convenient and simple but is poor in regard to reproducibility and quantification. Another method for occlusal analysis, the Dental Prescale™ system (Fuji Photo Film Co., Japan), has been developed. It is a horseshoe-shaped thin film that consists of two layers: a layer of microcapsules containing colour-forming materials and a layer of colour-developing materials. The colour-developing materials, producing a red colour in the contact area when a force is generated, absorb the released colour-forming materials. The Dental Prescale™ system has already been used for analysing occlusion in dentures[16,17], dental implants[18] and orthognathic surgery[7,8].

Many methods for the quantitative measurement of masticatory efficiency have been introduced, but none stands out as ideal. Spectrophotometric methods for the evaluation of masticatory efficiency have been reported, involving measurement of the absorbance of adenosine triphosphate (ATP) granules[4,7,12]. This technique shows accuracy and reproducibility but is complicated. A new chewing-gum system has been developed for the estimation of masticatory function by the Meiji Chewing Gum Corporation. It utilizes a phloxine–sodium bicarbonate reaction and measures a chromatic coordinate as an indicator. This low-adhesive colourdeveloping chewing-gum system has already been used for analyzing the masticatory function of dental implants[19] and dentures[20].

Force Sensing Sensors:

The FS Series sensors provide precise reliable force sensing performance in a compact commercial grade package. The sensor features a proven sensing technology that uses a specialized piezoresistive micromachined silicon sensing element. The low power, unamplified, uncompensated wheatstone bridge circuit design provides inherently stable mV outputs over the force range.

Force sensors operate on the principle that the resistance of silicon-implanted piezoresistors will increase when the resistors flex under any applied force. The sensor concentrates force from the applications, through the stainless steel ball, directly to the silicon-sensing element. The amount of resistance changes in proportion to the amount of force being applied. This change in circuit resistance results in a corresponding mV output level change.

The stainless steel ball provides mechanical stability and is adaptable to a variety of applications. The FSS sensor delivered 20 million operations in Mean Cycles to Failure (MCTF) reliability testing at 50°C [122°F]. This test determines the number of possible sensor operations at full scale until failure. Various electric interconnects can accept prewired connectors, printed circuit board mounting, and surface mountings. The sensor design also provides a variety of mounting options that include mounting brackets, as well as application specific mounting requirements.

Figure 1: Schematic illustration of the FSS sensor

Materials and Methods:

Ten patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol:
a) Bite Training Machine: In order to provide adequate training to the patients and teach how to bite in the same way during the study a bite training machine was developed. The major components of this new machine were: a dynamometer, a force indicator and an occlusal contact area indicator. The occlusal contact area was built in an hard photosensitive resin with a similar strength of the occlusal force diagnostic system, and two springs were placed to allow movement return. The dynamometer was order from Mitutoyo™ (Mitutoyo Corporation, USA) and ensure that patient was biting hard enough to see the reading.

The occlusal contact area indicator was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized in the dynamometer and the procedure was repeated after 10 minutes until the patient felt comfortable.
b) Occlusal Force Diagnostic System: The system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and 1 month after surgery (T2).
The occlusal force diagnostic system has been developed between CEiiA - Centre of Engineering and Product Development in Oporto and the UCL, Eastman Dental Institute in London. One sensor was for the anterior teeth (central and lateral incisors), two sensors for the canine and first pre-molar and another two sensors for the second pre-molar and first molar. The objective of this sensors distribution was to make measurements of occlusal contact areas and occlusal pressures individually and in total. The sensors were connected between them, and the cables connected to a transducer that shows the digital reading in kilograms.

The five sensors were distributed in the following order, the readings were in kilograms:
Sensor A: right maxillary second pre-molar and right maxillary first molar between 1st and 4th quadrants;
Sensor B: right maxillary canine and right maxillary first pre-molar between 1st and 4th quadrants;
Sensor C: right and left maxillary central incisors and right and left maxillary lateral incisors area;
Sensor D: left maxillary second pre-molar and left maxillary first molar between 2nd and 3rd quadrants, and finally
Sensor E: left maxillary canine and left maxillary first pre-molar between 2nd and 3rd quadrants.

In this study, the bite force and occlusal pressure were measured for 10 patients twice by two different observers. These 10 patients were scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible.

The dental arch in a horseshoe-shaped form was built by a superior and an inferior 3mm height metal foil covered by an hard resin, with the following intra-oral measures: 63mm total width, 62mm total length, 15mm width in anterior occlusal contact area, 19mm width in posterior occlusal contact area, 30mm anterior height and 15mm posterior height. The dental arch dimensions were based on the majority of the dental arches studied during the improvement process.

The experimental design devised for this study is depicted in Figure 2, comprising a combination of different examiners, sensors and times of measurement.

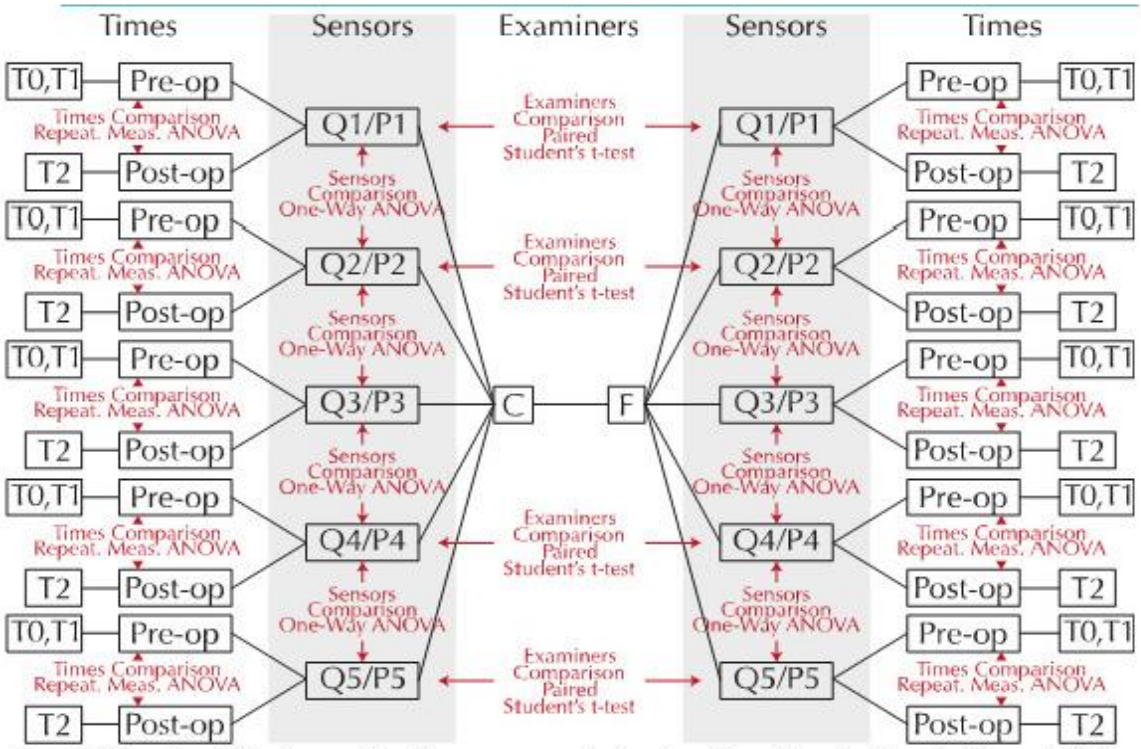

Figure 2: Experimental design used for the measurement of occlusal force. The study involved the contribution of two independent examiners (F and C), that measured the bite pressure (psi) in five different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at three different time moments (Time 0, Time 1 and Time 2).

IBM® SPSS® version 25 was used to analyze the data obtained. The data were first tested to ensure they conformed to a normal distribution by using the Kolmogorov-Smirnov test, the Shapiro-Wilks test or by determining the values of skewness (acceptable values for normality between -2 and +2) and kurtosis (acceptable values for normality between -2 and +2). Descriptive statistics included the arithmetic mean ($\bar{x}$), standard deviation (SD), and standard error of the mean (SE), as well as the 95% confidence interval (95% CI). Where the data were not normally distributed, the median and the inter-quartile range (IQR) were noted.

In those situations where the data were normally distributed and the variances were constant, comparative analysis involved either the unpaired or paired two-tailed Student's t test. Multiple comparisons were made using the One-Way Analysis of Variance (ANOVA) or Repeated Measure Analysis of Variance (ANOVA) depending if the data were, respectively, unpaired or paired.

Post-Hoc Gabriel test and post-hoc Bonferroni test were used, respectively for One-Way ANOVA and Repeated Measures ANOVA, to identify the pairs where the significant statistical differences were located.

Where the requirements for parametric statistical analysis were not met, the data were analyzed using either the Wilcoxon Signed Rank (U) test for paired data or the Mann-Whitney (U) test for unpaired data as appropriate. Comparison between three or more groups were made using the Kruskal-Wallis (H) or the Friedman (H) test depending if the data were, respectively, unpaired or paired.

The minimum level of significance (α level) accepted throughout the development studies was 0.05 (*), considered to be "moderately significant". Levels of 0.01 (**) were considered as "significant" and 0.001 (***) designated as "highly significant". A lack of statistical significance was designated as (ns).

Comparison A – Testing the Differences between Examiners (F versus C)

Research question: Are there any significant statistical differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions?

H0: There are no significant statistical differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions.

H1: There are significant statistical differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions.

Comparison B – Testing the Differences between Times (T0 versus T1 versus T2)

Research question: Are there any significant statistical differences in the mean bite pressure (psi) measured between moments Time 0 (before surgery), Time 1 (10 minutes after T1) and Time 2 (1 month after surgery) in the same experimental conditions?

H0: There are no significant statistical differences in the mean bite pressure (psi) measured at moments

Time 0, Time 1 and Time 2 in the same experimental conditions.
H1: There are significant statistical differences in the mean bite pressure (psi) measured at moments Time 0, Time 1 and Time 2 in the same experimental conditions.

Comparison C – Testing the Differences between Sensors (Q1/P1 versus Q2/P2 versus Q3/P3 versus Q4/P4 versus Q5/P5)

Research question: Are there any significant statistical differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions?
H0: There are no significant statistical differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions.
H1: There are significant statistical differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions.

Results:

Table 1 presents the experimental data for the measurement of mean bite pressure (psi), as well as its SD and variance values.

Variable	Mean (psi)	SD (psi)	Variance
P1_F_T0	87,400	22,775	518,711
P1_F_T1	89,111	23,793	566,111
P1_F_T2	92,600	29,364	862,267
P1_C_T0	87,100	23,202	538,322
P1_C_T1	87,200	23,275	541,733
P1_C_T2	92,600	28,737	825,822
P2_F_T0	66,800	39,197	1536,400
P2_F_T1	66,800	39,194	1536,178
P2_F_T2	71,200	29,005	841,289
P2_C_T0	66,600	39,036	1523,822
P2_C_T1	66,400	40,153	1612,267
P2_C_T2	71,200	29,192	852,178
P3_F_T0	5,200	7,757	60,178
P3_F_T1	5,200	7,757	60,178
P3_F_T2	34,600	14,653	214,711
P3_C_T0	5,200	7,685	59,067
P3_C_T1	5,100	7,622	58,100
P3_C_T2	34,100	14,693	215,878
P4_F_T0	65,200	36,820	1355,733
P4_F_T1	65,500	36,782	1352,944
P4_F_T2	70,600	26,391	696,489
P4_C_T0	66,800	35,010	1225,733
P4_C_T1	66,200	35,661	1271,733
P4_C_T2	68,600	29,636	878,267
P5_F_T0	86,200	24,091	580,400
P5_F_T1	85,900	23,914	571,878
P5_F_T2	89,500	29,114	847,611
P5_C_T0	86,600	23,782	565,600
P5_C_T1	86,700	23,655	559,567
P5_C_T2	90,100	29,464	868,100

Table 1: Values of bite pressure (psi) measured at the different experimental conditions shown in Figure 1.

Comparison A – Testing the Differences between Examiners (F versus C)

The statistical comparison between examiners F and C regarding the measurement of mean bite pressure (psi) was performed using a Paired Student's t-test for the five different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at the three different time moments (Time 0, Time 1 and Time 2) (Figure 3 and Table 2).

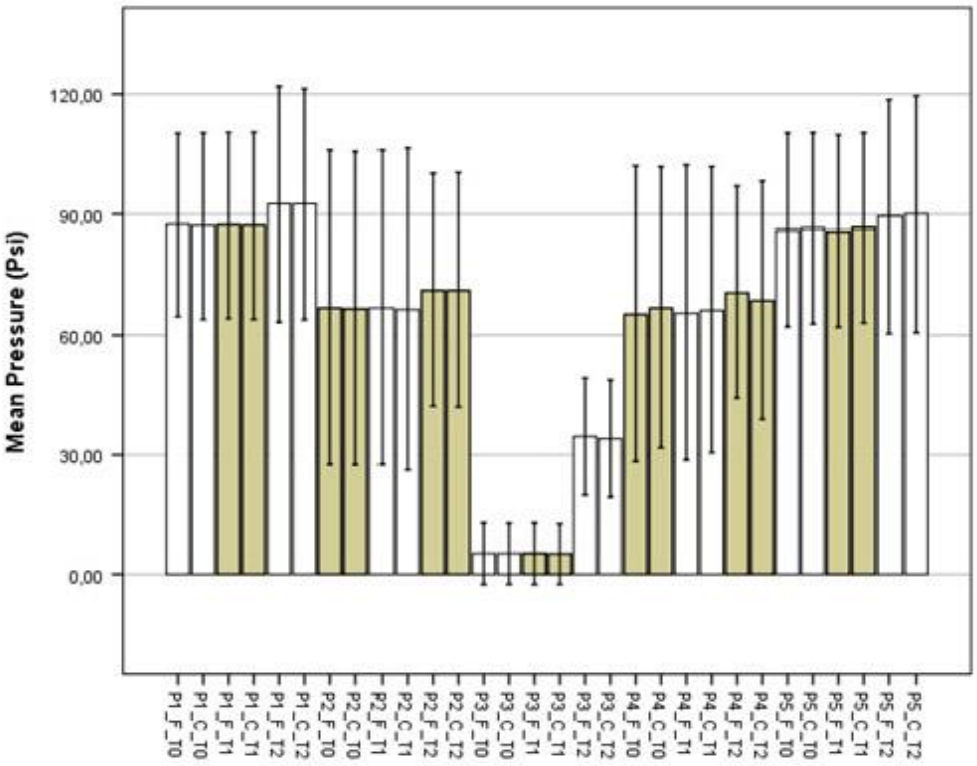

Figure 3: Mean bite pressure (psi) measured by Examiner F and Examiner C in five different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at three different time moments (Time 0, Time 1 and Time 2). Error bars represent standard deviation values.

Examiners Comparison	Mean Difference	Standard Deviation of Differences	Degrees of Freedom (df)	Test statistic from Paired t-test	P-value from Paired t-test
Examiner F versus Examiner C, P1, Time 0	0,300	0,823	9	1,152	0,279
Examiner F versus Examiner C, P1, Time 1	0,100	0,876	9	0,361	0,726
Examiner F versus Examiner C, P1, Time 2	0,000	1,054	9	0,000	1,000
Examiner F versus Examiner C, P2, Time 0	0,200	0,919	9	0,688	0,509
Examiner F versus Examiner C, P2, Time 1	0,400	1,647	9	0,768	0,462
Examiner F versus Examiner C, P2, Time 2	0,000	0,471	9	0,000	1,000
Examiner F versus Examiner C, P3, Time 0	0,000	0,471	9	0,000	1,000
Examiner F versus Examiner C, P3, Time 1	0,100	0,316	9	1,000	0,343
Examiner F versus Examiner C, P3, Time 2	0,500	0,850	9	1,861	0,096
Examiner F versus Examiner C, P4, Time 0	-1,600	4,061	9	-1,246	0,244
Examiner F versus Examiner C, P4, Time 1	-0,700	2,263	9	-0,978	0,354
Examiner F versus Examiner C, P4, Time 2	2,000	7,055	9	0,896	0,393
Examiner F versus Examiner C, P5, Time 0	-0,400	1,075	9	-1,177	0,269
Examiner F versus Examiner C, P5, Time 1	-0,800	1,033	9	-2,449	0,037*
Examiner F versus Examiner C, P5, Time 2	-0,600	1,506	9	-1,260	0,239

Table 2: Statistical parameters obtained in the Paired Student's t-test for the comparison of examiners F and C when measuring the mean bite pressure (psi) in different experimental conditions.
* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Comparison B – Testing the Differences between Times (T0 versus T1 versus T2)

The statistical comparison between the three-time moments (Time 0, Time 1 and Time 2) regarding the measurement of mean bite pressure (psi) was performed using a Repeated Measures ANOVA for the five FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) and the different examiners F and C (Figure 4 and Table 3).

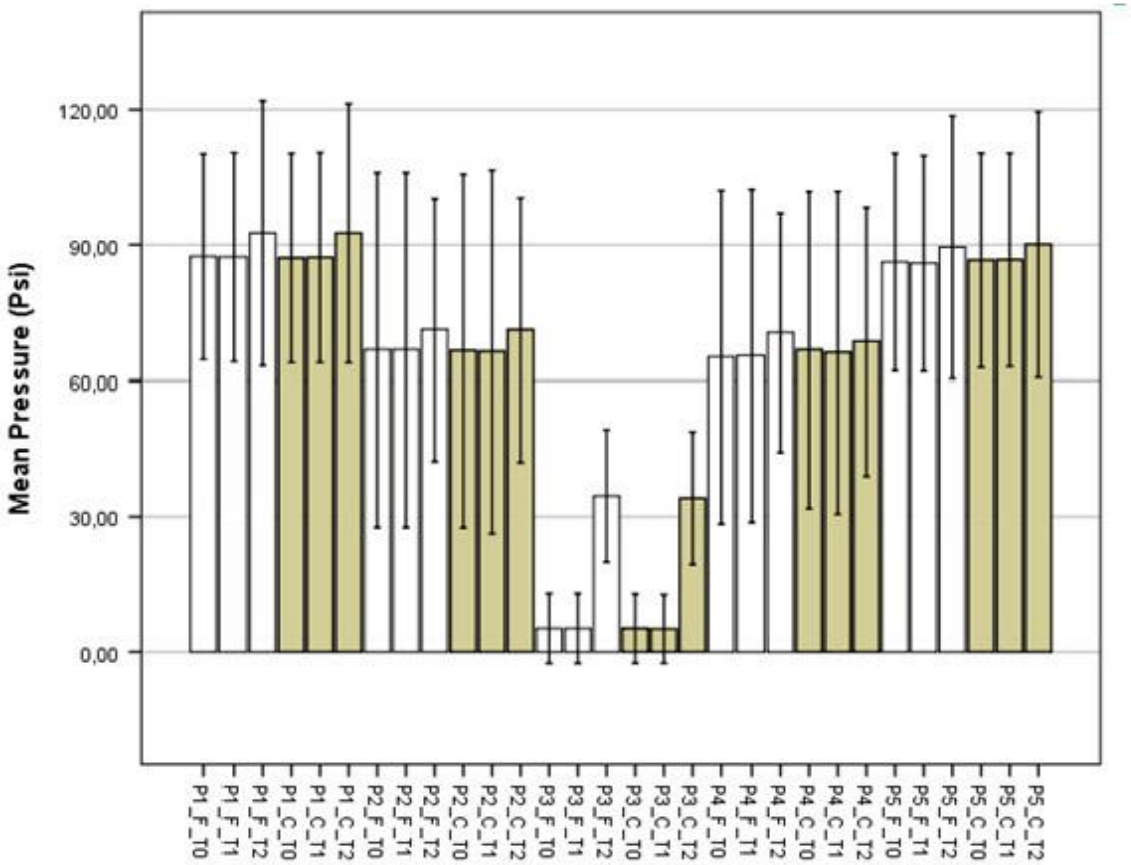

Figure 4: Mean bite pressure (psi) measured in three-time moments (Time 0, Time 1 and Time 2) by Examiner F and Examiner C in five different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5). Error bars represent standard deviation values.

Times Comparison	Degrees of Freedom (df)	Test statistic (F)	P-value (Sig)
Time 0 vs Time 1 vs Time 2, Examiner F, P1	2, 18	2,711	0,094
Time 0 vs Time 1 vs Time 2, Examiner C, P1	2, 18	3,372	0,057
Time 0 vs Time 1 vs Time 2, Examiner F, P2	2, 18	0,599	0,560
Time 0 vs Time 1 vs Time 2, Examiner C, P2	2, 18	0,665	0,527
Time 0 vs Time 1 vs Time 2, Examiner F, P3	2, 18	52,762	0,000**
Time 0 vs Time 1 vs Time 2, Examiner C, P3	2, 18	49,924	0,000**
Time 0 vs Time 1 vs Time 2, Examiner F, P4	2, 18	1,042	0,373
Time 0 vs Time 1 vs Time 2, Examiner C, P4	2, 18	0,232	0,796
Time 0 vs Time 1 vs Time 2, Examiner F, P5	2, 18	0,832	0,451
Time 0 vs Time 1 vs Time 2, Examiner C, P5	2, 18	0,808	0,461

Table 3: Statistical parameters obtained in the Repeated Measures ANOVA for the comparison of time moments (Time 0, Time 1 and Time 3) when measuring the mean bite pressure (psi) in different experimental conditions. * moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Because Repeated Measures ANOVA only gives information about the presence of differences, not specifying where these differences are located, a Post-Hoc Bonferroni test was used to perform pairwise comparisons between the times, and these results are represented in Table 4.

Independent Variable			Mean Difference (I-J)	Std. Error	Sig.
F_Q3/P3	T0	T1	0,000	0,000	-
		T2	-29,400	4,047	0,000***
	T1	T0	0,000	0,000	-
		T2	-29,400	4,047	0,000***
	T2	T0	29,400	4,047	0,000***
		T1	29,400	4,047	0,000***
C_Q3/P3	T0	T1	0,100	0,233	1,000
		T2	-28,900	4,140	0,000***
	T1	T0	-0,100	0,233	1,000
		T2	-29,000	4,047	0,000***
	T2	T0	28,900	4,140	0,000***
		T1	29,000	4,047	0,000***

Table 4: Statistical parameters obtained in the Post-Hoc Bonferroni test for the comparison of Times (Time 0, Time 1 and Time 2) when measuring the mean bite pressure (psi) in different experimental conditions. * moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Comparison C – Testing the Differences between Sensors (Q1/P1 versus Q2/P2 versus Q3/P3 versus Q4/P4 versus Q5/P5)

The statistical comparison between the five FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) regarding the measurement of mean bite pressure (psi) was performed using a One-Way ANOVA for the different examiners F and C at the three different time moments (Time 0, Time 1 and Time 2) (Figure 5 and Table 5).

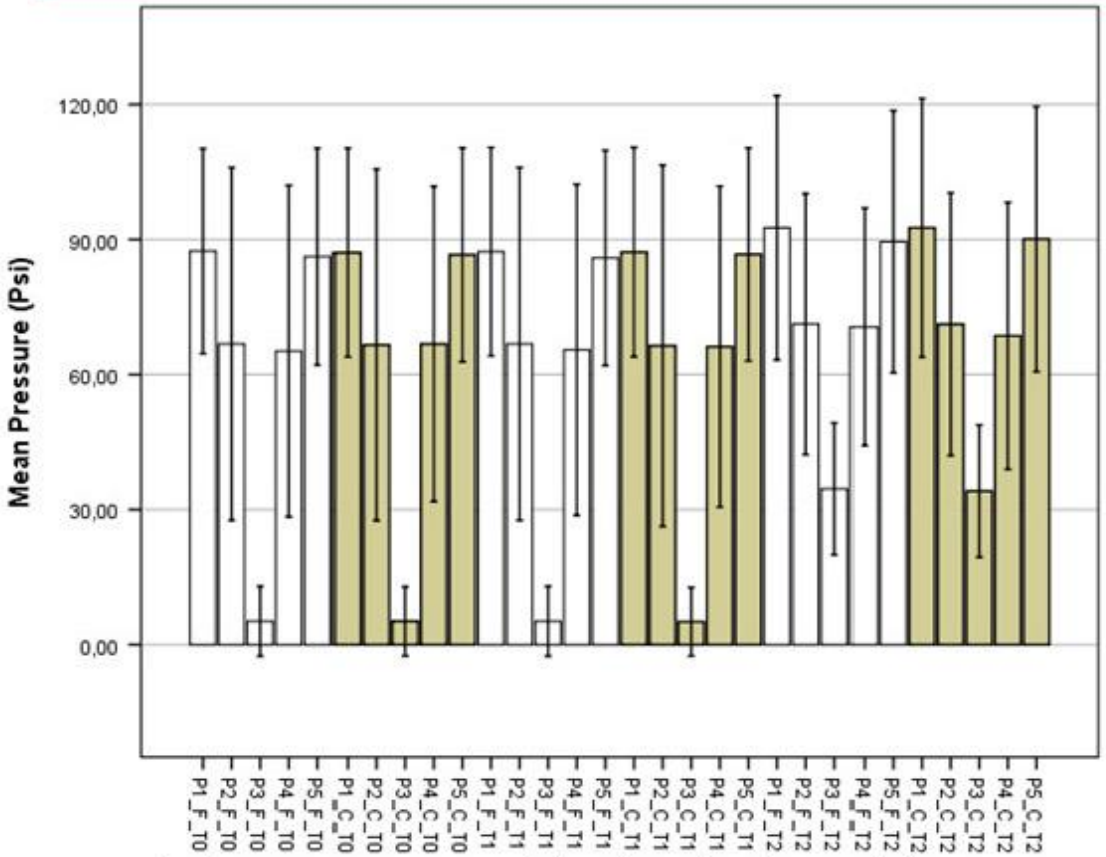

Figure 5: Mean bite pressure (psi) measured in five FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) by Examiner F and Examiner C at three different time moments (Time 0, Time 1 and Time 2). Error bars represent standard deviation values.

Sensors Comparison		Sum of Squares	Degrees of Freedom (df)	Mean Square	Test statistic (F)	P-value (Sig)
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 0	Between Groups	44901,920	4	11225,480	13,854	0,000***
	Within Groups	36462,800	45	810,284		
	Total	81364,720	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 1	Between Groups	44727,320	4	11181,830	13,780	0,000***
	Within Groups	36514,700	45	811,438		
	Total	81242,020	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 2	Between Groups	21315,200	4	5328,800	7,695	0,000***
	Within Groups	31161,300	45	692,473		
	Total	52476,500	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 1	Between Groups	45045,520	4	11261,380	14,391	0,000***
	Within Groups	35212,900	45	782,509		
	Total	80258,420	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 2	Between Groups	45192,280	4	11298,070	13,971	0,000***
	Within Groups	36390,600	45	808,680		
	Total	81582,880	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 2	Between Groups	21982,680	4	5495,670	7,548	0,000***
	Within Groups	32762,200	45	728,049		
	Total	54744,880	49	-		

Table 5: Statistical parameters obtained in the One-Way ANOVA for the comparison of FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions.
* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Because One-Way ANOVA only gives information about the presence of differences, not specifying where these differences are located, a Post-Hoc Gabriel test was used to perform pairwise comparisons between the FSS sensors, and these results are represented in Table 6.

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
F_T0	Q1/P1	Q2/P2	20,600	12,730	0,673
		Q3/P3	82,200	12,730	0,000***
		Q4/P4	22,200	12,730	0,579
		Q5/P5	1,200	12,730	1,000
	Q2/P2	Q1/P1	-20,600	12,730	0,673
		Q3/P3	61,600	12,730	0,000***
		Q4/P4	1,600	12,730	1,000
		Q5/P5	-19,400	12,730	0,741
	Q3/P3	Q1/P1	-82,200	12,730	0,000***
		Q2/P2	-61,600	12,730	0,000***
		Q4/P4	-60,000	12,730	0,000***
		Q5/P5	-81,000	12,730	0,000***
	Q4/P4	Q1/P1	-22,200	12,730	0,579
		Q2/P2	-1,600	12,730	1,000
		Q3/P3	60,000	12,730	0,000***
		Q5/P5	-21,000	12,730	0,650
	Q5/P5	Q1/P1	-1,200	12,730	1,000
		Q2/P2	19,400	12,730	0,741
		Q3/P3	81,000	12,730	0,000***
		Q4/P4	21,000	12,730	0,650
F_T1	Q1/P1	Q2/P2	20,500	12,739	0,680
		Q3/P3	82,100	12,739	0,000***
		Q4/P4	21,800	12,739	0,603
		Q5/P5	1,400	12,739	1,000
	Q2/P2	Q1/P1	-20,500	12,739	0,680
		Q3/P3	61,600	12,739	0,000***
		Q4/P4	1,300	12,739	1,000
		Q5/P5	-19,100	12,739	0,758
	Q3/P3	Q1/P1	-82,100	12,739	0,000***
		Q2/P2	-61,600	12,739	0,000***
		Q4/P4	-60,300	12,739	0,000***
		Q5/P5	-80,700	12,739	0,000***
	Q4/P4	Q1/P1	-21,800	12,739	0,603
		Q2/P2	-1,300	12,739	1,000
		Q3/P3	60,300	12,739	0,000***
		Q5/P5	-20,400	12,739	0,686
	Q5/P5	Q1/P1	-1,400	12,739	1,000
		Q2/P2	19,100	12,739	0,758
		Q3/P3	80,700	12,739	0,000***
		Q4/P4	20,400	12,739	0,686

F_T2	Q1/P1	Q2/P2	21,400	11,768	0,523
		Q3/P3	58,000	11,768	0,000***
		Q4/P4	22,000	11,768	0,485
		Q5/P5	3,100	11,768	1,000
	Q2/P2	Q1/P1	-21,400	11,768	0,523
		Q3/P3	36,600	11,768	0,031*
		Q4/P4	0,600	11,768	1,000
		Q5/P5	-18,300	11,768	0,719
	Q3/P3	Q1/P1	-58,000	11,768	0,000***
		Q2/P2	-36,600	11,768	0,031*
		Q4/P4	-36,000	11,768	0,036*
		Q5/P5	-54,900	11,768	0,000***
	Q4/P4	Q1/P1	-22,000	11,768	0,485
		Q2/P2	-0,600	11,768	1,000
		Q3/P3	36,000	11,768	0,036*
		Q5/P5	-18,900	11,768	0,682
	Q5/P5	Q1/P1	-3,100	11,768	1,000
		Q2/P2	18,300	11,768	0,719
		Q3/P3	54,900	11,768	0,000***
		Q4/P4	18,900	11,768	0,682

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
C_T0	Q1/P1	Q2/P2	20,500	12,510	0,658
		Q3/P3	81,900	12,510	0,000***
		Q4/P4	20,300	12,510	0,670
		Q5/P5	,500	12,510	1,000
	Q2/P2	Q1/P1	-20,500	12,510	0,658
		Q3/P3	61,400	12,510	0,000***
		Q4/P4	-,200	12,510	1,000
		Q5/P5	-20,000	12,510	0,688
	Q3/P3	Q1/P1	-81,900	12,510	0,000***
		Q2/P2	-61,400	12,510	0,000***
		Q4/P4	-61,600	12,510	0,000***
		Q5/P5	-81,400	12,510	0,000***
	Q4/P4	Q1/P1	-20,300	12,510	0,670
		Q2/P2	,200	12,510	1,000
		Q3/P3	61,600	12,510	0,000***
		Q5/P5	-19,800	12,510	0,699
	Q5/P5	Q1/P1	-,500	12,510	1,000
		Q2/P2	20,000	12,510	0,688
		Q3/P3	81,400	12,510	0,000***
		Q4/P4	19,800	12,510	0,699

C_T1	Q1/P1	Q2/P2	20,800	12,718	0,660
		Q3/P3	82,100	12,718	0,000***
		Q4/P4	21,000	12,718	0,649
		Q5/P5	,500	12,718	1,000
	Q2/P2	Q1/P1	-20,800	12,718	0,660
		Q3/P3	61,300	12,718	0,000***
		Q4/P4	,200	12,718	1,000
		Q5/P5	-20,300	12,718	0,689
	Q3/P3	Q1/P1	-82,100	12,718	0,000***
		Q2/P2	-61,300	12,718	0,000***
		Q4/P4	-61,100	12,718	0,000***
		Q5/P5	-81,600	12,718	0,000***
	Q4/P4	Q1/P1	-21,000	12,718	0,649
		Q2/P2	-,200	12,718	1,000
		Q3/P3	61,100	12,718	0,000***
		Q5/P5	-20,500	12,718	0,678
	Q5/P5	Q1/P1	-,500	12,718	1,000
		Q2/P2	20,300	12,718	0,689
		Q3/P3	81,600	12,718	0,000***
		Q4/P4	20,500	12,718	0,678
C_T2	Q1/P1	Q2/P2	21,400	12,067	0,556
		Q3/P3	58,500	12,067	0,000***
		Q4/P4	24,000	12,067	0,401
		Q5/P5	2,500	12,067	1,000
	Q2/P2	Q1/P1	-21,400	12,067	0,556
		Q3/P3	37,100	12,067	0,035*
		Q4/P4	2,600	12,067	1,000
		Q5/P5	-18,900	12,067	0,711
	Q3/P3	Q1/P1	-58,500	12,067	0,000***
		Q2/P2	-37,100	12,067	0,035*
		Q4/P4	-34,500	12,067	0,061
		Q5/P5	-56,000	12,067	0,000***
	Q4/P4	Q1/P1	-24,000	12,067	0,401
		Q2/P2	-2,600	12,067	1,000
		Q3/P3	34,500	12,067	0,061
		Q5/P5	-21,500	12,067	0,550
	Q5/P5	Q1/P1	-2,500	12,067	1,000
		Q2/P2	18,900	12,067	0,711
		Q3/P3	56,000	12,067	0,000***
		Q4/P4	21,500	12,067	0,550

Table 6: Statistical parameters obtained in the Post-Hoc Gabriel test for the comparison of FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions.
* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Discussion:

Comparison A – Testing the Differences between Examiners (F vs C)

No significant statistical differences in the mean bite pressure (psi) measured have been identified between Examiner F and Examiner C, when the measurement was made in the same experimental conditions. Almost all experiments revealed p-values above the cut-off value of 0,05 ($p > 0,05$), which means that H0 proposition is valid. The results obtained for sensor Q5/P5 at time 1 were not considered significant, as the general trend of data is the absence of statistical differences between examiners. Thus, it is concluded that the choice of examiner is not a variable that affects the mean bite pressure (psi) measured in any of the experimental conditions tested.

Comparison B – Testing the Differences between Times (T0 vs T1 vs T2)

No significant statistical differences in the mean bite pressure (psi) measured have been identified between Time 0, Time 1 and Time 2, when the measurement was made in the same experimental conditions, with exception to sensor FSS Q3/P3.

Significant statistical differences ($p < 0,05$) have been identified between Time 2 (1 month after surgery) and Times 0 and 1 (prior to surgery) in the FSS sensor P3/Q3 located in the anterior region of the maxillae/mandibulae. Given the nature of the surgical procedure performed in the 10 patients – a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible – it was expected that it would reflect in the mean pressure (psi) measured in the anterior region of the maxillae/mandibulae, as now it is statistically demonstrated.

Comparison C – Testing the Differences between Sensors (Q1/P1 vs Q2/P2 vs Q3/P3 vs Q4/P4 vs Q5/P5)

Significant statistical differences in the mean bite pressure (psi) have been identified between different FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5), when the measurement if made in the same experimental conditions. All experiments revealed p-values below the cut-off value of 0,05 ($p < 0,05$), meaning that H0 proposition is invalid. These differences have been identified between certain pairs of FSS sensors (Table 6 and Fig. 5), allowing the definition of a three-pressure region model where the key-factor seems to be the relative distance of the sensors to the occlusion region: the higher the distance to the occlusion region, the lower is the mean bite pressure (psi).

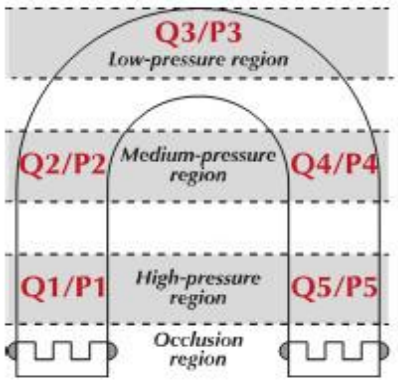

Figure 6: Three-pressure region model for dental occlusion

Another interesting observation is that, when two FSS sensors are located in the same pressure region (i.e., Q1/P1+Q5/P5 and Q2/P2+Q4/P4), no statistical differences are recognisable within the pairs of FSS sensors, meaning that the pressures detected are statistically identical to one another ($p > 0,05$).

On the opposite side, whenever two FSS sensors are located in different pressure regions, statistically significant differences ($p < 0,05$) have been found between the measured pressures (Table 5), showing the high sensibility of measurement of the experimental device.

Conclusions:

The innovation in this study resides in the construction of a prototype device called the Occlusal Force Diagnostic System accompanied by a second prototype device called the Bite Training Machine to measure patients' occlusal force.

No significant statistical differences in the mean bite pressure (psi) were detected between examiners when the measurement was made in the same experimental conditions ($p > 0,05$).

When comparing pre-op (Times 0 and 1) and post-op (Time 2) data, significant statistical differences have been found in the mean bite pressure measured by FSS sensor Q3/P3 located in the anterior region of the maxilla/ mandible ($p < 0,05$), those differences being absent in the remaining FSS sensors Q1/P1, Q2/P2, Q4/P4 and Q5/P5 ($p > 0,05$).

Given the nature of the surgical procedure performed in the 10 patients – a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement

of the mandible – it was expected that the major changes in the patients would be concentrated in the anterior region of the maxilla/mandible, as it was statistically demonstrated.

Significant differences ($p < 0,05$) have been identified between certain pairs of FSS sensors, allowing the definition of a three-pressure region model where the key-factor seems to be the relative distance of the sensors to the occlusion region: the higher the distance to the occlusion region, the lower is the mean bite pressure (psi).

Another interesting observation is that, when two FSS sensors are located in the same pressure region (i.e., Q1/P1+Q5/P5 and Q2/P2+Q4/P4), no statistical differences are recognisable within the pairs of FSS sensors, meaning that the pressures detected are statistically identical to one another ($p > 0,05$). On the opposite side, whenever two FSS sensors are located in different pressure regions, statistically significant differences ($p < 0,05$) have been found between the measured pressures, showing the high sensibility of measurement of the experimental device.

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ARTICLE 3

Duarte F., Silva JN., Ramos C., Hopper C. Occlusal Force Diagnostic System – A Device for Clinical Application in Orthognathic Surgery. International Journal of Modern Engineering Research (IJMER) 2024; 14(1):46-53

Authors	**Duarte F.,** Silva JN., Ramos C., Hopper C.
Journal	International Journal of Modern Engineering Research (IJMER)
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Contribution by F Duarte	Concept Performance of systematic review of literature Appraisal of included studies Development of recurrence risk stratification Manuscript writing & editing
ISSN	**2249-6645**
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Post-Viva Addenda:

-The masseter muscle was chosen because of its penniform structure, specifically due to the presence of alternating muscular and aponeurotic layers. Anatomical sections and magnetic resonance imaging in the same plane allowed us to define the appearance of the intramuscular aponeurotic layers on magnetic resonance imaging.

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Occlusal Force Diagnostic System – A Device for Clinical Application in Orthognathic Surgery

Fernando Duarte, DMD, MSc, MSc
Oral Surgeon Specialist by OMD (Portuguese Dental Association)
Master of Science in Oral and Maxillofacial Surgery at Eastman Dental Institute - University College of London
Master of Science in Laser Dentistry at Universitá Cattolica del Sacro Cuore - Rome – Italy
CEO and Clinical Director of Clitrofa - Trofa - Portugal

João Neves Silva, BsC, MSc, PhD
Professor at ISAVE - Instituto Superior de Saúde - Portugal
Member of the Interdisciplinary Center for Health Sciences (ICHS) - ISAVE - Instituto Superior de Saúde

Carina Ramos, DMD
MSc Student in Oral Rehabilitationat IUCS – Instituto Universitário de Ciências da Saúde - Portugal

Colin Hopper, MD FRCS FHEA
UCL Eastman Dental Institute
Oral &Maxillofacial Surgery Department

CorrespondingAuthor: *Fernando Duarte*
Clitrofa - Centro Médico, Dentário e Cirúrgico
Avenida de Paradela 622, 4785-248 Trofa - Portugal

Abstract:
This research project was designed to apply several, newly developed and more sophisticated methods of measuring muscle structure and function to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach, as is the case with orthognathic surgery.
The masseter muscle displays a penniform structure typically characterized by the presence of alternating muscular/aponeurotic layers. The anatomical sections and the MRI section in the same plane allowed the appearance of the intra-muscular aponeurotic layers on the MRI to be defined. Given these characteristics, the masseter muscle was chosen in preference to the medial pterygoid muscle.
A prototype device called the Occlusal Force Diagnostic System accompanied by a second prototype device called the Bite Training Machine were constructed to measure patients' occlusal force. This system was applied in a repeatability test with 30 patients that attend the combined orthodontic/orthognathic surgery outpatient clinic of Clitrofa - Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal.
KEY-WORDS
Occlusal Force Measurement; Orthognathic Surgery;Clinical Application

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I. INTRODUCTION

One of the main purposes of orthognathic treatment in patients with a dentofacial deformity is to improve masticatory function as well as aesthetics. Numerous studies have documented masticatory function, for example:bite force, occlusal contact and masticatory efficiency, in patients with mandibular prognathism before and after orthognathic surgery [1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13]; but few reports compared the results with those in controls with normal occlusion [1, 3, 6, 7, 8, 9, 12, 13]. There have also been few studies that involved

evaluation of these parameters at the initial medical consultation for patients undergoing orthognathic surgery [14, 15]. No reports were found that simultaneously evaluated the relationships between bite force, occlusal contact and masticatory efficiency in patients with mandibular prognathism and in controls with normal occlusion.

Previously, changes in bite force and occlusal contact before and after orthognathic surgery were investigated and presented using the T-Scan system™ (Tekscan, USA) [3]. This system is convenient and simple but is poor in regard to reproducibility and quantification.

Another method for occlusal analysis, the Dental Prescale™ system (Fuji Photo Film Co., Japan), has been developed. This is a computerized system intended to assist occlusal analysis by providing information as to the magnitude of the bite force and the distribution of occlusal contacts. The system is capable of simultaneously measuring these parameters for teeth separated by less than 10mm and has potential for research in centric occlusion. It is a horseshoe-shaped thin film that consists of two layers: a layer of microcapsules containing colour-forming materials and a layer of colour-developing materials. The colour-developing materials, producing a red colour in the contact area when a force is generated, absorb the released colour-forming materials. The Dental Prescale™ system has already been used for analysing occlusion in dentures [16, 17] dental implants [18] and orthognathic surgery [2, 8].

Many methods for the quantitative measurement of masticatory efficiency have been introduced, but none stands out as ideal. Spectrophotometric methods for the evaluation of masticatory efficiency have been reported, involving measurement of the absorbance of adenosine triphosphate (ATP) granules [6, 7, 12]. This technique shows both accuracy and reproductibility, but it has an high cost and an high complexity. Achewing-gum system has been developed for the estimation of masticatory function by the Meiji Chewing Gum Corporation. It utilizes a phloxine–sodium bicarbonate reaction and measures a chromatic coordinate as an indicator. This low-adhesive colourdeveloping chewing-gum system has already been used for analyzing the masticatory function of dental implants [19] and dentures [20], but it does not allow quantitative determination[21].

OCCLUSAL FORCE DIAGNOSTIC SYSTEM

1. SENSORS

The FS Series sensors provide precise reliable force sensing performance in a compact commercial grade package. The sensor features a proven sensing technology that uses a specialized piezoresistive micromachined silicon sensing element. The low power, unamplified, uncompensated wheatstone bridge circuit design provides inherently stable mV outputs over the force range[22].

Force sensors operate on the principle that the resistance of silicon-implanted piezoresistors will increase when the resistors flex under any applied force. The sensor concentrates force from the applications, through the stainless-steel ball, directly to the silicon-sensing element. The amount of resistance changes in proportion to the amount of force being applied. This change in circuit resistance results in a corresponding mV output level change[22].

The stainless-steel ball provides mechanical stability and is adaptable to a variety of applications. The FSS sensor delivered 20 million operations in Mean Cycles to Failure (MCTF) reliability testing at 50°C [122°F]. This test determines the number of possible sensor operations at full scale until failure. Various electric interconnects can accept prewired connectors, printed circuit board mounting, and surface mountings. The sensor design also provides a variety of mounting options that include mounting brackets, as well as application specific mounting requirements.

The typical applications of this sensors are: medical infusion pumps, ambulatory non-invasive pump pressure, occlusion detection, kidney dialysis machines, load and compression sensing, variable tensions control, robotic end-effectors and wire bonding equipment [22].

2. SENSOR CIRCUIT

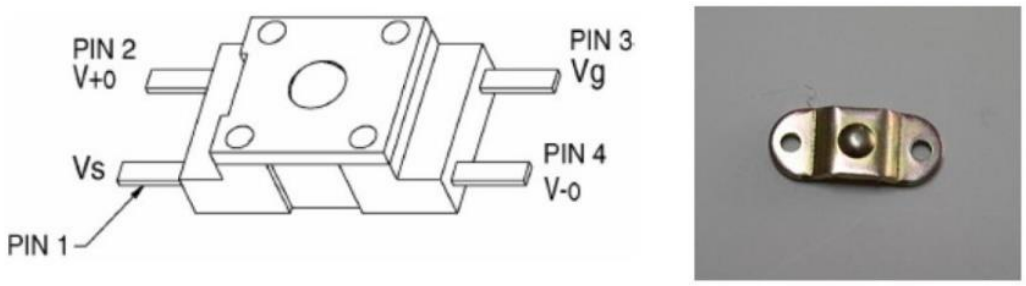


Fig. 1 - Schematic illustration of Sensor Circuit. 1- Sensor terminals (pins): Pin 1 = Supply VS (+), Pin 2 = Output VO (+), Pin 3 = Ground Vg (-) Pin 4 = Output VO (-). 2 - The force sensor may be powered by voltage or current. Maximum supply voltage is not to exceed 12 volts. Maximum supply current is not to exceed 1.6 mA. Power is applied across Pin 1 and Pin 3.3- The sensor output should be measured as a differential voltage across Pin 2 and Pin 4 (VO = V2 - V4). The output is ratiometric to the supply voltage. Shifts in supply voltage will cause shifts in output. Neither Pin 2 nor Pin 4 should be tied to ground or voltage supply.

3. SENSORS DISTRIBUTION

The first idea was to place seven sensors distributed by the dental arch in a horseshoe-shaped form designated by bite force, but because of the sensors dimensions was decided to place only five. One sensor was for the anterior teeth (central and lateral incisors), two sensors for the canine and first pre-molar and another two sensors for the second pre-molar and first molar. The objective of this sensor's distribution was to make measurements of occlusal contact areas and occlusal pressures individually and in total. The sensors were connected between them, and the cables connected to a transducer that shows the digital reading in kilograms.

During the process of development was felt interesting to have the five sensors reading at the same time, and to achieve this several changes were introduced, namely the inclusion of five digital screens, each one corresponding to one sensor, the construction of a portable suitcase able to accommodate all the occlusal diagnostic system and an on-off bottom. Each digital screen works with its own battery placed in the suitcase under a metal foil that cover all the electrical connections.

