A COMPARISON OF INFECTIVE COMPLICATIONS ASSOCIATED WITH THE TWO TECHNIQUES EMPLOYED IN MINIPLATE OSTEOSYNTHESIS FOR FRACTURES OF THE MANDIBULAR ANGLE

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ABSTRACT

This pilot-study evaluated a population of 24 patients with fractures of the mandibular angle as they present or were referred for treatment at the Maxillofacial Unit at University College London Hospitals. There were 4 females and 20 males with an age range of 16-39 years.

The patients were randomised into one of two treatment groups, these were internal fixation using either the transoral or transbuccal approaches, both of which are acceptable forms of treatment. The osteosynthesis miniplate system used was the Leibinger system which uses 2 mm titanium miniplates.

14 patients were treated via the transbuccal approach and 10 patients with the transoral approach.

Patients were reviewed at fortnightly intervals for the first month, then at 3 months following surgery and then as required.

Post-operative radiographs consisting of an orthopantomogram and postero-anterior (PA) mandible were taken immediately post-operative, and again at 3 months.

A non-parametric test to evaluate the groups for each of the outcome variables was used.

Whilst not statistically significant, there appears to be a trend, towards a lower complication rate for the transbuccal approach.

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

DECLARATION

"Except for the help listed in the Acknowledgements, the contents of this thesis are entirely my own work. This work has not been previously submitted, in part or in full, for a degree or diploma of this or any other University or examination board".

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

INDEX

CHAPTER 1 - INTRODUCTION

Treatise on mandible fractures appeared as early as 1650 BC, when an Egyptian papyrus described the examination, diagnosis, and treatment of mandibular fractures and other surgical ailments. Such cases were thought to be incurable and therefore were not treated, with death of the patient a common sequela.

Hippocrates described direct reapproximation of the fracture segments with the use of circumdental wires, similar to today's bridle wire. He advocated wiring of the adjacent teeth with external bandaging to immobilize the fracture. He had the insight to realize that reapproximation and immobilization are paramount in the treatment of mandibular fractures. Many authors and physicians have described the treatment of mandibular fractures. Ideas have varied, but all treatments were subtle modifications of the hippocratic concept of reapproximation and immobilization.

It was not until 1180 that a textbook written in Salermo, Italy, described the importance of establishing a proper occlusion. In 1492, an edition of the book *Cyrurgia* printed in Lyons made first mention of the use of maxillomandibular fixation in the treatment of mandible fractures. In 1795, Chopart and Desault described the effects of the elevator and depressor muscles on the mandibular fragments. Chopart was also the first to use dental prosthetic devices in an attempt to immobilize fracture segments.

Through the 1800s and early 1900s, several methods were used to reduce and immobilize mandibular fractures. Although many techniques were advocated in the literature, most were variations of bandaging; extraoral and intraoral appliances; monomaxillary wiring, (including bars, monomaxillary splints, intermaxillary wiring and splints); guides or glides; and internal fixation (including wires, plates and screws), (Fonseca *et al*., 1997).

Today, as in the past the aim of mandibular fracture treatment is the restoration of anatomic form and function, with particular care to restablish the occlusion (Iizuka *et al*., 1991; Fedok *et al*., 1998).

CHAPTER 2 - LITERATURE REVIEW

2.1 - APPLIED SURGICAL ANATOMY OF THE MANDIBULAR BODY: BIOMECHANICAL CONSIDERATIONS

The mandibular body is a parabola-shaped curved bone composed of external and internal cortical layers surrounding a central core of cancellous bone. The outer cortical layer is particularly strong and gives good anchorage for osteosynthesis devices. In the chin region the cortical bone is thickest at the lower border, whereas more posteriorly it is relatively thin. At the angle, stronger parts are found along the external oblique line which runs from the coronoid process to the molar region, forming a ridge. Cross-sections in the subapical area reveal on average a thickness of 2.2-2.4 mm at the symphysis and in the canine regions. From the first bicuspid to the first molar the density increases from 2.5 to 3.4 mm. In the tooth-bearing alveolar process the bone is of variable thickness.

Another important anatomic factor with reference to fracture treatment using internal fixation is the mandibular canal, containing the neurovascular bundle. The mandibular canal runs from the lingula of the mandible to the mental foramen in a concave course directed upwards and forwards. The distance between the canal and the outer cortical layer averages 4.0 mm in the bicuspid region, increasing to 5.9 mm at the second molar. The distance between the root apices varies from 3.7 mm (central incisors) to 6.3 mm (third molar).

The most important anatomic factor regarding the treatment of mandibular fractures, either by closed reduction or by direct skeletal fixation, is the presence of teeth in the mandible and maxilla. The teeth in occlusion form a very sensitively balanced system: any disturbance caused by displaced fragments leads to diminution of masticatory function and comfort. The main aim in fracture treatment is therefore the restoration of the normal occlusion and intermaxillary fixation can be used either as the definitive treatment or as a temporary measure to control and stabilize the reduced fragments, while performing direct skeletal fixation (Warren *et al.*, 1997; Booth *et al.*, 1999).

The masticatory function of the mandible is governed by the jaw-opening muscles inserted on to the lingual aspect of the anterior mandible (digastric, lateral pterygoid, geniohyoid, mylohyoid) and the jaw-closing muscles (masseter, medial pterygoid, temporalis) inserted on the posterior mandible (Ellis *et al*., 1992). Due to the action of these muscle groups, in the absence of early treatment of a fracture in the mandibular angle region, the proximal fragment is gradually displaced upwards and forward around an axis going through the condyle (Shetty *et al*., 1995).

Champy *et al*. (1978), describes zones of tension in the mandible, generally along the upper border, where strategic plate placement would provide not only fixation, but allow natural functional forces to apply compression at the lower border of the mandible. This provides a number of advantages: a) plate placement sites are usually easily accessible intraorally; b) only relatively small miniplates are required for fixation; c) the technique uses the natural functional forces, thus minimizing surgical procedures and operating time.

The anatomic form of the mandibular body and the influence of muscular pull create characteristic strains within the bone (Rudman *et al*., 1997). These are predominantly bending and torsion moments (Cawood, 1985; Shetty *et al*., 1995; Renton *et al*., 1996). Bending moments are found in the upper part of the mandible, increasing to a maximum at the angle, whereas exclusively compression strains are present along the lower border (Halling *et al*., 1991; Kroon *et al*., 1991; Ellis *et al*., 1992; Assael, 1994). Torsion moments are also evident in the anterior part (in adult patients between the canines), increasing in strength to the midline (Levy *et al*., 1991).

The actual stress patterns that occur in the human mandible are influenced by several factors that include the osseous anatomy, the forces exerted by the muscles of mastication, the occlusal loading pattern, and for fractured mandibles, the location of fixation appliances. The theory of tension band plating for the treatment of mandibular angle fractures appears to be accurate; however, the model that Champy used to illustrate this theory was imprecise (Rudman *et al*., 1997).

2.2 - CLOSED REDUCTION

The traditional closed reduction of mandibular fractures consists of direct or indirect interdental wiring to produce intermaxillary fixation.

In emergency situations or prior to definitive fracture treatment the Ernst ligature, which is especially popular in Germany, is recommended. A soft steel wire (diameter 0.4 mm) is used in a figure-of-eight to loop together two adjacent teeth. One wire