The dental arch in a horseshoe-shaped form was build by a superior and an inferior 3mm height metal foil covered by a hard resin, with the following intra-oral measures: 63mm total width, 62mm total length, 15mm width in anterior occlusal contact area, 19mm width in posterior occlusal contact area, 30mm anterior height and 15mm posterior height. The dental arch dimensions were based on the majority of the dental arches studied during the improvement process.

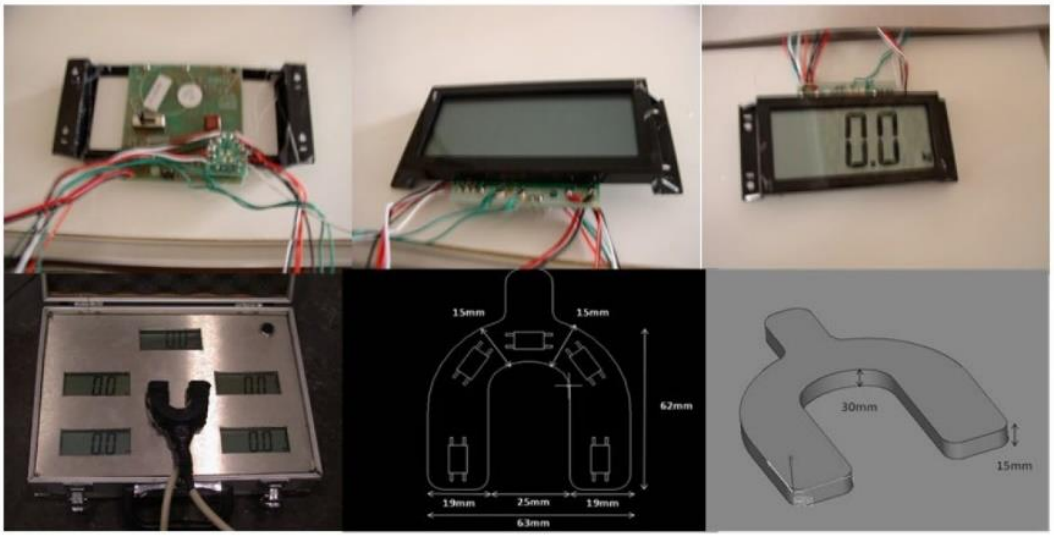


Fig. 2 - Image of the digital screens and sensors distribution

4. COMPATIBILITY

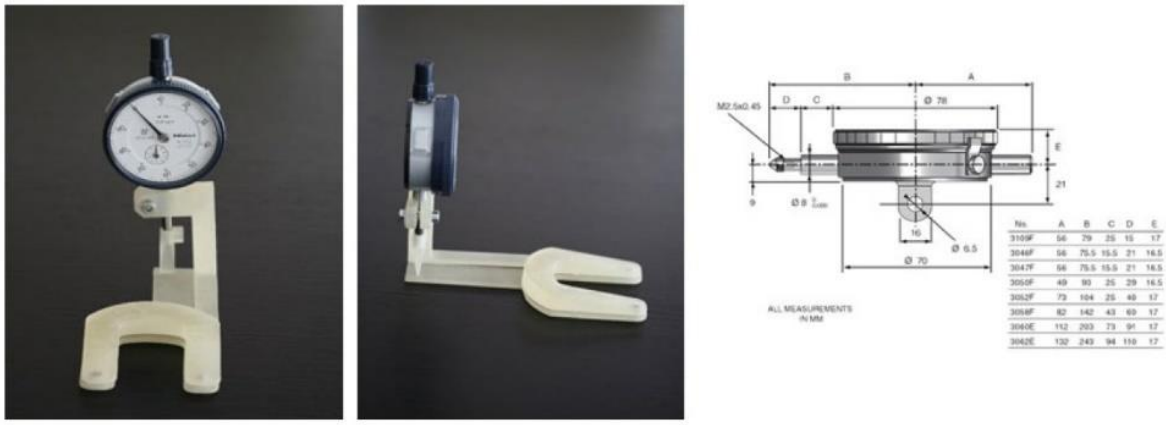
It is very important to ensure compatibility between the pressure or force sensor and the application in which it is used. The following should be considered before a sensor selection is made: (1) material; (2) chemicals; (3) concentration; (4) temperature; (5) exposure time; (6) type of exposure; (7) criteria for failure; and (8) general information such as application environment, protection of the device, and other foreign substances in the area.

BITE TRAINING MACHINE

In order to provide adequate training to the patients and teach how to bite in the same way during the study a bite training machine was developed. The major components of this new machine were: a dynamometer, a force indicator and an occlusal contact area indicator [23].

The occlusal contact area was built in a hard photosensitive resin with a similar strength of the occlusal force diagnostic system, and two springs were placed to allow movement return. The dynamometer was order from Mitutoyo™ (Mitutoyo Corporation, USA) and ensure that patient was biting hard enough to see the reading [23].

The occlusal contact area indicator was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized in the dynamometer and the procedure was repeated after 10 minutes until the patient felt comfortable.



No.	A	B	C	D	E
3109F	56	79	25	15	17
3046F	56	75.5	15.5	21	16.5
3047F	56	75.5	15.5	21	16.5
3050F	49	90	25	29	16.5
3052F	73	104	25	46	17
3058F	82	142	43	60	17
3060E	112	203	73	91	17
3062E	132	243	94	110	17

Fig. 3 - Major components of the Bite Training Machine: dynamometer, force indicator and occlusal area. Schematic illustration of the dynamometer

REPEATABILITY TEST

Thirty patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol:

a) Bite Training Machine: The occlusal contact area indicator was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized in the dynamometer and the procedure was repeated after 10 minutes until the patient felt comfortable.

b) Occlusal Force Diagnostic System: The system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and after 1 month (T2).

The five sensors were distributed in the following order, the readings were in kilograms: Sensor A: right maxillary second pre-molar and right maxillary first molar between 1st and 4th quadrants; Sensor B: right maxillary canine and right maxillary first pre-molar between 1st and 4th quadrants; Sensor C: right and left maxillary central incisors and right and left maxillary lateral incisors area; Sensor D: left maxillary second pre-molar and left maxillary first molar between 2nd and 3rd quadrants, and finally Sensor E: left maxillary canine and left maxillary first pre-molar between 2nd and 3rd quadrants.

In the proposed repeatability test, the bite force and occlusal pressure were measured for 30 consecutive patients twice by two different observers (F and C).A combination of different parametric tests has been used to compare the different experimental variables.

EXPERIMENTAL STRATEGY AND STATISTICAL ANALYSIS

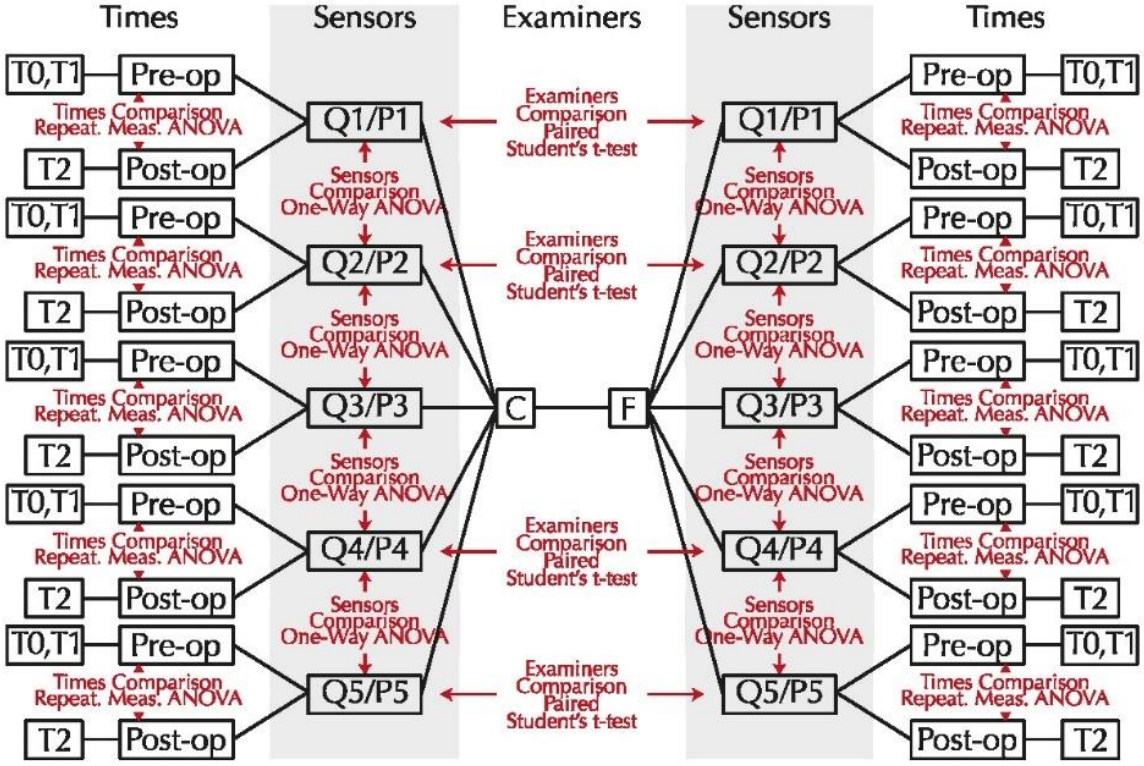


Fig. 4 -Experimental design used for the measurement of occlusal force.The present study is an observational prospective study with quantitative methodology.

IBM® SPSS® version 25, was used to analyze the data obtained. The data were first tested to ensure they conformed to a normal distribution by using Kolmogorov-Smirnov test. The data were then tested to ensure they complied with variance homogeneity by using Levene test.

Descriptive statistics measures included the arithmetic mean ($\bar{x}$) and standard deviation (SD) if the data were normally distributed and the variance was constant. Where the data were not normally distributed nor the variance was constant, the median and the inter-quartile range (IQR) were noted.

Where the requirements for parametric statistical analysis were met, inferential analysis involved the use of paired two-tailed Student's t test (examiners comparison), repeated measures ANOVA (times comparison) and One-Way ANOVA (sensors comparison). In the non-parametrical conditions, the equivalent inferential tests were respectively, Wilcoxon, Friedman and Kruskal-Wallis.

Where statistically significant differences were found by One-Way ANOVA test, the multiple-comparison Post-Hoc Bonferroni or Gabriel test was performed to identify the pairs of categories were the statistically significant differences were located.

The minimum level of significance (α level) accepted throughout the development studies was 0.05 (*), considered to be moderately significant. Levels of 0.01 (**) were considered as significant and 0.001 (***) designated as highly significant. A lack of statistical significance was designated as (ns).

II. RESULTS

Comparison A – Testing the Differences betweenExaminers (F versus C)

Table 1 - Statistical parameters obtained in the Paired Student's t-test for the comparison of examiners F and C when measuring the mean bite pressure (psi) in different experimental conditions.

ExaminersComparison	Mean Diference	Standard DeviationofDifferences	DegreesofFreedom(*df*)	Test statistic from Paired *t*-test	*P-value* fromPaired *t*-test
Examiner F *versus* Examiner C, P1, Time 0	0,300	0,823	9	1,152	0,279
Examiner F *versus* Examiner C, P1, Time 1	0,100	0,876	9	0,361	0,726
Examiner F *versus* Examiner C, P1, Time 2	0,000	1,054	9	0,000	1,000

Examiner F *versus* Examiner C, P2, Time 0	0,200	0,919	9	0,688	0,509
Examiner F *versus* Examiner C, P2, Time 1	0,400	1,647	9	0,768	0,462
Examiner F *versus* Examiner C, P2, Time 2	0,000	0,471	9	0,000	1,000
Examiner F *versus* Examiner C, P3, Time 0	0,000	0,471	9	0,000	1,000
Examiner F *versus* Examiner C, P3, Time 1	0,100	0,316	9	1,000	0,343
Examiner F *versus* Examiner C, P3, Time 2	0,500	0,850	9	1,861	0,096
Examiner F *versus* Examiner C, P4, Time 0	-1,600	4,061	9	-1,246	0,244
Examiner F *versus* Examiner C, P4, Time 1	-0,700	2,263	9	-0,978	0,354
Examiner F *versus* Examiner C, P4, Time 2	2,000	7,055	9	0,896	0,393
Examiner F *versus* Examiner C, P5, Time 0	-0,400	1,075	9	-1,177	0,269
Examiner F *versus* Examiner C, P5, Time 1	-0,800	1,033	9	-2,449	0,037*
Examiner F *versus* Examiner C, P5, Time 2	-0,600	1,506	9	-1,260	0,239

** moderately significant to 0.05 level;*
*** significant to 0.01 level;*
**** highly significant to 0.001 level.*

The statistical comparison between examiners F and C regardingthe measurement of mean bite pressure (psi) was performedusing a Paired Student's t-test for the five different FSS sensors(Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at the three differenttime moments (Time 0, Time 1 and Time 2).

There are no significant differences in the mean bite pressure(psi) measured by Examiner F and Examiner C, when themeasurement is made in the same experimental conditions. Almost all experiments reveal p-values above the cutoffvalue of 0,05 (p >0,05), which means that H0 proposition isvalid. Thus,it is concluded that the choice of examiner is not a variablethat affects the mean bite pressure (psi) measured in any of theexperimental conditions tested.

Comparison B – Testing the Differences between Times(T0 vs T1 vs T2)

Table 2 - Statistical parameters obtained in the Repeated Measures ANOVA for the comparison of time moments (Time 0, Time 1 and Time 2) when measuring the mean bite pressure (psi) in different experimental conditions.

Times Comparison	DegreesofFreedom*(df)*	Teststatistic*(F)*	*P-value (Sig)*
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P1	2, 18	2,711	0,094
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P1	2, 18	3,372	0,057
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P2	2, 18	0,599	0,560
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P2	2, 18	0,665	0,527
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P3	2, 18	52,762	0,000***
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P3	2, 18	49,924	0,000***
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P4	2, 18	1,042	0,373
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P4	2, 18	0,232	0,796
Time 0 *vs* Time 1 *vs* Time 2, Examiner F, P5	2, 18	0,832	0,451
Time 0 *vs* Time 1 *vs* Time 2, Examiner C, P5	2, 18	0,808	0,461

The statistical comparison between the three time moments(Time 0, Time 1 and Time 2) regarding the measurement of meanbite pressure (psi) was performed using a Repeated MeasuresANOVA for the five FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 andQ5/P5) and the different examiners F and C.

There are no significant differences in the mean bite pressure(psi) measured at Time 0, Time 1 or Time 2, for the sameExaminer (C or F) and the same Sensor (Q1/P1, Q2/P2, Q3/P3,Q4/P4 or Q5/P5) (p > 0,05). Almost all experimentsreveal p-values above the cut-off value of 0,05 (p > 0,05), whichmeans that H0 proposition is valid. Thus, it is concluded the mean bite pressure (psi) measured atdifferent time frames is consistently the same, showing the highreproducibility of the measurements.

Comparison C – Testing the Differences between Sensors(Q1/P1 vs Q2/P2 vs Q3/P3 vs Q4/P4 vs Q5/P5)

Table 3 - Statistical parameters obtained in the One-Way ANOVA for the comparison of FSS sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions.

SensorsComparison		Sum ofSquares	DegreesofFreedom*(df)*	MeanSquare	Teststatistic*(F)*	*P-value (Sig)*
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner F, Time 0	**Between Groups**	44901,920	4	11225,480	13,854	0,000****
	Within Groups	36462,800	45	810,284		
	Total	81364,720	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5,	**Between Groups**	44727,320	4	11181,830	13,780	0,000****

Examiner F, Time 1	**Within Groups**	36514,700	45	811,438		
	Total	81242,020	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner F, Time 2	**Between Groups**	21315,200	4	5328,800	7,695	0,000****
	Within Groups	31161,300	45	692,473		
	Total	52476,500	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner C, Time 1	**Between Groups**	45045,520	4	11261,380	14,391	0,000****
	Within Groups	35212,900	45	782,509		
	Total	80258,420	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner C, Time 2	**Between Groups**	45192,280	4	11298,070	13,971	0,000****
	Within Groups	36390,600	45	808,680		
	Total	81582,880	49	-		
P1 *vs* P2 *vs* P3 *vs* P4 *vs* P5, Examiner C, Time 2	**Between Groups**	21982,680	4	5495,670	7,548	0,000****
	Within Groups	32762,200	45	728,049		
	Total	54744,880	49	-		

** moderately significant to 0.05 level;*

The statistical comparison between the five FSS sensors (Q1/P1,Q2/P2, Q3/P3, Q4/P4 and Q5/P5) regarding the measurement ofmean bite pressure (psi) was performed using a One-Way ANOVAfor the different examiners F and C at the three different timemoments (Time 0, Time 1 and Time 2).

There are significant differences in the mean bite pressure (psi)measured by the different FSS sensors (Q1/P1, Q2/P2, Q3/P3,Q4/P4 and Q5/P5), when the measurement is made in the sameexperimental conditions. All experimentsreveal p-values below the cut-off value of 0,05 ($p < 0,05$), whichmeans that H0 proposition is invalid. Thus, it is concluded thatthe five FSS sensors detect different mean bite pressures (psi) forthe same Examiner (F or C) at the same time moment (Time 0,Time 1 or Time 2).

Because One-Way ANOVA only gives information about thepresence of differences, not specifying where these differencesare located, a Post-hoc Gabriel test was used to perform pairwisecomparisons between the FSS sensors.

Significant differences ($p < 0,05$) have been identified betweencertain pairs of FSS sensors, allowing the definitionof a three-pressure region model: 1) low-pressureregion located in the anterior part of the dental arch; 2) mediumpressureregion in the intermediate part of the dental arch; and3) high-pressure region located in the posterior part of the dentalarch.

Another interesting observation is that, when two FSS sensorsare located in the same pressure region (i.e., Q1/P1+Q5/P5 andQ2/P2+Q4/P4), no statistical differences are recognisable withinthe pairs of FSS sensors, meaning that the pressures detectedare statistically identical to one another ($p > 0,05$).

On the opposite side, whenever two FSS sensors are located indifferent pressure regions, statistically significant differences ($p < 0,05$) have been found between the measured pressures, showing the high sensibility of measurement ofthe experimental device.

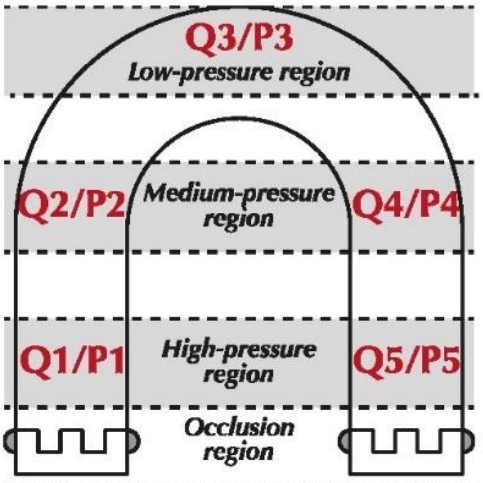


Fig. 5- Three-pressure region model for dental occlusion.

III. CONCLUSIONS

The piezoelectric sensors used in the present study have shownhigh reproducibility of measurement. Neither the variation ofexaminer, nor the variation of time have shown to influence thebite pressure (psi).In contrast, the occlusal force measurement system developedhas shown a high level of sensitivity due to the distribution of thefive FSS sensors in the horseshoe-shaped form.A three-pressure regionmodel fits the experimental data shownin this study, comprising a low-pressure region located in theanterior part of the dental

arch, a medium-pressure region inthe medial part of the dental arch and an high-pressure regionlocated in the posterior part of the dental arch.Due to the recent miniaturization of FSS sensors, the authorsare developing new occlusal force measurement systemscomprising a higher number of piezoelectric sensors, with theobjective of attaining even higher sensitivity of measurementthroughout the different region of the dental arches.

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ARTICLE 4

Duarte F., Silva JN., Ramos C., Hopper C. Evaluation of Occlusal Force Changes in Orthognathic Surgery using Force Sensing Sensors in 3 Years of Follow-up. Annals of Medicine & Surgery 2024; 86(9):5199-5205

Authors	**Duarte F.,** Silva JN., Ramos C., Hopper C.
Journal	Annals of Medicine & Surgery
DOI	10.1097/MS9.0000000000002386
Contribution by F Duarte	Concept Performance of systematic review of literature Appraisal of included studies Development of recurrence risk stratification Manuscript writing & editing
ISSN	2049-0801
IF	1,7

Post-Viva Addenda:

-A convenience non-probability sampling method is a research technique that selects participants based on their immediate availability, proximity, and ease of access to the researcher, rather than random selection.

-In results, Q3 is the lowest force, which means closer to the fulcrum, the higher the force.

Experimental Research

ANNALS OF MEDICINE & SURGERY

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Evaluation of occlusal force changes in orthognathic surgery using force-sensing sensors in 3 years of follow-up

Fernando Duarte, DMD, MSc, MSc[a,c,d,*], João Neves Silva, BSc, MSc, PhD[e], Carina Ramos, DMD[f], Colin Hopper, MD[b]

Purpose: The aim of this study was to test a prototype device called occlusal force diagnostic system in relation to occlusal force adaptation following orthognathic surgery.

Methods: Retrospective study of 10 patients scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible; in a 3 years follow-up period.

Results: The selection of examiner is not a variable that affects the occlusal force (N) measured by FSS sensors in any of the experimental conditions tested. The sensor position and the surgery recovery time affect the occlusal force irrespective of the examiner selection and/or the surgery recovery time.

Conclusion: The piezoelectric sensors used in the present study have shown high reliability and validity of measurement. The surgery recovery time impacts the occlusal force (N), with a 50% increase in occlusal force (N) measured after 6 months post-surgery, with the value keeping stable at 36 months. This suggests that the patient is only fully recovered from the functional point-of-view at 6 months, having from that point on an improved and stable masticatory function.

Keywords: force-sensing sensors, occlusal force, orthognathic surgery

Introduction

One of the main purposes of orthognathic treatment in patients with a dentofacial deformity is to improve masticatory function as well as aesthetics[1–3]. Numerous studies have documented masticatory function, for example bite force, occlusal contact and masticatory efficiency, in patients with mandibular prognathism before and after orthognathic surgery[4–13]; but few reports compared the results with those in controls with normal occlusion[1,3,6–9,12,13]. There have also been few studies that involved the evaluation of these parameters at the initial medical consultation for patients undergoing orthognathic surgery[14,15]. No reports were found that simultaneously evaluated the relationships between bite force, occlusal contact and masticatory efficiency in patients with mandibular prognathism and in controls with normal occlusion.

[a]Eastman Dental Institute, University College of London, [b]UCL Eastman Dental Institute, London, UK, [c]Universitá Cattolica del Sacro Cuore, Rome, Italy, [d]Clitrofa, Trofa, [e]Instituto Superior de Saúde and [f]Instituto Universitário de Ciências da Saúde, Portugal

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*Corresponding author. Address: Clitrofa, Centro Médico, Dentário e Cirúrgico, Avenida de Paradela 622, 4785 248 Trofa, Portugal. Tel.: +351 252 428 961. fax: +351 252 428 961. E-mail: fduarte@clitrofa.com (F. Duarte).

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Previously, changes in bite force and occlusal contact before and after orthognathic surgery were investigated and presented using the T-Scan system (Tekscan, USA)[3]. This system is convenient and simple but is poor in regard to reproducibility and quantification.

Another method for occlusal analysis, the Dental Prescale system (Fuji Photo Film Co.), has been developed. This is a computerised system intended to assist occlusal analysis by providing information as to the magnitude of the bite force and the distribution of occlusal contacts. The system is capable of simultaneously measuring these parameters for teeth separated by less than 10 mm and has the potential for research in centric occlusion. It is a horseshoe-shaped thin film that consists of two layers: a layer of microcapsules containing colour-forming materials and a layer of colour-developing materials. The colour-developing materials, producing a red colour in the contact area when a force is generated, absorb the released colour-forming materials. The Dental Prescale system has already been used for analysing occlusion in dentures[16,17] dental implants[18] and orthognathic surgery[2,8].

Many methods for the quantitative measurement of masticatory efficiency have been introduced, but none stands out as ideal. Spectrophotometric methods for the evaluation of masticatory efficiency have been reported, involving measurement of the absorbance of adenosine triphosphate (ATP) granules[6,7,12]. This technique shows both accuracy and reproductibility, but it has an high cost and complexity. A chewing-gum system has been developed for the estimation of masticatory function by the Meiji Chewing Gum Corporation. It utilises a phloxine–sodium bicarbonate reaction and measures a chromatic coordinate as an indicator. This low-adhesive colour-developing chewing-gum system has already been used for analysing the masticatory

function of dental implants[19] and dentures[20], but it does not allow quantitative determination[21].

It is now accepted that because there is no single method of assessing masticatory function, several measures should be taken, and whenever possible, simultaneously. This pilot investigation is designed to apply newly developed and more sophisticated methods of measuring muscle function to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach.

Materials and methods

The stability of orthognathic surgery is related to the adaptation of the masseter muscle, recurrence is a constant in the post-surgical course most frequently within 6 months from the operation. The aim of this study was to test a prototype device called occlusal force diagnostic system that will provide information in relation to occlusal force adaptation following orthognathic surgery.

The FSS sensors provide precise reliable force-sensing performance in a compact commercial-grade package. The sensor features a proven sensing technology that uses a specialized piezoresistive micromachined silicon-sensing element. The low-power, unamplified, uncompensated wheatstone bridge circuit design provides inherently stable mV outputs over the force range[22].

Force sensors operate on the principle that the resistance of silicon-implanted piezoresistors will increase when the resistors flex under any applied force. The sensor concentrates force from the applications, through the stainless-steel ball, directly to the silicon-sensing element. The amount of resistance changes in proportion to the amount of force being applied. This change in circuit resistance results in a corresponding mV output level change (Fig. 1)[22,23].

In this prototype device called occlusal force diagnostic system, five sensors were distributed in the following order with the readings in kilograms. Sensor A: right maxillary second pre-molar and right maxillary first molar between 1st and 4th quadrants; Sensor B: right maxillary canine and right maxillary first pre-molar between 1st and 4th quadrants; Sensor C: right and left maxillary central incisors and right and left maxillary lateral incisors area; Sensor D: left maxillary second pre-molar and left maxillary first molar between 2nd and 3rd quadrants, and finally Sensor E: left maxillary canine and left maxillary first pre-molar between 2nd and 3rd quadrants (Fig. 1).

The dental arch in a horseshoe-shaped form was built by a superior and an inferior 3 mm height metal foil covered by a hard resin, with the following intra-oral measures: 63 mm total width, 62 mm total length, 15 mm width in the anterior occlusal contact area, 19 mm width in the posterior occlusal contact area, 30 mm anterior height and 15 mm posterior height. The dental arch dimensions were based on the majority of the dental arches studied during the improvement process (Fig. 1).

The present study is a retrospective study with quantitative methodology. A study group of 10 patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa, Centro Médico, Dentário e Cirúrgico, in Trofa, Portugal was selected to the present study by a convenience non-probability sampling method. All the selected patients were scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible were select to form the study group.

The Occlusal Force Diagnostic System was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered by two different observers (F and C) in different moments: (T0) - before surgery, (T1) - 10 min after surgery, (T2) - 1 month after surgery, (T3) - 6 months after surgery and (T4) - 36 months after surgery.

Statistical analysis

IBM SPSS, version 25, was used to analyse the data obtained. Exploratory data analysis was performed by Kolmogorov–Smirnov (D) test to assess the normality of the frequency distributions and by Levene test (L) to assess the variance homogeneity of the variables.

Descriptive statistics of the study variables was performed by determination of mode and frequencies (nominal variables), median and interquartile range (ordinal variables), and arithmetic mean and standard deviation (numerical variables). Bar graphs were also added to facilitate data description and results interpretation.

Inferential statistics was used to compare examiner selection (paired two-tailed Student's t-test), sensor position (Repeated Measures ANOVA) and surgery recovery time (Repeated Measures ANOVA). Where the requirements for parametric statistical analysis were not met, the inferential tests were replaced, respectively, by Wilcoxon, Friedman and Friedman tests.

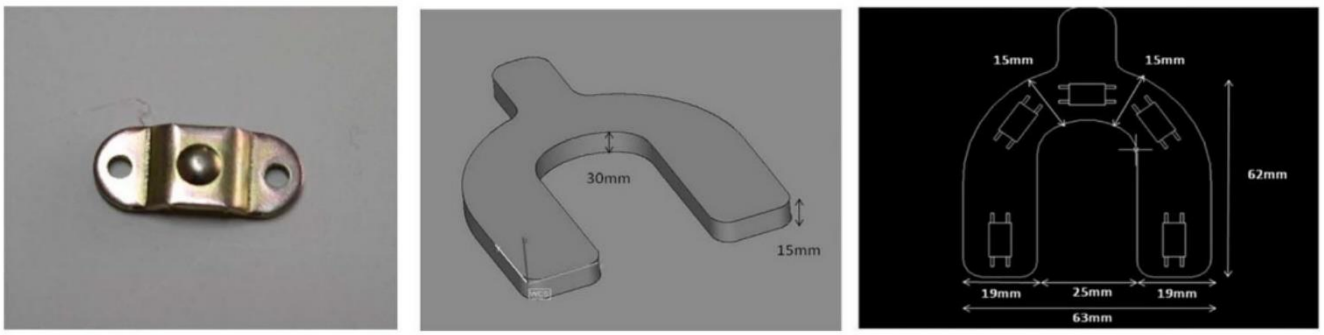

Figure 1. FSS sensor image, arch dimensions and sensors distribution.

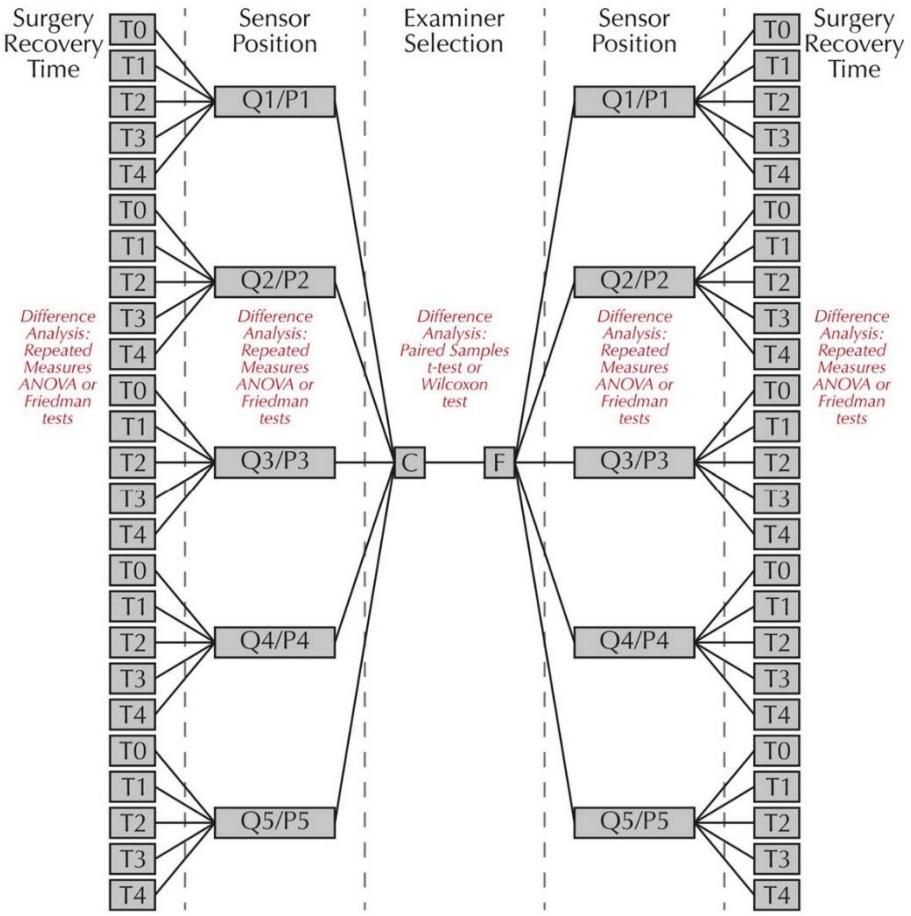

Figure 2. Experimental design used in the present study to evaluate the effect of examiner selection (F or C), sensor position (Q1/P1, Q2/P2, Q3/P3, Q4/P4 or Q5/P5) and surgery recovery time (T0 - before surgery, T1 - 10 min after surgery, T2 - 1 month after surgery, T3 - 6 months after surgery, or T4 - 36 months after surgery) on the occlusal force (N) measured by FSS sensors in the 10 patients of the sample.

The experimental design used in this study is depicted in Figure 2 and comprises 3 separate researches:

(1) Research A, which investigated the effect of examiner selection on the occlusal force (N) measured by FSS sensors;
(2) Research B, which investigated the effect of sensor position on the occlusal force (N) measured by FSS sensors;
(3) Research C, which investigated the effect of surgery recovery time on the occlusal force (N) measured by FSS sensors.

Table 1

Data exploratory analysis

Study variables	Central tendency measures	Dispersion measures	Kolmogorov–Smirnov test (D); P	Levene test (L); P
Examiner selection	Mode: C, F	Frequencies: C (50.0%); F (50.0%)	D: 0.339 Pvalue: 0.000***	L: 0.000 Pvalue: 0.989
Sensor position	Mode: Q1/P1; Q2/P2; Q3/P3 ; Q4/P4 ; Q5/P5	Frequencies: Q1/P1 (20.0%); Q2/P2 (20.0%); Q3/P3 (20.0%); Q4/P4 (20.0%); Q5/P5 (20.0%)	D: 0.158 Pvalue: 0.003***	L: 29.295 Pvalue: 0.000***
Surgery recovery time	Median: 3 (T2)	Interquartile Range: 2	D: 0.158 Pvalue: 0.003***	L: 0.911 Pvalue: 0.466
Occlusal force (N)	Mean: 46.87	SD: 19.56	NA	NA

NA, not applicable.
*Significant statistical difference to an alpha level of 0.05.
**Highly significant statistical difference to an alpha level of 0.01.
***Very highly significant statistical difference to an alpha level of 0.001.

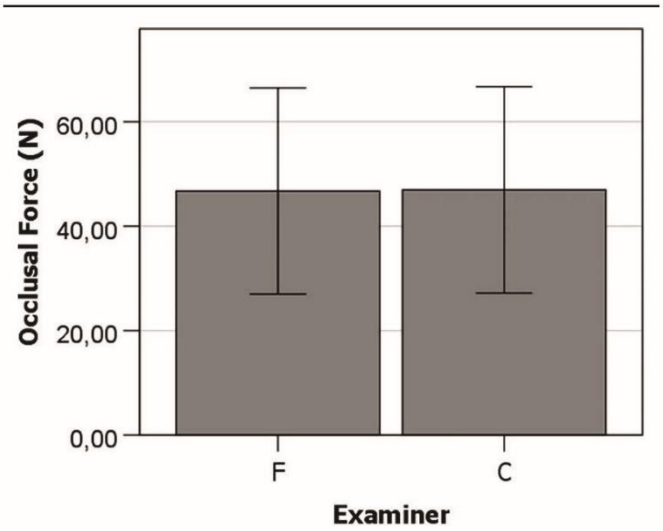

Figure 3. Effect of examiner selection on the occlusal force (N) measured by FSS sensors. Error bars represent standard deviation.

Where statistically significant differences were found by repeated measures ANOVA tests, the multiple-comparison Post-Hoc Bonferroni or Gabriel tests were performed to identify the pairs of categories were the statistically significant differences were located (Fig. 2).

Three thresholds of statistical significance (α level) were considered throughout the present study: p values below 0.05 (*) were considered statistically significant; p values below 0.01 (*) were considered highly statistically significant, and p values below 0.001 (*) were considered very highly statistically significant. The lack of statistical significance was designated as non-significant (ns).

Results

In order to make the presentation of results easier to understand; they were subdivided into four items, as follows: data exploratory analysis, the effect of examiner selection, the effect of sensor position and effect of surgery recovery time.

Data exploratory analysis

Kolmogorov–Smirnov (D) and Levene (L) assumption tests have revealed that the study variables do not comply the minimum requirements for an inferential parametric analysis (normality of frequency distributions and variance homogeneity), thus meaning that the effects of examiner selection, sensor position and surgery recovery time on the occlusal force (N) measured by FSS sensors will be analysed by the differences tests of Wilcoxon (U), Friedman (H) and Friedman (H), respectively presented in Table 1.

Research a: effect of examiner selection on the occlusal force (n) measured by FSS sensors

Figure 3 shows the similarity of occlusal force (N) measurements made by examiners F and C. The relatively high standard deviation of the measures depicted in Figure 3 arises from the fact that the examiners have been compared in different experimental conditions (sensors positions and surgery recovery times), which are in the graphic are presented in the same group of values.

Wilcoxon (U) tests have revealed the general absence of significant statistical differences between examiners F and C regarding the occlusal force (N) measured by FSS sensors in the 10 patients of the sample, in the different experimental conditions tested, presented in Table 2.

Research b: effect of sensor position on the occlusal force (n) measured by FSS sensors

Figure 4 shows the variation of occlusal force (N) measurements made with the different sensor positions. Results indicate a decrease in occlusal force (N) as the sensor position is placed closer to the temporomandibular joint. Additionally, pairs of sensors placed on the same left/right plan (pairs P2/P4 and P1/P5) detect identical occlusal forces (N), which show a homogeneous bite force in the frontal plane of the patients that compose the sample. The relatively high standard deviation of the measures depicted in Figure 4 arises from the fact that the sensor positions have been compared in different experimental conditions (examiner selection and surgery recovery times), which are in the graphic are presented in the same group of values.

Friedman (H) tests have revealed the presence of presence of very highly significant statistical differences between the different sensor positions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) regarding the occlusal force (N) measured by FSS sensors in the 10 patients of the sample, in the different experimental conditions tested, presented in Table 3.

Table 2

Effect of examiner selection on the occlusal force (N) measured by FSS sensors (Wilcoxon (U) test)

Experimental conditions	Wilcoxon (U)	P
F vs. C, Q1/P1, T0	−0.135	0.893
F vs. C, Q1/P1, T1	−10.763	0.078
F vs. C, Q1/P1, T2	−0.355	0.723
F vs. C, Q1/P1, T3	−0.271	0.786
F vs. C, Q1/P1, T4	−0.577	0.564
F vs. C, Q2/P2, T0	−10.633	0.102
F vs. C, Q2/P2, T1	−0.061	0.952
F vs. C, Q2/P2, T2	0.000	1.000
F vs. C, Q2/P2, T3	−0.632	0.527
F vs. C, Q2/P2, T4	−10.633	0.102
F vs. C, Q3/P3, T0	0.000	1.000
F vs. C, Q3/P3, T1	0.000	1.000
F vs. C, Q3/P3, T2	0.000	1.000
F vs. C, Q3/P3, T3	−20.121	0.034*
F vs. C, Q3/P3, T4	0.000	1.000
F vs. C, Q4/P4, T0	0.000	1.000
F vs. C, Q4/P4, T1	−0.137	0.891
F vs. C, Q4/P4, T2	−10.550	0.121
F vs. C, Q4/P4, T3	0.000	1.000
F vs. C, Q4/P4, T4	−0.816	0.414
F vs. C, Q5/P5, T0	−10.236	0.216
F vs. C, Q5/P5, T1	−0.141	0.888
F vs. C, Q5/P5, T2	0.000	1.000
F vs. C, Q5/P5, T3	−0.302	0.763
F vs. C, Q5/P5, T4	−10.633	0.102

*Significant statistical difference to an alpha level of 0.05.
**Highly significant statistical difference to an alpha level of 0.01.
***Very highly significant statistical difference to an alpha level of 0.001.

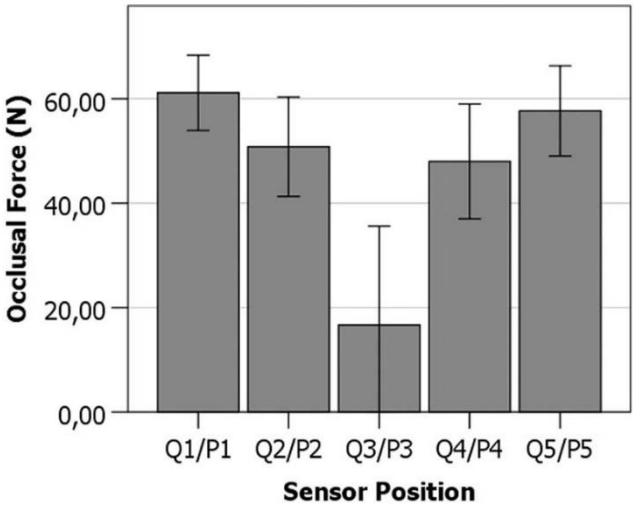

Figure 4. Effect of sensor position on the occlusal force (N) measured by FSS sensors. Error bars represent standard deviation.

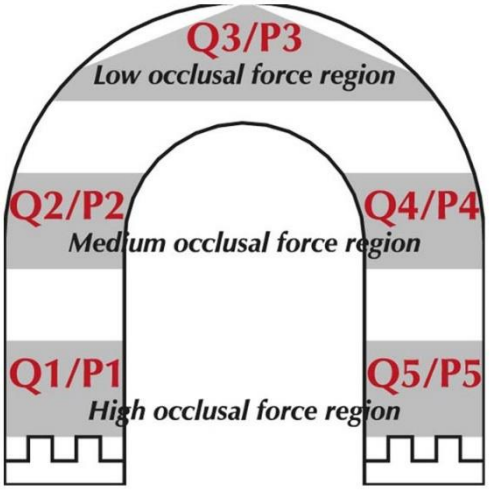

Figure 5. Three-pressure region model for dental occlusion.

This variation in occlusal force (N) measured by FSS sensors due to the sensor position was already expected and is related to the dynamics of the human masticatory function, where the temporomandibular joint (biomechanically characterised as a third-class lever (inter-potent), the different masticatory muscles (active and passive) and the complex jaw movements play an important role to mandible occlusion[24]. From the occlusal force (N) measurement point-of-view, the higher the distance between the sensor position and the temporomandibular joint, the higher the occlusal force (N) measured, as suggested by the following illustrative model in Figure 5:

Research c: effect of surgery recovery time on the occlusal force (n) measured by FSS sensors

Figure 6 shows the variation of occlusal force (N) measurements at different surgery recovery times. One of the most innovative aspects of the present study is that the follow-up period of the patients has been extended and reported until 36 months, thus allowing a more complete view of the patient's recovery process, as viewed by the masticatory force generated by the mandible. The data suggest a 50% increase in occlusal force (N) from 1 to 6 months in the patients, with the value stabilizing from that point until 36 months. It now becomes apparent that the increase in occlusal force produced by the surgery has a long-term stability, which shows the success of the clinical approach and the improvement of the patient's life quality.

'Friedman (H) tests have revealed the presence of very highly significant statistical differences between the different surgery recovery times (T0, T1, T2, T3 and T4) regarding the occlusal force (N) measured by FSS sensors in the 10 patients of the sample, in the different experimental conditions tested; shown in Table 4.

Table 3

Effect of sensor position on the occlusal force (N) measured by FSS sensors (Friedman (H) test)

Experimental conditions	Friedman (H)	*P*
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, F, T0	21.340	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, F, T1	20.551	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, F, T2	20.447	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, F, T3	26.330	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, F, T4	25.980	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, C, T0	20.975	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, C, T1	20.469	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, C, T2	21.082	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, C, T3	24.914	0.000***
Q1/P1 vs. Q2/P2 vs. Q3/P3 vs. Q4/P4 vs. Q5/P5, C, T4	25.629	0.000***

*Significant statistical difference to an alpha level of 0.05.
**Highly significant statistical difference to an alpha level of 0.01.
***Very highly significant statistical difference to an alpha level of 0.001.

Discussion

Relapse is a potential risk after orthognathic surgery[25]. The incidence of relapse after orthognathic surgery has been the

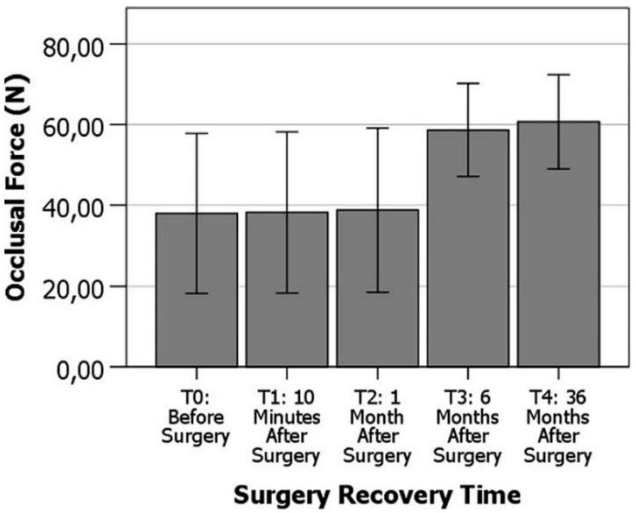

Figure 6. Effect of surgery recovery time on the occlusal force (N) measured by FSS sensors. Error bars represent standard deviation.

Table 4

Effect of surgery recovery time on the occlusal force (N) measured by FSS sensors (Friedman (*H*) test)

Experimental conditions	Friedman (*H*)	*P*
T0 vs. T1 vs. T2 vs. T3 vs. T4, F, Q1/P1	23.505	0.000***
T0 vs. T1 vs. T2 vs. T3 vs. T4, C, Q1/P1	21.751	0.000***
T0 vs. T1 vs. T2 vs. T3 vs. T4, F, Q2/P2	19.176	0.001***
T0 vs. T1 vs. T2 vs. T3 vs. T4, C, Q2/P2	19.311	0.001***
T0 vs. T1 vs. T2 vs. T3 vs. T4, F, Q3/P3	37.739	0.000***
T0 vs. T1 vs. T2 vs. T3 vs. T4, C, Q3/P3	38.717	0.000***
T0 vs. T1 vs. T2 vs. T3 vs. T4, F, Q4/P4	13.587	0.009**
T0 vs. T1 vs. T2 vs. T3 vs. T4, C, Q4/P4	12.645	0.013*
T0 vs. T1 vs. T2 vs. T3 vs. T4, F, Q5/P5	9.040	0.060
T0 vs. T1 vs. T2 vs. T3 vs. T4, C, Q5/P5	9.822	0.044*

*Significant statistical difference to an alpha level of 0.05.
**Highly significant statistical difference to an alpha level of 0.01.
***Very highly significant statistical difference to an alpha level of 0.001.

subject of extensive investigation in recent years, and it is a continuous process that needs to be assessed in the present and in the future[26]. Compared to the general population, the risk of relapse is greater in cleft lip and palate (CL/P) patients due to more risk factors[27]. The association between CL/P and a higher likelihood of relapse is well acknowledged, even though additional causes are not fully understood[27]. In a study of da Silva *et al.*[27], considering previous to surgery identical overjet values and degree of maxillary advancement in the groups with and without cleft, it was found that patients who had CL/P had an average relapse of 1248 cm, more than patients who did not have CL/P.

The first few days following surgery are quite challenging for the patients. Following the orthognathic surgery treatment, the postoperative healing period might take weeks or months[28]. The detection of relapse and its complex effect can be minimised by identifying their causes[28].

The relationship between occlusal and bite forces before and after orthognathic surgery has been extensively studied[29,30]. Most of these studies have evaluated bite force using different approaches and have reported varying outcomes[30].

In this study the selection of examiner was not a variable that affects the occlusal force measured by FSS sensors in any of the experimental conditions tested. The sensor position affects the occlusal force, irrespective of the examiner selection and/or the surgery recovery time.

In a recent systematic review and meta-analysis, with a protocol developed in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analysis Protocols (PRISMA-P), a search strategy was considered that resulted in 978 articles. The authors presented the following conclusions: occlusal strength increased after orthognathic surgery, although not to the level of the control group; however, maximum bite force remained unchanged. Immediately after orthognathic surgery, chewing and swallowing forces increased. Significant reductions in postoperative occlusal contact pressure areas were also observed[30]. The results of this work are in agreement with our study in terms of occlusal force.

Throckmorton and Ellis[31] presented a study comparing sagittal split ramus osteotomy with and without Le Fort I osteotomy. This study evaluated two variables: lip closing force and occlusal force. The occlusal force was evaluated using dental prescale and occluzer, which was connected to a computer interface; and they inferred that occlusal force improved postoperatively after orthognathic surgery[31].

In a publication of Harada *et al.*[32] performing Le Fort I and bilateral sagittal split osteotomy using occluzer, reported improved bite force postoperatively after orthognathic surgery. These authors were in agreement to the study published by Throckmorton and Ellis, which opined that increased bite force after orthognathic surgery could be due to a difference in the morphology of dentoskeletal structure[31,32].

In our study the surgery recovery time affects the occlusal force measured by FSS sensors, irrespective of the examiner selection and/or the sensor position. The duration of recovery of bite force has not been consistent among various studies[30]. The recovery was assessed in most of studies using variables including asymmetry, EMG activity of temporalis and masseter muscle attachments, dentoskeletal abnormalities, and lip function tests. In all of these studies, the recordings were performed preoperatively and at 1, 3, 6, and 12 months postoperatively[30].

In terms of the advantages of the device presented, we can highlight the high repeatability presented as well as the sensitivity in measuring pre and postoperative occlusal changes. From the point of view of limitations, we must mention the small number of clinical cases in which it was tested, which does not allow us to assess strong resolutions.

Conclusion

The piezoelectric sensors used in the present study have shown high reliability and validity of measurement. The selection of the examiner does not affect the measurement of occlusal force (N), which shows good inter-examiner reliability. The sensor position influences the occlusal force (N) that is measured, with the increase on sensor/temporomandibular joint distance increasing the occlusal force (N) measured, which is related to the complex dynamics of the human masticatory system. The surgery recovery time impacts the occlusal force (N), with a 50% increase in occlusal force (N) measured after 6 months post-surgery, with the value keeping stable at 36 months. This suggests that the patient is only fully recovered from the functional point-of-view at 6 months, having from that point on an improved and stable masticatory function.

Ethical approval

This project has approval by the Joint Research & Ethics Committee of UCL Hospitals NHS Trust, Reference No.03/E012.

Consent

Written informed consent was obtained from the patients for publication of this study and accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request.

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Author contribution

F.D., J.N.S., and C.R. read and wrote the manuscript. F.D. and C.R. were responsible for conducting surgeries. F.D. and J.N.S. were responsible for the data collection. F.D. designed and wrote the entire article. C.H. was responsible for the final revision of the manuscript. All authors read and approved the final manuscript.

Conflicts of interest disclosure

The authors declare that they have no competing interests.

Research registration unique identifying number (UIN)

This project is covered by the UCL Data Protection Registration Reference No. Z6364106, Section 19, Research: Health Research.

Guarantor

Fernando Duarte.

Data availability statement

No datasets were generated or analysed during the current study.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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2 PRESSURE MEASUREMENT

ARTICLE 5

Duarte F., Silva JN., Hopper C., Hunt N. The Importance of Pressure Measurement in Orthognathic Surgery. Scientific Archives of Dental Sciences 2020; 3(9):01-11

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Research Article

The Importance of Pressure Measurement in Orthognathic Surgery

Fernando Duarte[1]*, João Neves Silva[2], Colin Hopper[3] and Nigel Hunt[4]

[1]*Professor at ISAVE - Instituto Superior de Saúde and CEO and Clinical Director of Clitrofa, Trofa, Portugal*

[2]*Professor at ISAVE - Instituto Superior de Saúde and Member of the Interdisciplinary Center for Health Sciences (ICHS) - ISAVE - Instituto Superior de Saúde, Portugal*

[3]*Oral and Maxillofacial Surgery Department, UCL Eastman Dental Institute, United Kingdom*

[4]*Orthodontics Department, UCL Eastman Dental Institute, United Kingdom*

***Corresponding Author:** Fernando Duarte, Professor at ISAVE - Instituto Superior de Saúde and CEO and Clinical Director of Clitrofa, Trofa, Portugal.

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Abstract

Orthodontic and surgical technical advances in recent years have resulted in treatment opportunities for a whole range of craniofacial skeletal disorders either in the adolescent or adult patients.

Pressure is a critical variable in many converting operations. Despite its importance, pressure often receives very scant attention. Pressurex® **(SPL - Sensor Products LLC, USA) is a pressure indicating sensor film that reveals pressure distribution and magnitude** between any two contacting, mating or impacting surfaces.

This pilot investigation was designed to apply several, newly developed and more sophisticated methods of measuring muscle structure and function to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach.

Patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa - Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol: The Pressure Sensor Film System was placed between the upper and lower dental arch and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and after 1 month (T2). In the proposed repeatability test, the occlusal pressure was measured for 30 consecutive patients twice by two different observers.

Keywords: *Orthognathic Surgery; Masseter Muscle; Pressure Measurement, Pressurex®*

Introduction

Orthodontic and surgical technical advances in recent years have resulted in treatment opportunities for a whole range of craniofacial skeletal disorders either in the adolescent or adult patients. In the growing child these can include myofunctional orthodontic appliance therapy or distraction osteogenesis procedures, whilst in the adult the mainstay approach revolves around orthognathic surgery.

Research evidence suggests that in those cases requiring orthognathic surgery, the stability of the result depends upon such factors as the direction and extent of the surgical move of the facial **skeleton, the method of surgical fixation applied and the operative** technique employed. Yet, even when the best evidence-based **practice is followed, there remains a significant proportion of cases** where the surgical outcome (stability) is both unexpected and undesirable [1].

Our understanding of the biological adaptive mechanisms occurring in both the hard and soft tissues of the face and which are fundamental to all these treatment approaches remains, at a rather basic level. There is little information concerning the distribution of bite force on the dental arch during clenching in normal dentitions [2].

Bite force has been used to evaluate masticatory function in patients before and after orthognathic surgery [3-7]. Usually, it has been measured with a custom bite force transducer [5,6,8].

In 1977, a pressure-sensitive sheet was developed for industrial examination by Fuji Photo Film Co (Tokyo, Japan). In 1978, it was reported that the pressure-sensitive sheet may be useful for measuring bite pressure and occlusal balance [9]. Recently, the pressure-sensitive sheet has been improved for dental use (Dental-Prescale, Fuji Photo Film Co). Bite force, occlusal contact area, and occlusal balance are measured and analysed using the pressure-sensitive sheet and its analysis apparatus (Occluzer, Fuji Photo Film Co) [10].

Pressure is a critical variable in many converting operations. It can be the single factor that determines the success or failure of a flexible packaging laminating adhesive, a heat seal adhesive, or numerous other products. Despite its importance, pressure often receives very scant attention. Converters usually set pressure to a certain predetermined level and vary it when problems occur in an attempt to provide a quick fix. This approach obviously has little scientific merit and is definitely a seat-of-the-pants approach that frequently does not provide optimum results.

Tactile pressure-sensor films are an accurate, efficient, and inexpensive method to determine pressure. These films offer the converting industry an opportunity to determine both the distribution and magnitude of most operations where pressure is important.

Pressurex® (SPL - Sensor Products LLC, USA) is a pressure indicating sensor film that reveals pressure distribution and magnitude between any two contacting, mating or impacting surfaces. Pressurex® consists of a thin mylar film (4 to 8 mils) that contains a layer of tiny microcapsules. Because Pressurex® is extremely thin, it is ideal for invasive intolerant environments and curvaceous surfaces that are not accessible to electronic pressure transducers.

The application of force upon the film causes the microcapsules to rupture, producing an instantaneous and permanent high resolution "topographical" map of pressure variations across the contact area. Simply place sensor film, between any two surfaces that touch, mate or impact. Apply pressure, release it; immediately the film reveals a profile of the pressure distribution that occurred between the surfaces. The colour intensity of the image created is directly related to the amount of pressure applied, the greater the pressure, the more intense colour.

Pressurex® system

Film description

The sensor consists of a polyester film contact sheet and a separate polyester film developer sheet. Adhered to the transfer sheet is a microencapsulated layer containing indicator material. Adjacent to this is a colour developing layer. Pressure applied to either side of the composite film causes the microencapsulated indicator to rupture and react with the colour developing layer. The resultant colour relates directly to the magnitude of pressure applied to the film. Higher pressure gives a more intense colour. This is very similar to use of pH indicating paper to determine the amount of acidity in an aqueous solution by the colour that develops when a drop of the solution contacts the pH indicating paper.

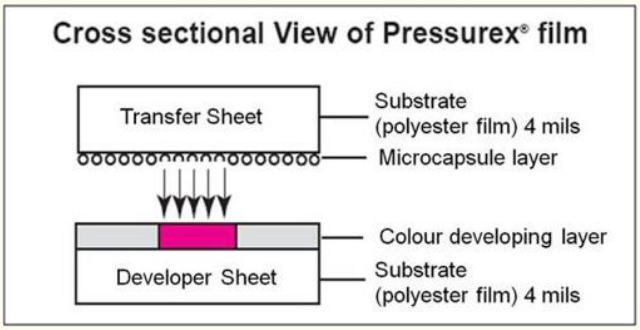

Figure 1: Cross sectional view of Pressurex® film.

During use, visual comparison of colour intensity to a colour correlation chart provides a pressure-measurement reading that is accurate to ± 10%. With the use of optical measuring systems, the pressure reading may be more accurately quantified to ± 2%. Use of a pressure-sensor film is an alternative to strain gauges and pressure transducers with accompanying electronic equipment.

Various films are offered, with some in a range of sensitivities to accommodate varying amounts of pressure. Pressure ranges can start as low as 2 - 20 psi (0.14 - 1.4 Kg/cm^2) and go as high as 7,100 - 18,500 psi (500 - 1,300 Kg/cm^2). Roll and sheet sizes are available with active shelf life varying, but it can be as much as two years. Normal temperature application is 41 deg F to 95 deg F (5 deg C to 35 deg C), but some material can withstand much higher temperatures for brief exposures.

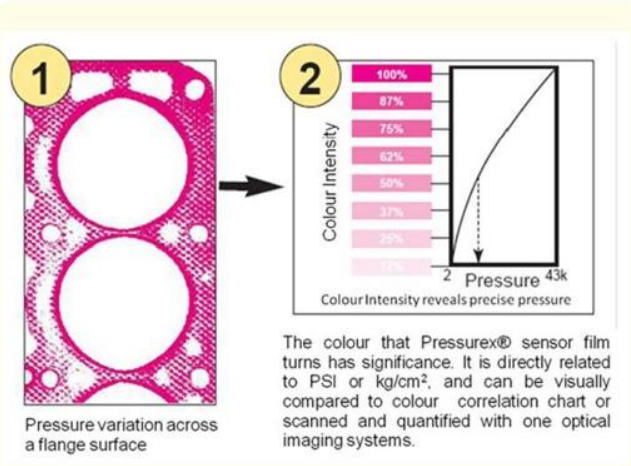

Figure 2: Colour intensity as a function of pressure.

Features

Offered in thicknesses from 4 mils to 20 mils, this system is flexible and allows natural occlusion and prevents mandibular displacement during clenching. The recording area cannot be easily damaged by artificial teeth materials or saliva as can articulating paper. The advantages of this system are as follows: (1) the thin material induces only a small change in the occlusal vertical dimension, making measurements at a position near the intercuspal position possible; (2) it is not necessary to prepare special measurement equipment; (3) many patients may be evaluated in short period of time; (4) record storage, even for an extended period, is simplified; and (5) it is easy to explain the treatment to patients by using images.

Density of coloration was measured with a colour image scanner (GT-1,000, Seiko-Epson, Co., Japan) in 256 grades, and converted to a pressure scale with a calibration curve. Image resolution of the scanner was 100 dpi. Load was obtained by integrating the pressure in the coloured area.

Framework

In order to provide adequate bite registration of the patients a new metal framework in a horseshoe-shaped form was developed. The metallic structure was designed based on the contour of the dental arch, occupying the external contour of the same without interfering with the occlusion. It was intended to support the Pressurex® film and contained 5 metallic re-intrances that held it during the patient's biting process and a handle to facilitate all the process.

The pressure sensor film system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were visualized and the procedure was repeated after 10 minutes until the patient felt comfortable.

Figure 3: Clinical application of the metal framework containing the Pressurex® film.

Repeatability test

The pressure sensor film system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1) and after 1 month (T2). In the proposed repeatability test, the occlusal pressure was measured for 30 consecutive patients twice by two different observers. The results analysis were performed using the Magics Software.

The five areas of analysis were distributed in the following order:

- Q1: Right maxillary second pre-molar and right maxillary **first molar between 1st and 4th** quadrants,
- **Q2: Right maxillary canine and right maxillary first pre-molar** between 1st **and 4th** quadrants,
- Q3: Right and left maxillary central incisors and right and left maxillary lateral incisors area,
- **Q4: Left maxillary second pre-molar and left maxillary first** molar between 2nd and 3rd quadrants,
- **Q5: Left maxillary canine and left maxillary first pre-molar** between 2nd and 3rd quadrants.

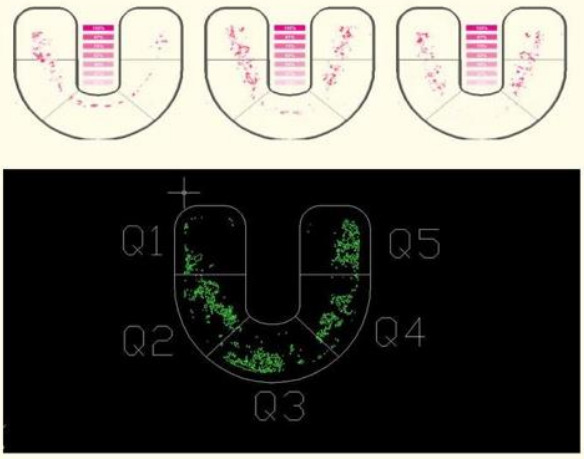

Figure 4: Biting area and pressure distribution in 5 areas.

Magics software

Materialize Magics is a versatile and intelligent data preparation software for (Additive Manufacturing), equipped with an intuitive and customizable user interface. This industry-leading **software efficiently guides the user through every step of the 3D printing workflow. Materialize Magics is a modular solution with** neutral technology. It allows to view slices, detect collisions, save platforms and generate useful reports.

A great design for 3D printing usually starts with a CAD project, a simulation result or digitized data as input. To take advantage of **the possibilities offered by 3D printing, is important a flexible tool to make specific modifications or improvements to the design, usu**ally at the mesh level.

With Magics, is possible natively import a large number of formats with 3D geometric information and also with the import of **colors directly from the source file, which means that it is not necessary to create any intermediate files thus maintaining a better** control of the original data.

Materials and Methods

Patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa - Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol: The Pressure Sensor Film System was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and after 1 month (T2). In the proposed repeatability test, the occlusal pressure was measured for 30 consecutive patients twice by two different observers.

A combination of different parametric tests has been used to compare the different experimental variables. The experimental **design devised for this study is depicted in figure 5, comprising a** combination of different examiners, sensors and times of measurement.

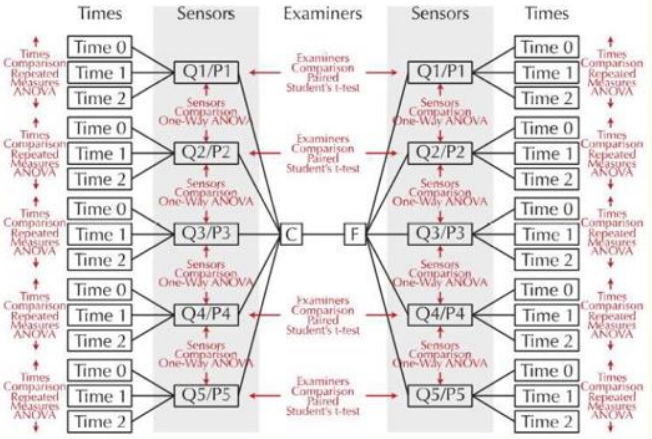

Figure 5: Experimental design used for the measurement of **pressure sensor film. The study involved the contribution of two** independent examiners (F and C), that measured the bite pressure **(psi) in five different pressure sensor film regions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at three different time moments (Time** 0, Time 1 and Time 2).

Comparison A - Testing the differences between examiners (F versus C)

- Research question: Are there any differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions?
- **H0: There are no differences in the mean bite pressure (psi)** measured by Examiner F and Examiner C in the same experimental conditions.
- **H1: There are differences in the mean bite pressure (psi)** measured by Examiner F and Examiner C in the same experimental conditions.

Comparison B - Testing the differences between times (T0 versus T1 versus T2)

- Research question: Are there any differences in the mean bite pressure (psi) measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions?
- **H0: There are no differences in the mean bite pressure (psi)** measured at moments Time 0, Time 1 and Time 2 in the same experimental conditions.
- **H1: There are differences in the mean bite pressure (psi)** measured at moments Time 0, Time 1 and Time 2 in the same experimental conditions.

Comparison C - Testing the differences between pressure sensor film regions (Q1/P1 versus Q2/P2 versus Q3/P3 versus Q4/P4 versus Q5/P5)

- Research question: Are there any differences in the mean bite **pressure (psi) measured by pressure sensor film regions Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions?**
- **H0: There are no differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5** in the same experimental conditions.
- **H1: There are differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5** in the same experimental conditions.

Results and Discussion

Table 1 presents the experimental data for the measurement of mean bite pressure (psi) by Pressurex® system, as well as its SD and variance values.

Variable	Mean (psi)	SD (psi)	Variance (psi^2)
P1_F_T0	**843,717**	**464,065**	215356,281
P1_F_T1	**878,345**	357,570	127856,313
P1_F_T2	991,738	377,066	**142178,838**
P1_C_T0	**1018,804**	296,992	**88204,323**
P1_C_T1	928,723	**416,187**	173211,229
P1_C_T2	939,296	363,078	**131825,476**
P2_F_T0	885,162	**404,791**	**163855,645**
P2_F_T1	**914,293**	338,307	**114451,662**
P2_F_T2	996,813	323,275	**104506,900**
P2_C_T0	1023,033	279,275	**77994,444**
P2_C_T1	1038,681	**276,343**	76365,289
P2_C_T2	**1042,910**	176,101	31011,687
P3_F_T0	869,515	**429,721**	**184660,248**
P3_F_T1	793,339	**449,685**	202216,903
P3_F_T2	768,860	**462,253**	213677,913
P3_C_T0	**938,450**	372,302	138608,610
P3_C_T1	915,712	369,571	136582,765
P3_C_T2	806,077	**420,978**	**177222,340**
P4_F_T0	763,362	**383,415**	**147007,393**
P4_F_T1	**791,646**	**296,446**	87880,126
P4_F_T2	**847,521**	**245,193**	**60119,824**
P4_C_T0	906,307	228,538	**52229,594**
P4_C_T1	890,236	237,800	**56548,717**
P4_C_T2	889,813	237,800	**58473,239**
P5_F_T0	753,635	**457,656**	**209448,945**
P5_F_T1	835,630	327,232	107081,072
P5_F_T2	906,731	326,063	**106317,248**
P5_C_T0	923,225	306,928	**94204,631**
P5_C_T1	880,510	**345,404**	**119304,143**
P5_C_T2	**848,368**	302,521	91518,686

Table 1: Values of bite pressure (psi) measured by Pressurex® system **at the different experimental conditions shown in figure 5.**

Comparison A - Testing the differences between examiners (F versus C)

The statistical comparison of examiners F and C regarding the measurement of mean bite pressure (psi) was performed using a **Paired Student's t-test for the five different pressure sensor film regions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at the three different** time moments (Time 0, Time 1 and Time 2).

Most of the results show no significant differences in the mean bite pressure (psi) measured by Examiner F and Examiner C, when the measurement is made in the same experimental conditions. The few differences observed ($p < 0,05$) where detected at Time 0 and/or Time 1 of measurement for the different pressure sensor **film regions, probably due to small discrepancies in the experimental** methodology that disappear by repetition of the protocol (at **Time 2, e.g. no statistically significant differences were detected).**

Overall, these results show that the choice of examiner is not a variable that greatly affects the mean bite pressure (psi) measured by PressureX® **pressure indicating sensor film, although special at-**

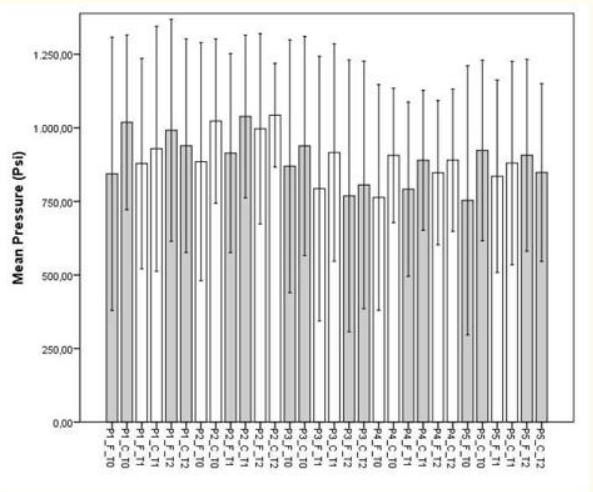

Figure 6: Mean bite pressure (psi) measured by Examiner F **and Examiner C in five different pressure sensor film regions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at three different** time moments (Time 0, Time 1 and Time 2). Error bars represent standard deviation values.

Examiners Comparison	Mean Diference	Standard Deviation of Differences	Degrees of Freedom (df)	Test statistic from Paired t-test	P-value from Paired t-test
Examiner F versus Examiner C, P1, Time 0	-175,087	**65,014**	29	-2,693	0,012*
Examiner F versus Examiner C, P1, Time 1	-50,378	81,802	29	-0,616	**0,543**
Examiner F versus Examiner C, P1, Time 2	**52,442**	50,651	29	1,035	0,309
Examiner F versus Examiner C, P2, Time 0	-137,871	95,180	29	**-1,449**	0,158
Examiner F versus Examiner C, P2, Time 1	**-124,388**	51,539	29	**-2,413**	0,022*
Examiner F versus Examiner C, P2, Time 2	**-46,097**	**60,452**	29	-0,763	**0,452**
Examiner F versus Examiner C, P3, Time 0	-68,935	**87,943**	29	**-0,784**	**0,439**
Examiner F versus Examiner C, P3, Time 1	-122,373	52,226	29	**-2,343**	0,026*
Examiner F versus Examiner C, P3, Time 2	-37,216	69,925	29	-0,532	0,599
Examiner F versus Examiner C, P4, Time 0	**-142,946**	**74,162**	29	-1,927	**0,064**
Examiner F versus Examiner C, P4, Time 1	-98,167	**57,347**	29	-1,712	0,098
Examiner F versus Examiner C, P4, Time 2	**-42,715**	66,029	29	**-0,647**	0,523
Examiner F versus Examiner C, P5, Time 0	-169,590	**80,479**	29	-2,107	**0,044***
Examiner F versus Examiner C, P5, Time 1	**-44,880**	63,775	29	**-0,704**	**0,487**
Examiner F versus Examiner C, P5, Time 2	58,363	**54,388**	29	1,073	0,292

Table 2: Statistical parameters obtained in the Paired Student's t-test for the comparison of examiners F and C when measuring the mean bite pressure (psi) in different experimental conditions.

(*): The mean difference is significant at the 0,05 level.

tention must be given for the standardization/homogenisation of the experimental methodology used, in order to avoid the differences detected among different examiners.

Comparison B - Testing the differences between times (T0 versus T1 versus T2)

The statistical comparison between the three time moments (Time 0, Time 1 and Time 2) regarding the measurement of mean bite pressure (psi) was performed using a Repeated Measures **ANOVA for the five pressure sensor film regions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) and the different examiners F and C.**

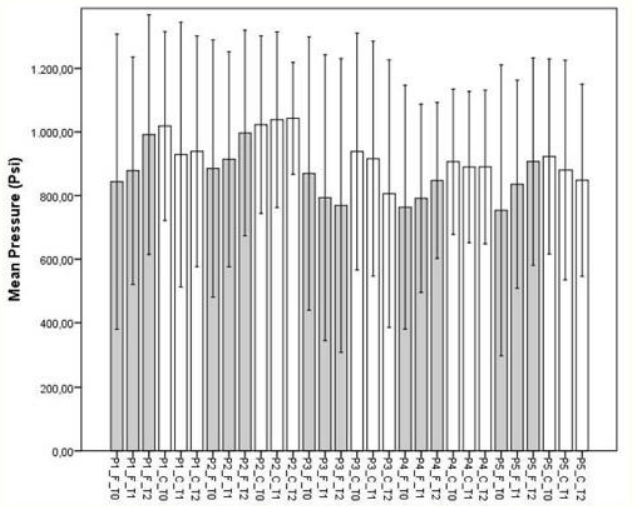

Figure 7: Mean bite pressure (psi) measured in three time moments (Time 0, Time 1 and Time 2) by Examiner F and **Examiner C in five different pressure sensor film regions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5). Error bars** represent standard deviation values.

There are no significant differences in the mean bite pressure (psi) measured at Time 0, Time 1 or Time 2, for the same Examiner **(C or F) and the same pressure sensor film region (Q1/P1, Q2/P2, Q3/P3, Q4/P4 or Q5/P5) (p > 0,05). Almost all experiments reveal p-values above the cut-off value of 0,05 (p > 0,05), which means that H0 proposition is valid. The results obtained for Examiner C, pressure sensor film region Q3/P3, were not considered significant, as sphericity principle was not verified. Thus, it is concluded**

Times Comparison	Degrees of Freedom (df)	Test statistic (F)	P-value (Sig)
Time 0 vs Time 1 vs Time 2, Examiner F, P1	2, 58	1,926	0,155
Time 0 vs Time 1 vs Time 2, Examiner C, P1	2, 58	1,602	0,210
Time 0 vs Time 1 vs Time 2, Examiner F, P2	2, 58	0,908	**0,409**
Time 0 vs Time 1 vs Time 2, Examiner C, P2	2, 58	0,098	0,907
Time 0 vs Time 1 vs Time 2, Examiner F, P3	2, 58	0,702	0,500
Time 0 vs Time 1 vs Time 2, Examiner C, P3	2, 58	**3,234**[a]	**0,047**[a]
Time 0 vs Time 1 vs Time 2, **Examiner F, P4**	2, 58	**0,704**	**0,499**
Time 0 vs Time 1 vs Time 2, **Examiner C, P4**	2, 58	**0,142**	0,868
Time 0 vs Time 1 vs Time 2, Examiner F, P5	2, 58	1,928	0,155
Time 0 vs Time 1 vs Time 2, Examiner C, P5	2, 58	**1,784**	0,177

Table 3: Statistical parameters obtained in the Repeated Measures ANOVA for the comparison of time moments (Time 0, Time 1 and Time 2) when measuring the mean bite pressure (psi) in different experimental conditions.

a) Mauchly's Test of Sphericity ($p < 0,05$) reveals violation of sphericity principle, indicating distortion in the calculation of variance, F-ratio and p-value obtained in these results for the Repeated Measures ANOVA.

the mean bite pressure (psi) measured at different time frames is consistently the same, showing the high reproducibility of the measurements.

Comparison C - Testing the differences between pressure sensor film regions (Q1/P1 versus Q2/P2 versus Q3/P3 versus Q4/P4 versus Q5/P5)

The statistical comparison between the five pressure sensor film regions sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) regarding the measurement of mean bite pressure (psi) was performed using a One-Way ANOVA for the different examiners F and C at the three different time moments (Time 0, Time 1 and Time 2).

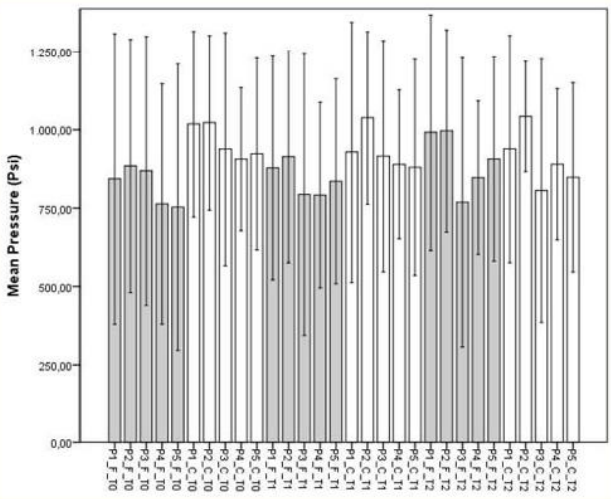

Figure 8: Mean bite pressure (psi) measured in five pressure sensor film regions sensors (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) by Examiner F and Examiner C at three different time moments (Time 0, Time 1 and Time 3). Error bars represent standard deviation values.

Most of the results show no significant differences in the mean bite pressure (psi) measured by the different pressure sensor film regions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5), when the measurement is made in the same experimental conditions. All experiments reveal p-values above the cut-off value of 0,05 (p > 0,05), with exception of the pressure sensor film regions at Time 2 for Examiner C (p = 0,041).

Because One-Way ANOVA only gives information about the presence of differences, not specifying where these differences are **located, a Post-Hoc Gabriel test was used to perform pairwise comparisons between the pressure sensor film regions at Time 2 for Examiner C, in order to detect the specific pairs of pressure sensor film regions where statistically significant differences were identified (Table 5).**

Post-Hoc Gabriel Test has determined that the differences observed between pressure sensor film regions at Time 2 for Examiner C (One-Way ANOVA, Table 4) are located in the pair of sensors Q2/P2 and Q3/P3 (p = 0,038). These differences are not observed

Sensors Comparison		Sum of Squares	Degrees of Freedom (df)	Mean Square	Test statistic (F)	P-value (Sig)
P1 vs P2 vs P3 vs **P4 vs P5, Examiner F, Time 0**	Between Groups	**444755,025**	**4**	111188,756	**0,604**	0,660
	Within Groups	26689526,855	**145**	**184065,702**		
	Total	**27134281,880**	**149**	-		
P1 vs P2 vs P3 vs **P4 vs P5, Examiner F, Time 1**	Between Groups	**344673,468**	**4**	86168,367	**0,674**	0,611
	Within Groups	**18545096,189**	**145**	127897,215		
	Total	18889769,658	**149**	-		
P1 vs P2 vs P3 vs **P4 vs P5, Examiner F, Time 2**	Between Groups	**1132748,174**	**4**	**283187,043**	2,259	0,066
	Within Groups	18177220,971	**145**	**125360,145**		
	Total	**19309969,145**	**149**	-		
P1 vs P2 vs P3 vs **P4 vs P5, Examiner C, Time 0**	Between Groups	**363347,870**	**4**	90836,967	1,007	**0,406**
	Within Groups	**13086006,451**	**145**	**90248,320**		
	Total	**13449354,321**	**149**	-		
P1 vs P2 vs P3 vs **P4 vs P5, Examiner C, Time 1**	Between Groups	**482377,818**	**4**	**120594,455**	1,073	0,372
	Within Groups	16298352,160	**145**	**112402,429**		
	Total	16780729,979	**149**	-		
P1 vs P2 vs P3 vs **P4 vs P5, Examiner C, Time 2**	Between Groups	**1002170,542**	**4**	**250542,635**	2,556	**0,041***
	Within Groups	**14211491,376**	**145**	98010,285		
	Total	15213661,918	**149**	-		

Table 4: Statistical parameters obtained in the One-Way ANOVA for the comparison of pressure sensor film regions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions. (*): The mean difference is significant at the 0,05 level.

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.	Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
F_T0	Q1/P1	Q2/P2	**-41,445**	110,775	1,000	C_T0	Q1/P1	Q2/P2	**-4,229**	77,566	1,000
		Q3/P3	-25,798	110,775	1,000			Q3/P3	**80,354**	77,566	0,970
		Q4/P4	80,355	110,775	0,998			**Q4/P4**	**112,497**	77,566	**0,794**
		Q5/P5	90,082	110,775	0,995			Q5/P5	95,580	77,566	0,912
	Q2/P2	Q1/P1	**41,445**	110,775	1,000		Q2/P2	Q1/P1	**4,229**	77,566	1,000
		Q3/P3	**15,648**	110,775	1,000			Q3/P3	**84,583**	77,566	0,958
		Q4/P4	121,801	110,775	0,956			**Q4/P4**	116,726	77,566	0,757
		Q5/P5	131,527	110,775	0,929			Q5/P5	99,809	77,566	0,888
	Q3/P3	Q1/P1	25,798	110,775	1,000		Q3/P3	Q1/P1	**-80,354**	77,566	0,970
		Q2/P2	**-15,648**	110,775	1,000			Q2/P2	**-84,583**	77,566	0,958
		Q4/P4	106,153	110,775	0,983			**Q4/P4**	**32,143**	77,566	1,000
		Q5/P5	115,880	110,775	0,968			Q5/P5	15,225	77,566	1,000
	Q4/P4	Q1/P1	-80,355	110,775	0,998		**Q4/P4**	Q1/P1	**-112,497**	77,566	**0,794**
		Q2/P2	-121,801	110,775	0,956			Q2/P2	-116,726	77,566	0,757
		Q3/P3	-106,153	110,775	0,983			Q3/P3	**-32,143**	77,566	1,000
		Q5/P5	9,727	110,775	1,000			Q5/P5	-16,917	77,566	1,000
	Q5/P5	Q1/P1	-90,082	110,775	0,995		Q5/P5	Q1/P1	-95,580	77,566	0,912
		Q2/P2	-131,527	110,775	0,929			Q2/P2	-99,809	77,566	0,888
		Q3/P3	-115,880	110,775	0,968			Q3/P3	-15,225	77,566	1,000
		Q4/P4	-9,727	110,775	1,000			**Q4/P4**	16,917	77,566	1,000
F_T1	Q1/P1	Q2/P2	**-35,948**	92,339	1,000	C_T1	Q1/P1	Q2/P2	-109,958	86,565	0,895
		Q3/P3	85,006	92,339	0,987			Q3/P3	13,011	86,565	1,000
		Q4/P4	86,699	92,339	0,985			**Q4/P4**	38,910	86,565	1,000
		Q5/P5	**42,715**	92,339	1,000			Q5/P5	**48,213**	86,565	1,000
	Q2/P2	Q1/P1	**35,948**	92,339	1,000		Q2/P2	Q1/P1	109,958	86,565	0,895
		Q3/P3	**120,954**	92,339	0,876			Q3/P3	122,969	86,565	0,813
		Q4/P4	**122,647**	92,339	0,867			**Q4/P4**	**148,868**	86,565	0,593
		Q5/P5	78,663	92,339	0,993			Q5/P5	158,171	86,565	0,508
	Q3/P3	Q1/P1	-85,006	92,339	0,987		Q3/P3	Q1/P1	-13,011	86,565	1,000
		Q2/P2	**-120,954**	92,339	0,876			Q2/P2	-122,969	86,565	0,813
		Q4/P4	1,693	92,339	1,000			**Q4/P4**	25,899	86,565	1,000
		Q5/P5	**-42,291**	92,339	1,000			Q5/P5	35,202	86,565	1,000
	Q4/P4	Q1/P1	-86,699	92,339	0,985		**Q4/P4**	Q1/P1	-38,910	86,565	1,000
		Q2/P2	**-122,647**	92,339	0,867			Q2/P2	**-148,868**	86,565	0,593
		Q3/P3	-1,693	92,339	1,000			Q3/P3	-25,899	86,565	1,000
		Q5/P5	**-43,984**	92,339	1,000			Q5/P5	9,303	86,565	1,000
	Q5/P5	Q1/P1	**-42,715**	92,339	1,000		Q5/P5	Q1/P1	**-48,213**	86,565	1,000
		Q2/P2	-78,663	92,339	0,993			Q2/P2	-158,171	86,565	0,508
		Q3/P3	**42,291**	92,339	1,000			Q3/P3	-35,202	86,565	1,000
		Q4/P4	**43,984**	92,339	1,000			**Q4/P4**	-9,303	86,565	1,000

F_T2	Q1/P1	Q2/P2	-5,075	**91,419**	1,000	C_T2	Q1/P1	Q2/P2	**-103,614**	80,833	0,890
		Q3/P3	222,878	**91,419**	**0,147**			Q3/P3	133,219	80,833	**0,649**
		Q4/P4	**144,217**	**91,419**	**0,704**			**Q4/P4**	**49,060**	80,833	1,000
		Q5/P5	85,007	**91,419**	0,986			Q5/P5	90,928	80,833	**0,949**
	Q2/P2	Q1/P1	5,075	**91,419**	1,000		Q2/P2	Q1/P1	**103,614**	80,833	0,890
		Q3/P3	227,952	**91,419**	0,128			Q3/P3	236,83333*	80,833	0,038*
		Q4/P4	**149,291**	**91,419**	0,661			**Q4/P4**	**152,674**	80,833	**0,460**
		Q5/P5	90,082	**91,419**	0,979			Q5/P5	**194,542**	80,833	0,159
	Q3/P3	Q1/P1	-222,878	**91,419**	**0,147**		Q3/P3	Q1/P1	-133,219	80,833	**0,649**
		Q2/P2	-227,952	**91,419**	0,128			Q2/P2	-236,83333*	80,833	0,038*
		Q4/P4	-78,661	**91,419**	0,992			**Q4/P4**	**-84,160**	80,833	0,969
		Q5/P5	-137,870	**91,419**	0,755			Q5/P5	**-42,291**	80,833	1,000
	Q4/P4	Q1/P1	**-144,217**	**91,419**	**0,704**		**Q4/P4**	Q1/P1	**-49,060**	80,833	1,000
		Q2/P2	**-149,291**	**91,419**	0,661			Q2/P2	**-152,674**	80,833	**0,460**
		Q3/P3	78,661	**91,419**	0,992			Q3/P3	**84,160**	80,833	0,969
		Q5/P5	-59,209	**91,419**	0,999			Q5/P5	**41,869**	80,833	1,000
	Q5/P5	Q1/P1	-85,007	**91,419**	0,986		Q5/P5	Q1/P1	-90,928	80,833	**0,949**
		Q2/P2	-90,082	**91,419**	0,979			Q2/P2	**-194,542**	80,833	0,159
		Q3/P3	137,870	**91,419**	0,755			Q3/P3	**42,291**	80,833	1,000
		Q4/P4	59,209	**91,419**	0,999			**Q4/P4**	**-41,869**	80,833	1,000

Table 5: Statistical parameters obtained in the Post-Hoc Gabriel test for the comparison of pressure sensor film regions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions. (*): The mean difference is significant at the 0,05 level.

in the same conditions for Examiner F, which supports the absence **of significant variations in the mean bite pressure (Psi) detected by the five pressure sensor film regions used in the experimental** design.

Conclusion

The versatility of PressureX® system as a pressure indicating **sensor film was tested to evaluate the bite pressure distribution of** a number of patients following orthodontic/orthognathic surgery. For this purpose, a metal framework in a horseshoe-shaped form **was developed to accommodate this sensor film for orthodontic** and a measurement procedure was developed to attain optimal measurement repeatability.

Results have shown that PressureX® system can be successfully used for qualitative evaluation of bite pattern, although it presents some limitations in terms of quantitative assessment of bite pressure (psi), such as examiners and repeatability variations.

Although it is still not clear the origin of these experimental variations, two different strategies will be explored in the future to attain higher levels of reproducibility: 1) development of an optimized measurement procedure and; 2) testing of a new image processing software such as the Java-based software ImageJ.

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Research Article

Measurement of Pressure in Orthognathic Surgery using Pressurex®

Fernando Duarte*[1], João Neves Silva[2], Carina Ramos[3], Colin Hopper[4]

[1]Oral Surgeon Specialist by OMD (Portuguese Dental Association), Master of Science in Oral and Maxillofacial Surgery at Eastman Dental Institute University College of London, PhD student at UCL - University College of London
[2]Professor at ISAVE - Instituto Superior de Saúde - Portugal, Member of the Interdisciplinary Center for Health Sciences (ICHS) - ISAVE -Instituto Superior de Saúde
[3]MSc student in Oral Oncology at Instituto de Ciências Biomédicas Abel Salazar - Oporto University – Portugal
[4] Oral and Maxillofacial Surgery Department at Eastman Dental Institute – University College of London

Corresponding author: Fernando Duarte
Clitrofa - Centro Médico, Dentário e Cirúrgico, Avenida de Paradela 622, 4785-248 Trofa - Portugal
Tel: +351252428960 E-mail: fduarte@clitrofa.com

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Abstract

Purpose: Despite its importance, the measurement of pressure in orthognathic surgery often receives little attention. Pressurex® (SPL – Sensor Products LLC, USA) is one of a few pressure indicating sensor films that reveals pressure distribution and magnitude between any two contacting, mating or impacting surfaces, and is currently viewed as a golden standard for that purpose.
This study was designed to apply other alternative and innovative methods of measuring muscle area, volume, structure, function and fibre orientation to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach.
Materials and Methods: Ten patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol: The pressure sensor film system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and after 1 month after surgery (T2). The occlusal pressure was measured by two different observers. The results have been measured by two different observers and the results analysis were performed using the Magics® RP software. These 10 patients were scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible.
Conclusions: Significant statistical differences in the mean bite pressure (psi) have been detected between pre-op (Times 0 and 1) and post-op (Time 2) periods for the film pressure areas Q2/P2, Q3/P3 and Q4/P4, irrespective of the Examiner (C or F) ($p < 0,05$). Interestingly, these differences in the mean bite pressure (psi) at different times are concentrated in the anterior and mid region of the maxilla/ mandible, whereas in the posterior region of the maxilla/ mandible (Q1/P1 and Q5/P5), no significant statistical differences have been detected throughout time ($p > 0,05$).

Keywords

Orthognathic Surgery, Masseter Muscle, Pressure Measurement, Pressurex®

Declaration of Conflicting Interest

The authors declare that they have no conflict of interest.

Introduction:

Orthodontic and surgical technical advances in recent years have resulted in treatment opportunities for a whole range of craniofacial skeletal disorders either in the adolescent or adult patients. In the growing child these can include myofunctional orthodontic appliance therapy or distraction osteogenesis procedures, whilst in the adult the mainstay approach revolves around orthognathic surgery.

Research evidence suggests that in those cases requiring orthognathic surgery, the stability of the result depends upon such factors as the direction and extent of the surgical move of the facial skeleton, the method of surgical fixation applied and the operative technique employed. Yet, even when the best evidence-based practice is followed, there remains a significant proportion of cases where the surgical outcome (stability) is both unexpected and undesirable1.

Our understanding of the biological adaptive mechanisms occurring in both the hard and soft tissues of the face, and which are fundamental to all these treatment approaches remains, at a rather basic level. There is little information concerning the distribution of bite force on the dental arch during clenching in normal dentitions2.

Bite force has been used to evaluate masticatory function in patients before and after orthognathic surgery3,4,5,6,7. Usually, it has been measured with a custom bite force transducer5,6,8.

Pressure is a critical variable in many converting operations. Tactile pressure-sensor films are an accurate, efficient, and inexpensive method to determine pressure. These films offer the converting industry an opportunity to determine both the distribution and magnitude of most operations where pressure is important.

Pressurex® System:

Pressurex® (SPL – Sensor Products LLC, USA) is a pressure indicating sensor film that reveals pressure distribution and magnitude between any two contacting, mating or impacting surfaces. Pressurex® consists of a thin mylar film (4 to 8 mils) that contains a layer of tiny microcapsules. Because Pressurex® is extremely thin, it is ideal for invasive intolerant environments and curvaceous surfaces that are not accessible to electronic pressure transducers.

The application of force upon the film causes the microcapsules to rupture, producing an instantaneous and permanent high resolution "topographical" map of pressure variations across the contact area. Simply place sensor film, between any two surfaces that touch, mate or impact. Apply pressure, release it; immediately the film reveals a profile of the pressure distribution that occurred between the surfaces. The colour intensity of the image created is directly related to the amount of pressure applied, the greater the pressure, the more intense colour.

During use, visual comparison of colour intensity to a colour correlation chart provides a pressure-measurement reading that is accurate to ±10%. With the use of optical measuring systems, the pressure reading may be more accurately quantified to ±2%. Use of a pressure-sensor film is an alternative to strain gauges and pressure transducers with accompanying electronic equipment. Various films are offered, with some in a range of sensitivities to accommodate varying amounts of pressure. Pressure ranges can start as low as 2-20 psi (0.14-1.4 Kg/cm2) and go as high as 7,100-18,500 psi (500-1,300 Kg/cm2). Roll and sheet sizes are available with active shelf life varying, but it can be as much as two years. Normal temperature application is 41 deg F to 95 deg F (5 deg C to 35 deg C), but some material can withstand much higher temperatures for brief exposures.

Density of coloration was measured with a colour image scanner (GT-1,000, Seiko-Epson, Co., Japan) in 256 grades, and converted to a pressure scale with a calibration curve. Image resolution of the scanner was 100 dpi. Load was obtained by integrating the pressure in the coloured area.

Materials and Methods:

Ten patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol: In order to provide adequate bite registration of the patients a new metal framework in a horseshoe-shaped form was developed. The metallic structure was designed based on the contour of the dental arch, occupying the external contour of the same without interfering with the occlusion. It was intended to support the Pressurex® film and contained 5 metallic re-intrances that held it during the patient's biting process and a handle to facilitate all the process.

The pressure sensor film system was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered (T0) and the procedure was repeated after 10 minutes (T1), and after 1 month after surgery (T2). The occlusal pressure was measured by two different observers. The results have been measured by two different observers and the results analysis were performed using the Magics® RP software.

The five areas of analysis were distributed in the following order: Q1: right maxillary second pre-molar and right maxillary first molar between 1st and 4th quadrants; Q2: right maxillary canine and right maxillary first pre-molar between 1st and 4th quadrants; Q3: right and left maxillary central incisors and right and left maxillary lateral incisors area; Q4: left maxillary second pre-molar and left maxillary first molar between 2nd and 3rd quadrants, and finally Q5: left maxillary canine and left maxillary first pre-

molar between 2nd and 3rd quadrants.

These 10 patients were scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible.

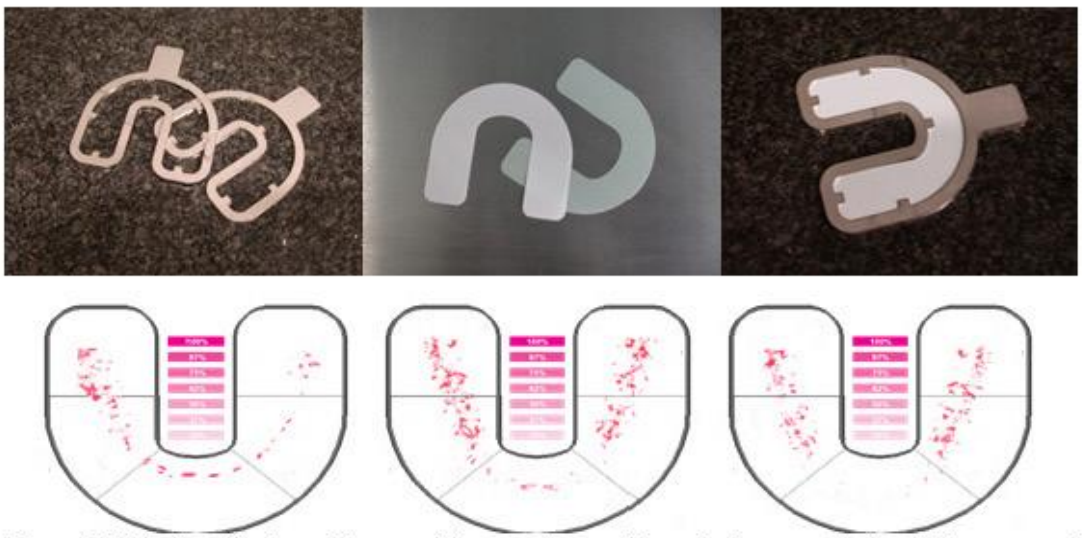

Figure 1: Clinical application of the metal framework containing the Pressurex® film. Biting area and pressure distribution in 5 areas

The experimental design devised for this study is depicted in Figure 2, comprising a combination of different examiners, film pressure areas and times of measurement.

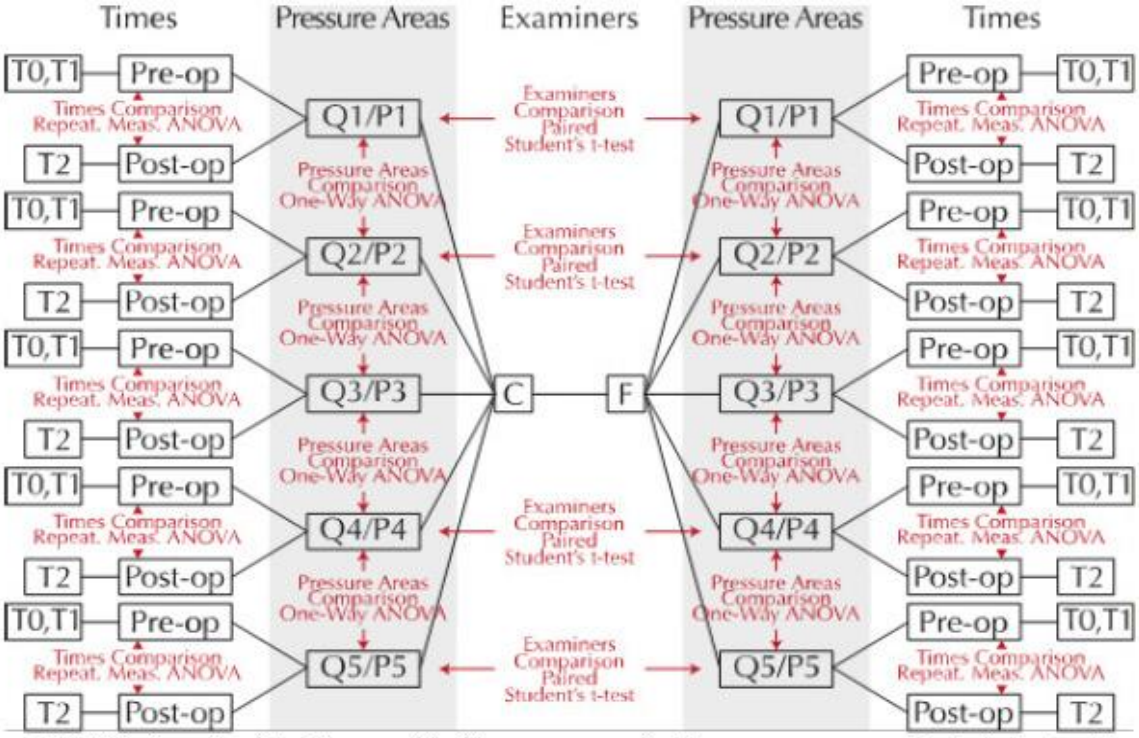

Figure 2: Experimental design used for the measurement of film pressure areas. The study involved the contribution of two independent examiners (F and C), that measured the bite pressure (psi) in five different film pressure areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at three different time moments (Time 0, Time 1 and Time 2).

IBM® SPSS® version 25 was used to analyze the data obtained. The data were first tested to ensure they conformed to a normal distribution by using the Kolmogorov-Smirnov test, the Shapiro-Wilks test or by determining the values of skewness (acceptable values for normality between -2 and +2) and kurtosis (acceptable values for normality between -2 and +2). Descriptive statistics included the arithmetic mean ($\bar{x}$), standard deviation (SD), and standard error of the mean (SE), as well as the 95% confidence interval (95% CI). Where the data were not normally distributed, the median and the inter-quartile range (IQR) were noted.

In those situations where the data were normally distributed and the variances were constant, comparative analysis involved either the unpaired or paired two-tailed Student's t test. Multiple comparisons were made using the One-Way Analysis of Variance (ANOVA) or Repeated Measure Analysis of Variance (ANOVA) depending if the data were, respectively, unpaired or paired.

Post-Hoc Gabriel test and post-hoc Bonferroni test were used, respectively for One-Way ANOVA and Repeated Measures ANOVA, to identify the pairs where the significant statistical differences were located.

Where the requirements for parametric statistical analysis were not met, the data were analyzed using either the Wilcoxon Signed Rank (U) test for paired data or the Mann-Whitney (U) test for unpaired data as appropriate. Comparison between three or more groups were made using the Kruskal-Wallis (H) or the Friedman (H) test depending if the data were, respectively, unpaired or paired.

The minimum level of significance (α level) accepted throughout the development studies was 0.05 (*), considered to be "moderately significant". Levels of 0.01 (**) were considered as "significant" and 0.001 (***) designated as "highly significant". A lack of statistical significance was designated as (ns).

Comparison A – Testing the Differences between Examiners (F versus C)

Research question: Are there any significant statistical differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions?

H0: There are no significant statistical differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions.

H1: There are significant statistical differences in the mean bite pressure (psi) measured by Examiner F and Examiner C in the same experimental conditions.

Comparison B – Testing the Differences between Times (T0 versus T1 versus T2)

Research question: Are there any significant statistical differences in the mean bite pressure (psi) measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions?

H0: There are no significant statistical differences in the mean bite pressure (psi) measured at moments Time 0, Time 1 and Time 2 in the same experimental conditions.

H1: There are significant statistical differences in the mean bite pressure (psi) measured at moments Time 0, Time 1 and Time 2 in the same experimental conditions.

Comparison C – Testing the Differences between Film Pressure Areas (Q1/P1 versus Q2/P2 versus Q3/P3 versus Q4/P4 versus Q5/P5)

Research question: Are there any significant statistical differences in the mean bite pressure (psi) measured by film pressure areas Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions?

H0: There are no significant statistical differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions.

H1: There are significant statistical differences in the mean bite pressure (psi) measured by sensors Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5 in the same experimental conditions.

Results:

Table I presents the experimental data for the measurement of mean bite pressure (psi) by Pressurex® system, as well as its SD and variance values.

Variable	Mean (psi)	SD (psi)	Variance (psi2)
P1_F_T0	790,427	343,272	117835,719
P1_F_T1	790,427	343,272	117835,719
P1_F_T2	839,909	318,445	101407,316
P1_C_T0	790,427	343,272	117835,719
P1_C_T1	790,427	343,272	117835,719
P1_C_T2	839,909	318,445	101407,316
P2_F_T0	684,822	364,488	132851,739
P2_F_T1	684,822	364,488	132851,739
P2_F_T2	790,427	340,656	116046,767
P2_C_T0	1155,830	201,272	40510,513
P2_C_T1	1122,842	192,534	37069,204
P2_C_T2	775,202	328,271	107761,982
P3_F_T0	40,000	51,640	2666,667
P3_F_T1	40,000	51,640	2666,667
P3_F_T2	282,476	139,769	19535,323
P3_C_T0	40,000	51,640	2666,667
P3_C_T1	40,000	51,640	2666,667
P3_C_T2	283,745	160,185	25659,107
P4_F_T0	581,903	340,854	116181,760
P4_F_T1	581,903	340,854	116181,760
P4_F_T2	742,214	315,706	99670,246
P4_C_T0	660,566	406,047	164874,351
P4_C_T1	613,622	375,063	140672,528
P4_C_T2	688,777	328,546	107942,470
P5_F_T0	931,259	275,139	75701,369
P5_F_T1	931,259	275,139	75701,369
P5_F_T2	916,034	221,200	48929,258
P5_C_T0	931,259	275,139	75701,369
P5_C_T1	931,259	275,139	75701,369
P5_C_T2	932,528	241,935	58532,394

Table I: Values of bite pressure (psi) measured at the different experimental conditions shown in Figure 1.

Comparison A – Testing the Differences between Examiners (F versus C)

The statistical comparison of examiners F and C regarding the measurement of mean bite pressure (psi) was performed using a Paired Student's t-test for the five different film pressure areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at the three different time moments (Time 0, Time 1 and Time 2) (Figure 3 and Table 2).

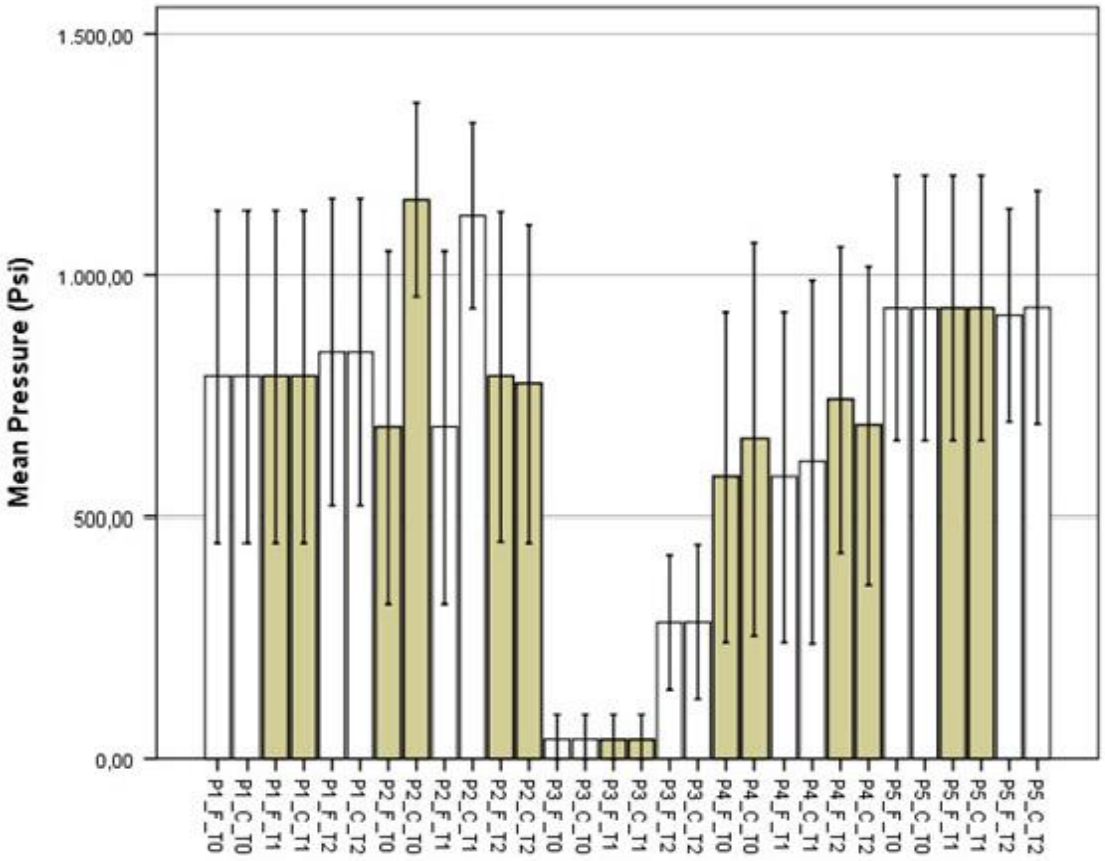

Figure 3: Mean bite pressure (psi) measured by Examiner F and Examiner C in five different film pressure areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) at three different time moments (Time 0, Time 1 and Time 2). Error bars represent standard deviation values.

Examiners Comparison	Mean Diference	Standard Deviation of Differences	Degrees of Freedom (df)	Test statistic from Paired t-test	P-value from Paired t-test
Examiner F versus Examiner C, P1, Time 0	-471,008	471,83052	9	-	-
Examiner F versus Examiner C, P1, Time 1	-438,020	488,60659	9	-	-
Examiner F versus Examiner C, P1, Time 2	15,225	86,42414	9	-	-
Examiner F versus Examiner C, P2, Time 0	-1,269	74,81025	9	-3,157	0,012*
Examiner F versus Examiner C, P2, Time 1	-78,663	152,34482	9	-2,835	0,020*
Examiner F versus Examiner C, P2, Time 2	-31,719	98,14074	9	0,557	0,591
Examiner F versus Examiner C, P3, Time 0	53,437	87,55778	9	-	-
Examiner F versus Examiner C, P3, Time 1	-16,494	52,15861	9	-	-
Examiner F versus Examiner C, P3, Time 2	-471,008	471,83052	9	-0,054	0,958
Examiner F versus Examiner C, P4, Time 0	-438,020	488,60659	9	-1,633	0,137
Examiner F versus Examiner C, P4, Time 1	15,225	86,42414	9	-1,022	0,333
Examiner F versus Examiner C, P4, Time 2	-1,269	74,81025	9	1,930	0,086
Examiner F versus Examiner C, P5, Time 0	-78,663	152,34482	9	-	-
Examiner F versus Examiner C, P5, Time 1	-31,719	98,14074	9	-	-
Examiner F versus Examiner C, P5, Time 2	53,437	87,55778	9	-1,000	0,343

Table II: Statistical parameters obtained in the Paired Student's t-test for the comparison of examiners F and C when measuring the mean bite pressure (psi) in different experimental conditions.

* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Most of the results show no significant statistical differences in the mean bite pressure (psi) measured by Examiner F and Examiner C, when the measurement is made in the same experimental conditions.

Comparison B – Testing the Differences between Times (T0 vs T1 vs T2)

The statistical comparison between the three-time moments (Time 0, Time 1 and Time 2) regarding the measurement of mean bite pressure (psi) was performed using a Repeated Measures ANOVA for the five film pressure areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) and the different examiners F and C (Figure 4 and Table III).

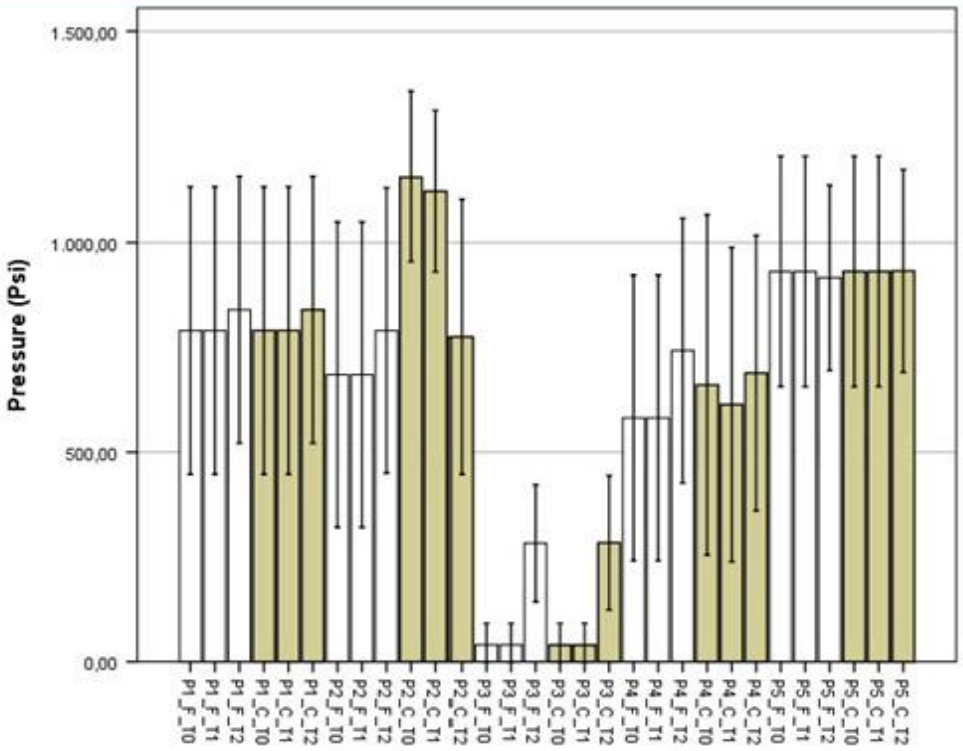

Figure 4: Mean bite pressure (psi) measured in three-time moments (Time 0, Time 1 and Time 2) by Examiner F and Examiner C in five different film pressure areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5). Error bars represent standard deviation values.

Times Comparison	Degrees of Freedom (df)	Test statistic (F)	P-value (Sig)
Time 0 vs Time 1 vs Time 2, Examiner F, P1	2, 18	2,129	0,148
Time 0 vs Time 1 vs Time 2, Examiner C, P1	2, 18	2,129	0,148
Time 0 vs Time 1 vs Time 2, Examiner F, P2	2, 18	7,734	0,004**
Time 0 vs Time 1 vs Time 2, Examiner C, P2	2, 18	6,021	0,010*
Time 0 vs Time 1 vs Time 2, Examiner F, P3	2, 18	47,605	0,000***
Time 0 vs Time 1 vs Time 2, Examiner C, P3	2, 18	32,456	0,000***
Time 0 vs Time 1 vs Time 2, Examiner F, P4	2, 18	12,676	0,000***
Time 0 vs Time 1 vs Time 2, Examiner C, P4	2, 18	1,682	0,214
Time 0 vs Time 1 vs Time 2, Examiner F, P5	2, 18	0,277	0,761
Time 0 vs Time 1 vs Time 2, Examiner C, P5	2, 18	0,001	0,999

Table III: Statistical parameters obtained in the Repeated Measures ANOVA for the comparison of time moments (Time 0, Time 1 and Time 2) when measuring the mean bite pressure (psi) in different experimental conditions.

* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Significant statistical differences in the mean bite pressure (psi) have been detected among different times (Time 0, Time 1 and Time 2) for the film pressure areas Q2/P2, Q3/P3 and Q4/P4, irrespective of the Examiner (C or F) ($p < 0,05$).

Because Repeated Measures ANOVA only gives information about the presence of differences, not specifying where these differences are located, a Post-Hoc Bonferroni test was used to perform pairwise comparisons between the times, and these results are represented in Table IV.

Independent Variable			Mean Difference (I-J)	Std. Error	Sig.
F_Q2/P2	T0	T1	0,000	0,000	-
		T2	-105,605	37,974	0,064
	T1	T0	0,000	0,000	-
		T2	-105,605	37,974	0,064
	T2	T0	105,605	37,974	0,064
		T1	105,605	37,974	0,064
C_Q2/P2	T0	T1	32,988	21,992	0,504
		T2	380,628	146,431	0,086
	T1	T0	-32,988	21,992	0,504
		T2	347,640	149,635	0,136
	T2	T0	-380,628	146,431	0,086
		T1	-347,640	149,635	0,136
F_Q3/P3	T0	T1	0,000	0,000	-
		T2	-242,476	35,143	0,000***
	T1	T0	0,000	0,000	-
		T2	-242,476	35,143	0,000***
	T2	T0	242,476	35,143	0,000***
		T1	242,476	35,143	0,000***
C_Q3/P3	T0	T1	0,000	0,000	-
		T2	-243,745	42,784	0,001**
	T1	T0	0,000	0,000	-
		T2	-243,745	42,784	0,001**
	T2	T0	243,745	42,784	0,001**
		T1	243,745	42,784	0,001**
F_Q4/P4	T0	T1	0,000	0,000	-
		T2	-160,311	45,027	0,018*
	T1	T0	0,000	0,000	-
		T2	-160,311	45,027	0,018*
	T2	T0	160,311	45,027	0,018*
		T1	160,311	45,027	0,018*

Table IV: Statistical parameters obtained in the Post-Hoc Bonferroni test for the comparison of Times (Time 0, Time 1 and Time 3) when measuring the mean bite pressure (psi) in different experimental conditions.

* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Comparison C – Testing the Differences between Film Pressure Areas (Q1/P1 versus Q2/P2 versus Q3/P3 versus Q4/P4 versus Q5/P5)

The statistical comparison between the five pressure sensor film areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) regarding the measurement of mean bite pressure (psi) was performed using a One-Way ANOVA for the different examiners F and C at the three different time moments (Time 0, Time 1 and Time 2) (Figure 5 and Table V).

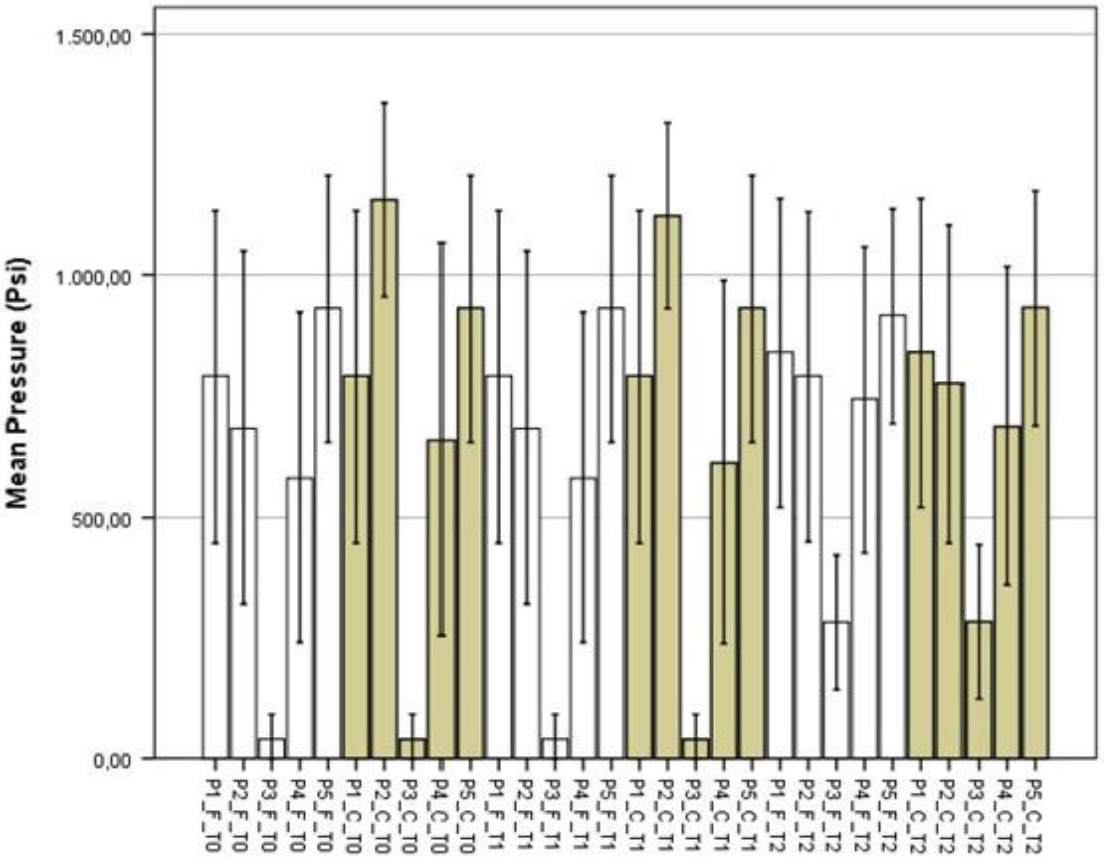

Figure 5: Mean bite pressure (psi) measured in five pressure sensor film areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) by Examiner F and Examiner C at three different time moments (Time 0, Time 1 and Time 2). Error bars represent standard deviation values.

Sensors Comparison		Sum of Squares	Degrees of Freedom (df)	Mean Square	Test statistic (F)	P-value (Sig)
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 0	Between Groups	4669558,035	4	1167389,509	13,110	0,000***
	Within Groups	4007135,280	45	89047,451		
	Total	8676693,315	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 1	Between Groups	4669558,035	4	1167389,509	13,110	0,000***
	Within Groups	4007135,280	45	89047,451		
	Total	8676693,315	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner F, Time 2	Between Groups	2495206,674	4	623801,669	8,089	0,000***
	Within Groups	3470300,193	45	77117,782		
	Total	5965506,867	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 0	Between Groups	7053744,369	4	1763436,092	21,956	0,000***
	Within Groups	3614297,563	45	80317,724		
	Total	10668041,932	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 1	Between Groups	6835135,988	4	1708783,997	22,848	0,000***
	Within Groups	3365509,385	45	74789,097		
	Total	10200645,372	49	-		
P1 vs P2 vs P3 vs P4 vs P5, Examiner C, Time 2	Between Groups	2526120,274	4	631530,069	7,868	0,000***
	Within Groups	3611729,427	45	80260,654		
	Total	6137849,702	49	-		

Table V: Statistical parameters obtained in the One-Way ANOVA for the comparison of film pressure areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions.
* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

There are significant statistical differences in the mean bite pressure (psi) measured by the different film pressure areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5), when the measurement if made in the same experimental conditions.

Because One-Way ANOVA only gives information about the presence of differences, not specifying where these differences are located, a Post-Hoc Gabriel test was used to perform pairwise comparisons between the film pressure areas, and these results are represented in Table VI.

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
F_T0	Q1/P1	Q2/P2	105,605	133,452	0,995
		Q3/P3	750,427	133,452	0,000***
		Q4/P4	208,524	133,452	0,714
		Q5/P5	-140,832	133,452	0,963
	Q2/P2	Q1/P1	-105,605	133,452	0,995
		Q3/P3	644,822	133,452	0,000***
		Q4/P4	102,919	133,452	0,996
		Q5/P5	-246,437	133,452	0,502
	Q3/P3	Q1/P1	-750,427	133,452	0,000***
		Q2/P2	-644,822	133,452	0,000***
		Q4/P4	-541,903	133,452	0,002**
		Q5/P5	-891,259	133,452	0,000***
	Q4/P4	Q1/P1	-208,524	133,452	0,714
		Q2/P2	-102,919	133,452	0,996
		Q3/P3	541,903	133,452	0,002**
		Q5/P5	-349,356	133,452	0,110
	Q5/P5	Q1/P1	140,832	133,452	0,963
		Q2/P2	246,437	133,452	0,502
		Q3/P3	891,259	133,452	0,000***
		Q4/P4	349,356	133,452	0,110
F_T1	Q1/P1	Q2/P2	105,605	133,452	0,995
		Q3/P3	750,427	133,452	0,000***
		Q4/P4	208,524	133,452	0,714
		Q5/P5	-140,832	133,452	0,963
	Q2/P2	Q1/P1	-105,605	133,452	0,995
		Q3/P3	644,822	133,452	0,000***
		Q4/P4	102,919	133,452	0,996
		Q5/P5	-246,437	133,452	0,502
	Q3/P3	Q1/P1	-750,427	133,452	0,000***
		Q2/P2	-644,822	133,452	0,000***
		Q4/P4	-541,903	133,452	0,002**
		Q5/P5	-891,259	133,452	0,000***
	Q4/P4	Q1/P1	-208,524	133,452	0,714
		Q2/P2	-102,919	133,452	0,996
		Q3/P3	541,903	133,452	0,002**
		Q5/P5	-349,356	133,452	0,110
	Q5/P5	Q1/P1	140,832	133,452	0,963
		Q2/P2	246,437	133,452	0,502
		Q3/P3	891,259	133,452	0,000***
		Q4/P4	349,356	133,452	0,110

F_T2	Q1/P1	Q2/P2	49,482	124,192	1,000
		Q3/P3	557,433	124,192	0,000***
		Q4/P4	97,695	124,192	0,996
		Q5/P5	-76,125	124,192	0,999
	Q2/P2	Q1/P1	-49,482	124,192	1,000
		Q3/P3	507,951	124,192	0,002**
		Q4/P4	48,213	124,192	1,000
		Q5/P5	-125,607	124,192	0,972
	Q3/P3	Q1/P1	-557,433	124,192	0,000***
		Q2/P2	-507,951	124,192	0,002**
		Q4/P4	-459,738	124,192	0,006**
		Q5/P5	-633,558	124,192	0,000***
	Q4/P4	Q1/P1	-97,695	124,192	0,996
		Q2/P2	-48,213	124,192	1,000
		Q3/P3	459,738	124,192	0,006**
		Q5/P5	-173,820	124,192	0,822
	Q5/P5	Q1/P1	76,125	124,192	0,999
		Q2/P2	125,607	124,192	0,972
		Q3/P3	633,558	124,19	0,000***
		Q4/P4	173,820	124,192	0,822

Dependent Variable			Mean Difference (I-J)	Std. Error	Sig.
C_T0	Q1/P1	Q2/P2	-365,403	126,742	0,057
		Q3/P3	750,427	126,742	0,000***
		Q4/P4	129,861	126,742	0,970
		Q5/P5	-140,832	126,742	0,949
	Q2/P2	Q1/P1	365,403	126,742	0,057
		Q3/P3	1115,830	126,742	0,000***
		Q4/P4	495,264	126,742	0,003**
		Q5/P5	224,571	126,742	0,558
	Q3/P3	Q1/P1	-750,427	126,742	0,000***
		Q2/P2	-1115,830	126,742	0,000***
		Q4/P4	-620,566	126,742	0,000***
		Q5/P5	-891,259	126,742	0,000***
	Q4/P4	Q1/P1	-129,861	126,742	0,970
		Q2/P2	-495,264	126,742	0,003**
		Q3/P3	620,566	126,742	0,000***
		Q5/P5	-270,693	126,742	0,309
	Q5/P5	Q1/P1	140,832	126,742	0,949
		Q2/P2	-224,571	126,742	0,558
		Q3/P3	891,259	126,742	0,000***
		Q4/P4	270,693	126,742	0,309

C_T1	Q1/P1	Q2/P2	-332,415	122,302	0,087
		Q3/P3	750,427	122,302	0,000***
		Q4/P4	176,805	122,302	0,793
		Q5/P5	-140,832	122,302	0,937
	Q2/P2	Q1/P1	332,415	122,302	0,087
		Q3/P3	1082,842	122,302	0,000***
		Q4/P4	509,220	122,302	0,001**
		Q5/P5	191,583	122,302	0,711
	Q3/P3	Q1/P1	-750,427	122,302	0,000***
		Q2/P2	-1082,842	122,302	0,000***
		Q4/P4	-573,622	122,302	0,000***
		Q5/P5	-891,259	122,302	0,000***
	Q4/P4	Q1/P1	-176,805	122,302	0,793
		Q2/P2	-509,220	122,302	0,001**
		Q3/P3	573,622	122,302	0,000***
		Q5/P5	-317,637	122,302	0,116
	Q5/P5	Q1/P1	140,832	122,302	0,937
		Q2/P2	-191,583	122,302	0,711
		Q3/P3	891,259	122,302	0,000***
		Q4/P4	317,637	122,302	0,116
C_T2	Q1/P1	Q2/P2	64,707	126,697	1,000
		Q3/P3	556,164	126,697	0,001**
		Q4/P4	151,132	126,697	0,923
		Q5/P5	-92,619	126,697	0,998
	Q2/P2	Q1/P1	-64,707	126,697	1,000
		Q3/P3	491,457	126,697	0,003**
		Q4/P4	86,425	126,697	0,999
		Q5/P5	-157,326	126,697	0,903
	Q3/P3	Q1/P1	-556,164	126,697	0,001**
		Q2/P2	-491,457	126,697	0,003**
		Q4/P4	-405,032	126,697	0,025*
		Q5/P5	-648,783	126,697	0,000***
	Q4/P4	Q1/P1	-151,132	126,697	0,923
		Q2/P2	-86,425	126,697	0,999
		Q3/P3	405,032	126,697	0,025*
		Q5/P5	-243,751	126,697	0,446
	Q5/P5	Q1/P1	92,619	126,697	0,998
		Q2/P2	157,326	126,697	0,903
		Q3/P3	648,783	126,697	0,000***
		Q4/P4	243,751	126,697	0,446

Table VI: Statistical parameters obtained in the Post-Hoc Gabriel test for the comparison of film pressure areas (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) when measuring the mean bite pressure (psi) in different experimental conditions.
* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Discussion

Comparison A – Testing the Differences between Examiners (F vs C)

The few differences detected between Examiners (F versus C) were observed at Time 0 and Time 1 of measurement for the P2 film pressure area, probably due to small discrepancies in the experimental methodology. The overall results seem to indicate that the choice of examiner is not a variable that greatly affects the mean bite pressure (psi) measured by PressureX® pressure indicating sensor film, although special attention must be given for the standardization/homogenisation of the experimental methodology used, in order to avoid the differences detected among different examiners.

Comparison B – Testing the Differences between Times (T0 vs T1 vs T2)

The variations in the mean bite pressure (psi) at different times (Time 0 versus Time 1 versus Time 2) are concentrated in the anterior and mid region of the maxillae/ mandibulae, whereas in the posterior region of the maxillae/ mandibulae (Q1/P1 and Q5/P5), no significant statistical differences have been detected throughout time ($p > 0,05$). These differences have also been identified between Time 2 (1 month after surgery) and Times 0 and 1 (prior to surgery) in the film pressure area P3/Q3 located in the anterior region of the maxillae/mandibulae. Given the nature of the surgical procedure performed in the 10 patients – a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible – it was expected that it would reflect in the mean pressure (psi) measured in the anterior region of the maxillae/mandibulae, as now it is statistically demonstrated.

Comparison C – Testing the Differences between Film Pressure Areas (Q1/P1 vs Q2/P2 vs Q3/P3 vs Q4/P4 vs Q5/P5)

Regarding the possible differences between film pressure areas (Q1/P1 vs Q2/P2 vs Q3/P3 vs Q4/P4 vs Q5/P5) for the same Examiner (F or C) and the same time moment (Time 0, Time 1 or Time 2), the inferential tests do confirm their existence ($p < 0,05$).

Post-Hoc Gabriel Test has determined that the significant statistical differences observed between the different film pressure areas mainly involve the film pressure area Q3/P3, when compared with the remaining film pressure areas ($p < 0,05$).

When the pairs of film pressure areas don't involve Q3/P3, almost no significant statistical differences are identifiable ($p > 0,05$), meaning that the best film pressure area to evaluate the efficacy of a bimaxillary osteotomy throughout time should be the anterior region of the maxillae/mandibulae.

Conclusions

The results show little significant statistical differences in the mean bite pressure (psi) between examiners, when the measurement is made in the same experimental conditions. The few differences observed ($p < 0,05$) were detected at Time 0 and Time 1 of measurement for the P2 film pressure area, probably due to small discrepancies in the experimental methodology used.

Significant statistical differences in the mean bite pressure (psi) have been detected between pre-op (Times 0 and 1) and post-op (Time 2) periods for the film pressure areas Q2/P2, Q3/P3 and Q4/P4, irrespective of the Examiner (C or F) ($p < 0,05$). Interestingly, these differences in the mean bite pressure (psi) at different times are concentrated in the anterior and mid region of the maxilla/ mandible, whereas in the posterior region of the maxilla/ mandible (Q1/P1 and Q5/P5), no significant statistical differences have been detected throughout time ($p > 0,05$).

The overall results presented for PressureX® pressure indicating sensor film show that this device can be successfully used for quantitative and qualitative evaluation of bite pattern, especially if the sensor film is placed in the anterior region of maxilla/mandible (i.e., in the film pressure area Q3/P3).

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ARTICLE 7

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Evaluation of Pressure Changes in Orthognathic Surgery using Pressurex® in 3 Years of Follow-up

Fernando Duarte, João Neves Silva, Carina Ramos, Colin Hopper

Fernando Duarte, DMD, MSc, MSc
Oral Surgeon Specialist by OMD (Portuguese Dental Association)
Master of Science in Oral and Maxillofacial Surgery at Eastman Dental Institute - University College of London
Master of Science in Laser Dentistry at Universitá Cattolica del Sacro Cuore - Rome - Italy
CEO and Clinical Director of Clitrofa - Trofa - Portugal

João Neves Silva, BsC, MSc, PhD
Professor at ISAVE - Instituto Superior de Saúde - Portugal
Member of the Interdisciplinary Center for Health Sciences (ICHS) - ISAVE - Instituto Superior de Saúde

Carina Ramos, DMD
MScStudent in Oral Rehabilitationat IUCS – Instituto Universitário de Ciências da Saúde - Portugal

Colin Hopper, MD FRCS FHEA
UCL Eastman Dental Institute
Oral &Maxillofacial Surgery Department

Corresponding Author: Fernando Duarte
Clitrofa - Centro Médico, Dentário e Cirúrgico
Avenida de Paradela 622, 4785-248 Trofa – Portugal

ABSTRACT

Purpose: *Despite its importance, the measurement of pressure in orthognathic surgery often receives little attention. Pressurex® (SPL – Sensor Products LLC, USA) is one of a few pressureindicating sensor films that reveals pressure distribution and magnitude between any two contacting, mating or impacting surfaces, and is currently viewed as a golden standard for that purpose. This study was designed to test Pressurex® in orthognathic surgery.*

Methods: *Retrospective analysis of 10 patients scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible; in a 3 years follow-up period.*

Results: *The selection of examiner is not a variable that affects the occlusal pressure (Psi) measured by pressure indicating films in any of the experimental conditions tested. Pressure indicating film position and surgery recovery time does not seem to affect the occlusal pressure measured by pressure indicating films.*

Conclusion: *The pressure indicating film positions used in the present study have shown poor reliability and validity of measurement. Although selection of examiner does not affect the measurement of occlusal pressure (Psi) by pressure indicating films, which is positive, this method lacks sensitivity in detecting variations caused the pressure indicating film position and the recovery surgery time.*

Keywords: *Pressure Measurement; Orthognathic Surgery; Pressurex®*

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I. INTRODUCTION

Orthodontic and surgical technical advances in recent years have resulted in treatmentopportunities for a whole range of craniofacial skeletal disorders either in the adolescent or adultpatients. In the growing child these can include myofunctional orthodontic appliance therapy or distractionosteogenesis procedures, whilst in the adult the mainstay approach revolves around orthognathic surgery.

Research evidence suggests that in those cases requiring orthognathic surgery, the stabilityof the result depends upon such factors as the direction and extent of the surgical move of the facialskeleton, the method of surgical fixation applied and the operative technique employed. Yet, even whenthe best evidence-based practice is followed, there remains a significant proportion of cases where thesurgical outcome (stability) is both unexpected and undesirable[1].

Bite force has been used to evaluate masticatory function in patients before and after orthognathicsurgery[2, 3,4,5,6,7]. Usually, it has been measured with a custom bite force transducer[5,6,8].Pressure is a critical variable in many converting operations. Tactile pressure-sensor films arean accurate, efficient, and inexpensive method to determine pressure. These films offer the convertingindustry an opportunity to determine both the distribution and magnitude of most operations wherepressure is important.

II. PRESSUREX®SYSTEM

Pressurex® (SPL – Sensor Products LLC, USA) is a pressure indicating sensor film that reveals pressure distribution and magnitude between any two contacting, mating or impacting surfaces. Consists of a thin mylar film (4 to 8 mils) that contains a layer of tiny microcapsules.

The application of force upon the film causes the microcapsules to rupture, producing an instantaneous and permanent high resolution "topographical" map of pressure variations across the contact area. Simply place sensor film, between any two surfaces that touch, mate or impact. Apply pressure, release it; immediately the film reveals a profile of the pressure distribution that occurred between the surfaces. The colour intensity of the image created is directly related to the amount of pressure applied, the greater the pressure, the more intense colour.

During use, visual comparison of colour intensity to a colour correlation chart provides a pressure-measurement reading that is accurate to ±10%. With the use of optical measuring systems, the pressure reading may be more accurately quantified to ±2%. Use of a pressure-sensor film is an alternative to strain gauges and pressure transducers with accompanying electronic equipment. Various films are offered, with some in a range of sensitivities to accommodate varying amounts of pressure. Pressure ranges can start as low as 2-20 psi (0.14-1.4 Kg/cm2) and go as high as 7,100-18,500 psi (500-1,300 Kg/cm2).

Five areas were considered in the following order, the readings were in Psi.Area A: right maxillary second pre-molar and right maxillary first molar between 1st and 4th quadrants; Area B: right maxillary canine and right maxillary first pre-molar between 1st and 4th quadrants; Area C: right and left maxillary central incisors and right and left maxillary lateral incisors area; Area D: left maxillary second pre-molar and left maxillary first molar between 2nd and 3rd quadrants, and finally Area E: left maxillary canine and left maxillary first pre-molar between 2nd and 3rd quadrants.

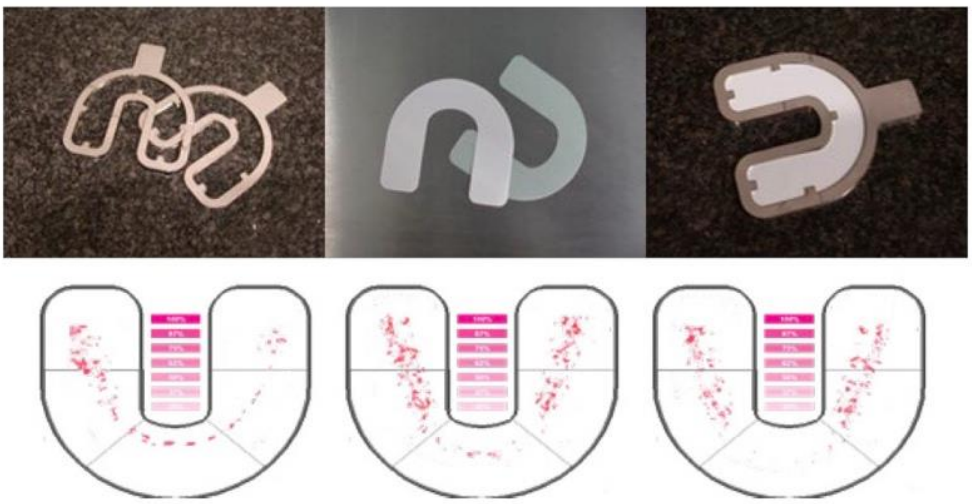

Fig. 1-Clinical application of the metal framework containing the Pressurex® film. Biting area andpressure distribution in 5 areas.

III. MATERIALS AND METHODS

The present study is an observational prospective study with quantitative methodology. A study group of 10 patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal was selected to the present study by a convenience non-probability sampling method. All the selected patients were scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible were select to form the study group.

The Pressurex® System was placed between the upper and lower dental arch, and the subjects were instructed to bite as forcefully as possible for about 3 seconds. The values were registered by two different observers (F and C) in different moments: (T0) - before surgery, (T1) - 10 minutes after surgery, (T2) - 1 month after surgery, (T3) - 36 months after surgery.

STATISTICAL ANALYSIS

IBM® SPSS®, version 25, was used to analyse the data obtained. Exploratory data analysis was performed by Kolmogorov-Smirnov (D) test to assess the normality of the frequency distributions and by Levene test (L) to assess the variance homogeneity of the variables.

Descriptive statistics of the study variables was performed by determination of mode and frequencies (nominal variables), median and inter-quartile range (ordinal variables), and arithmetic mean and standard deviation (numerical variables). Bar graphs were also added to facilitate data description and results interpretation.

Inferential statistics was used to compare examiner selection (paired two-tailed Student's t test), pressure indicating film position (Repeated Measures ANOVA) and surgery recovery time (Repeated Measures ANOVA). Where the requirements for parametric statistical analysis were not met, the inferential tests were replaced, respectively, by Wilcoxon, Friedman and Friedman tests.

The experimental design used in this study is depicted in Figure 1 and comprises 3 separate researches:

1) Research A, which investigated the effect of examiner selection on the occlusal pressure (Psi) measured by pressure indicating films;
2) Research B, which investigated the effect of pressure indicating film position on the occlusal pressure (Psi) measured by pressure indicating films;
3) Research C, which investigated the effect of surgery recovery time on the occlusal pressure (Psi) measured by pressure indicating films.

Where statistically significant differences were found by Repeated Measures ANOVA tests, the multiple-comparison Post-Hoc Bonferroni or Gabriel tests were performed to identify the pairs of categories were the statistically significant differences were located.

Three thresholds of statistical significance (α level) were considered throughout the present study: $p-values$ below 0.05 (*) were considered statistically significant;$p-values$ below 0.01 (*) were considered highly statistically significant, and $p-values$ below 0.001 (*) were considered very highly statistically significant. The lack of statistical significance was designated as non-significant (ns).

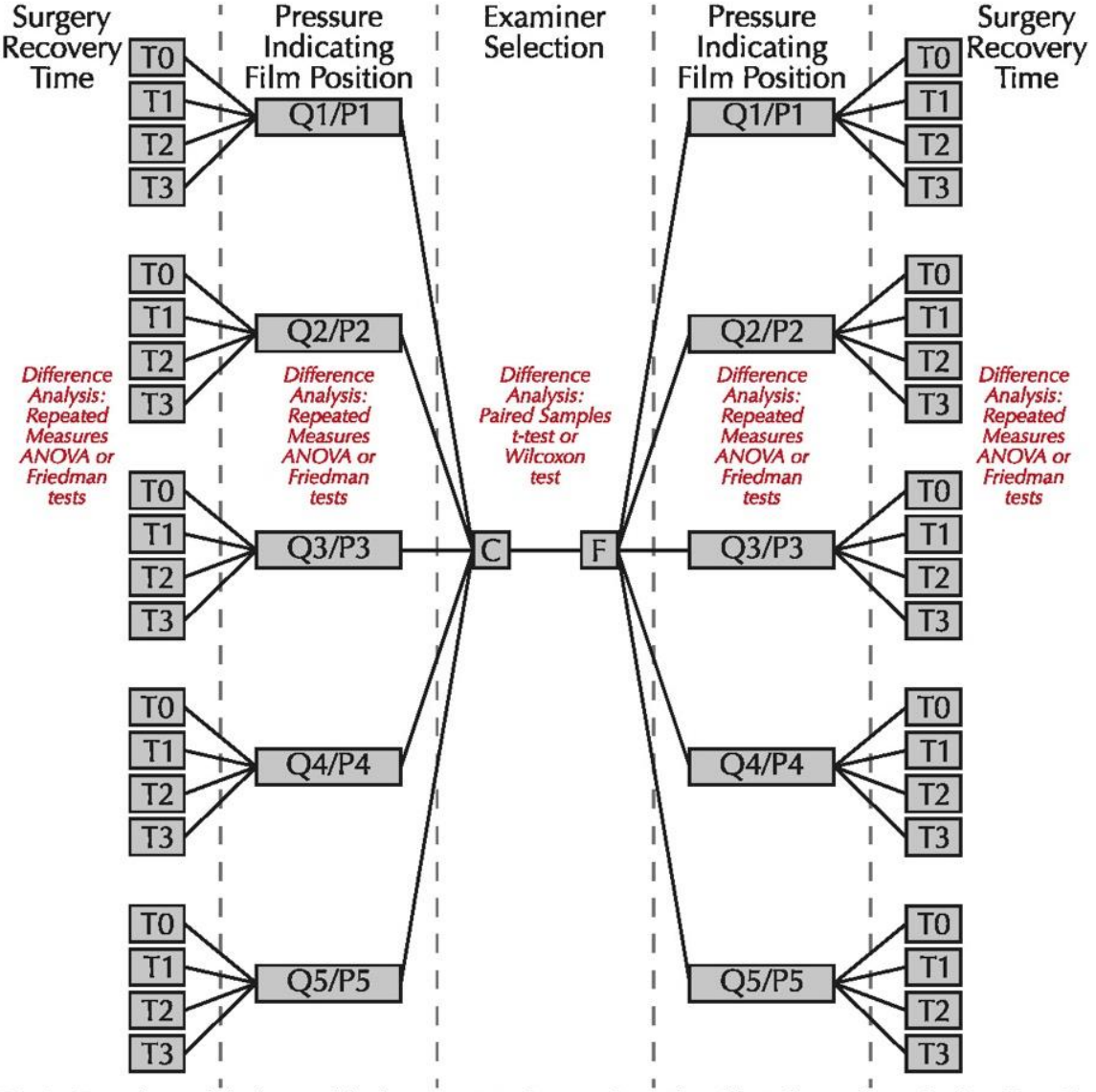

Fig.2 - Experimental design used in the present study to evaluate the effect of examiner selection (F or C), pressure indicating film position (Q1/P1, Q2/P2, Q3/P3, Q4/P4 or Q5/P5) and surgery recovery time (T0 - before surgery, T1 - 10 minutes after surgery, T2 - 1 month after surgery, or T3 - 36 months after surgery) on the occlusal pressure (Psi) measured by pressure indicating films in the 10 patients of the sample.

IV. RESULTS

DATA EXPLORATORY ANALYSIS

Kolmogorov-Smirnov (D) and Levene (L)assumption tests have revealed that the study variables comply with the minimum requirements for aninferential parametric analysis (normality of frequency distributions and variance homogeneity), thus meaning that the effects of examiner selection, pressure indicating film position and surgery recovery time on the occlusal pressure (Psi) measured by pressure indicating films will be analysed by the differences tests of Paired-Samples of Student (t), Repeated Measures ANOVA (F) and Repeated Measures ANOVA (F), respectively.

Table I – Data exploratory analysis.

Study Variables	Central Tendency Measures	Dispersion Measures	Kolmogorov-Smirnov test (D); $p-value$	Levene test (L); $p-value$
Examiner Selection	Mode: C, F	Frequencies: C (50.0%); F (50.0%)	D: 0.163 $p-value$: 0.173	L: 0.327 $p-value$: 0.571
Pressure Indicating Film Position	Mode: Q1/P1; Q2/P2; Q3/P3 ; Q4/P4 ; Q5/P5	Frequencies: Q1/P1 (20.0%); Q2/P2 (20.0%);	D: 0.249 $p-value$: 0.156	L: 1.029 $p-value$: 0.406

		Q3/P3 (20.0%); Q4/P4 (20.0%); Q5/P5 (20.0%)		
SurgeryRecovery Time	Median:2.5	Interquartile Range: 2	D: 0.231 $p-value$: 0.138	L: 2.695 $p-value$: 0.060
Occlusal pressure (Psi)	Mean:950.19	SD:81.09	n/a	n/a

(*) significant statistical difference to an alpha level of 0.05;
(**) highly significant statistical difference to an alpha level of 0.01;
(***) very highly significant statistical difference to an alpha level of 0.001.

RESEARCH A: EFFECT OF EXAMINER SELECTION ON THE OCCLUSAL PRESSURE (PSI) MEASURED BY PRESSURE INDICATING FILMS

Figure 3 shows the similarity of occlusal pressure (Psi) measurements made by examiners F and C. The relatively high standard deviation of the measures depicted in Figure 3 arises from the fact that the examiners have been compared in different experimental conditions (pressure indicating film positions and surgery recovery times), which are in the graphic are presented in the same group of values.

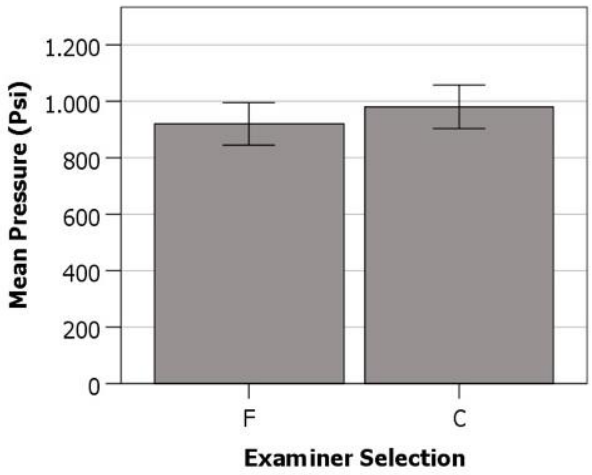

Fig.3 - Effect of examiner selection on the occlusal pressure (Psi) measured by pressure indicating films. Error bars represent standard deviation.

Paired Samples (t) tests have revealed the general absence of significant statistical differences between examiners F and C regarding the occlusal pressure (Psi) measured by pressure indicating films in the 10 patients of the sample, in the different experimental conditionstested (Table II). The differences observed between Examiners F and C regarding T0 at pressure indicating film positions Q1/P1 and Q2/P2 are probably due to the lack of standardization in the measurement procedure, as this was the first moment where the measurement of occlusal pressure was performed. It is interesting to notice, however, that these differences have not been identified with other methods such as piezoelectric sensors, which may indicate a reliability/validity limitation of the current method that uses pressure indicating films [9, 10].

Table II – Effect of examiner selection on the occlusal pressure (Psi) measured by pressure indicating films (Paired Samples (t) test).

Experimental Conditions	Paired Samples (t)	$p-value$
F *vs* C, Q1/P1, T0	-2,486	0,035*
F *vs* C, Q1/P1, T1	-0,045	0,965
F *vs* C, Q1/P1, T2	1,395	0,197
F *vs* C, Q1/P1, T3	0,000	1,000
F *vs* C, Q2/P2, T0	-2,393	0,040*
F *vs* C, Q2/P2, T1	-2,094	0,066
F *vs* C, Q2/P2, T2	0,273	0,791
F *vs* C, Q2/P2, T3	n/a	n/a
F *vs* C, Q3/P3, T0	-0,736	0,480
F *vs* C, Q3/P3, T1	-1,426	0,188
F *vs* C, Q3/P3, T2	-1,252	0,242
F *vs* C, Q3/P3, T3	n/a	n/a
F *vs* C, Q4/P4, T0	-0,640	0,538

F *vs* C, Q4/P4, T1	-0,527	0,611
F *vs* C, Q4/P4, T2	-0,163	0,874
F *vs* C, Q4/P4, T3	n/a	n/a
F *vs* C, Q5/P5, T0	-1,130	0,288
F *vs* C, Q5/P5, T1	-0,920	0,382
F *vs* C, Q5/P5, T2	1,484	0,172
F *vs* C, Q5/P5, T3	n/a	n/a

(*) significant statistical difference to an alpha level of 0.05;
(**) highly significant statistical difference to an alpha level of 0.01;
(***) very highlysignificant statistical difference to an alpha level of 0.001.
(n/a) t cannot be computed because the standard error of the difference is 0.

RESEARCH B: EFFECT OF PRESSURE INDICATING FILM POSITION ON THE OCCLUSAL PRESSURE (PSI) MEASURED BY PRESSURE INDICATING FILMS

Figure 4 shows the variation of occlusal pressure (Psi) measurements made with the different pressure indicating film positions. Results indicate little variation in occlusal pressure (Psi) as the pressure indicating film positionvaries in relation to the position of the temporomandibular joint. The relatively high standard deviation of the measures depicted in Figure 4 arises from the fact that the pressure indicating film positions have been compared in different experimental conditions (examiner selection and surgery recovery times), which are in the graphic are presented in the same group of values.

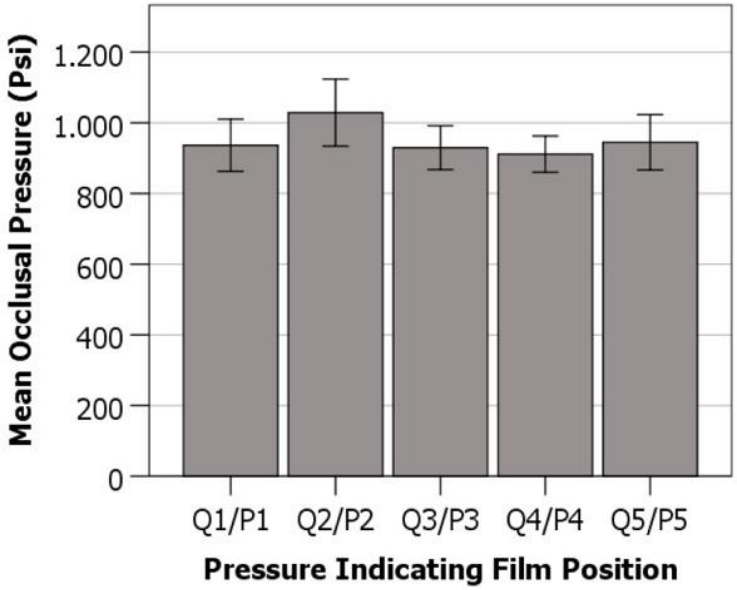

Fig.4 - Effect of pressure indicating film position on the occlusal pressure (Psi) measured by pressure indicating films. Error bars represent standard deviation.

Repeated Measures ANOVA (*F*) tests have confirmed the absence of significant statistical differences between the different pressure indicating film positions (Q1/P1, Q2/P2, Q3/P3, Q4/P4 and Q5/P5) regarding the occlusal pressure (Psi) measured by pressure indicating films in the 10 patients of the sample, in the different experimental conditions tested (Table III).Once again, data suggests that this method that uses pressure indicating films presents a lower reliability/validity than other methods that use piezoelectric sensors[9, 10].

Table III – Effect of pressure indicating film position on the occlusal pressure (Psi) measured by pressure indicating films (Repeated Measures ANOVA (*F*) test).

Experimental Conditions	RepeatedMeasures ANOVA (*F*)	$p - value$
Q1/P1*vs*Q2/P2*vs*Q3/P3*vs*Q4/P4*vs*Q5/P5	3,069	0,069

(*) significant statistical difference to an alpha level of 0.05;
(**) highly significant statistical difference to an alpha level of 0.01;
(***) very highly significant statistical difference to an alpha level of 0.001.

RESEARCH C: EFFECT OF SURGERY RECOVERY TIME ON THE OCCLUSAL PRESSURE (PSI) MEASURED BY PRESSURE INDICATING FILMS

Figure 5 shows the variation of occlusal pressure (Psi) measurements at different surgery recovery times. One of the most innovative aspects of the present study is that the follow-up period of the patients has been extended and reported until 36 months, thus allowing a more complete view of the patient's recovery process, as viewed by the masticatory pressure generated by the mandible. Although a marginal increase in occlusal pressure (Psi)is observed at T3 (36 months after surgery) in the patients, when compared to previous timepoints (T0, T1 and T2), the variation is within the standard deviation value, and therefore is not statistically significant. This may be due to the lack of reliability/validity of the pressure indicating film, because piezoelectric sensors seem to present higher sensitivities in the same conditions [9, 10].

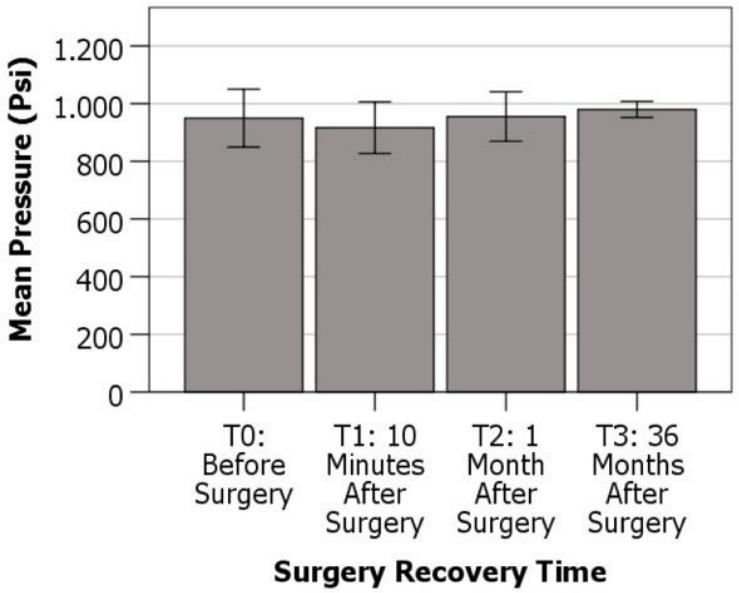

Fig.5 - Effect of surgery recovery time on the occlusal pressure (Psi) measured by pressure indicating films. Error bars represent standard deviation.

Table IV – Effect of surgery recovery time on the occlusal pressure (Psi) measured by pressure indicating films (Friedman (*H*) test).

Experimental Conditions	RepeatedMeasures ANOVA (*F*)	$p - value$
T0 *vs* T1 *vs* T2 *vs* T3 *vs* T4	1.032	0.390

(*) significant statistical difference to an alpha level of 0.05;
(**) highly significant statistical difference to an alpha level of 0.01;
(***) very highly significant statistical difference to an alpha level of 0.001.

Repeated Measures ANOVA (*F*) tests have confirmed the absence of significant statistical differences between the different surgery recovery times (T0, T1, T2, T3 and T4) regarding the occlusal pressure (Psi) measured by pressure indicating films in the 10 patients of the sample, in the different experimental conditions tested (Table IV).

V. DISCUSSION

In the timepoints (T1, T2 and T3) no statistical differences were observed for the pressure indicating films, it is concluded that the selection of examiner is not a variable that affects the occlusal pressuremeasured by pressure indicating films in any of the experimental conditions tested.

The pressure indicating film position and the surgery recovery time does not seem to affect the occlusal pressure measured by pressure indicating films, irrespective of the examiner selection and/or the surgery recovery time.

VI. CONCLUSION

The pressure indicating film positions used in the present study have shown poor reliability and validity of measurement. Although selection of examiner does not affect the measurement of occlusal pressure (Psi) by pressure indicating films, which is positive, this method lacks sensitivity in detecting variations caused the pressure indicating film position and the recovery surgery time.

This inferior performance compared to piezoelectric sensors, makes pressure indicating films not so suitable to study the follow-up period of patients subjected to surgical dental operations.

Authors' contributions

FD, JNS, and CR read and wrote the manuscript. FD and CR were responsible for conducting surgeries. FD and JNS were responsible for the data collection. FD designed and wrote the entire article. CH was responsible for the final revision of the manuscript. All authors read and approved the final manuscript.

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Data availability

No datasets were generated or analyzed during the current study.

Declarations

Ethics approval and consent to participate

Ethical approval: This project has approval by the Joint Research & Ethics Committee of UCL Hospitals NHS Trust, Reference No.03/E012.

Data registration: This project is covered by the UCL Data Protection Registration Reference No. Z6364106, Section 19, Research: Health Research.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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3 MAGNETIC RESONANCE IMAGING

ARTICLE 8

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Post-Viva Addenda:

-The observed differences in statistical significance ($p < 0.05$ vs. $p > 0.05$) regarding occlusal deformities are explained by the severity and functional impact of the specific bite patterns being compared.

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Research Article

Masseter Muscle Adaptation Following Orthognathic Surgery - MRI Analysis

Fernando Duarte[1]*, João Neves Silva[2], Colin Hopper[3] and Nigel Hunt[4]

[1]*CEO and Clinical Director of Clitrofa, Trofa, Portugal*

[2]*Professor at ISAVE, Instituto Superior de Saúde, Portugal*

[3]*Oral and Maxillofacial Surgery Department, UCL Eastman Dental Institute, UK*

[4]*Orthodontics Department, UCL Eastman Dental Institute, UK*

***Corresponding Author:** Fernando Duarte, CEO and Clinical Director of Clitrofa, Trofa, Portugal.

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Abstract

Orthodontic and surgical technical advances in recent years have resulted in treatment opportunities for a whole range of craniofacial skeletal disorders either in the adolescent or adult patient. In the growing child these can include myofunctional orthodontic appliance therapy or distraction osteogenesis procedures, whilst in the adult the mainstay approach revolves around orthognathic surgery.

The literature agrees that for a change in craniofacial morphology to remain stable, the muscles acting upon the facial skeleton must be capable of adaptation in their structure and, therefore, their function. Failure of the muscles to adapt to the change in their length or orientation will place undesirable forces on the muscle attachments leading to potential instability of the skeleton. Adaptation can occur through various processes including those within the neuromuscular feedback mechanism, through changes within muscle structure or through altered muscle physiology, and through changes at the muscle/bone interface.

This prospective, case controlled clinical study was designed to provide information in relation to masticatory muscle adaptation following orthognathic surgery. Both for ease of access, and in order to provide data suitable for comparison with previous studies of muscle function, the muscle chosen for investigation was the masseter muscle.

It is now accepted that because there is no single method of assessing masticatory function, several measures should be taken, and whenever possible, simultaneously.

This pilot investigation was designed to apply several, newly developed and more sophisticated methods of measuring muscle structure and function to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach.

Patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa - Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were screen. Ten patients scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible were select to form the study group.

The 10 patients have Magnetic Resonance Imaging (MRI) of the masseter muscle to evaluate the masseter muscle volume and **fibre orientation changes. This exam was taken before surgery and 6 to 12 months after surgery according to the protocol jointly developed** between the Eastman Dental Institute - University of London and the MRI Centre - Department of Radiology at John Radcliffe Hospital - University of Oxford.

Keywords: Orthognathic Surgery; Masseter Muscle; MRI Analysis

Introduction

Orthognathic surgery is a practical art, the surgeon often uses direct physical intervention in the treatment of patients. To minimize operative morbidity and mortality, and to maximize therapeutic success, surgical strategies are tailored to each patient and must be carefully planned using the best possible anatomical information. The traditional way for a surgeon to gain basic experience without risk to the patient is to dissect cadavers and to examine carefully preserved pathological specimens. This serves to provide a conceptual anato-pathological framework from which operative interventions may be safely made. However, every patient is **unique. Thus, there is a need for the surgeon to attain a specific** understanding of the individual's anatomy pre-operatively. Thorough physical examination may be all that is needed for conditions in which the anato-pathology is common and the surgeon experienced. With complicated anato-pathology, detailed information relating to the morphology of internal structures is often required by the surgeon to enhance understanding. To obtain this internal ana-

tomical information non-invasively, the surgeon relies on medical imaging [1].

Advances in medical imaging have created ever increasing volumes of complex data obtained from the patient. The interpretation of such information has become a specialty in itself and the surgeon at times may be left bewildered as to how best to apply the available information to the practicalities of physical intervention. The surgeon seeks to understand the exact morphology of the abnormality, its relationships to surrounding anatomy and the best way to access and correct the pathology operatively. Such specific information is not readily available in the radiologist's report and however experienced the surgeon may be at interpreting images such questions often cannot be easily answered [1].

Three-dimensional (3-D) imaging has been developed to narrow the communication gap between radiologist and surgeon. By using 3-D imaging a vast number of complex slice images can be quickly appreciated. The term "three-dimensional" however, is not a truly accurate description of these images as they are still displayed on a radiological film or flat screen in only two dimensions.

The advent of 3-D imaging has not only improved data display but also promoted the development of even more useful technologies to assist the surgeon in diagnosis and planning [1].

Magnetic resonance imaging-MRI

Magnetic resonance imaging has become accepted as a powerful imaging tool. A customised software programme has been developed at John Radcliffe Hospital - Oxford University which enables the reconstruction of 3D images allowing measurement of muscle volume and area with a high level of accuracy.

To date this technology had only been applied to tongue muscles, when applied to the muscles of mastication the resolution and results were disappointing.

The goal was to develop the system and software to produce accurate and reproducible data for masticatory muscles which not only provided data for muscle area and volume, but also was of sufficient detail to enable analysis of muscle fibre orientation in particular of masseter muscle.

The masseter muscle displays a penniform structure typically characterized by the presence of alternating muscular/aponeurotic layers. The anatomical sections and the MRI section in the same plane allowed the appearance of the intra-muscular aponeurotic layers on the MRI to be defined [2].

The architecture of the masseter muscle has been studied for a long time but the lack of clinical applications led to descriptions which were often global or contradictory, giving the muscle sometimes two bundles sometimes three [2]. The successive studies of Gaspard [3-5], Yoshikawa [6,7] and Gaudy [8] allowed the definition of the arrangement of the muscular aponeurotic layers making up the human masseter muscle. Unger [9] affirmed the value of magnetic resonance imaging in the oro-facial field for the study of the musculature of the tongue and the walls of the oral cavity, but gave only very general information on the masticatory muscles [10].

Anatomics™ software

The Anatomics™ Rx software is a 3D DICOM viewer and allows to view CT and MRI scan data in both slice format and fully interactive 3D. Anatomics™ can convert 3D images to the STL format for rapid prototyping, or as a bridge from medical imaging to Computer Aided Design (CAD). A good quality 3D scan is required to create an accurate biomodel or implant.

To standardise the scanning process, a scanning protocol was developed and applied that describe the preferred imaging parameters and provide the imaging technician with an area to note specifics.

The patient must remain completely still during the scan, if the patient moves during the scan, it will need to be repeated. Only the original fine slice data must be used in the software, reformats will not be accepted.

Fine overlapping slices must be used, the thickness of 1 mm (or nearest to) and a spacing of 0.8 mm.

The objective was to extract the muscle from the image (margins identification, extract the muscle considering the 3 planes of space, calculation of area and volume). The software allows the correction of limits at any time what gives the observer the capacity of double-check all the process.

During this study the MRI machine used was a Sigma MR/I Twinspeed from GE Medical Systems, after several attempts the software was further developed to produce slices through the muscle at 1mm intervals rather than 2 mm; the scanning time was about seven minutes.

The first masseter muscle 3D images reconstruction were acceptable in terms of definition, area and volume but with a lack of

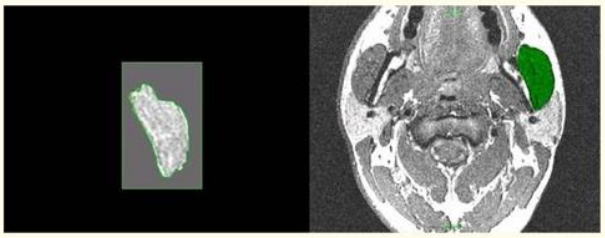

Figure 1: Identification of masseter muscle limits in a sagittal plane.

detail in terms of muscle fibres visualisation and orientation. Increasing the scanning time from five to seven minutes and changing the muscle slices to 1mm intervals was possible the acquisition of more muscle details. As a consequence, the resolution of the **muscles was greatly enhanced and the final masseter muscle 3D images reconstruction permits a good visualisation of muscle fi**bres and their orientation. This type of reconstruction have also allowed visualisation of the muscle's bony attachments and enabled the measurement of potential changes in orientation in relation to a static landmark unaffected by surgery (e.g. Frankfort plane) or in **relation to functional identifiers (e.g. Occlusal plane).**

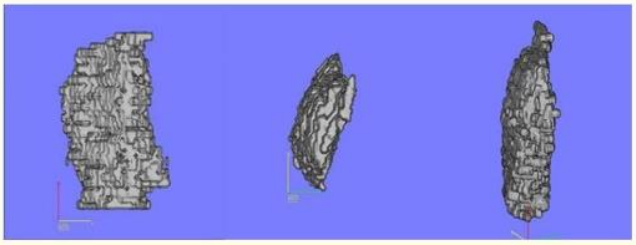

Figure 2: Final images from the left masseter muscle reconstruction using AnatomicsTM Software.

Facial deformity

To ascertain whether identifiable and measurable changes occur in parameters in conditions which simulate those occurring during the correction of both horizontal and vertical facial deformities a repeatability test was performed.

To build the occlusal splints, a subject was chosen to take dental impressions in silicone from upper and lower dental arches. The cast models were digitalized using the Anatomics™ software and placed in occlusion.

Using Stereolithography "surgical wafers" were built in photosensitive resin designed to mimic skeletal discrepancies. These **were extremely accurate occlusal splints which hold the lower jaw** of a Class I (normal) patient in a position which mimics an increasingly Class III deformity or alternatively with an increasingly severe vertical skeletal deformity with associated anterior open bite.

The horizontal simulation deformities starts with a Class I and **progress to a 3 mm overject, 6 mm overject and a 9 mm overject.** In terms of vertical simulation deformities starts with a Class I and progress to 5 mm anterior open bite and 10 mm anterior open bite.

The occlusal splint was placed between the upper and lower **dental arch, and the subject was instructed to bite for about 7 min**utes. The values were registered (T0) and the procedure was repeated after 30 minutes (T1). The process was repeated twice for each surgical wafer after rest period. In the proposed repeatability test the area and volume were measured using the same developed MRI protocol for the right and left masseter muscles.

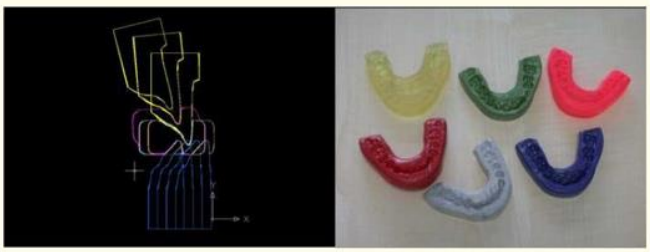

Figure 3: Demonstration of all the skeletal discrepancies simulated and the occlusal splints colour code

Materials and Methods

Patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa - Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were screen. Ten patients scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible were select to form the study group.

The 10 patients have Magnetic Resonance Imaging (MRI) of the **masseter muscle to evaluate the masseter muscle volume and fibre orientation changes. This exam was taken before surgery and 6 to 12 months after surgery according to the protocol jointly devel**oped between the Eastman Dental Institute - University of London and the MRI Centre - Department of Radiology at John Radcliffe Hospital - University of Oxford.

A combination of different parametric tests has been used to compare the different experimental variables. The experimental **design devised for this study is depicted in figure 4, comprising a** combination of different examiners, patients, MRI analysis parameters and occlusal deformities.

Comparison A - Testing the differences between examiners (F *versus* C) → Study A

The statistical comparison between examiners F and C regarding the measurement of mean left masseter area (mm^2) and mean left masseter volume (mm^3) of ten patients by MRI was performed using a Paired Student's *t*-test.

Comparison B - Testing the differences between masseters (Left masseter *versus* right masseter) → Study B

The statistical comparison between left and right masseters of a **selected patient subjected to different levels of occlusal deformity**

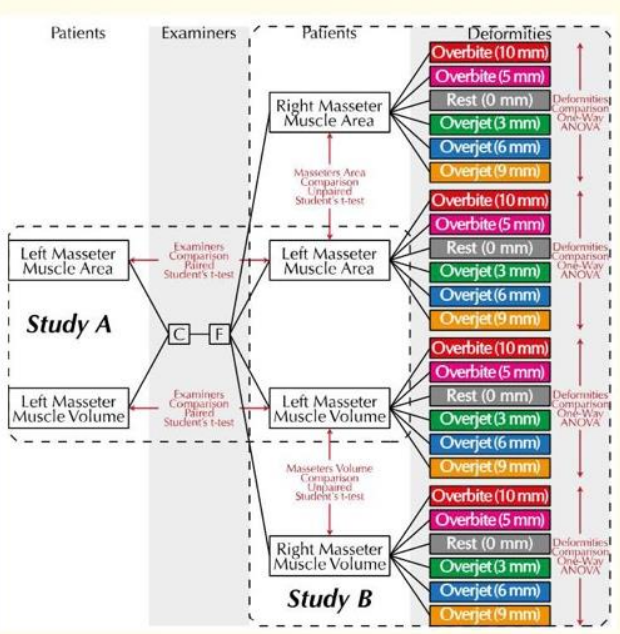

Figure 4: Experimental design used for the analysis of magnetic resonance imaging. Study A involved the contribution of two independent examiners (F and C), that measured the left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of ten patients. Study B investigated the left/right masseter muscle area (mm^2) and left/right masseter muscle volume (mm^3) of one **selected patient (two replicas per experimental condition) subjected** to different levels of occlusal deformity (overbite 10 mm, overbite **5 mm, rest 0 mm, overjet 3 mm, overjet 6 mm and overjet 9 mm).**

MRI Analysis Parameter	Examiner F	Examiner C
Left Masseter Area (mm^2) (Average ± SD)	12493 ± 904	12531 ± 871
Left Masseter Volume (mm^3) (Average ± SD)	**31066 ± 2936**	**31164 ±** 2922

Table 1: Mean left masseter area (mm^2) and mean left masseter volume (mm^3) of ten patients analysed by independent examiners F and C. Data was obtained by MRI.

MRI Analysis Parameter	Overbite (10 mm)	Overbite (5 mm)	Rest (0 mm)	Overjet (3 mm)	Overjet (6 mm)	Overjet (9 mm)
Left Masseter Area (mm^2) (Average ± SD)	**10356 ± 145**	9433 ± 132	**11963 ± 86**	12398 ± 88	13059 ± 93	9992 ± 209
Right Masseter Area (mm^2) (Average ± SD)	**9884 ± 69**	8270 ± 173	**12617 ± 88**	**12164 ± 170**	11719 ± 82	9422 ± 197
Left Masseter Volume (mm^3) (Average ± SD)	**27934 ± 196**	28412 ± 199	**26842 ± 190**	25105 ± 351	**26398 ± 185**	**36488 ± 257**
Right Masseter Volume (mm^3) (Average ± SD)	25927 ± 182	25821 ± 181	29212 ± 205	25855 ± 182	28704 ± 202	32003 ± 225

Table 2: Mean left/right masseter area (mm^2) and mean left/right masseter volume (mm^3) **of one patient subjected to different levels of occlusal deformity (overbite 10 mm, overbite 5 mm, rest 0 mm, overjet 3 mm, overjet 6 mm and overjet 9 mm). Data was obtained by MRI.**

Examiners Comparison	Mean Diference	Standard Deviation of Differences	Degrees of Freedom (df)	Test statistic from Paired t-test	P-value from Paired t-test
Examiner F versus Examiner C, Left Masseter Muscle Area (mm^2)	-38,200	**41,016**	9	-0,931	**0,376**
Examiner F versus Examiner C, Left Masseter Muscle Volume (mm^3)	-97,300	39,518	9	**-2,462**	**0,036**

Table 3: Statistical parameters obtained in the Paired Student's t-test for the comparison of examiners F and C regarding the measurement of mean left masseter area (mm^2) and mean left masseter volume (mm^3) of ten patients by MRI.

(*): The mean difference is significant at the 0,05 level.

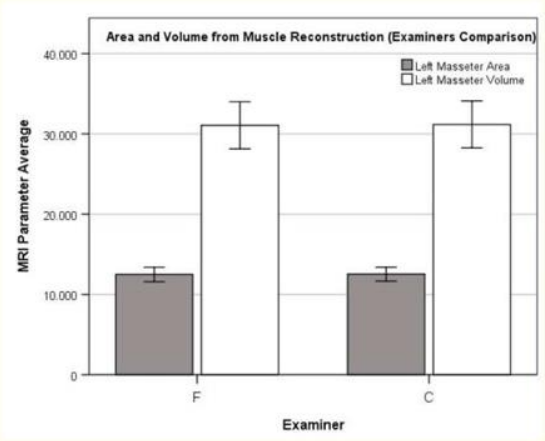

Figure 5: Mean left masseter area (grey, mm^2) and mean left masseter volume (white, mm^3) of ten patients analysed by two independent examiners (F and C) through the technique of MRI.

was performed using an Unpaired Student's *t*-test, regarding the measurement of mean masseter muscle area (mm^2) and mean masseter muscle volume (mm^3) by MRI.

Comparison C - Testing the differences between occlusal splints (Overbite versus rest versus overjet)

The statistical comparison between the different levels of occlusal deformity (overbite 10 mm, overbite 5 mm, rest 0 mm, **overjet 3 mm, overjet 6 mm and overjet 9 mm) to which a selected patient was subjected, was performed using an One-Way ANOVA** test, regarding the measurement of mean left/right masseter area (mm^2) and mean left/right masseter volume (mm^3).

Examiners Comparison	Mean Diference	Standard Deviation of Differences	Degrees of Freedom (df)	Test statistic from Unpaired t-test	P-value from Unpaired t-test
Left Masseter versus Right Masseter, Masseter Muscle Area (mm^2)	520,583	**628,854**	22	0,830	0,415
Left Masseter versus Right Masseter, Masseter Muscle Volume (mm^3)	**609,417**	1318,328	22	**0,462**	**0,648**

Table 4: Statistical parameters obtained in the Unpaired Student's t-test for the comparison of left and right masseter muscle area (mm^2) and masseter muscle volume (mm^3) **of the selected patient analysed by MRI and subjected to different levels of occlusal deformity.**

(*): The mean difference is significant at the 0,05 level.

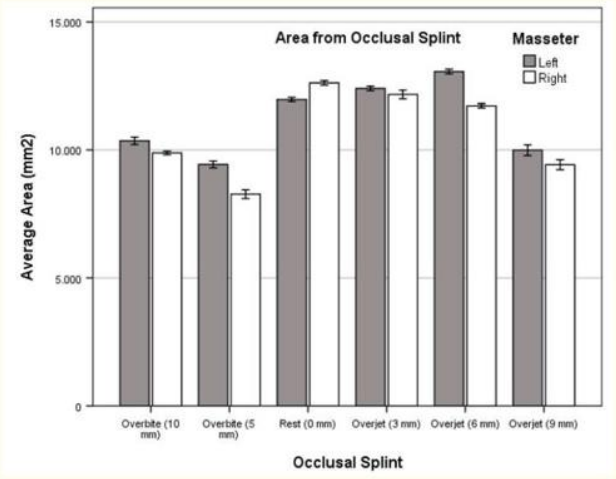

Figure 6: Mean left masseter area (grey, mm^2) and mean right masseter area (white, mm^2) of one patient analysed by the technique of MRI, and subjected to different levels of occlusal deformity (overbite 10 mm, overbite 5 mm, rest 0 mm, overjet 3 mm, overjet 6 mm and overjet 9 mm).

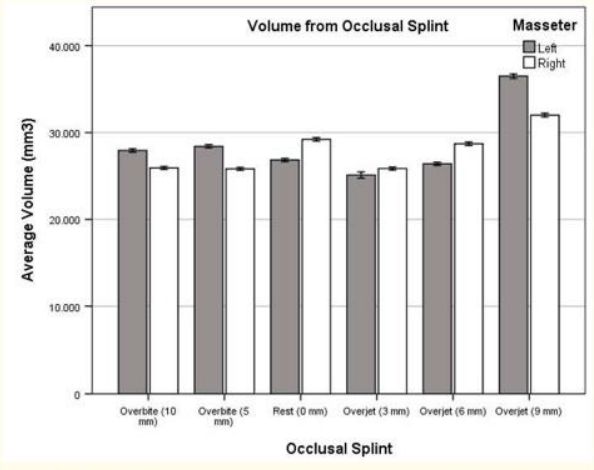

Figure 7: Mean left masseter volume (grey, mm3) and mean right masseter volume (white, mm3) of one patient analysed by the technique of MRI, and subjected to different levels of occlusal deformity (overbite 10 mm, overbite 5 mm, rest 0 mm, overjet 3 mm, overjet 6 mm and overjet 9 mm).

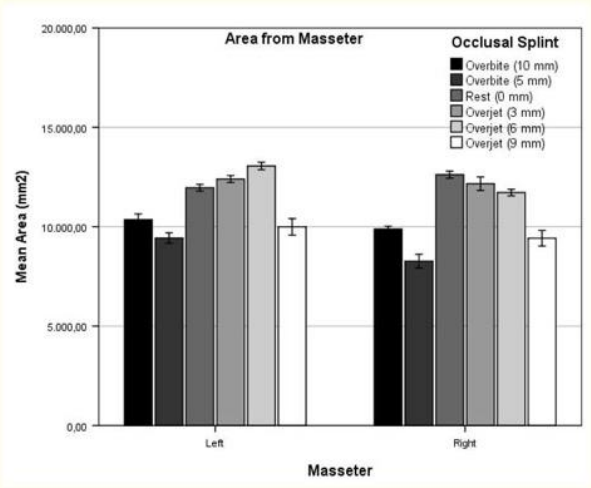

Figure 8: Mean left and right masseter area (mm²) of one patient **analysed by the technique of MRI, and subjected to different levels** of occlusal deformity (overbite 10 mm, overbite 5 mm, rest 0 mm, **overjet 3 mm, overjet 6 mm and overjet 9 mm).**

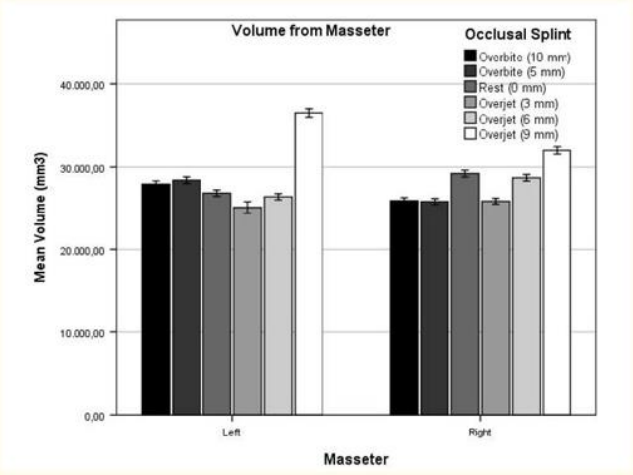

Figure 9: Mean left and right masseter volume (mm3) of one **patient analysed by the technique of MRI, and subjected to differ**ent levels of occlusal deformity (overbite 10 mm, overbite 5 mm, **rest 0 mm, overjet 3 mm, overjet 6 mm and overjet 9 mm).**

Occlusal Deformities Comparison		Sum of Squares	Degrees of Freedom (df)	Mean Square	Test statistic (F)	P-value (Sig)
OB10mm vs OB5mm vs Rest-**0mm vs OJ3mm vs OJ6mm vs** OJ9mm, Masseter Muscle Area	Between Groups	**49095633,708**	5	**9819126,742**	**40,176**	0,000
	Within Groups	4399270,250	18	244403,903		
	Total	53494903,958	23	-		
OB10mm vs OB5mm vs **Rest0mm vs OJ3mm vs OJ6mm** vs OJ9mm, Masseter Muscle Volume	Between Groups	188723573,708	5	37744714,742	15,830	0,000
	Within Groups	42919230,250	18	**2384401,681**		
	Total	**231642803,958**	23	-		

Table 5: Statistical paramete Mean left and right masseter volume (mm3) of one patient analysed by the technique of MRI, and subjected to different levels of occlusal deformity (overbite 10 mm, overbite 5 mm, rest 0 mm, overjet 3 mm, overjet 6 mm and overjet 9 mm). rs obtained in the One-Way ANOVA test for the comparison of the different levels of occlusal deformity to which a selected patient was subjected, regarding the measurement of mean left/right masseter area (mm²) and mean left/right masseter volume (mm³).

Results and Discussion

Comparison A - Testing the differences between examiners - Study A

Research question: Are there any differences between Examiners F and C regarding the measurement of mean left masseter area (mm²) and left masseter volume (mm³) of ten patients by MRI?

H0: There are no differences between Examiners F and C regarding the measurement of mean left masseter area (mm²) and left masseter volume (mm³) of ten patients by MRI.

H1: There are differences between Examiners F and C regarding the measurement of mean left masseter area (mm²) and left masseter volume (mm³) of ten patients by MRI.

Comparison B - Testing the differences between masseters - Study B

Research question(s): Are there any differences between the left and right masseter muscle area (mm²) and masseter muscle volume (mm³) **of the selected patient analysed by MRI, and subjected** to different levels of occlusal deformity?

Dependent Variable	(I) Occlusal_Splint	(J) Occlusal_Splint	Mean Difference (I-J)	Std, Error	Sig.
Masseter Muscle Area (mm^2)	Overbite (10 mm)	Overbite (5 mm)	**1268,250***	349,574	**0,026**
		Rest (0 mm)	**-2169,750***	349,574	0,000
		Overjet (3 mm)	**-2161,000***	349,574	0,000
		Overjet (6 mm)	**-2269,250***	349,574	0,000
		Overjet (9 mm)	413,000	349,574	0,970
	Overbite (5 mm)	Overbite (10 mm)	**-1268,250***	349,574	**0,026**
		Rest (0 mm)	-3438,000*	349,574	0,000
		Overjet (3 mm)	-3429,250*	349,574	0,000
		Overjet (6 mm)	-3537,500*	349,574	0,000
		Overjet (9 mm)	-855,250	349,574	0,273
	Rest (0 mm)	Overbite (10 mm)	**2169,750***	349,574	0,000
		Overbite (5 mm)	3438,000*	349,574	0,000
		Overjet (3 mm)	8,750	349,574	1,000
		Overjet (6 mm)	-99,500	349,574	1,000
		Overjet (9 mm)	2582,750*	349,574	0,000
	Overjet (3 mm)	Overbite (10 mm)	**2161,000***	349,574	0,000
		Overbite (5 mm)	3429,250*	349,574	0,000
		Rest (0 mm)	-8,750	349,574	1,000
		Overjet (6 mm)	-108,250	349,574	1,000
		Overjet (9 mm)	2574,000*	349,574	0,000
	Overjet (6 mm)	Overbite (10 mm)	**2269,250***	349,574	0,000
		Overbite (5 mm)	3537,500*	349,574	0,000
		Rest (0 mm)	99,500	349,574	1,000
		Overjet (3 mm)	108,250	349,574	1,000
		Overjet (9 mm)	**2682,250***	349,574	0,000
	Overjet (9 mm)	Overbite (10 mm)	-413,000	349,574	0,970
		Overbite (5 mm)	855,250	349,574	0,273
		Rest (0 mm)	-2582,750*	349,574	0,000
		Overjet (3 mm)	-2574,000*	349,574	0,000
		Overjet (6 mm)	**-2682,250***	349,574	0,000
Masseter Muscle Volume (mm^3)	Overbite (10 mm)	Overbite (5 mm)	**-186,500**	1091,879	1,000
		Rest (0 mm)	**-1096,750**	1091,879	0,992
		Overjet (3 mm)	1450,500	1091,879	0,931
		Overjet (6 mm)	**-620,750**	1091,879	1,000
		Overjet (9 mm)	-7315,250*	1091,879	0,000
	Overbite (5 mm)	Overbite (10 mm)	**186,500**	1091,879	1,000
		Rest (0 mm)	-910,250	1091,879	0,999
		Overjet (3 mm)	**1637,000**	1091,879	0,859
		Overjet (6 mm)	-434,250	1091,879	1,000
		Overjet (9 mm)	-7128,750*	1091,879	0,000
	Rest (0 mm)	Overbite (10 mm)	**1096,750**	1091,879	0,992
		Overbite (5 mm)	910,250	1091,879	0,999
		Overjet (3 mm)	2547,250	1091,879	0,329
		Overjet (6 mm)	**476,000**	1091,879	1,000
		Overjet (9 mm)	**-6218,500***	1091,879	0,000
	Overjet (3 mm)	Overbite (10 mm)	-1450,500	1091,879	0,931
		Overbite (5 mm)	**-1637,000**	1091,879	0,859
		Rest (0 mm)	-2547,250	1091,879	0,329
		Overjet (6 mm)	-2071,250	1091,879	**0,606**
		Overjet (9 mm)	**-8765,750***	1091,879	0,000
	Overjet (6 mm)	Overbite (10 mm)	**620,750**	1091,879	1,000
		Overbite (5 mm)	434,250	1091,879	1,000
		Rest (0 mm)	**-476,000**	1091,879	1,000
		Overjet (3 mm)	2071,250	1091,879	**0,606**
		Overjet (9 mm)	**-6694,500***	1091,879	0,000
	Overjet (9 mm)	Overbite (10 mm)	7315,250*	1091,879	0,000
		Overbite (5 mm)	7128,750*	1091,879	0,000
		Rest (0 mm)	**6218,500***	1091,879	0,000
		Overjet (3 mm)	**8765,750***	1091,879	0,000
		Overjet (6 mm)	**6694,500***	1091,879	0,000

Table 6: Statistical parameters obtained in the Post-Hoc Gabriel test for the comparison of the different levels of occlusal **deformity to which a selected patient was subjected, regarding the measurement of mean left/right masseter area (mm^2)** and mean left/right masseter volume (mm^3).

H0: There are no differences between the left and right masseter muscle area (mm^2) and masseter muscle volume (mm^3) of the **selected patient analysed by MRI and subjected to different levels** of occlusal deformity.

H1: There are differences between the left and right masseter muscle area (mm^2) and masseter muscle volume (mm^3) of the **selected patient analysed by MRI and subjected to different levels of** occlusal deformity.

Comparison C - Testing the differences between occlusal splints (Overbite versus rest versus overjet)

Research question(s): Are there any differences between the occlusal deformities (overbite 10 mm, overbite 5 mm, rest 0 mm, **overjet 3 mm, overjet 6 mm and overjet 9 mm) to which the selected patient was subjected, regarding the left/right masseter muscle** area (mm^2) and left/right masseter muscle volume (mm^3)?

H0: There are no differences between the occlusal deformities **to which the selected patient was subjected, regarding the left/** right masseter muscle area (mm^2) and left/right masseter muscle volume (mm^3) analysed by MRI.

H1: There are differences between the occlusal deformities to **which the selected patient was subjected, regarding the left/right** masseter muscle area (mm^2) and left/right masseter muscle volume (mm^3) analysed by MRI.

Conclusion

Comparison A - Testing the differences between examiners - Study A

The results show no significant difference between Examiner F and Examiner C regarding the measurement of left masseter area (mm^2) of ten patients through MRI, when the measurement is made in the same experimental conditions ($p > 0,05$). Regarding the mean left masseter volume (mm^3), statistical differences have **been identified between Examiners F and C** ($p < 0,05$), probably due to small discrepancies in the experimental methodology used by both examiners.

In view of these results, it is recommended the standardization/homogenisation of the experimental methodology used, in order to avoid the differences detected in this study.

Comparison B - Testing the differences between masseters - Study B

The results show no significant difference between the left and right masseter muscle area (mm^2) and masseter muscle volume (mm^3) **of the selected patient, despite having been subjected to different levels of occlusal deformity (overbite 10 mm, overbite 5 mm, rest 0 mm, overjet 3 mm, overjet 6 mm and overjet 9 mm). This** means that the patient presents a rather left/right symmetrical bite in the frontal plane, even when he is using different occlusal splints.

Comparison C - Testing the differences between occlusal splints (Overbite versus rest versus overjet)

There are significant differences in the masseter muscle area (mm^2) and masseter muscle volume (mm^3) of the selected patient, **when he is subjected to different levels of occlusal deformity (overbite 10 mm, overbite 5 mm, rest 0 mm, overjet 3 mm, overjet 6 mm and overjet 9 mm). All experiments reveal *p-values*** below the cut-off value of 0,05 ($p < 0,05$), which means that H0 proposition is invalid. Thus, it is concluded that the MRI analysis is capable of detecting differences in the masseter muscle area (mm^2) and masseter muscle volumes (mm^3) of patients presenting different levels of occlusal deformities.

Because One-Way ANOVA only gives information about the presence of differences, not specifying where these differences are located, a Post-Hoc Gabriel test was used to perform pairwise comparisons between the occlusal deformities, and these results are **represented in table 6.**

Significant differences ($p < 0,05$) have been identified between certain pairs of occlusal deformities (Table 6), particularly when one of the elements of the comparison is an overbite pattern (10 or **5 mm) or an overjet pattern (9 mm).**

This contrasts with the near absence of significant differences ($p > 0,05$) in pairs of occlusal deformities where all the included **bite patterns are rest pattern (0 mm) and overjet pattern (3 or 6** mm).

MRI therefore seems to be a valid tool for measuring differences in the masseter muscle area (mm^2) and masseter muscle volume (mm^3) associated with high-severity occlusal deformities, although **showing not to be as efficient in detecting the same differences in** cases of low-severity occlusal deformities.

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Post-Viva Addenda:

-In the background, the results of Lee and Yu's (2012) study suggest that patients, prior to treatment, may experience differences in sensory feedback or have lower motivation to generate large forces due to pain and discomfort.

-It is not a surprise to researchers and clinicians that the masseter muscle thickens and expands laterally during contraction. While the complex internal, multipennate architecture (fibres running obliquely between tendon sheets) makes it difficult to predict exactly how different parts of the muscle will behave, the general phenomenon is consistent with muscle mechanics and the conservation of volume.

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Maxillofacial Plastic and Reconstructive Surgery

RESEARCH Open Access

Anatomic and functional masseter muscle adaptation following orthognathic surgery—MRI analysis in 3 years of follow-up

Fernando Duarte[1,2,3,4*], João Neves Silva[5,6], Carina Ramos[7] and Colin Hopper[2,8]

Abstract

Background Orthodontic and surgical technical advances in recent years have resulted in treatment opportunities for a whole range of craniofacial skeletal disorders either in the adolescent or adult patient. In the growing child, these can include myofunctional orthodontic appliance therapy or distraction osteogenesis procedures, while in the adult, the mainstay approach revolves around orthognathic surgery.

The literature agrees that for a change in craniofacial morphology to remain stable, the muscles acting upon the facial skeleton must be capable of adaptation in their structure and, therefore, their function. Failure of the muscles to adapt to the change in their length or orientation will place undesirable forces on the muscle attachments leading to potential instability of the skeleton. Adaptation can occur through various processes including those within the neuromuscular feedback mechanism, through changes within muscle structure or through altered muscle physiology, and through changes at the muscle/bone interface.

It is now accepted that because there is no single method of assessing masticatory function, several measures should be taken, and whenever possible, simultaneously.

Methods This investigation was designed to apply several, newly developed and more sophisticated methods of measuring muscle structure and function to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach. Patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa, Portugal, were screened. Ten patients scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible were selected to form the study group.

The patients have MRI of the masseter muscle to evaluate the masseter muscle volume and fibre orientation changes. This exam was taken before surgery (T0), 6 to 12 months after surgery (T1), and 3 years after surgery (T2), by two independent observers, according to the protocol jointly developed between the Eastman Dental Institute – University of London and the MRI Centre - Department of Radiology at John Radcliffe Hospital – University of Oxford.

Results Significant differences ($p < 0.05$) have been identified between Time 0 (pre-op) and Time 1 (6–12 months post-op) regarding the masseter area (mm^2). The differences against Time 0 (pre-op) seem to disappear at Time 2 (3 years post-op).

*Correspondence:
Fernando Duarte
fduarte@clitrofa.com
Full list of author information is available at the end of the article

Conclusions MRI therefore seems to be a valid tool for measuring differences in the masseter muscle area and volume associated with high-severity occlusal deformities, although showing not to be as efficient in detecting the same differences in cases of low-severity occlusal deformities.

Keywords Orthognathic surgery, Masseter muscle fibres, MRI analysis

Background

Changes in masticatory musculature structure and function may be either developmental, as seen in anomalies of vertical facial form, or adaptative, as seen during procedures such as orthognathic surgery and functional appliance orthodontic therapy [1, 2].

The principal goals of orthognathic surgery are the improvement of occlusal relationships, facial esthetics, and function of the masticatory system in patients with dentoskeletal deformities [3, 4].

The results of some studies indicate that patients scheduled for orthognathic surgery will tend to have lower mastication forces than controls [5, 6]. The lower forces in patients, however, do not seem to be the result of lower efficiency in the jaw muscles. Instead, the results of this study suggest that patients, prior to treatment, may experience differences in sensory feedback or have lower motivation to generate large forces [7].

Advances in medical imaging have created ever increasing volumes of complex data obtained from the patient. The interpretation of such information has become a specialty in itself and the surgeon at times may be left bewildered as to how best to apply the available information to the practicalities of physical intervention. The surgeon seeks to understand the exact morphology of the abnormality, its relationships to surrounding anatomy, and the best way to access and correct the pathology operatively. Such specific information is not readily available in the radiologist's report and however experienced the surgeon may be at interpreting images such questions often cannot be easily answered [8].

Three-dimensional (3D) imaging has been developed to narrow the communication gap between radiologist and surgeon. By using 3D imaging, a vast number of complex slice images can be quickly appreciated. The term "three-dimensional", however, is not a truly accurate description of these images as they are still displayed on a radiological film or flat screen in only two dimensions. The advent of 3D imaging has not only improved data display but also promoted the development of even more useful technologies to assist the surgeon in diagnosis and planning [8].

Masseter muscle architecture

The average length of masseter muscle three-layer fibres is 19–30 mm; those in the posterior region are about 35% shorter than those in more anterior. This difference in length is almost certainly related to the need for differential fibre shortening during function, but it is not accounted for entirely by the relative sizes of the respective fibre lever arms measured from the jaw's function "center" of rotation, and it suggests that fibre tensions may be greater anteriorly than posteriorly as different opening movements are made during function. The masseter also contains at least five intramuscular aponeuroses, some of which descend from the zygomatic arch and interweave with others ascending from the ramus. Fibres pass obliquely between them. These flat tendon sheets can be visualized by magnetic resonance imaging (MRI) in living subjects, and their orientation varies. The motor unit territories are very small in the masseter, and the fibres from each unit tend to remain in close proximity. Differential activation of muscle fibres occurs in various regions of the masseter, causing various fibre collections in the masseter's mediolateral layers, or between tendon sheets, to contract differentially according to the task. There is probably considerable mechanical diversity within a given muscle and, since each muscle's structural elements vary from person to person, also equal mechanical diversity between individuals [9].

It is difficult to predict what actually happens internally when the masseter contracts. Depending upon a subject's morphological type, the task being attempted, and the highly individual contraction strategy used, various groups of muscle fibres will contract and shorten isovolumetrically. As they do so, they thicken, and their transverse diameters will increase. There will be regional changes in muscle thickness, presumably shaped by the relative balance between mutually-contracting fibre groups, thick, layered tendons near the zygomatic arch, and the extent to which tendon sheets move within the muscle. Localized distortion of tendon sheets is possible, and it is likely that regional tensions will be produced at muscle-tendon interfaces, while the net effect may be qualitatively similar between two individuals [10].

To complicate matters, the effects of these changing physical events are themselves uncertain. Different degrees of local intramuscular compression probably alter regional blood flow within the muscle, but presently,

there is no evidence describing specifically how vascular physiology in the masseter or any other human jaw muscle is affected selectively by local changes in its physical environment. Apart from any effect on the vascular bed, the production of differential, excessive internal muscle tension, if it follows the same pattern as it does elsewhere in the musculoskeletal system, can lead to local tissue injury. If so, it most probably will occur within the muscle fibres at a short distance from the muscle-tendon interface rather than at the interface itself. Finally, any excessive loading of tendons per se can result in persistent, local inflammation as is commonly found in other skeletal muscles. Any of these hypothetical events would cause biochemical changes in the masseter. The changes would be local and include the release of algesic chemicals [11].

Magnetic resonance imaging

MRI is a non-invasive imaging technique that is one of the most promising and leading imaging modalities for the diagnosis of diseases and other conditions in the head and neck region [12]. A major advantage of MRI over conventional X-ray imaging is the high soft tissue contrast, which allows much better visualization of specific anatomical structures (e.g. nerves, blood vessels) using magnetic fields without exposing patients to ionizing radiation [12]. Despite the limitations in hard tissue imaging, MRI has advanced rapidly over the past two decades with various technical innovations and advanced imaging protocols, offering a wide range of new diagnostic capabilities in dentistry [12, 13].

MRI scans provide the best definition of facial muscles when segmented from DICOMs [13, 14]. Previous works on facial tissue characterization have demonstrated that different areas of facial soft tissues have different biomechanical properties in terms of longitudinal tissue stiffness (Young's modulus–E) and transverse behavior (Poisson's ratio–ν) [13, 14].

The residual limitations of MRI in the oral cavity are susceptibility to motion artifacts, complex anatomic courses of small-sized blood vessels and nerves, and image distortion and artifacts due to magnetic field inhomogeneities caused by metallic dental restorations [13].

A customised software programme has been developed at John Radcliffe Hospital - Oxford University which enables the reconstruction of 3D images allowing measurement of muscle volume and area with a high level of accuracy.

To date, this technology had only been applied to tongue muscles, and when applied to the muscles of mastication, the resolution and results were disappointing.

The goal was to develop the system and software to produce accurate and reproducible data for masticatory muscles which not only provided data for muscle area and volume, but also was of sufficient detail to enable analysis of muscle fibre orientation in particular of masseter muscle.

The masseter muscle displays a penniform structure typically characterized by the presence of alternating muscular/aponeurotic layers. The anatomical sections and the MRI section in the same plane allowed the appearance of the intra-muscular aponeurotic layers on the MRI to be defined [15].

Methods

Research design

The present study is an observational prospective study with quantitative methodology.

Sample

A study group of 10 patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa, Portugal, were selected for the present study by a convenience non-probability sampling method. All the selected patients present skeletal class III malocclusion characterized by a concave facial profile with lower lip protrusion or upper lip retrusion or a combination of the two. The most consistent characteristics of skeletal class III malocclusion seem to be the dental Angle's class III canines and molars, the presence of anterior cross-bite, and retroclined mandibular incisors.

During the sequential MRI image period, all patients received ear protectors and were instructed to maintain a relaxed muscle posture and closed jaw position (maximal intercuspal position of the lower jaw).

The patients scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible were selected to form the study group. Vertical moves of 2 mm for minor, 4 mm for intermediate, and 6 mm for major impactions are appropriate for all cases. These three categories also simplify the decision-making process. Before surgery, all patients signed their informed consent form.

The inclusion criteria are as follows: All patients presenting at joint orthodontic/orthognathic clinic purposed to orthognathic surgery and that accept the treatment. Diabetic patients were included but noted.

The exclusion criteria are as follows: Patients who gave a history of myopathies, endocrine disorders, connective tissue disorders, autoimmune diseases, bone disease, bleeding disorders, and regular use of prescribed drugs were excluded from the study.

Osteotomies were performed using piezoelectric surgery that is based on the use of ultrasound. It offers

precise bone cuts without damaging any soft tissue, minimizing the invasiveness of surgical procedure, and the opportunity of working in a field which is almost totally blood-free. It reduces the impact on soft tissues (vessels and nerves) which lie adjacent to the areas of treatment.

Maxillomandibular fixation (MMF) was performed with surgical archwire fixation, L-shaped osteosynthesis plates, and self-tapping screws. Postoperative orthodontic treatment lasted an average of 6 months. The final occlusion should provide unhindered closure in centric relation, smooth-sliding lateral and protrusive movements, and an optimal bilateral vertical contact dimension.

Data collection instruments

The anatomical and functional heterogeneities of the masseter muscle may influence the spatial differences in muscle thickness. For the sake of systematization and reduction of variables, it was decided to use only the left masseter muscle.

MRI technique was used to measure masseter muscle volume and fibre orientation changes in the selected patients. This evaluation was taken before surgery (T0), 6 to 12 months after surgery (T1), and 3 years after surgery (T2), by two independent observers, according to the protocol jointly developed between the Eastman Dental Institute – University of London and the MRI Centre - Department of Radiology at John Radcliffe Hospital – University of Oxford. It should be considered that during the different evaluation periods, the patients' occlusion changed, namely, T0-skeletal class III, T1-skeletal class I, and T2-skeletal class I.

Anatomics™ software

The Anatomics™ Rx software is a 3D DICOM viewer and allows to view CT and MRI scan data in both slice format and fully interactive 3D. Anatomics™ can convert 3D images to the STL format for rapid prototyping, or as a bridge from medical imaging to computer-aided design (CAD). A good quality 3D scan is required to create an accurate biomodel or implant.

To standardize the scanning process, a scanning protocol was developed and applied that describes the preferred imaging parameters and provides the imaging technician with an area to note specifics. The patient must remain completely still during the scan; if the patient moves during the scan, it will need to be repeated. Only the original fine-slice data must be used in the software, reformats will not be accepted. Fine overlapping slices must be used, the thickness of 1 mm (or nearest to) and a spacing of 0.8 mm.

The objective was to extract the muscle from the image (margins identification, extract the muscle considering the 3 planes of space, calculation of area and volume). The software allows the correction of limits at any time which gives the observer the capacity to double-check all the processes.

During this study, the MRI machine used was a Sigma MR/I Twinspeed from GE Medical Systems; after several attempts, the software was further developed to produce slices through the muscle at 1-mm intervals rather than 2 mm; the scanning time was about 7 min.

The first masseter muscle 3D image reconstruction was acceptable in terms of definition, area, and volume but with a lack of detail in terms of muscle fibre visualization and orientation (Fig. 1). Increasing the scanning time from 5 to 7 min and changing the muscle slices to 1-mm intervals was possible for the acquisition of more muscle details. As a consequence, the resolution of the muscles was greatly enhanced, and the final masseter muscle 3D image reconstruction permits a good visualization of muscle fibres and their orientation (Fig. 2). This type of reconstruction has also allowed visualization of the muscle's bony attachments and enabled the measurement of potential changes in orientation in relation to a static landmark unaffected by surgery (e.g.

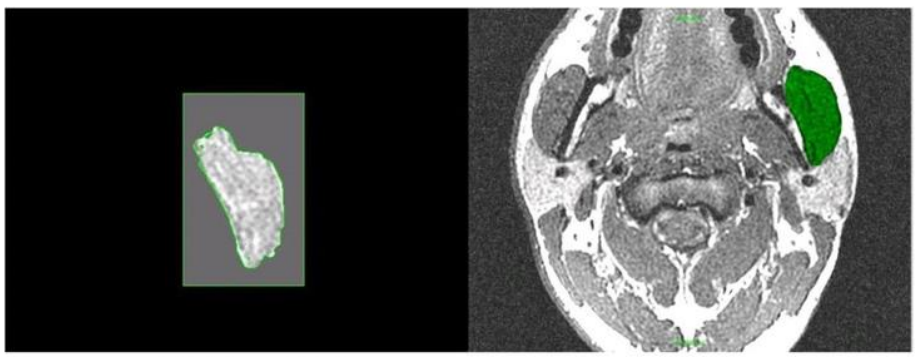

Fig. 1 Identification of masseter muscle limits in a sagittal plane

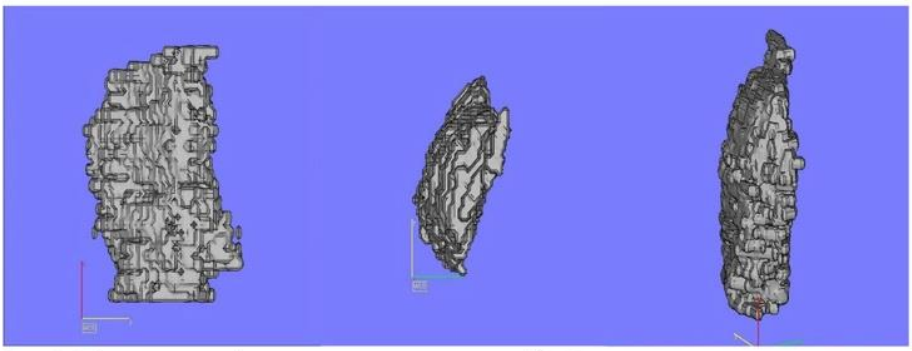

Fig. 2 Final images from the left masseter muscle reconstruction using Anatomics™ software

Frankfort plane) or in relation to functional identifiers (e.g. occlusal plane).

Experimental procedure

The experimental design used for this work is depicted in Fig. 3 and involves two different studies: Study A, which investigates the effect of examiner change on the measurement of left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of ten different patients by two independent observers; and Study B, which investigates the variation of left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) in three different times: before surgery (T0), 6 to 12 months after surgery (T1), and 3 years after surgery (T2).

Study A—Effect of examiner (F or C) change on the measurement of left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of ten selected patients

Research question: Are there any significant statistical differences between examiners F and C regarding the measurement of mean left masseter area (mm^2) and left masseter volume (mm^3) of ten patients by MRI?

H0: There are no significant statistical differences between examiners F and C regarding the measurement of mean left masseter area (mm^2) and left masseter volume (mm^3) of ten patients by MRI.

H1: There are significant statistical differences between examiners F and C regarding the measure-

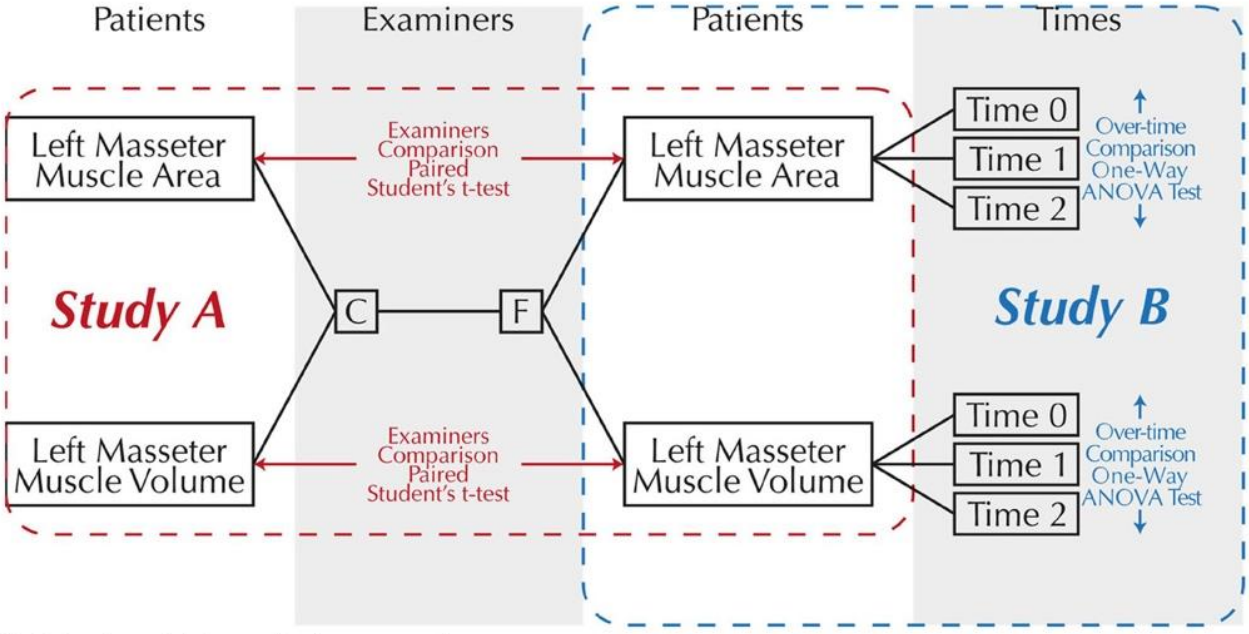

Fig. 3 Experimental design used in the present work

ment of mean left masseter area (mm^2) and left masseter volume (mm^3) of ten patients by MRI.

Study B—Effect of time (Time 0, pre-op versus Time 1, 6–12 months post-op versus Time 2, 3 years post-op) on the left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of ten selected patients

Research question(s): Are there any differences between the left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of the ten selected patients over time (Time 0, pre-op; Time 1, 6–12 months post-op; and Time 2, 3 years post-op).

H0: There are no differences between the left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of the ten selected patients over time (Time 0, pre-op; Time 1, 6–12 months post-op; and Time 2, 3 years post-op).

H1: There are differences between the left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of the ten selected patients over time (Time 0, pre-op; Time 1, 6–12 months post-op; and Time 2, 3 years post-op).

Statistical analysis

IBM® SPSS® version 25 was used to analyze the data obtained in the present work. The data were first tested to ensure they conformed to a normal distribution by using Kolmogorov-Smirnov test. The data were then tested to ensure they complied with variance homogeneity by using the Levene test.

Descriptive statistics measures included the arithmetic mean ($\bar{x}$) and standard deviation (SD) if the data were normally distributed and the variance was constant. Where the data were not normally distributed nor the variance was constant, the median and the inter-quartile range (IQR) were noted.

Where the requirements for parametric statistical analysis were met, inferential analysis of examiner comparison in Study A involved the use of paired two-tailed Student's *t*-test. In the same conditions, the inferential analysis of times comparison in Study B involved the use of one-way analysis of variance (ANOVA).

Where the requirements for parametric statistical analysis were not met, inferential analysis of examiner comparison in Study A involved the use of the Wilcoxon signed rank (U) test for paired data. In the same conditions, inferential analysis of times comparison in Study B involved the use of the Kruskal-Wallis (H) test.

Where statistically significant differences were found by one-way ANOVA test, the multiple-comparison post hoc Bonferroni test was performed to identify the pairs of categories where the statistically significant differences were located.

The minimum level of significance (α level) accepted throughout the development studies was 0.05 (*), considered to be moderately significant. Levels of 0.01 (**) were considered significant and 0.001 (***) was designated as highly significant. A lack of statistical significance was designated as ns.

Results

In order to make the presentation of results easier to understand, they were subdivided into two items: effect of examiner selection and effect of time. Because one-way ANOVA only gives information about the presence of differences, not specifying where these differences are located, a post hoc Bonferroni test was used to perform pairwise comparison regarding the time points.

Study A—Effect of examiner (F or C) change on the measurement of left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of ten selected patients

The following Table 1 presents the mean left masseter areas (mm^2) and mean left masseter volumes (mm^3) of ten selected patients measured by two independent examiners (F and C).

The statistical comparison between examiners F and C regarding the measurement of mean left masseter area (mm^2) and mean left masseter volume (mm^3) of ten patients by MRI was performed using a paired Student's *t*-test, and the results are presented in the following Table 2.

Table 1 Mean left masseter area (mm^2) and mean left masseter volume (mm^3) of ten patients measured by independent examiners F and C. Data was obtained by MRI

MRI analysis parameter	Examiner F	Examiner C
Left masseter area (mm^2) (average ± SD)	12,034.77 ± 998.32	12,039.40 ± 997.30
Left masseter volume (mm^3) (average ± SD)	29,939.83 ± 3104.06	29,954.67 ± 569.333

Study B—Effect of time (Time 0, pre-op versus Time 1, 6–12 months post-op versus Time 2, 3 years post-op) on the left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) of ten selected patients

The following Table 3 presents the variation of mean left masseter area (mm^2) and mean left masseter volume (mm^3) of ten selected patients over time (Time 0, pre-op; Time 1, 6–12 months post-op; and Time 2, 3 years post-op).

The statistical comparison between the three time points (Time 0, pre-op; Time 1, 6–12 months post-op; and Time 2, 3 years post-op) regarding the left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) by MRI of the ten selected patients was performed using a one-way ANOVA test, and the results are presented in the following Table 4.

Post hoc Bonferroni test

Study A: The results show no significant statistical differences between examiner F and examiner C regarding the measurement of the left masseter area (mm^2) and left masseter volume (mm^3) of the ten selected patients through MRI, when the measurement is made in the same experimental conditions ($p > 0.05$).

In view of these results, the change of examiner is not a factor that influences the measurement of left masseter area (mm^2) and left masseter volume (mm^3).

Study B: The results show significant differences in the left masseter muscle area (mm^2) over time (p-value = 0.017), although these differences have not been identified regarding the left masseter muscle volume (mm^3) (p-value > 0.05).

Because one-way ANOVA only gives information about the presence of differences, not specifying where these differences are located, a post hoc Bonferroni test was used to perform pairwise comparison regarding

Table 2 Statistical parameters obtained in the paired Student's *t*-test for the comparison of examiners F and C regarding the measurement of mean left masseter area (mm^2) and mean left masseter volume (mm^3) of ten patients by MRI

Examiner comparison	Mean difference*	Standard deviation of differences	Degrees of freedom (*df*)	Test statistic from paired *t*-test	*P*-value from paired *t*-test
Examiner F versus examiner C, left masseter muscle area (mm^2)	−4.633	79.466	29	−0.319	0.752
Examiner F versus examiner C, left masseter muscle volume (mm^3)	−14.833	94.659	29	−0.858	0.398

* The mean difference is significant at the 0.05 level

Table 3 Variation of mean left masseter area (mm^2) and mean left masseter volume (mm^3) of ten patients measured over time (Time 0, pre-op; Time 1, 6–12 months post-op; and Time 2, 3 years post-op)

MRI analysis parameter	Time 0 (pre-op)	Time 1 (6–12 months post-op)	Time 2 (3 years post-op)
Left masseter area (mm^2) (average ± SD)	12,511.60 ± 864.22	11,648.40 ± 986.73	11,951.25 ± 956.54
Left masseter volume (mm^3) (average ± SD)	31,114.85 ± 2851.57	29,116.70 ± 3234.68	29,610.20 ± 2945.05

Table 4 Statistical parameters obtained in the one-way ANOVA test for the statistical comparison between the three time points (Time 0, pre-op; Time 1, 6–12 months post-op; and Time 2, 3 years post-op) regarding the left masseter muscle area (mm^2) and left masseter muscle volume (mm^3) by MRI

Examiner comparison	Degrees of freedom (*df*)	Test statistic from paired one-way ANOVA test	*P*-value from paired *t*-test
Time 0, pre-op versus Time 1, 6–12 months post-op versus Time 2, 3 years post-op, masseter muscle area (mm^2)	2 / 57	4.367	0.017*
Time 0, pre-op versus Time 1, 6–12 months post-op versus Time 2, 3 years post-op, masseter muscle volume (mm^3)	2 / 57	2.364	0.101

* The mean difference is significant at the 0.05 level

the time points regarding the left masseter muscle area (mm^2) of the ten selected patients, and these results are represented in the following Table 5.

Discussion

Altered muscle function is implicated in the aetiology of vertical facial deformities. The contractile properties of muscle are largely determined by a number of different isoforms of myosin heavy chain (MyHC), and the pattern of MyHC gene expression is one measure of the phenotype and functional potential of a muscle [16].

Two extremes of vertical facial form have been described, long face syndrome and short face syndrome [17]. The long face syndrome (LFS) is characterized by the clinical and radiographic features of increased lower anterior face height, increased maxillary/mandibular plane angle, increased gonial angle, and tendency to anterior open bite. The short face syndrome (SFS) exhibits the reverse of these features. The differences between the two syndromes reflect their divergent growth patterns, where LFS subjects exhibit a downward and posterior growth rotation of the mandible, and SFS subjects exhibit an anterior growth rotation [18]. A significant proportion of the patients presenting with extreme vertical facial discrepancies require surgery to correct their jaw relationship [19, 20].

It has been proposed that the muscles of mastication are important determinants of vertical facial growth [21]. Studies of masseter muscle function have shown significant differences between LFS and SFS subjects with respect to electromyographic (EMG) activity and the magnitude of maximum voluntary bite force; SFS subjects demonstrate higher EMG activity and exert greater bite forces than LFS subjects [22], whether the observed differences in muscle function are primary causal factors or are secondary to the development of vertical facial form [23]. Furthermore, changes in vertical facial form have been induced by either increasing or decreasing the normal activity of the elevator muscles during postnatal growth [21, 24].

The molecular motors of muscle are the myosin heavy chains (MyHC) located in the myofibrillar apparatus of muscle fibres [25]. Muscle fibres are the functional, contractile components of muscle, and the physiological properties of these fibres are largely determined by a number of different MyHC isoforms variously distributed between fibres with different contractile properties [25].

The masseter differs from somatic skeletal muscle in the range of MyHC isoforms expressed in the adult muscle [26]. The myosin heavy chains are encoded by a multigene family, and the major adult isoforms expressed in human skeletal muscle are the slow or ß-cardiac, IIa, and IIx MyHCs that are expressed in the type I, type IIa, and type IIb fibres, respectively [25]. A human homologue to the IIb MyHC isoform described in the rat and other species has yet to be identified [27]. Additionally, the adult human masseter expresses embryonic, perinatal, and α-cardiac MyHCs [28].

The few studies of the distribution of fibre type in the muscles of subjects with extremes of vertical facial form suggest that the contribution of different fibre components to the masseter phenotype overall may vary between normal subjects and those with vertical facial deformity (VFD). Comparisons of the fibre-type distribution and cross-sectional areas in biopsies of the anterior deep masseter have revealed a reduced contribution of type II fibres to the total percentage cross-sectional area in LFS subjects [29]. However, the masseters of SFS subjects have demonstrated either no differences from a control group or an increased type II fibre contribution in the same region of the muscle [29].

The differential increase in anterior and posterior face heights produced at surgery may not only stretch the muscle attachments but also change the orientation of the muscle fibres to the occlusal plane. Adaptation would be necessary with regard to the resting length and also in relation to altered functional activity. It has been noted that such adaptation may occur up to 12 months following surgery [30]. In a study of Hunt and Cunningham [30], surgical alteration of the vertical facial heights was accompanied by an immediate adaptation of the clinical freeway space, presumably mediated through the proprioceptive system. The physiological rest position can be identified by eliminating the sensorimotor feedback from the teeth, so allowing the mandible to adopt a posture dependent upon the resting length of the elevator

Table 5 Statistical parameters obtained in the post hoc Bonferroni test for the comparison of the different time points (Time 0, pre-op; Time 1, 6–12 months post-op; and Time 2, 3 years post-op) regarding the mean left masseter area (mm^2) of ten selected patients

Independent variable	Mean difference (I-J)	Std. error	Sig.
Time 0 (pre-op)			
Time 1 (6–12 months post-op)	863.200	296.394	0.015*
Time 2 (3 years post-op)	560.350	296.394	0.191
Time 1 (6–12 months post-op)			
Time 0 (pre-op)	−863.200	296.394	0.015*
Time 2 (3 years post-op)	−302.850	296.394	0.934
Time 2 (3 years post-op)			
Time 0 (pre-op)	−560.350	296.394	0.191
Time 1 (6–12 months post-op)	302.850	296.394	0.934

*The mean difference is significant at the 0.05 level

muscles is partially adapted to the skeletal change immediately following operation, but continued to adapt up to 12 months post-surgery, especially in the vertical excess patients [30].

Any increase in posterior vertical facial dimension is prone to relapse in the long term. At least three possibilities exist as to how this may occur. Firstly, stretching of the pterygo-masseteric sling could lead to increased pressure at the osteotomy site with subsequent bone resorption and loss of vertical dimension. Secondly, in an attempt to maintain an efficient muscular system, both at rest and during function, muscle adaptation could occur through migration of the attachments in preference to increasing the number of sarcomeres. As a consequence, the area of bone devoid of attachment could remodel or resorb thereby reducing the vertical height. Thirdly, a combination of these two hypotheses could exist [30].

The architecture of the masseter muscle has been studied for a long time, but the lack of clinical applications led to descriptions which were often global or contradictory, giving the muscle sometimes two bundles sometimes three. The successive studies of Gaspard [31–33], Yoshikawa [34, 35], and Gaudy [36] allowed the definition of the arrangement of the muscular aponeurotic layers making up the human masseter muscle. Unger [37] affirmed the value of magnetic resonance imaging in the oro-facial field for the study of the musculature of the tongue and the walls of the oral cavity, but gave only very general information on the masticatory muscles [38].

Several studies investigated the changes in the size and masticatory force of the masticatory muscles after orthognathic surgery. Katsumata et al. indicated that in mandibular prognathism, the cross-sectional area of the masses decreases after 3 months of mandibular setback but shows a tendency to return to normal after 1 year [39]. In addition, Ueki et al. reported that there are no significant differences in the cross-sectional area of the masseter in mandibular prognathism 1 year after SSRO in comparison with the preoperative area [40]. Trawitzki et al. also reported that when mandibular setback was conducted on patients with a class III dentofacial deformity, the thickness of the masseter muscle increased [41]. The study of Kanga et al. showed that the volume-to-length ratio of the masseter and lateral pterygoid muscles at 1 year after the mandibular setback did not show a significant difference compared with the preoperative value [42].

In a study with 30 skeletal class III patients with dentofacial deformities, 17 were treated by sagittal split ramus osteotomy with rigid osteosynthesis, and 13 were treated by intraoral vertical ramus osteotomy without osteosynthesis; Katsumata et al. reported that masseter muscle crosssectional area was lower in the group who underwent sagittal split ramus osteotomy and intraoral vertical ramus osteotomy. The evaluation was done using three-dimensional CT imaging [39].

Kikuta et al. reported that occlusal force was decreased 3 months after orthognathic surgery, but increased 6 months after the surgery [43]. The results of this study suggest that particular attention should be paid to masseter muscle atrophy in patients with worse open bite after preoperative orthodontic treatment and in those with maxillary undergrowth. However, it is not clear if masticatory ability would be compromised by masseter muscle atrophy immediately after the surgery.

Decreased maximum occlusal force in patients with open bite has been reported, which supports results that increased open bite led to decreased masseter muscle cross-sectional area [44, 45].

Conclusions

A number of studies have reported increased bite force, occlusal contact area, and EMG activity and improved masticatory efficiency after surgery; however, the reason for this improvement is unclear [7]. Previous studies reported that the postoperative improvements in muscular activity were due to better occlusal stability and not to surgically induced biomechanical advantages [46, 47]. The importance of occlusion for the neuromuscular equilibrium and dental supports was investigated in patients undergoing orthognathic surgery. Changes in muscle size; increased occlusal contact area providing greater dental support; sensitivity of teeth, muscles, and the temporomandibular joints; and even the patients' willingness to exert maximum effort have been suggested as factors in determining the occlusal force after surgery [7].

The continuous changes in masseter muscle size in our study indicate that not only was the skeletal environment altered by surgery, but additional adaptation to new stomatognathic environments also occurred over time with improved occlusion and masticatory activity by orthodontic treatments.

Significant differences ($p<0.05$) have been identified between Time 0 (pre-op) and Time 1 (6–12 months post-op) regarding the mean left masseter area (mm^2).

It is interesting to notice, however, that the differences against Time 0 (pre-op) seem to disappear at Time 2 (3 years post-op), which may reveal the long-term decrease in the area of mean left masseter area (mm^2) or relapse.

An adequate sample makes the investigation more efficient: the data generated is reliable, and the investment of resources is as limited as possible, while at the same time complying with ethical principles. The use of the sampling design directly influences the research results. The sample of 10 patients reveals that this is an uncommon

type of surgery, carried out in the vast majority of cases in private health services and requiring the patient's economic power.

MRI therefore seems to be a valid tool for measuring differences in the masseter muscle area and volume associated with high-severity occlusal deformities (maxillary Le Fort I impaction of 6 mm), although showing not to be as efficient in detecting the same differences in cases of low-severity occlusal deformities (maxillary Le Fort I impaction of 2 mm for minor and 4 mm for intermediate cases).

Future studies comprising larger samples of patients and other different methods of measuring changes in masticatory muscle structure and function are currently being equated to measure the efficacy of orthognathic surgery.

Abbreviations

3D	Three-dimensional
MRI	Magnetic resonance imaging
MyHC	Myosin heavy chain
VFD	Vertical facial deformity
CAD	Computer-aided design
SD	Standard deviation
IQR	Inter-quartile range

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Not applicable.

Authors' contributions
FD, JNS, and CR read and wrote the manuscript. FD and CR were responsible for conducting surgeries. FD and JNS were responsible for the data collection. FD designed and wrote the entire article. CH was responsible for the final revision of the manuscript. All authors read and approved the final manuscript.

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Declarations

Ethics approval and consent to participate
This project has approval by the Joint Research & Ethics Committee of UCL Hospitals NHS Trust, Reference No.03/E012. This project is covered by the UCL Data Protection Registration Reference No. Z6364106, Section 19, Research: Health Research.

Consent for publication
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Competing interests
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Author details
[1]OMD (Portuguese Dental Association), Porto, Portugal. [2]Eastman Dental Institute - University College of London, London, UK. [3]Universitá Cattolica del Sacro Cuore, Rome, Italy. [4]Clitrofa, Centro MédicoDentário e Cirúrgico, Avenida de Paradela 622, Trofa 4785-248, Portugal. [5]ISAVE - Instituto Superior de Saúde, Amares, Portugal. [6]Interdisciplinary Center for Health Sciences (ICHS), ISAVE - Instituto Superior de Saúde, Amares, Portugal. [7]IUCS – Instituto Universitário de Ciências da Saúde, Gandra, Portugal. [8]Oral & Maxillofacial Surgery Department, UCL Eastman Dental Institute, London, UK.

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Publisher's Note

4 BIO-MODELLING ANALYSIS

ARTICLE 10

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Masseter muscle adaptation following orthognathic surgery – Biomodelling analysis – A pilot study

Duarte F[1], Silva JN[2], Hopper C[3], Hunt N[4]

Affiliations:
1. Oral Surgeon Specialist by OMD (Portuguese Dental Association)
Post-Graduation in Oral and Maxillofacial Surgery at Eastman Dental Institute - University College of London
Master of Science in Oral and Maxillofacial Surgery at Eastman Dental Institute - University College of London
PhD student at UCL - University College of London
Professor at ISAVE - Instituto Superior de Saúde - Portugal
CEO and Clinical Director of Clitrofa - Trofa - Portugal
2.Professor at ISAVE - Instituto Superior de Saúde - Portugal
Member of the Interdisciplinary Center for Health Sciences (ICHS) - ISAVE -Instituto Superior de Saúde
3.UCL Eastman Dental Institute ,Oral & Maxillofacial Surgery Department
4.UCL Eastman Dental Institute, Orthodontics Department

Corresponding author:
Fernando Duarte
Clitrofa - Centro Médico, Dentário e Cirúrgico
fduarte@clitrofa.com

ABSTRACT
Purpose: This pilot investigation was designed to apply several, newly developed and more sophisticated methods of measuring muscle structure, function and fibre orientation to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach.
Materials and Methods: Patients attending the combined orthodontic / orthognathic surgery clinic at Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were screened using Magnetic Resonance Imaging protocol. Ten patients scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible were select to form the study group. An Experimental design used to provide information in relation to masticatory muscle adaptation following orthognathic surgery. The study involved the contribution of two independent examiners that measured the changes in fibre orientation at the different jaw positions using Anatomics™ software, at three different time moments. A combination of different parametric tests has been used to compare the different experimental variables.
Results: Statistical differences have been identified between examiners measurements and between operations. There were no significant differences testing different times.
Conclusions: The discrepancies between examiners probably arise from small variations in the experimental methodology used by them. The differences between operations reveal masseter muscle adaptation following orthognathic surgery. The measurement of "P1 masseter muscle/ zygomatic bone / process mastoid anterior angle" and "P2 masseter muscle / mandibular angle" can therefore be a valuable tool for controlling the reworking of masseter muscle upon orthognathic surgery.

KEYWORDS
Orthognathic surgery, masseter muscle, biomodelling analysis

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INTRODUCTION

Orthognathic surgery is a practical art, the surgeon often uses direct physical intervention in the treatment of patients. To minimize operative morbidity and mortality, and to maximize therapeutic success, surgical strategies are tailored to each patient and must be carefully planned to use the best possible anatomical information. The traditional way for a surgeon to gain basic experience without risk to the patient is to dissect cadavers and to examine carefully preserved pathological specimens. This serves to provide a conceptual anatomopathological framework from which operative interventions may be safely made. However, every patient is unique. Thus, there is a need for the surgeon to attain a specific understanding of the individual's anatomy pre-operatively. Thorough physical examination may be all that is needed for conditions in which the anatomopathology is common and the surgeon experienced. With complicated anatomopathology, detailed information relating to the morphology of internal structures is often required by the surgeon to enhance understanding. To obtain this internal anatomical information non-invasively, the surgeon relies on medical imaging.[1]

Advances in medical imaging have created ever increasing volumes of complex data obtained from the patient. The interpretation of such information has become a specialty in itself and the surgeon at times may be left bewildered as to how best to apply the available information to the practicalities of physical intervention. The surgeon seeks to understand the exact morphology of the abnormality, its relationships to the surrounding anatomy and the best way to access and correct the pathology operatively. Such specific information is not readily available in the radiologist's report and however experienced the surgeon may be at interpreting images such questions often cannot be easily answered.[1]

Three-dimensional (3D) imaging has been developed to narrow the communication gap between radiologist and surgeon. By using 3D imaging a vast number of complex slice images can be quickly appreciated. The term "three-dimensional" however, is not a truly accurate description of these images as they are still displayed in a radiological film or flat screen in only two dimensions1. The advent of 3D imaging has not only improved data display, but also promoted the development of even more useful technologies to assist the surgeon in the diagnosis and planning.[1]

For harmonious vertical facial growth and development to exist, the growth on the front of the face must be the same as on the back. If this does not occur, there may be a relative growth rotation of the mandible. For example, if the growth in the posterior part of the face exceeds what occurred previously, the net effect will be an anterior rotation of the mandible, producing the typical deformity of the short face and the deep overbite associated with the short face syndrome.[2] At the opposite end, where growth at the back of the face can be severely reduced compared to what occurred earlier, a clockwise opening or rotation of the jaw is evident, with the net effect of being an excessive anterior facial height and often a bitten anterior opening, associated with a deformity of the long face.[3]

For generations, both clinicians and scientists have argued as to the respective contribution of genetics and, so called, environmental factors in influencing ultimated facial form and associated malocclusion. Of all the possible environmental influences, it is not surprising that bearing in mind the origins and insertions of the muscles of mastication, and in particular the masseter and medial pterygoid muscle, that the question has arisen as to whether or not abnormalities in the structure and function of the muscular pterygomasseteric sling (PMS) could, in any way, influence vertical development in the posterior part of the face. Furthermore, if treatment interventions necessitate a change in function of the muscles that support the mandible, do the adaptive capability of these muscles in any way influence the stability of the treatment outcome.[4]

BIOMODELLING

Biomodelling is the generic term describing the ability to replicate the morphology of a biological structure in a solid substance. Specifically, biomodelling has been defined as "the process of using radiant energy to capture morphological data on a biological structure and the processing of such data by a computer to generate the code required to manufacture the structure by rapid prototyping apparatus". A biomodel is the product of this process, and virtual reality is the generic term coined for the visualization medium.[1]

Computers are used increasingly as a supportive tool for the diagnosis, operation planning, and treatment in medicine and dentistry. They are used in connection with the modern digital imaging techniques such as computer tomography and magnetic resonance imaging, as well as ultrasound to improve the visualization of anatomical and physiological conditions in keeping with the human imagination.[5]

The ability to extract accurate three-dimensional (3D) images from MRI, has proven to be a very useful diagnostic tool, using a standardize scanning process, with fine overlapping slices of 1 mm thickness and a spacing of 0.8 mm during 7 minutes, was possible to extract the muscles and the facial bones from same scan.[6]

The objective was to extract the muscle from the scan with secure margins identification and also to extract the facial bones with considerable detail. The software used was the Anatomics™ that allows the correction of muscle and bone limits at any time. The reconstruction of muscles and bone from the same scan has allowed visualisation of the muscle fibre orientation in relation to the muscle's bony attachments. This could enable the measurement of potential changes in orientation in relation to a static landmark unaffected by surgery (e.g. Frankfort plane) or in relation to functional identifiers (e.g. Occlusal plane).

MUSCLES ROLE

Many forms of interceptive treatment, whether they be purely orthodontic in nature or in combination with surgery, bring about changes in the muscles of mastication with regard to one or more of the following changes: a) in muscle fibre orientation, b) changes in the functioning length of fibres, c) changes in muscle structure and d) changes in muscle phenotype. Successful treatment requires both reorganization in the connective tissue and regeneration of muscle fibres. Reorganization of connective tissue is an extremely complex process involving muscle derived stem cells (satellite cells), extra-cellular matrix molecules and receptors for the extra-cellular matrix (for example integrins). Remodeling of the extra-cellular matrix is mediated by a family of enzymes known as matrix metalloproteinases (MMPs).[7,8] MMP2 is expressed during the regeneration of new myofibres and is a known mechano-responsive gene. A knowledge of how muscles respond to clinical interventions is pivotal to treatment success and can influence the way in which a particular treatment modality is applied. Functional appliances, for example, can be either fixed or removable, can be constructed to varying degrees of vertical opening and there are protagonists and antagonists for both gradual versus one-step activation of the appliances. Similarly, distraction osteogenesis is considered by many to be preferable to orthognathic surgery in specific cases because it induces a gradual as opposed to a one-step activation believed

to be more physiologically appropriate for bone and possibly, muscle adaptation.[7,8]

With regard to orthognathic surgery the golden rule is that surgery must not stretch the pterygomasseteric sling, otherwise relapse is likely to occur. This is predominantly through the speed of insult to the muscle in relation to the timing of the muscle adaptive process. The consequence is either an immediate reversion back to the original functioning length of the muscle and return of the bony fragments back to their original pre-surgical position, and/or migration of the muscle attachment along the surface of the bone, thereby leading to an area of bone denuded of muscle force, which ultimately leads to resorption of the bony muscular processes.

One way in which this can be studied more closely is through refinements in protocols for 3D magnetic resonance imaging of the face and jaws. Increasing the resolution of the tomographic cuts to 1.0mm has led to a resolution which facilitates the identification of not only the origins and insertions of the muscles of mastication but even the orientation of individual muscle fibre bundles (Figure 1A and B). It is therefore possible to study the changes in muscle fibre orientation in relation to landmarks such as the functional occlusal plane and also those landmarks unaffected by surgery, for example the cranial base (Figure 1C and D). Ideally, as mentioned, surgery to correct an increased vertical facial deformity should involve posterior maxillary impaction together with a mandibular procedure where the final outcome does not increase the posterior facial height and hence, does not stretch the pterygomasseteric sling. As such the orientation of the muscle fibres in relation to their functioning occlusal plane remains unaltered (Figure 1E). However, if there is failure to adequately impact the posterior part of the maxilla in such cases, then there is a rotation of the mandibular segments around the premolar/first molar region, resulting in a reduction of the anterior face height but, an unwelcome increase in the posterior vertical dimension (Figure 1F) and thereby leading to an increase in the length of the pterygomasseteric sling (Figure 1G). Furthermore, this leads to a much less efficient musculo-occlusal relationship and as such more extensive adaptation must take place within the muscles in order to be able to accommodate the unwanted surgical change. In clinical cases where this unwanted change has occurred, there is not only a return towards the original pre-surgical bony relationships (Figure 1H) but also migration of the muscle attachment leaving an area of bone at the gonial angle which subsequently resorbs and leads to the unwanted and unsightly hour glass deformity of the mandibular border (Figure 1I).

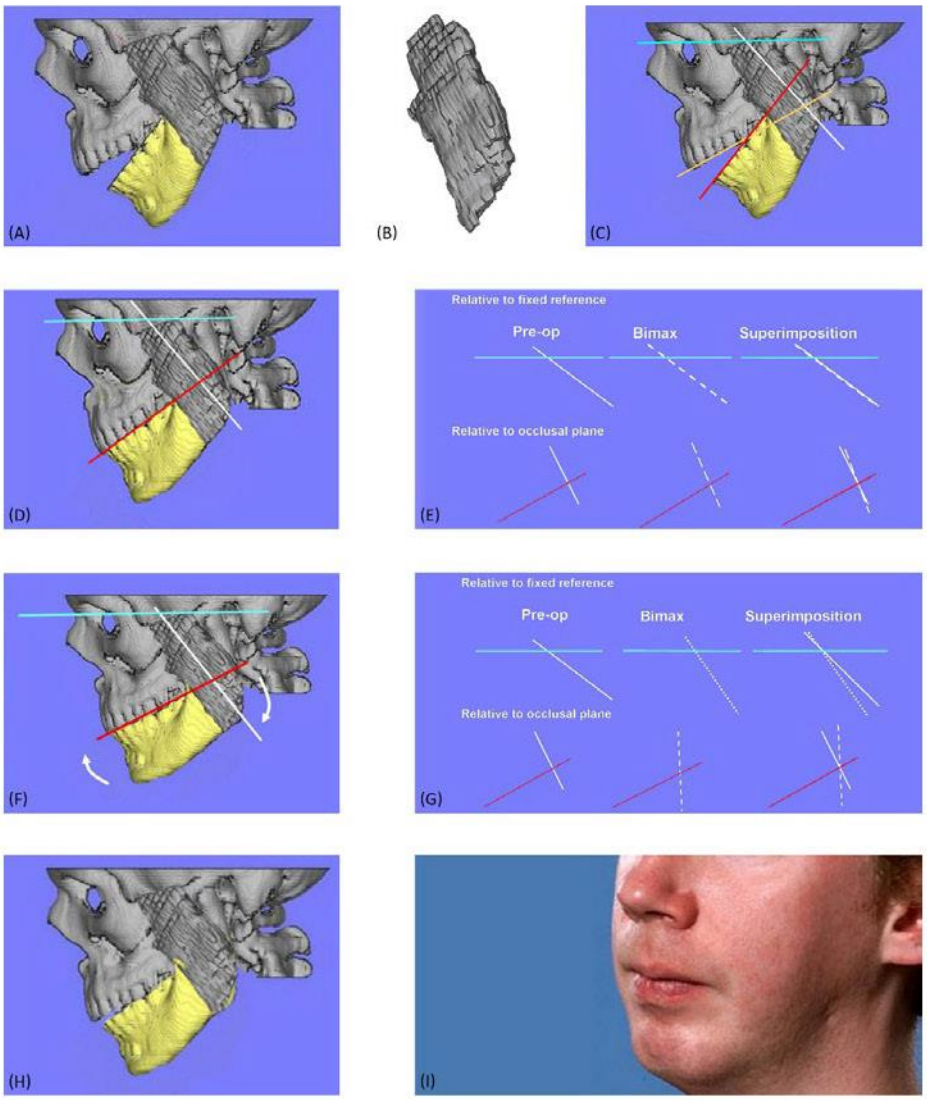

Figure 1. 3D MRI (Magnetic Resonance Imaging) shows detail of masseter muscle fibre bundle orientation (A and B). Favorable change in muscle length and fibre orientation following maxillary impaction and mandibular advancement surgery for closure of anterior open bite (C, D and E). Unfavorable change following insufficient posterior maxillary impaction with resultant stretch of pterygomandibular sling (F and G) and subsequent relapse (H and I).

MATERIALS AND METHODS

Patients attending the combined orthodontic/orthognathic surgery clinic at Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were screened. Ten patients scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible were selected to form the study group.

The patients have Magnetic Resonance Imaging (MRI), using the scan data obtained, together with the technique of 3D representation, changes in fibre orientation at the different jaw positions were evaluated with Anatomics™ Software. The landmarks considered for this study were: (a) the anterior angle from the long axis of masseter muscle versus angle between lower border of the zygomatic bone and the mastoid process, (b) the anterior angle from the long axis of the masseter muscle versus the mandibular plane.

The values were registered before surgery (T0) and 6 to 12 months after surgery (T1) and 1 week later (T2). The results have been measured by two different observers, according to the protocol jointly developed between the Eastman Dental Institute – University of London and the MRI Centre - Department of Radiology at John Radcliffe Hospital – University of Oxford. A combination of different parametric tests has been used to compare the different experimental variables. The experimental design devised for this study is depicted in Figure 2, comprising a combination of different examiners, surgical angles and times of measurement (pre- and post-operation).

Comparison A – Testing the Differences between Examiners (F versus N)

Research question: Are there any differences in the mean values of P1 and P2 angles measured by Examiner F and Examiner N in the same experimental conditions?

H0: There are no differences in the mean values of P1 and P2 angles measured by Examiner F and Examiner N in the same experimental conditions.

H1: There are differences in the mean values of P1 and P2 angles measured by Examiner F and Examiner N in the same experimental conditions.

The statistical comparison between the examiners F and N regarding the measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients was performed using a Paired Student's t-test for three different time moments of measurement (Time 0, Time 1 and Time 2).

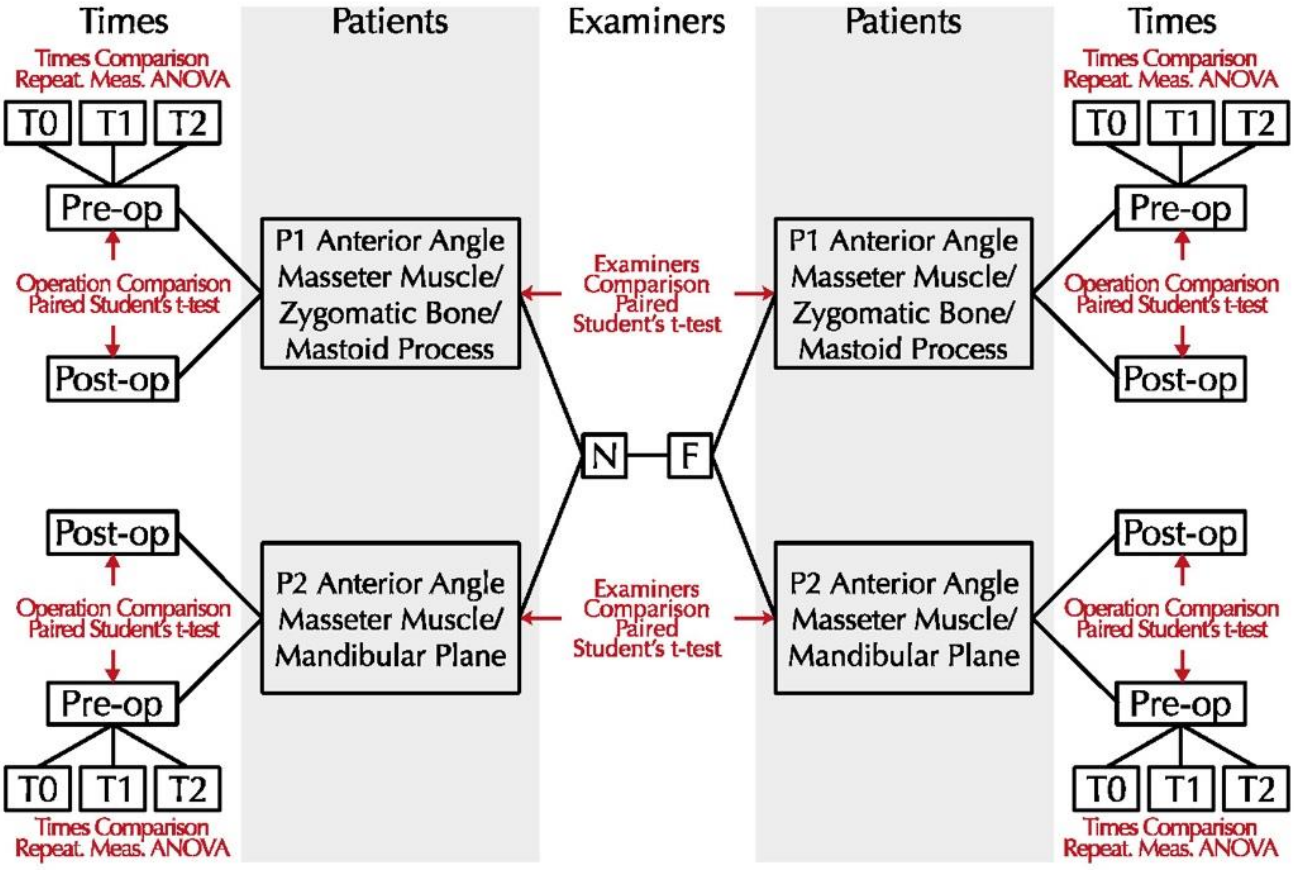

Figure 2. Experimental design used for assessing the biomodelling analysis. The study involved the contribution of two independent examiners (F and N), that measured the "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and the "P2 Masseter Muscle/Mandibular Angle" at two different times (pre- and post-operation)

Comparison B – Testing the Differences between Times (Time 0 versus Time 1 versus Time 2)

Research question: Are there any differences in the mean values of P1 and P2 angles measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions?

H0: There are no differences in the mean values of P1 and P2 angles measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions.

H1: There are differences in the mean values of P1 and P2 angles measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions.

The statistical comparison between the three time moments (Time 0, Time 1 and Time 2) regarding the measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients was performed using a Repeated Measure ANOVA for Examiner F and Examiner N.

Comparison C – Testing the Differences between Operations (Pre-op versus Post-op)

Research question: Are there any differences in the mean values of P1 and P2 angles measured between prior ("pre-op") and after ("post-op") surgical intervention in the same experimental conditions?

H0: There are no differences in the mean values of P1 and P2 angles measured between "pre-op" and "post-op" moments in the same experimental conditions.

H1: There are differences in the mean values of P1 and P2 angles measured between "pre-op" and "post-op" moments in the same experimental conditions.

The statistical comparison between pre-operative ("pre-op") and post-operative (post-op") values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of one selected patient observed by Examiners F and N was performed using a Paired Student's t-test.

RESULTS

Tables 1 and 2 present the experimental data for the measurement of P1 and P2 angles, showing low experimental variability, as can be assessed by SD and variance values.

Table 1. Values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed prior to surgical operation ("pre-op"), at the different experimental conditions shown in Figure 2.

Variable	Mean (°)	SD (°)	Variance (°^2)
P1_F_T0	81,700	14,283	204,011
P1_F_T1	81,800	14,390	207,067
P1_F_T2	81,900	14,700	216,100
P1_N_T0	83,400	15,421	237,822
P1_N_T1	84,200	15,648	244,844
P1_N_T2	83,500	14,744	217,389
P2_F_T0	77,500	6,704	44,944
P2_F_T1	77,400	6,518	42,489
P2_F_T2	77,300	6,567	43,122
P2_N_T0	79,700	5,851	34,233
P2_N_T1	80,100	5,259	27,656
P2_N_T2	79,400	5,542	30,711

Table 2. Values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of a selected patient observed prior ("pre-op") and after ("post-op") the surgical operation, at the different experimental conditions shown in Figure 2.

Variable	Mean (°)	SD (°)	Variance (°^2)
P1_F_Pre-op	95,500	0,837	0,700
P1_N_Pre-op	88,833	0,753	0,567
P2_F_Post-op	71,333	0,516	0,267
P2_N_Post-op	69,500	0,548	0,300

COMPARISON A – TESTING THE DIFFERENCES BETWEEN EXAMINERS

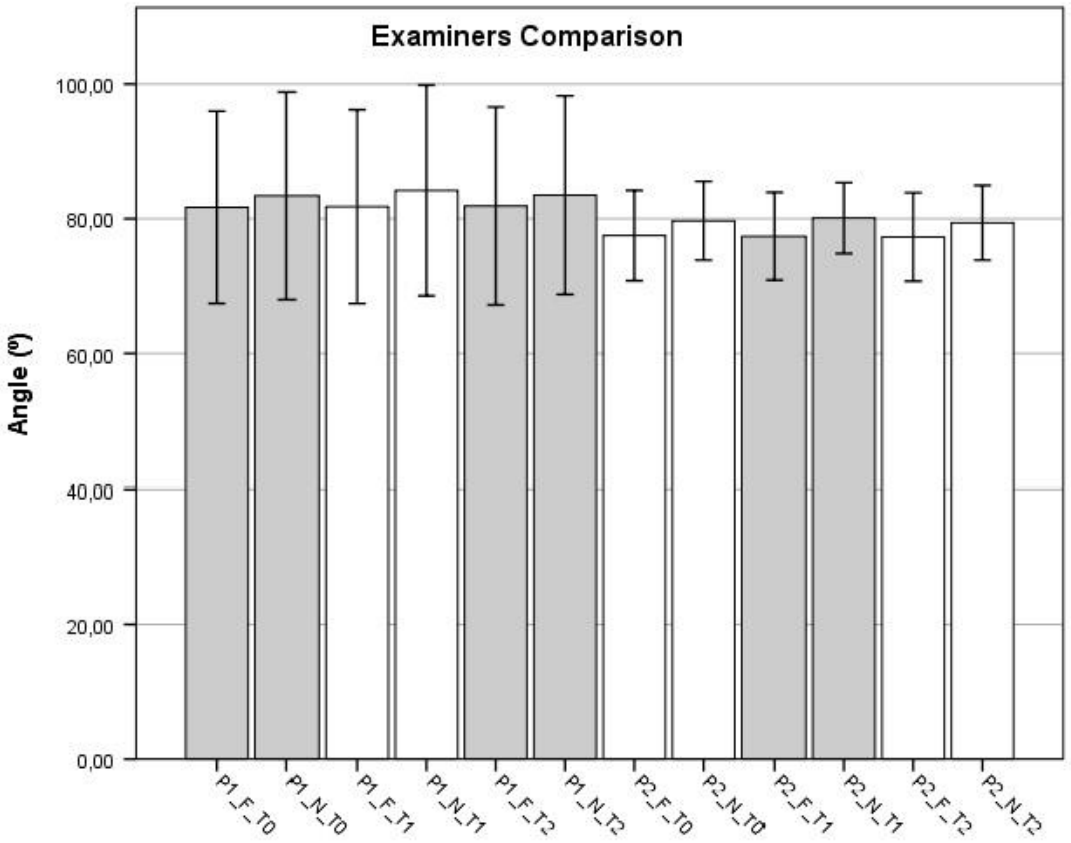

Figure 3. Mean values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed Examiner F and Examiner F at three different time moments (Time 0, Time 1 and Time 2).

Table 3. Statistical parameters obtained in the Paired Student's t-test for comparison of examiners F and N is regarding the measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed at three different time moments (Time 0, Time 1 and Time 2).

Examiners Comparison	Mean Difference	Standard Deviation of Differences	Degrees of Freedom *(df)*	Test statistic from Paired *t*-test	P-value from Paired *t*-test
Examiner F versus Examiner N, Time 0, P1 Angle	-1,700	2,497	9	-2,153	0,060
Examiner F versus Examiner N, Time 1, P1 Angle	-2,400	2,221	9	-3,417	0,008
Examiner F versus Examiner N, Time 2, P1 Angle	-1,600	1,838	9	-2,753	0,022
Examiner F versus Examiner N, Time 0, P2 Angle	-2,200	3,910	9	-1,779	0,109
Examiner F versus Examiner N, Time 1, P2 Angle	-2,700	3,529	9	-2,419	0,039
Examiner F versus Examiner N, Time 2, P2 Angle	-2,100	3,213	9	-2,067	0,069

Statistical differences have been identified between Examiner F and Examiner N regarding the measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of the ten patients analysed ($p < 0,05$). These discrepancies probably arise from small variations in the experimental methodology used by both examiners.

The standardization of the experimental protocol probably would reduce the differences detected. However, the maintenance of the same examiner in the evaluation of P1 and P2 angles for each patient would be the better approach to attain a high reproducibility.

COMPARISON B – TESTING THE DIFFERENCES BETWEEN TIMES

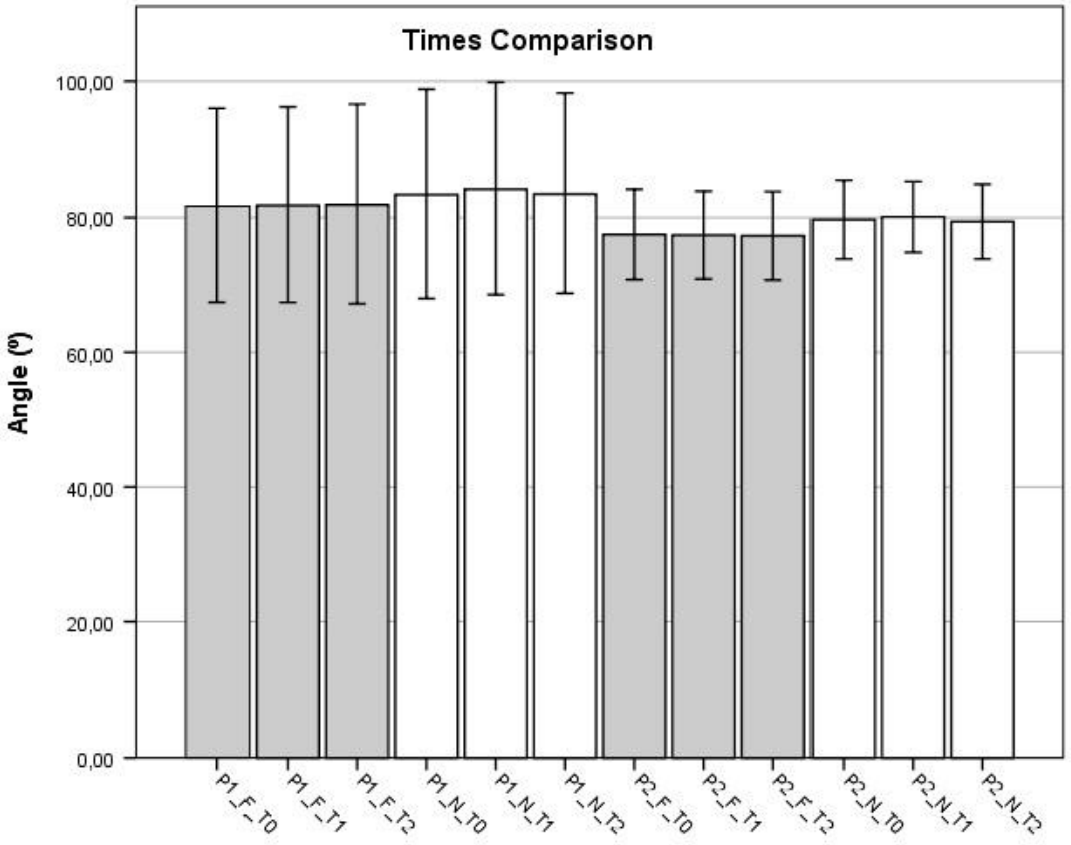

Figure 4. Mean values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed at three different time moments (Time 0, Time 1 and Time 2) by Examiner F and Examiner F.

Table 4. Statistical parameters obtained in the Repeated Measures ANOVA for the comparison of time moments (Time 0, Time 1 and Time 3) when measuring the "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed by Examiner F and Examiner F.

Times Comparison	Degrees of Freedom (*df*)	Test statistic (F)	P-value (Sig)
Time 0 vs Time 1 vs Time 2, Examiner F, P1 Angle	2,18	0,403	0,674
Time 0 vs Time 1 vs Time 2, Examiner N, P1 Angle	2,18	2,803	0,087
Time 0 vs Time 1 vs Time 2, Examiner F, P2 Angle	2,18	0,474	0,630
Time 0 vs Time 1 vs Time 2, Examiner N, P2 Angle	2,18	2,043	0,159

There are no significant differences in the mean P1 and P2 angles measured at Time 0, Time 1 or Time 2, as long as the measurements are made by the same the same Examiner (F or N). All experiments reveal p-values above the cut-off value of 0,05 ($p > 0,05$), which means that H0 proposition is valid. Thus, it is concluded the mean P1 and P2 angles (°) measured at different time frames are consistently the same, showing the high reproducibility of the measurements.

COMPARISON C – TESTING THE DIFFERENCES BETWEEN OPERATIONS

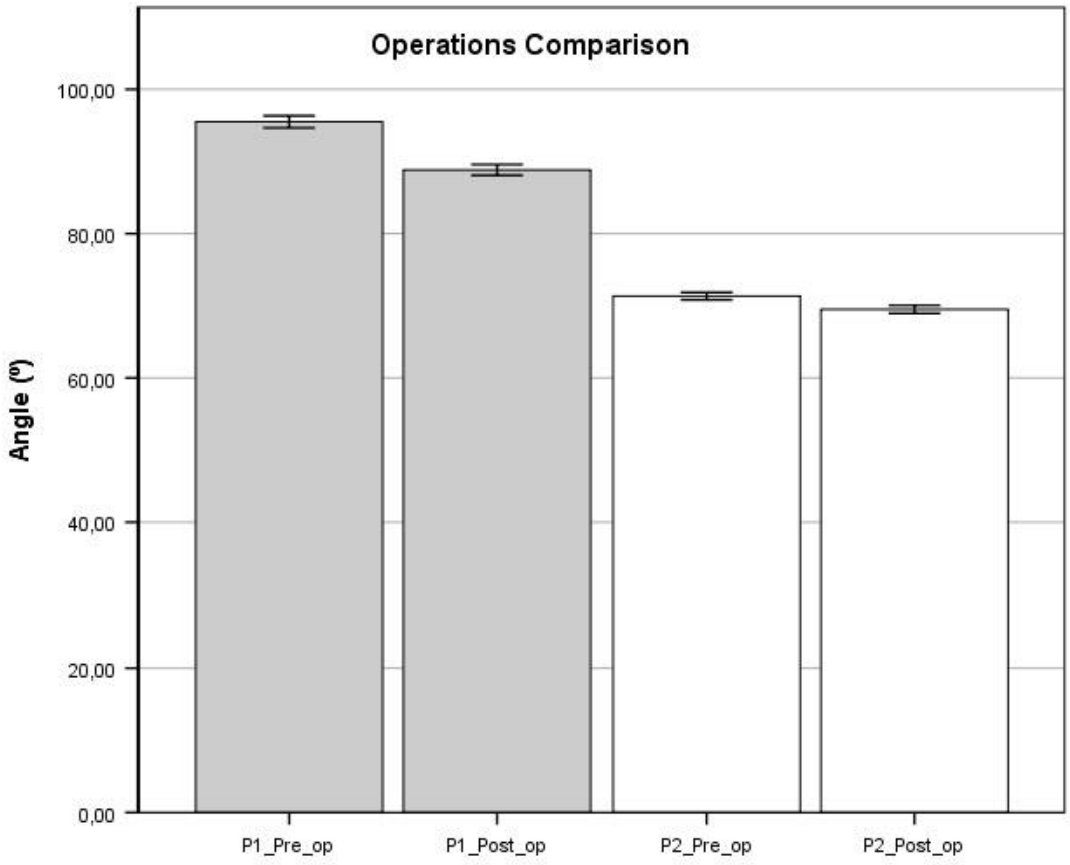

Figure 5. Mean values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of a selected patient observed prior to surgical intervention ("pre-op") and after surgical intervention ("post-op").

Table 5. Statistical parameters obtained in the Paired Student's t-test for the comparison of "pre-op" and "post-op" values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of a selected patient.

Examiners Comparison	Mean Difference	Standard Deviation of Differences	Degrees of Freedom *(df)*	Test statistic from Paired *t*-test	P-value from Paired *t*-test
Pre-op versus Post-op, P1 Angle	6,66667	1,36626	5	11,952	0
Pre-op versus Post-op, P2 Angle	1,83333	0,75277	5	5,966	0,002

The Paired Student's t-test reveals the existence of statistical differences in the mean values of P1 and P2 angles before ("pre-op") and after ("post-op") the surgical intervention of the selected patient ($p < 0,05$).

These differences reveal the masseter muscle adaptation following orthognathic surgery in this study-case. The measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" can therefore be a valuable tool for controlling the reworking of masseter muscle upon orthognathic surgery.

CONCLUSIONS

Results show that the choice of the examiner may cause experimental variation on MRI data obtained for each patient, thus advising the use of standardized protocols to minimize these measurement differences. As for time reproducibility, the measurement of P1 and P2 angles has demonstrated to be consistent throughout the three time periods analysed, showing the high sensitivity of the MRI technique. Major statistical differences have been encountered, however, when comparing pre-op and post-op data for P1 and P2 angles, proving the applicability of MRI technique to evaluate masseter muscle adaptation following orthognathic surgery. These results indicate the high potential of MRI and biomodelling to predict the outcome of individual orthognathic surgeries, thus increasing the efficiency of these correction procedures.

CONFLICT OF INTEREST

The author declares that there is no conflict of interest regarding the publication of this article.

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ARTICLE 11

Duarte F., Silva JN., Ramos C., Hopper C. Correlation between MRI and Biomodelling Analysis in Masseter Muscle Following Orthognathic Surgery. Int J of Dent & Ora Hea 2021; 7(7):50-58

Authors	**Duarte F.,** Silva JN., Ramos C., Hopper C.
Journal	International Journal of Dentistry and Oral Health
DOI	
Contribution by F Duarte	Concept Performance of systematic review of literature Appraisal of included studies Development of recurrence risk stratification Manuscript writing & editing
ISSN	2471-657X
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Post-Viva Addenda:

-The study evaluated two primary angular relationships: The angle formed between the long axis of the masseter muscle and the zygomaxillary-mastoid plane (defined by the inferior border of the zygomatic bone and the mastoid process). The angle formed between the long axis of the masseter muscle and the mandibular plane. Measurements were performed by two independent observers. Data were collected at three time points: baseline (TO), one-hour post-measurement (T1) to assess intra-examiner reliability, and 6 to 12 months postoperatively (T2) to evaluate long-term surgical outcomes.

-Standard clinical MR scans do not possess the spatial resolution to image individual muscle fibres in the masseter. Instead, they visualise muscle fascicles, connective tissue septa, and the "grain" (pinnation angle/fibre orientation) of the muscle bundles. MRI scanners used for muscle imaging typically have an in-plane resolution of 0.5mm to 1mm (500-1000µm).

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Research Article

Correlation between MRI and Biomodelling Analysis in Masseter Muscle Following Orthognathic Surgery

Fernando Duarte*[1], João Neves Silva[2], Carina Ramos[3], Colin Hopper[4]

[1]Oral Surgeon Specialist by OMD (Portuguese Dental Association), Master of Science in Oral and Maxillofacial Surgery at Eastman Dental Institute University College of London, PhD student at UCL - University College of London
[2]Professor at ISAVE - Instituto Superior de Saúde - Portugal, Member of the Interdisciplinary Center for Health Sciences (ICHS) - ISAVE -Instituto Superior de Saúde
[3]MSc student in Oral Oncology at Instituto de Ciências Biomédicas Abel Salazar - Oporto University – Portugal
[4] Oral and Maxillofacial Surgery Department at Eastman Dental Institute – University College of London

Corresponding author: Fernando Duarte
Clitrofa - Centro Médico, Dentário e Cirúrgico, Avenida de Paradela 622, 4785-248 Trofa - Portugal
Tel: +351252428960 E-mail: fduarte@clitrofa.com

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Abstract

Purpose: This pilot investigation was designed to apply several and innovative methods of measuring muscle area, volume, structure, function and fibre orientation to a situation where adaptation of muscle is pivotal to the success of a therapeutic approach.

Materials and Methods: Patients attending the combined orthodontic/orthognathic surgery clinic at Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were screened using a standardized Magnetic Resonance Imaging protocol, with fine overlapping slices of 1 mm thickness and a spacing of 0.8 mm during 7 minutes. The software used was the AnatomicsTM that allows the correction of muscle and bone limits.

The landmarks considered for this study were: a) the anterior angle from the long axis of masseter muscle versus angle between lower border of the zygomatic bone and the mastoid process; and b) the anterior angle from the long axis of the masseter muscle versus the mandibular plane. The angles were measured by two different observers. The values were registered (T0) and the procedure was repeated after 1 hour (T1), and 6 to 12 months after surgery (T2).

Conclusions: Significant statistical differences ($p < 0,05$) have been identified between Time 2 (1-6 months after surgery) and Times 0 and 1 (prior to surgery) in the mean P2 angle measured, both for Examiner F and C. These differences reveal the masseter muscle adaptation following bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible in this study-case. The measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" can therefore be a valuable tool for controlling the reworking of masseter muscle upon orthognathic surgery.

Keywords

Orthognathic Surgery, Masseter Muscle, MRI Analysis, Biomodelling Analysis

Declaration of Conflicting Interest

The authors declare that they have no conflict of interest.

Introduction:

Advances in medical imaging have created ever increasing volumes of complex data obtained from the patient. The interpretation of such information has become a specialty in itself and the surgeon at times may be left bewildered as to how best to apply the available information to the practicalities of physical intervention. The surgeon seeks to understand the exact morphology of the abnormality, its relationships to surrounding anatomy and the best way to access and correct the pathology operatively. Such specific information is not readily available in the radiologist's report and however experienced the surgeon may be at interpreting images such questions, often cannot be easily answered[1].

Three-dimensional (3-D) imaging has been developed to narrow the communication gap between radiologist and surgeon. By using 3-D, imaging a vast number of complex slice images can be quickly appreciated. The term "three-dimensional" however, is not a truly accurate description of these images as they are still displayed on a radiological film or flat screen in only two dimensions[1].

For harmonious vertical facial growth and development to exist, the growth on the front of the face must be the same as on the back. If this does not occur, there may be a relative growth rotation of the mandible. For example, if the growth in the posterior part of the face exceeds what occurred previously, the net effect will be an anterior rotation of the mandible, producing the typical deformity of the short face and the deep overbite associated with the short face syndrome[2]. At the opposite end, where growth at the back of the face can be severely reduced compared to what occurred earlier, a clockwise opening or rotation of the jaw is evident, with the net effect of being an excessive anterior facial height and often a bitten anterior opening, associated with a deformity of the long face[3].

For generations, both clinicians and scientists have argued as to the respective contribution of genetics and, so called, environmental factors in influencing ultimate facial form and associated malocclusion. Of all the possible environmental influences, it is not surprising that bearing in mind the origins and insertions of the muscles of mastication, and in particular the masseter and medial pterygoid muscle, that the question has arisen as to whether, or not, abnormalities in the structure and function of the muscular pterygo-masseteric sling could, in any way, influence vertical development in the posterior part of the face. Furthermore, if treatment interventions necessitate a change in function of the muscles that support the mandible, do the adaptive capability of these muscles in any way influence the stability of the treatment outcome[4].

MRI and Bio-Modelling:

Computers are used increasingly as a supportive tool for the diagnosis, operation planning, and treatment in medicine and dentistry. They are used in connection with the modern digital imaging techniques such as computer tomography and magnetic resonance imaging, as well as ultrasound to improve the visualization of anatomical and physiological conditions in keeping with the human imagination[5].

The ability to extract accurate three-dimensional (3D) images from magnetic resonance imaging (MRI), has proven to be a very useful diagnostic tool to extract the muscle from the scan with secure margins identification and also to extract the facial bones with considerable detail[6].

The reconstruction of muscles and bone from the same scan have allowed visualisation of the muscle fibre orientation in relation to the muscle's bony attachments. This could enabled the measurement of potential changes in orientation in relation to a static landmark unaffected by surgery (eg. Frankfort plane) or in relation to functional identifiers (eg. Occlusal plane).

Muscles Role

Many forms of interceptive treatment, whether they be purely orthodontic in nature or in combination with surgery, bring about changes in the muscles of mastication with regard to one or more of the following changes: a) in muscle fibre orientation; b) changes in the functioning length of fibres; c) changes in muscle structure; and d) changes in muscle phenotype. Successful treatment requires both reorganisation in the connective tissue and regeneration of muscle fibres. Reorganisation of connective tissue is an extremely complex process involving muscle derived stem cells (satellite cells), extra-cellular matrix molecules and receptors for the extra-cellular matrix (for example integrins). Remodeling of the extra-cellular matrix is mediated by a family of enzymes known as matrix metalloproteinases (MMPs)[7,8]. MMP2 is expressed during the regeneration of new myofibres and is a known mechano-responsive gene. A knowledge of how muscles respond to clinical interventions is pivotal to treatment success and can influence the way in which a particular treatment modality is applied[7,8].

With regard to orthognathic surgery the golden rule is that surgery must not stretch the pterygo-masseteric sling, otherwise relapse is likely to occur. This is predominantly through the speed of insult to the muscle in relation to the timing of the muscle adaptive process. The consequence is either an immediate reversion back to the original functioning length of the muscle and return of the bony fragments back to their original pre-surgical position, and/or migration of the muscle attachment along the surface of the bone, thereby leading to an area of bone denuded of muscle force, which ultimately leads to resorption of the bony muscular processes.

One way in which this can be studied more closely is through refinements in protocols for 3-D MRI of the face and jaws. Increasing the resolution of the tomographic cuts has led to a resolution which

facilitates the identification of not only the origins and insertions of the muscles of mastication but even the orientation of individual muscle fibre bundles. It is therefore possible to study the changes in muscle fibre orientation in relation to landmarks such as the functional occlusal plane and also those landmarks unaffected by surgery, for example the cranial base.

Materials and Methods:

Ten patients attending the combined orthodontic/orthognathic surgery clinic at the Clitrofa – Centro Médico, Dentário e Cirúrgico, in Trofa - Portugal were tested according to the following protocol:

Accurate extraction of muscles and facial bones using the same scan from MRI three-dimensional (3D), using a standardize scanning process, with fine overlapping slices of 1 mm thickness and a spacing of 0.8 mm during 7 minutes[5]. The software used was the AnatomicsTM that allows the correction of muscle and bone limits at any time[6].

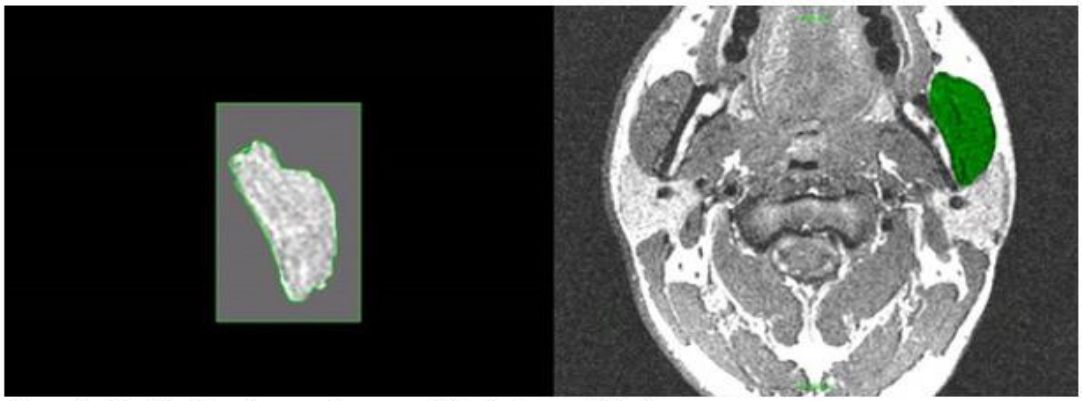

Figure 1: Identification of masseter muscle limits in a sagital plane.

The landmarks considered for this study were: (a) the anterior angle from the long axis of masseter muscle versus angle between lower border of the zygomatic bone and the mastoid process, (b) the anterior angle from the long axis of the masseter muscle versus the mandibular plane[9].

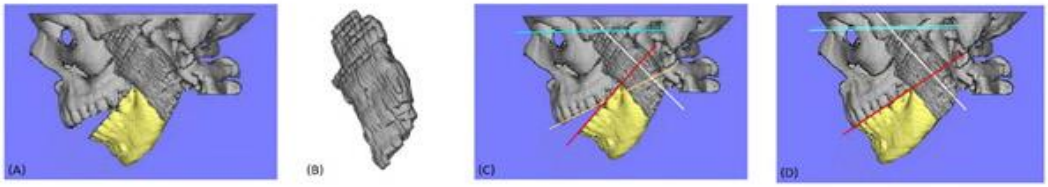

Figure 2: 3-D MRI showing detail of masseter muscle fibre bundle orientation (A and B). Favourable change in muscle length and fibre orientation following maxillary impaction and mandibular advancement surgery for closure of anterior open bite (C, D).

In this pilot study, the angles were measured by two different observers. The values were registered (T0) and the procedure was repeated after 1 hour (T1), and 6 to 12 months after surgery (T2). The results have been measured by two different observers. These 10 patients were scheduled for a bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible. A combination of different parametric tests has been used to compare the different experimental variables.

The experimental design devised for this study is depicted in Figure 3, comprising a combination of different examiners, surgical angles and times of measurement (pre- and post-operation).

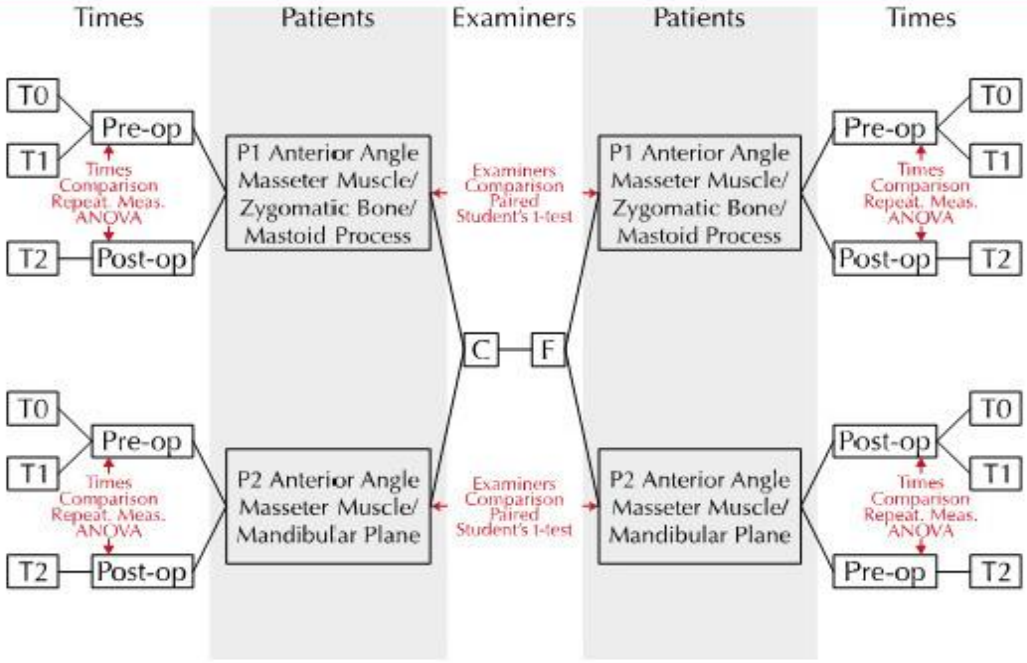

Figure 3: Experimental design used for assessing the biomodelling analysis. The study involved the contribution of two independent examiners (F and C), that measured the "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and the "P2 Masseter Muscle/Mandibular Angle" at two different times (pre- and post-operation).

IBM® SPSS® version 25 was used to analyze the data obtained. The data were first tested to ensure they conformed to a normal distribution by using the Kolmogorov-Smirnov test, the Shapiro-Wilks test or by determining the values of skewness (acceptable values for normality between -2 and +2) and kurtosis (acceptable values for normality between -2 and +2). Descriptive statistics included the arithmetic mean ($\bar{x}$), standard deviation (SD), and standard error of the mean (SE), as well as the 95% confidence interval (95% CI). Where the data were not normally distributed, the median and the inter-quartile range (IQR) were noted.

In those situations where the data were normally distributed and the variances were constant, comparative analysis involved either the unpaired or paired two-tailed Student's t test. Multiple comparisons were made using the One-Way Analysis of Variance (ANOVA) or Repeated Measure Analysis of Variance (ANOVA) depending if the data were, respectively, unpaired or paired.

Post-Hoc Gabriel test and post-hoc Bonferroni test were used, respectively for One-Way ANOVA and Repeated Measures ANOVA, to identify the pairs where the significant statistical differences were located.

Where the requirements for parametric statistical analysis were not met, the data were analyzed using either the Wilcoxon Signed Rank *(U)* test for paired data or the Mann-Whitney *(U)* test for unpaired data as appropriate. Comparison between three or more groups were made using the Kruskal-Wallis *(H)* or the Friedman *(H)* test depending if the data were, respectively, unpaired or paired.

The minimum level of significance (α level) accepted throughout the development studies was 0.05 (*), considered to be "moderately significant". Levels of 0.01 (**) were considered as "significant" and 0.001 (***) designated as "highly significant". A lack of statistical significance was designated as (ns).

Comparison A – Testing the Differences between Examiners (F *versus* C)

Research question: Are there any significant statistical differences in the mean values of P1 and P2 angles measured by Examiner F and Examiner C in the same experimental conditions?

H0: There are no significant statistical differences in the mean values of P1 and P2 angles measured by Examiner F and Examiner C in the same experimental conditions.

H1: There are significant statistical differences in the mean values of P1 and P2 angles measured by Examiner F and Examiner C in the same experimental conditions.

Comparison B – Testing the Differences between Times (Time 0 versus Time 1 versus Time 2)

Research question: Are there any significant statistical differences in the mean values of P1 and P2 angles measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions?

H0: There are no significant statistical differences in the mean values of P1 and P2 angles measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions.

H1: There are significant statistical differences in the mean values of P1 and P2 angles measured between moments Time 0, Time 1 and Time 2 in the same experimental conditions.

Results:

Variable	Mean (°)	SD (°)	Variance (°^2)
P1_F_T0	81,000	14,787	218,667
P1_F_T1	81,000	14,787	218,667
P1_F_T2	80,800	15,208	231,289
P1_C_T0	80,900	14,881	221,433
P1_C_T1	81,000	14,787	218,667
P1_C_T2	80,800	15,208	231,289
P2_F_T0	77,100	6,887	47,433
P2_F_T1	77,100	6,887	47,433
P2_F_T2	75,300	6,734	45,344
P2_C_T0	77,300	7,134	50,900
P2_C_T1	77,100	6,887	47,433
P2_C_T2	75,400	6,620	43,822

Table I: Values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed prior to surgical operation ("pre-op"), at the different experimental conditions shown in Figure 4.

Comparison A – Testing the Differences between Examiners (F *versus* C)

The statistical comparison between the examiners F and C regarding the measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients was performed using a Paired Student's t-test for three different time moments of measurement (Time 0, Time 1 and Time 2) (Figure 4 and Table II).

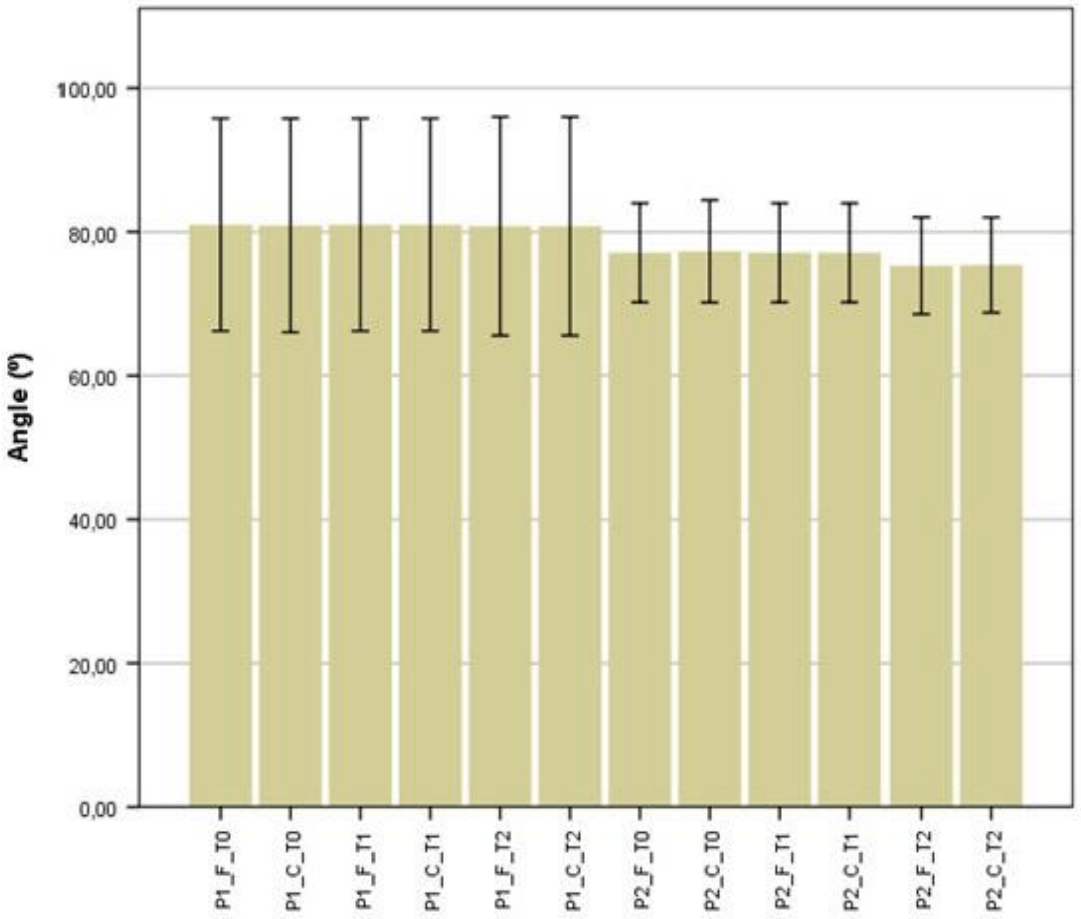

Figure 4: Mean values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed Examiner F and Examiner C at three different time moments (Time 0, Time 1 and Time 2).

Examiners Comparison	Mean Difference	Standard Deviation of Differences	Degrees of Freedom (*df*)	Test statistic from Paired *t*-test	*P-value* from Paired *t*-test
Examiner F versus Examiner C, Time 0, P1 Angle	0,100	0,316	9	1,000	0,343
Examiner F versus Examiner C, Time 1, P1 Angle	0,000	0,000	9	-	-
Examiner F versus Examiner C, Time 2, P1 Angle	0,000	0,000	9	-	-
Examiner F versus Examiner C, Time 0, P2 Angle	-0,200	0,422	9	-1,500	0,168
Examiner F versus Examiner C, Time 1, P2 Angle	0,000	0,000	9	-	-
Examiner F versus Examiner C, Time 2, P2 Angle	-0,100	0,316	9	-1,000	0,343

Table II : Statistical parameters obtained in the Paired Student's t-test for comparison of examiners F and C regarding the measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed at three different time moments (Time 0, Time 1 and Time 2).
* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Comparison B –Testing the Differences between Times (Time 0 *versus* Time 1 *versus* Time 2)

The statistical comparison between the three-time moments (Time 0, Time 1 and Time 2) regarding the measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients was performed using a Repeated Measure ANOVA for Examiner F and Examiner C (Figure 5 and Table III).

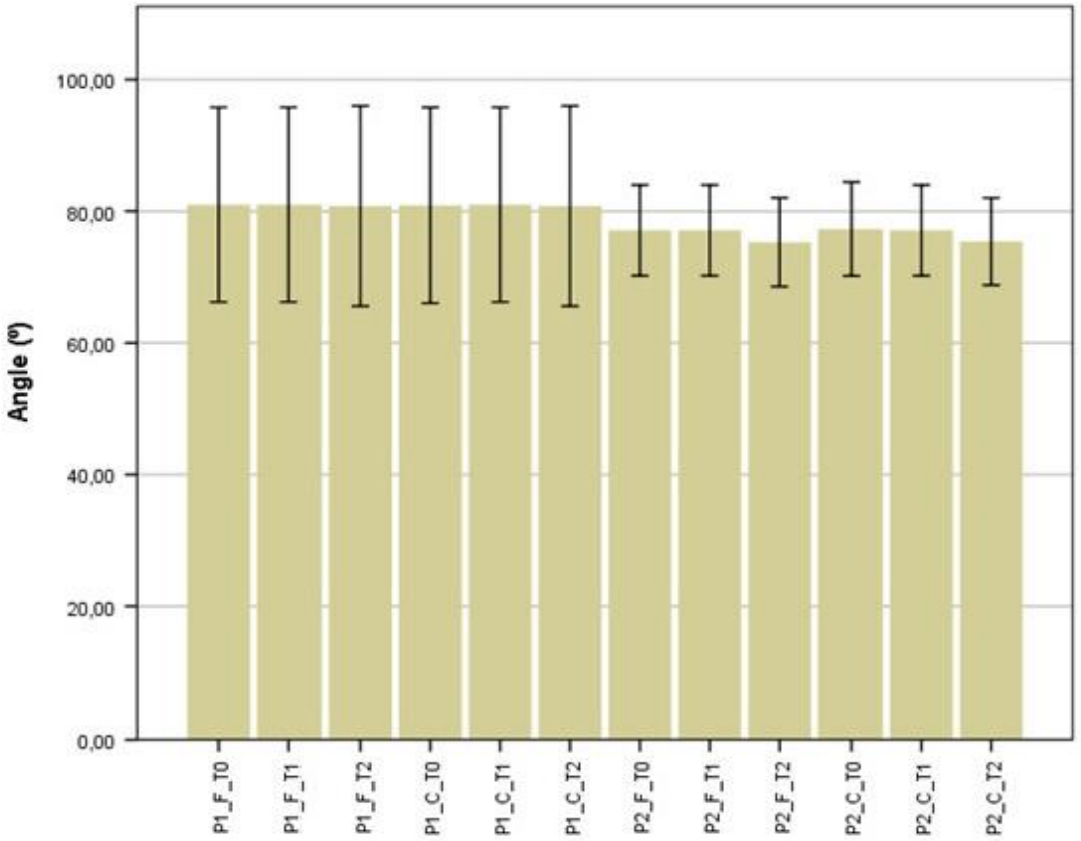

Figure 5: Mean values of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed at three different time moments (Time 0, Time 1 and Time 2) by Examiner F and Examiner C.

Times Comparison	Degrees of Freedom *(df)*	Test statistic *(F)*	*P-value (Sig)*
Time 0 vs Time 1 vs Time 2, Examiner F, P1 Angle	2, 18	1,000	0,387
Time 0 vs Time 1 vs Time 2, Examiner C, P1 Angle	2, 18	0,730	0,496
Time 0 vs Time 1 vs Time 2, Examiner F, P2 Angle	2, 18	14,878	0,000***
Time 0 vs Time 1 vs Time 2, Examiner C, P2 Angle	2, 18	15,249	0,000***

Table III: Statistical parameters obtained in the Repeated Measures ANOVA for the comparison of time moments (Time 0, Time 1 and Time 2) when measuring the "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of ten different patients observed by Examiner F and Examiner C.

Because Repeated Measures ANOVA only gives information about the presence of differences, not specifying where these differences are located, a Post-Hoc Bonferroni test was used to perform pairwise comparisons between the times in the mean P2 angle, and these results are represented in Table IV.

Independent Variable			Mean Difference (I-J)	Std. Error	Sig.
F_Q2/P2	T0	T1	0,000	0,000	-
		T2	1,800	0,467	0,012*
	T1	T0	0,000	0,000	-
		T2	1,800	0,467	0,012*
	T2	T0	-1,800	0,467	0,012*
		T1	-1,800	0,467	0,012*
C_Q2/P2	T0	T1	0,200	0,133	0,504
		T2	1,900	0,433	0,005**
	T1	T0	-0,200	0,133	0,504
		T2	1,700	0,473	0,017*
	T2	T0	-1,900	0,433	0,005**
		T1	-1,700	0,473	0,017*

Table IV: Statistical parameters obtained in the Post-Hoc Bonferroni test for the comparison of Times (Time 0, Time 1 and Time 2) when measuring the mean P2 angle in different experimental conditions.
* moderately significant to 0.05 level; ** significant to 0.01 level; *** highly significant to 0.001 level.

Discussion:

No significant statistical differences have been identified between Examiner F and Examiner C regarding the measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" of the ten patients analysed ($p > 0,05$).

No significant statistical differences have been detected in the mean P1 angle measured at Time 0, Time 1 or Time 2, irrespective of the Examiner (F or C), which means that H0 proposition is valid ($p > 0,05$).

With respect to the mean P2 angle, significant statistical differences have been identified throughout time (Time 0, Time 1 or Time 2), as can be observed in Table 3 ($p < 0,05$) The differences are mainly located in Time 2 (post-op), when compared with Times 0 and 1 (pre-op) as can be observed in Table 4, revealing that this technique can be successfully used to evaluate the reworking of masseter muscle upon orthognathic surgery.

Conclusions:

The innovation in this study resides in the combination of the protocol presented to obtain the area and volume of the left masseter muscle using Magnetic Resonance together with the bio-modelling reconstruction with the Anatomics™ software.

Significant statistical differences ($p < 0,05$) have been identified between Time 2 (1-6 months after surgery) and Times 0 and 1 (prior to surgery) in the mean P2 angle measured, both for Examiner F and C. These differences reveal the masseter muscle adaptation following bimaxillary osteotomy involving a combination of maxillary Le Fort I impaction procedure coupled with a sagittal split advancement of the mandible in this study-case. The measurement of "P1 Masseter Muscle/Zygomatic Bone/Process Mastoid Anterior Angle" and "P2 Masseter Muscle/Mandibular Angle" can therefore be a valuable tool for controlling the reworking of masseter muscle upon orthognathic surgery.

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ARTICLE 12

Duarte F., Silva JN., Ramos C., Hopper C. Bio-Modelling Reconstruction based on MRI Image Acquisition and their Application in Orthognathic Surgery. J Clin Med Img 2023; V7(10):1-6

Authors	**Duarte F.,** Silva JN., Ramos C., Hopper C.
Journal **DOI**	Journal of Clinical and Medical Images
Contribution by F Duarte	Concept Performance of systematic review of literature Appraisal of included studies Development of recurrence risk stratification Manuscript writing & editing
ISSN	2640-9615
IF	2,6

Post-Viva Addenda:

-Individual Fibre Diameter: Human skeletal muscle fibres, including those in the masseter, are generally 10 to 100 micrometers (µm) in diameter. Studies specifically on the human masseter have shown that average fibre diameters can range from roughly 17.9µm (Type II) to 46.7µm (Type I), with hybrid fibres falling in between. Fascicle Size: Muscle fibres are grouped into fascicles, which are surrounded by perimysium. These fascicles are significantly larger than individual fibres. Sarcomere Length: The sarcomere, the fundamental contractile unit, is roughly 2.27-2.55µm in length, depending on whether the jaw is open or closed.

-We are looking at the macro-architecture (muscle fascicles and connective tissue) rather than the micro-architecture (individual muscle fibres).

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Review Article

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Bio-Modelling Reconstruction Based on MRI Image Acquisition and there Application in Orthognathic Surgery

Duarte F[1*], Silva JN[2], Ramos C[3] and Hopper C[4]

[1]Oral Surgeon Specialist by OMD (Portuguese Dental Association), Master of Science in Oral and Maxillofacial Surgery at Eastman Dental Institute - University College of London, Master of Science in Laser Dentistry at Universitá Cattolica del Sacro Cuore, Italy, CEO and Clinical Director of Clitrofa, Portugal

[2]Member of the Interdisciplinary Center for Health Sciences (ICHS) - ISAVE - Instituto Superior de Saúde, Portugal

[3]MSc Student in Oral Rehabilitation at IUCS – Instituto Universitário de Ciências da Saúde - Portugal

[4]UCL Eastman Dental Institute, Oral & Maxillofacial Surgery Department

***Corresponding author:**

Fernando Duarte,
Clitrofa, Centro Médico, Dentário e Cirúrgico, Avenida de Paradela 622, 4785-248, Trofa, Portugal
ORCID: https://orcid.org/0000-0002-6885-2096

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1. Abstract

Orthodontic and surgical technical advances in recent years have resulted in treatment opportunities for a whole range of craniofacial skeletal disorders either in the adolescent or adult patient. In the growing child these can include myofunctional orthodontic appliance therapy or distraction osteogenesis procedures, whilst in the adult the mainstay approach revolves around orthognathic surgery.

The literature agrees that for a change in craniofacial morphology to remain stable, the muscles acting upon the facial skeleton must be capable of adaptation in their structure and, therefore, their function. Failure of the muscles to adapt to the change in their length or orientation will place undesirable forces on the muscle attachments leading to potential instability of the skeleton. Adaptation can occur through various processes including those within the neuromuscular feedback mechanism, through changes within muscle structure or through altered muscle physiology, and through changes at the muscle/bone interface.

The innovation in this study resides in the combination of the protocol presented to obtain the area and volume of the masseter muscle using Magnetic Resonance together with the bio-modelling reconstruction with the AnatomicsTM software.

2. Introduction

The size of the masticatory muscle varies with craniofacial morphology and is an important indicator of the functional capacity of the masticatory system [1-5]. The masseter muscle is considered to generate force biting or chewing and is one of the structures that is most altered by orthognathic surgery. Its postoperative status may influence the patient's physical appearance as well as masticatory function [1-3].

Orthognathic surgery in combination with orthodontic treatment, corrects the dentofacial deformity and improves occlusal contacts, masticatory efficiency, bite force, and electromyographic (EMG) activity. A number of studies reported the increased bite force and occlusal contact area after orthognathic surgery [2].

The functional and morphological characteristics of the masticatory muscle have been investigated in patients with dentofacial deformities. Patients with mandibular prognathism exhibit lower bite force, decreased occlusal contact, and lower electromyographic (EMG) activity than the normal subjects [2,3].

The masseter muscle displays a penniform structure typically characterized by the presence of alternating muscular/aponeurotic layers. The anatomical sections and the magnetic resonance imaging (MRI) section in the same plane allowed the appearance of the intra-muscular aponeurotic layers on the MRI to be defined [4].

The architecture of the masseter muscle has been studied for a long time but the lack of clinical applications led to descriptions which were often global or contradictory, giving the muscle sometimes two bundles sometimes three [4]. The successive studies of Gaspard [5-7], Yoshikawa [8,9] and Gaudy [10] allowed the definition of the arrangement of the muscular aponeurotic layers making up the human masseter muscle. Unger affirmed the value of magnetic resonance imaging in the oro-facial field for the study of the musculature of the tongue and the walls of the oral cavity, but gave only very general information on the masticatory muscle [11].

Orthognathic surgery in combination with orthodontic treatment, corrects the dentofacial deformity and improves occlusal contacts, masticatory efficiency, bite force, and EMG activity. A number of studies reported the increased bite force and occlusal contact area after orthognathic surgery [2].

Traditional methods in orthognathic surgery rely on the surgeon's skill and experience for precision, which can lead to variability in outcomes [12]. Moreover, translating two-dimensional pre-surgical plans into three-dimensional surgical procedures can be challenging and may affect the accuracy of the operation [13]. While experience and skill can help predict outcomes to some extent, the inherent unpredictability of human tissue responses post-surgery often leads to unexpected results [14]. This lack of predictability can result in dissatisfaction from patients who had different expectations of surgical results [15]. Every patient presents a unique anatomical framework and individual needs and expectations. Traditional methods, while customizable to an extent, do not provide the level of personalization and adaptability necessary to meet these varied needs [16].

As medicine moves towards patient-centric care, the demand for personalized surgical methods increases. Surgeons need to tailor surgical plans to the individual patient's anatomy and desired outcomes. The need for greater surgical precision and predictable outcomes is paramount in improving patient satisfaction rates and reducing complications [17]. Utilizing advanced technology can help achieve this by improving surgical planning, execution, and follow-up care. Incorporating 3D technology in surgical procedures can aid in better visualization of the surgical area, enhancing precision during surgery [18]. Furthermore, the ability to simulate different surgical scenarios can lead to better preparedness and more predictable outcomes. By enabling patients to visualize their surgical outcomes beforehand through virtual surgical planning, we can manage their expectations better and potentially enhance satisfaction rates. Moreover, less invasive surgery due to precise planning can lead to quicker recovery times and less post-operative discomfort, further improving the patient experience.

3. MRI Protocol Acquisition

MRI provides functional information in an anatomic presentation allowing to distinguish soft tissues with high sensitivity [19,20]. In a study of Dheyriat, to investigate the normal anatomy of masseter muscle, both at rest or during contraction by using three dimensional (3D) MRI the results are very interesting. The normal anatomical position of the masseter was reported to the skin plan as the mean internal distance (7.9 +/- 0.42 mm) and external distance (15.2 +/- 0.41 mm). While there was no difference between internal distance, for sex or side, the external distance was significantly ($p = 0.02$) shorter in male (7.7 +/- 0.5 mm) than in female (8.8 +/- 0.4 mm) for both sides. The mean volume for all subjects and both sides (20.3 +/- 1.1 cm3) did not change significantly between rest and exercise. The masseter volume was significantly ($p < 0.00001$) greater in male (24.2 +/- 2.0 cm3) than in female (16.4 +/- 3.6 cm3) groups [19]. These physiological references may be useful for further MRI investigations of masticatory system pathologies, like orthognathic surgery.

During this study the MRI machine used was a Sigma MR/I Twinspeed from GE Medical Systems, after several attempts the software was further developed to produce slices through the muscle at 1mm intervals rather than 2mm; the scanning time was about seven minutes. As a consequence, the resolution of the muscles was greatly enhanced. Further developments (reconstruction of muscles and bone from the same scan) have allowed visualisation of the muscle fibre orientation in relation to the muscle's bony attachments. Enabled the measurement of potential changes in orientation in relation to a static landmark unaffected by surgery (e.g., Frankfort plane) or in relation to functional identifiers (e.g., Occlusal plane) (Figure 1).

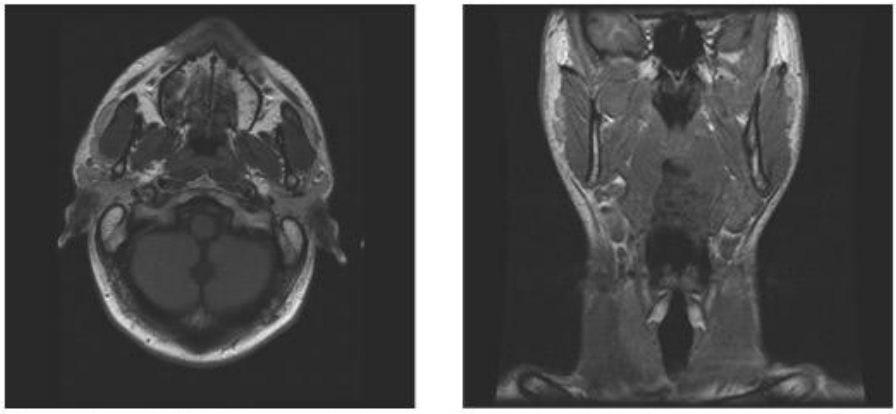

Figure 1: Images from the MRI scanner allowing the identification of the masseter muscle limits and fibres orientation.

4. Anatomics® Rx Software

The Anatomics® Rx software is a 3D DICOM viewer and allows to view CT and MRI scan data in both slice format and fully interactive 3D. Anatomics® can convert 3D images to the STL format for rapid prototyping, or as a bridge from medical imaging to Computer Aided Design (CAD). A good quality 3D scan is required to create an accurate biomodel or implant [21].

To standardise the scanning process, a scanning protocol was developed and applied that describe the preferred imaging parameters and provide the imaging technician with an area to note specifics. The patient must remain completely still during the scan, if the patient moves during the scan, it will need to be repeated. Only the original fine slice data must be used in the software, reformats will not be accepted. Fine overlapping slices must be used, the thickness of 1 mm (or nearest to) and a spacing of 0.8 mm.

The objective was to extract the muscle from the image (margins identification, extract the muscle considering the 3 planes of space, calculation of area and volume). The software allows the correction of limits at any time what gives the observer the capacity of double-check all the process (Figure 2).

The first masseter muscle 3D images reconstruction were acceptable in terms of definition, area and volume but with a lack of detail in terms of muscle fibres visualisation and orientation. Increasing the scanning time from five to seven minutes and changing the muscle slices to 1mm intervals was possible the acquisition of more muscle details. As a consequence, the resolution of the muscles was greatly enhanced and the final masseter muscle 3D images reconstruction permits a good visualisation of muscle fibres and their orientation. This type of reconstruction has also allowed visualisation of the muscle's bony attachments and enabled the measurement of potential changes in orientation in relation to a static landmark unaffected by surgery (eg. Frankfort plane) or in relation to functional identifiers (e.g., Occlusal plane) (Figure 3).

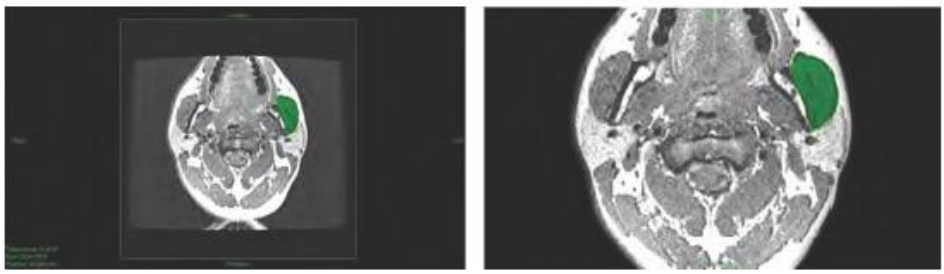

Figure 2: Identification of masseter muscle limits in a sagittal plane.

Figure 3: Final images from the left masseter muscle reconstruction using AnatomicsTM Software.

5. Bio-Modelling Reconstruction

Bio-Modelling is the generic term describing the ability to replicate the morphology of a biological structure in a solid substance. Specifically, bio-modelling has been defined as "the process of using radiant energy to capture morphological data on a biological structure and the processing of such data by a computer to generate the code required to manufacture the structure by rapid prototyping apparatus". A biomodel is the product of this process, and virtual reality is the generic term coined for the visualization medium [22].

The ability to extract accurate 3D images from MRI, has proven to be a very useful diagnostic tool, using the scanning process with fine overlapping slices of 1 mm thickness and a spacing of 0.8 mm during 7 minutes, was possible to extract the muscles and the facial bones from same scan. To judge the quality of the imaging protocol described and the bio-modelling reconstruction process in terms of detail, definition and fibre orientation two bilateral masseter muscles were printed using stereolithography.

The objective was to extract the muscle from the scan with secure margins identification and also to extract the facial bones with considerable detail. The software used was the AnatomicsTM that allows the correction of muscle and bone limits at any time. The reconstruction of muscles and bone from the same scan have allowed visualisation of the muscle fibre orientation in relation to the muscle's bony attachments. This could enable the measurement of potential changes in orientation in relation to a static landmark unaffected by surgery (eg. Frankfort plane) or in relation to functional identifiers (eg. Occlusal plane) (Figure 4).

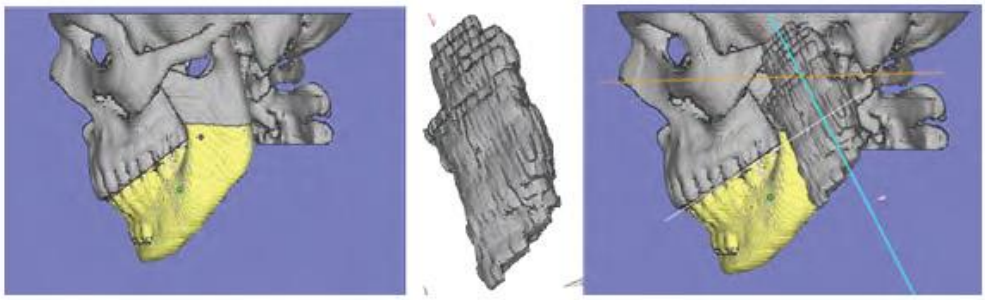

Figure 4: Bio-Modelling reconstruction of facial bones and masseter muscle.

6. Muscles Role

Many forms of interceptive treatment, whether they be purely orthodontic in nature or in combination with surgery, bring about changes in the muscles of mastication with regard to one or more of the following changes: a) in muscle fibre orientation, b) changes in the functioning length of fibres, c) changes in muscle structure and d) changes in muscle phenotype. Successful treatment requires both reorganisation in the connective tissue and regeneration of muscle fibres. Reorganisation of connective tissue is an extremely complex process involving muscle derived stem cells (satellite cells), extra-cellular matrix molecules and receptors for the extra-cellular matrix (for example integrins).

Remodelling of the extra-cellular matrix is mediated by a family of enzymes known as matrix metalloproteinases (MMPs) [9,10]. MMP2 is expressed during the regeneration of new myofibres and is a known mechano-responsive gene. A knowledge of how muscles respond to clinical interventions is pivotal to treatment success and can influence the way in which a particular treatment modality is applied. Functional appliances, for example, can be either fixed or removable, can be constructed to varying degrees of vertical opening and there are protagonists and antagonists for both gradual versus one-step activation of the appliances. Similarly, distraction osteogenesis is considered by many to be preferable to orthognathic surgery in specific cases because it induces a gradual as opposed to a one-step activation believed to be more physiologically appropriate for bone and possibly, muscle adaptation [9,10, 23, 24].

With regard to orthognathic surgery the golden rule is that surgery must not stretch the pterygo-masseteric sling, otherwise relapse is likely to occur. This is predominantly through the speed of insult to the muscle in relation to the timing of the muscle adaptive process. The consequence is either an immediate reversion back to the original functioning length of the muscle and return of the bony fragments back to their original pre-surgical position, and/or migration of the muscle attachment along the surface of the bone, thereby leading to an area of bone denuded of muscle force, which ultimately leads to resorption of the bony muscular processes [23,24].

One way in which this can be studied more closely is through refinements in protocols for 3-D magnetic resonance imaging of the face and jaws. Increasing the resolution of the tomographic cuts to 1.0mm has led to a resolution which facilitates the identification of not only the origins and insertions of the muscles of mastication but even the orientation of individual muscle fibre bundles (Figure 5A and B). It is therefore possible to study the changes in muscle fibre orientation in relation to landmarks such as the functional occlusal plane and also those landmarks unaffected by surgery, for example the cranial base (Figure 5C and D). Ideally, as mentioned, surgery to correct an increased vertical facial deformity should involve posterior maxillary impaction together with a mandibular procedure where the final outcome does not increase the posterior facial height and hence, does not stretch the pterygo-masseteric sling. As such the orientation of the muscle fibres

in relation to their functioning occlusal plane remains unaltered (Figure 5E). However, if there is failure to adequately impact the posterior part of the maxilla in such cases then there is a rotation of the mandibular segments around the premolar/first molar region resulting in a reduction of the anterior face height but an unwelcome increase in the posterior vertical dimension (Figure 5F) and thereby leading to an increase in the length of the ptergo-masseteric sling (Figure 5G). Furthermore, this leads to a much less efficient musculo-occlusal relationship and as such more extensive adaptation has to take place within the muscles in order to be able to accommodate the unwanted surgical change. In clinical cases where this unwanted change has occurred, there is not only a return towards the original pre-surgical bony relationships (Figure 5H) but also migration of the muscle attachment leaving an area of bone at the gonial angle which subsequently resorbs and leads to the unwanted and unsightly hour glass deformity of the mandibular border (Figure 5I).

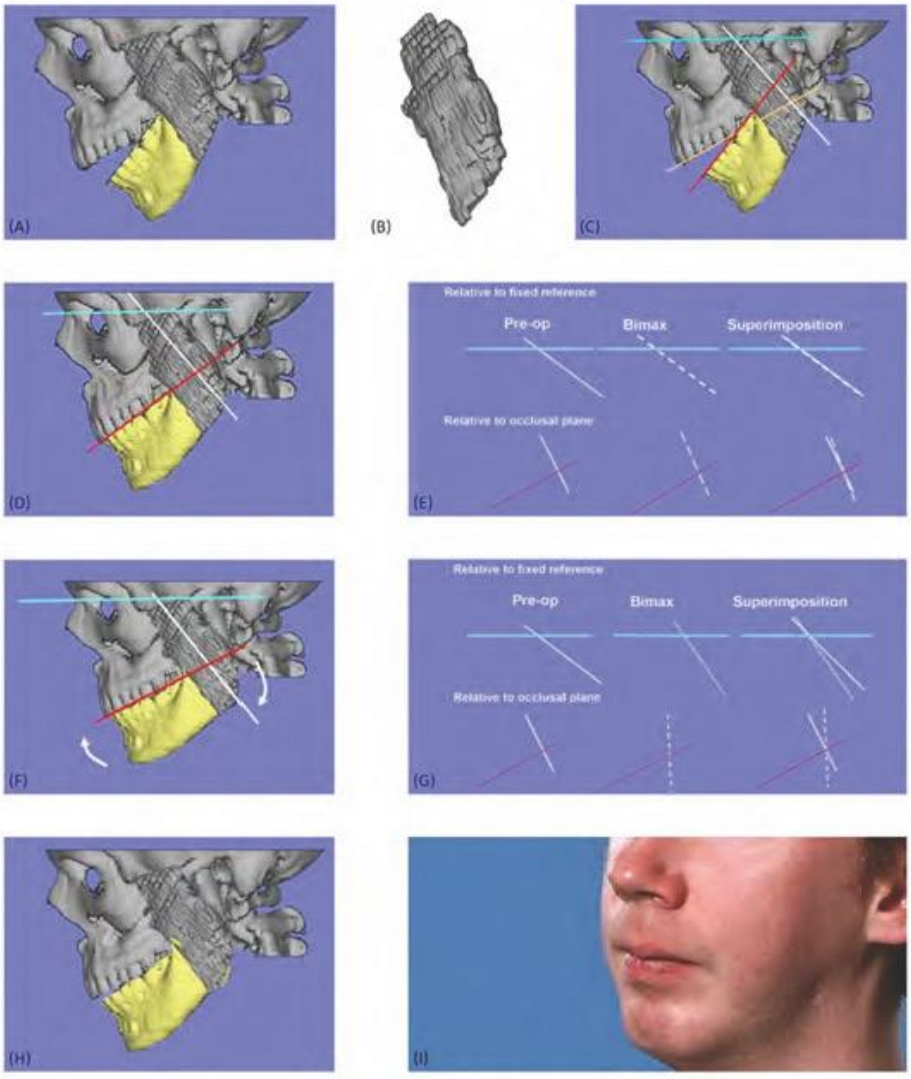

Figure 5: 3-D MRI showing detail of masseter muscle fibre bundle orientation (A and B). Favourable change in muscle length and fibre orientation following maxillary impaction and mandibular advancement surgery for closure of anterior open bite (C, D and E). Unfavourable change following insufficient posterior maxillary impaction with resultant stretch of pterygo-mandibular sling (F and G) and subsequent relapse (H and I).

7. Conclusions

A number of studies have reported increased bite force, occlusal contact area, and EMG activity and improved masticatory efficiency after surgery [25]; however, the reason for this improvement is unclear. It is a subject still under debate that surgery itself improves masticatory function. Previous studies reported that the postoperative improvements in muscular activity were due to better occlusal stability and not to surgically induced biomechanical advantages [25]. The importance of occlusion for the neuromuscular equilibrium and dental supports was investigated in patients undergoing orthognathic surgery. Changes in of muscle size; increased occlusal contact area providing greater dental support; sensitivity of teeth, muscles, and the temporomandibular joints; and even the patients' willingness to exert maximum effort have been suggested

as factors in determining the occlusal force after surgery [26].

MRI therefore seems to be a valid tool for measuring differences in the masseter muscle area (mm2) and masseter muscle volume (mm3) associated with high-severity occlusal deformities, although showing not to be as efficient in detecting the same differences in cases of low-severity occlusal deformities.

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INTEGRATED DISCUSSION

INTEGRATED DISCUSSION

Several studies have reported an increase in bite force, occlusal contact area, electromyographic (EMG) activity, and improved masticatory efficiency following surgery; however, the reasons for these improvements remain unclear (Lee & Yu, 2012). Previous research indicates that the improvements in muscular activity after surgery are primarily attributed to improved occlusal stability rather than direct biomechanical benefits from the surgery itself (Throckmorton *et al.*, 1996; Throckmorton & Ellis, 2001). A study investigated the significance of the occlusion in preserving neuromuscular balance and offering dental support for patients undergoing orthognathic surgery. Factors proposed to influence occlusal force postoperatively include changes in muscle size, an increased occlusal contact area that enhances dental support, sensory feedback from teeth, muscles, and the temporomandibular joints, as well as the patients' willingness to exert maximum effort (Lee & Yu, 2012).

Factors proposed to influence postoperative occlusal force

Relapse is a potential risk after orthognathic surgery (Minervini *et al.*, 2023). The incidence of relapse following orthognathic surgery has been the subject of extensive research in recent years. This ongoing process necessitates continuous assessment now and in the future (Sahoo *et al.*, 2022). Patients with cleft lip and palate (CL/P) have a higher risk of relapse compared to the general population, mainly due to the presence of additional risk factors like scarring (da Silva *et al.*, 2018). While the precise causes of this increased susceptibility are not fully understood, the association between CL/P and a higher likelihood of relapse is well established (da Silva *et al*., 2018). In a study by da Silva *et al.* (2018), patients with cleft lip and/or palate (CL/P) relapsed an average of 12.48 mm after surgery. In contrast, patients without cleft conditions exhibited significantly lower relapse. The groups had identical overjet values and maxillary advancement before surgery, ensuring a reliable comparison. An unstable, constricted, or hypoplastic maxilla in patients with cleft lip and palate is considered an iatrogenic consequence of previous surgical repairs (specifically palatoplasty and cheiloplasty) that create significant scar tissue, which in turn restricts, pulls, and inhibits normal maxillary growth.

The initial postoperative days can be particularly difficult for patients, and the healing process may take several weeks or even months (Inchingolo *et al*., 2023). To reduce the risk of relapse and its associated complications, it is crucial to identify the underlying causes (Inchingolo *et al*., 2023). Among these factors, the restoration of normal occlusal function and masticatory forces play a crucial role in maintaining postoperative stability. For this reason, the relationship between occlusal and bite forces before and after orthognathic surgery has been extensively studied (Ueki *et al.*, 2014; AlQahtani *et al*., 2023). Most of these studies have evaluated bite force using different approaches and have reported varying outcomes (AlQahtani *et al*., 2023).

However, the sensor positioning had a notable impact on the recorded occlusal forces, independent of the examiner or the postoperative period. This suggests that minor variations in sensor placement can lead to substantial differences in measured force distribution, potentially due to uneven contact pressure across the dental arch or the sensitivity of specific teeth to load. Sensor thickness is also very important as the more distal and thicker the sensor, the lower the anterior load will become by disocclusion and fulcrum physics/ geometry. Consequently, standardising sensor positioning protocols is essential to ensure accurate, reproducible assessments of occlusal force, particularly in patients recovering from orthognathic surgery, where small measurement discrepancies may obscure early signs of relapse or functional imbalance.

In a recent systematic review and meta-analysis, a protocol was developed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) and identified a total of 978 studies related to postoperative functional changes following orthognathic surgery (AlQahtani *et al*., 2024). The review concluded that occlusal strength generally increases after orthognathic surgery, though it does not reach the levels observed in healthy control groups. Conversely, maximum bite force did not show a significant improvement, whereas chewing and swallowing forces increased immediately after surgery. Occlusal strength/contact area: generally, increases and shows long-term improvement (stable at 6 months to 3 years) as the occlusion is anatomically corrected, improving interdigitation and skeletal stability; however, it often fails to reach the high levels of healthy control groups. Maximum bite force often shows little significant, immediate improvement, and in some cases, may even decrease temporarily due to nerve trauma or changes in muscle lever systems. While it shows improvement

over the long term (1–2 years), it rarely reaches the level of control groups. Chewing and swallowing forces, show an immediate increase after surgery; this is largely due to the improved occlusion, which allows patients to achieve better tooth contact and stability during functional, low-intensity, or moderate-intensity tasks (mastication) even if they cannot generate maximum voluntary force. The analysis revealed a significant reduction in postoperative occlusal contact pressure areas (AlQahtani *et al*., 2024). These findings are consistent with the results of our study, particularly regarding occlusal force behaviour.

Throckmorton and Ellis presented a study comparing sagittal split ramus osteotomy with and without Le Fort I osteotomy. This article evaluated two variables: lip closing force and occlusal force. The occlusal force was evaluated using a dental prescale and occluzer, which was connected to a computer interface, and they inferred that occlusal force improved postoperatively after orthognathic surgery (Throckmorton & Ellis, 2001).

Harada *et al.* (2003) reported that performing Le Fort I and bilateral sagittal split osteotomy using an occluzer improved bite force postoperatively after orthognathic surgery. These authors agreed with the study published by Throckmorton and Ellis, which opined that increased bite force after orthognathic surgery could be due to a difference in the morphology of dentoskeletal structure (Throckmorton & Ellis, 2001; Harada *et al*., 2003).

In our study, surgery recovery time affects the occlusal force measured by FSS sensors, irrespective of the examiner selection and/or the sensor position. The duration of recovery of bite force has not been consistent among various studies (AlQahtani *et al*., 2024). The recovery was assessed in most of the studies using variables including asymmetry, EMG activity of the temporalis and masseter muscle attachments, dentoskeletal abnormalities, and lip function tests. In all these studies, the recordings were performed preoperatively and at 1, 3, 6, and 12 months postoperatively (AlQahtani *et al.*, 2024).

The piezoelectric sensors used in the present studies have demonstrated high reliability and measurement validity. The selection of the examiner does not affect the measurement of occlusal force (N), which shows a good inter-examiner reliability. The sensor position influences the occlusal force (N) that is measured, with the increase in

sensor/temporomandibular joint distance increasing the occlusal force (N) measured, which is related to the complex dynamics of the human masticatory system. The surgery recovery time impacts the occlusal force (N), with a 50% increase in occlusal force (N) measured after 6 months post-surgery, with the value remaining stable at 36 months. This suggests that muscular adaptation is crucial, but does not inherently mean that reducing intermaxillary fixation is the sole cause of relapse. While muscle forces influence stability, relapses are more heavily influenced by factors like the magnitude of skeletal movement, specifically mandibular setback, rather than just the lack of intermaxillary fixation.

In terms of the advantages of the device presented, we can highlight the high repeatability as well as the sensitivity in measuring pre- and postoperative occlusal changes. From the point of view of limitations, we must mention the small number of clinical cases in which it was tested, which does not allow us to assess strong correlations.

Measurement of Occlusal Pressure

The Pressurex® positions used in the present studies have shown poor reliability and validity. Although the selection of the examiner does not affect the measurement of occlusal pressure (Psi) by pressure indicating films, which is positive, this method lacks sensitivity in detecting variations caused by the pressure indicating film position and the recovery surgery time.

This inferior performance compared to piezoelectric sensors makes Pressurex® operations, less suitable for studying the follow-up period of patients undergoing surgical dental procedures. However, this difference in pressure results may be related to the system’s smaller dimensions in clinical cases of anterior bite. It is also important to emphasise that these were pilot studies and, as such, comparison of the results obtained in these studies with similar ones is not possible.

MRI and Bio-Modelling

The architecture of the masseter muscle has been studied for a long time, but the lack of clinical applications led to descriptions which were often global or contradictory, giving the muscle sometimes two bundles, or sometimes three. The successive studies of Gaspard (Gaspard, 1987; Gaspard *et al*., 1976; Gaspard *et al*., 1973), Yoshikawa (Yoshikawa, 1961; Yoshikawa & Suzuki, 1962) and Gaudy (Gaudy *et al*., 1982) allowed the definition of the arrangement of the muscular aponeurotic layers making up the human masseter muscle. Unger affirmed the value of magnetic resonance imaging in the oro-facial field for the study of the musculature of the tongue and the walls of the oral cavity, but gave only very general information on the masticatory muscles (Unger, 1985).

Several studies investigated the changes in the size and masticatory force of the masticatory muscles after orthognathic surgery. Katsumata *et al.* indicated that in mandibular prognathism, the cross-sectional area of the masseter decreases after 3 months of mandibular setback but shows a tendency to return to normal after 1 year (Katsumata *et al*., 2004). In addition, Ueki *et al.* reported that there are no significant differences in the cross-sectional area of the masseter in mandibular prognathism 1 year after SSRO in comparison with the preoperative area (Ueki *et al.*, 2009). Trawitzki *et al*. also reported that when mandibular setback was conducted on patients with a class III dentofacial deformity, the thickness of the masseter muscle increased (Trawitzki *et al*., 2011). The study by Kang et al. showed that the volume-to-length ratio of the masseter and lateral pterygoid muscles at 1 year after mandibular setback did not differ significantly from the preoperative value (Kang *et al*., 2022).

In our study, significant differences ($p < 0,05$) were identified between Time 0 (pre-op) and Time 1 (6-12 months post-op) in the mean left masseter area (mm^2). It is interesting to notice, however, that the differences against Time 0 (pre-op) seem to disappear at Time 2 (3 years post-op), which may reveal the long-term decrease in the mean left masseter area (mm^2) or relapse Our results agree with those obtained by Katsumata but disagree with those reported by Ueki and Trawitzki. The masseter muscle generally takes 6 months to over 1 year to significantly remodel and realign to the new skeletal reality after orthognathic surgery, with substantial structural changes still occurring up to 4 years postoperatively, though key adaptation occurs in the first 6-12 months. This adaptation is crucial because surgery changes the length and orientation of

the mandible, requiring the muscles to adjust to new functional demands, such as corrected bite, altered chewing forces, and improved facial symmetry (Lee & Yu, 2012).

Continuous changes in masseter muscle size in our study indicate that not only was the skeletal environment altered by surgery, but additional adaptation to new stomatognathic environments also occurred over time, with improved occlusion and masticatory activity by orthodontic treatments. Our results partially agree with those reported by Katsumata (Katsumata *et al*., 2004).

Kikuta *et al.* reported that occlusal force was decreased 3 months after orthognathic surgery but increased 6 months after the surgery (Kikuta *et al*., 1994). The results of this study suggest that particular attention should be paid to the masseter muscle atrophy in patients with a worse open bite after preoperative orthodontic treatment and in those with maxillary undergrowth. However, in our opinion, it is unclear whether masticatory ability would be compromised by masseter muscle atrophy immediately after surgery, however, the biological response appears to have an important role to play.

Decreased maximum occlusal force has been reported in patients with open bite, supporting the finding that increased open bite was associated with decreased masseter muscle cross-sectional area (Piancino *et al.*, 2012; Jokaji *et al*., 2022).

An adequate sample size makes the investigation more representative: the data generated is reliable, the investment of resources is as limited as possible, while complying with ethical principles. The sampling design directly influences the research results. The sample of 10 patients shows that this is an uncommon type of surgery, performed in most cases in private health services and requiring the patient's financial means.

MRI therefore seems to be a valid tool for measuring differences in the masseter muscle area and volume associated with high-severity occlusal deformities (maxillary Le Fort I impaction of 6 mm), although showing not to be as efficient in detecting the same differences in cases of low-severity occlusal deformities (maxillary Le Fort I impaction of 2 mm for minor and 4 mm for intermediate cases), perhaps based on the limitations in detecting subtle, small-scale anatomical variations.

The explanation for the results obtained may lie in the following factors: a) High-Severity vs. Low-Severity Differences: In cases of high-severity malocclusion, the adaptation of the masseter muscle (changes in volume and cross-sectional area) is significant enough to be clearly distinguished from normal, pre-operative conditions. In contrast, for low-severity cases, the muscle alterations are more subtle, making it harder to differentiate these changes from the background noise. b) Resolution and Signal-to-Noise Ratio Limits: While MRI provides excellent soft-tissue contrast, the ability to measure minute variations depends on the voxel size (spatial resolution). If the physical change in the muscle size (e.g., a slight decrease in thickness) is smaller than the MRI's resolution limit or falls within the acceptable range of measurement error, the device cannot accurately detect it. c) Imaging Segmentation Challenges: Accurate measurement requires identifying the boundaries of the masseter muscle (segmentation). With minor atrophy or hypertrophy of low severity, it can be technically challenging to segment the muscle from surrounding fat and connective tissue, thereby reducing the reliability of the measurements.

Future Statistical Evaluation

In some of the publications, significant standard deviations were found, which can be explained as follows: On the one hand, in the repeatability studies, patients with different occlusal conditions were included, and the intended occlusal force and pressure measurement protocols were explained. The construction of a training machine was one of the ways found to minimise this discrepancy. On the other hand, in the group of patients undergoing surgery, with similar occlusal conditions, pilot and follow-up studies expected these types of results, given the skeletal changes that would be reflected in measurements of occlusal force and pressure.

Future studies should place special emphasis on reliability and validity, as these are fundamental criteria for evaluating the quality of measurements in surveys and statistical inferences. Reliability refers to the consistency, stability, and repeatability of measurements, while validity refers to the accuracy and truthfulness with which an instrument measures what it is intended to measure.

CONCLUSION & SUMMARY

CONCLUSION & SUMMARY

All methods discussed demonstrate at least one aspect of their effectiveness in detecting changes in the structure and function of masticatory muscles. However, the limitations of each method suggest that a combination of approaches would provide optimal sensitivity and reproducibility.

The piezoelectric sensors utilised in Phase 1 have demonstrated high reliability and validity in measurements. The examiner selection does not affect occlusal force measurement, indicating strong inter-examiner reliability. However, the sensor's position affects the measured occlusal force (N); specifically, increasing the distance between the sensor and the temporomandibular joint results in higher occlusal forces. Sensor thickness is also very important as more distal and thicker the sensor, the lower the anterior load will become by disocclusion and fulcrum physics/ geometry. This phenomenon is linked to the complex dynamics of the human masticatory system. The pterygomasseteric sling (composed of the masseter and medial pterygoid muscles) and the temporalis muscle act as powerful elevators of the mandible, creating a lift force that is optimised based on the distance from the temporomandibular joint (TMJ). In essence, the sling is most efficient at lifting when the jaw is positioned to capitalise on the maximum vector of the muscle, usually behind the incisors, where the lever arm is shorter than at the very tip, allowing for greater force.

The surgery recovery time impacts the occlusal force, with a 50% increase in occlusal force measured after 6 months post-surgery, with the value remaining stable at 36 months. This suggests that the patient is only fully recovered from the functional point of view at 6 months, having from that point on an improved and stable masticatory function.

The pressure-indicating film positions used in Phase 2 have demonstrated poor reliability and validity. While the choice of examiner does not influence the measurement of occlusal pressure (Psi) using pressure-indicating films—a positive aspect—this method lacks the sensitivity required to detect variations arising from the positioning of the pressure-indicating films and the timing of recovery surgery. Compared with piezoelectric sensors, the performance of pressure-indicating films is inferior, making

them less suitable for studying the postoperative period in patients who have undergone orthognathic surgery.

On the other hand, MRI, employed in Phases 3 and 4, appears to be a valid tool for assessing differences in the area and volume of the masseter muscle associated with high-severity occlusal deformities (such as a maxillary Le Fort I impaction of 6 mm). However, it has shown reduced efficiency in detecting similar differences in cases of low-severity occlusal deformities (with maxillary Le Fort I impactions of 2 mm for minor cases and 4 mm for intermediate cases).

Even with an identical diagnosis, surgeons may have different treatment goals based on their treatment philosophy and patient desires. Each surgeon has a unique cultural perspective on ideal aesthetics, balancing it with improvements in occlusion, skeletal discrepancies, and airway changes. Despite the publication of normal values, a degree of facial aesthetics will always be qualitative and will vary with age, sex, and culture.

Post-surgical stability is a key measure of a surgical procedure's effectiveness, as it directly reflects the ability to maintain the desired outcomes over time, whether in the short- or long-term. Relapse, defined as the loss of skeletal or dental corrections that were aimed for and achieved during the surgical procedure, is a significant concern and one of the most challenging post-surgical complications to manage. The causes of relapse are multi-factorial, encompassing both short-term and long-term factors. Short-term relapse may result from condylar dysmorphology, muscular tension due to significant surgical movements, and improper positioning of the condyles in the glenoid fossa. Since these issues can arise almost immediately after surgery, the initial post-operative phase is critical for monitoring and intervention. Long-term relapse, on the other hand, in adult orthognathic surgery is primarily associated with biological remodelling and structural changes rather than active facial growth. While skeletal growth is mostly complete, the mandibular condyle remains a dynamic, adaptable, and susceptible structure that can undergo progressive remodelling in response to modified loading conditions or systemic factors (Sahoo *et al*., 2022).

In most scientific publications, there is a predominant focus on bone tissue, often overlooking the study and evaluation of muscle tissue. In the literature, there are no studies that simultaneously evaluate masticatory function using multiple methods, thereby justifying this project. This research project was conceived to combine several recently developed, more sophisticated methods to enable surgical planning to also consider muscle function, which is essential for the success of the treatment.

The masseter muscle is critical in orthognathic surgery because it dictates postoperative stability, functional recovery, and facial aesthetics. Studying the masseter muscle alone is justified because it is the primary masticatory muscle that determines external facial width and aesthetics. It undergoes significant, measurable structural changes (volume and thickness) that directly correlate with facial asymmetry correction and surgical stability, unlike the more deeply located medial/lateral pterygoids that are harder to isolate.

We therefore believe that assessing the area, volume, and fibre orientation of the masseter muscle should be included as parameters in the development of a treatment plan. Ongoing studies with larger patient samples are evaluating the effectiveness of orthognathic surgery changing masticatory muscle structure and function.

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ANNEX

FORM UPR16

Research Ethics Review Checklist

Please include this completed form as an appendix to your thesis (see the Research Degrees Operational Handbook for more information

UNIVERSITY OF PORTSMOUTH

Postgraduate Research Student (PGRS) Information				Student ID:	2158917
PGRS Name:	Fernando Manuel Pinto Duarte				
Department:	Faculty of Science and Health	First Supervisor:	Prof. Chris Louca		
Start Date: (or progression date for Prof Doc students)	03/02/2025				
Study Mode and Route:	Part-time ☒	MPhil ☐	MD ☐		
	Full-time ☐	PhD ☒	Professional Doctorate ☐		

Title of Thesis:	Masseter Muscle Adaptation Following Orthognathic Surgery
Thesis Word Count: (excluding ancillary data)	14229

If you are unsure about any of the following, please contact the local representative on your Faculty Ethics Committee for advice. Please note that it is your responsibility to follow the University's Ethics Policy and any relevant University, academic or professional guidelines in the conduct of your study

Although the Ethics Committee may have given your study a favourable opinion, the final responsibility for the ethical conduct of this work lies with the researcher(s).

UKRIO Finished Research Checklist:
(If you would like to know more about the checklist, please see your Faculty or Departmental Ethics Committee rep or see the online ve the full checklist at: https://ukrio.org/publications/code-of-practice-for-research

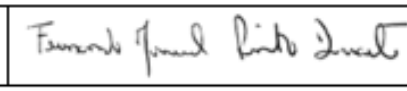
a) Have all of your research and findings been reported accurately, honestly and within a reasonable time frame?	YES ☒ NO ☐
b) Have all contributions to knowledge been acknowledged?	YES ☒ NO ☐
c) Have you complied with all agreements relating to intellectual property, publication and authorship?	YES ☒ NO ☐
d) Has your research data been retained in a secure and accessible form and will it remain so for the required duration?	YES ☒ NO ☐
e) Does your research comply with all legal, ethical, and contractual requirements?	YES ☒ NO ☐

Candidate Statement:

I have considered the ethical dimensions of the above named research project, and have successfully obtained the necessary ethical approval(s)

Ethical review number(s) from Faculty Ethics Committee (or from NRES/SCREC):	UCL Hospitals NHS Trust, Reference No.03/E012.

If you have *not* submitted your work for ethical review, and/or you have answered 'No' to one or more of questions a) to e), please explain below why this is so:

Signed *(PGRS)*:		Date: 10/11/2025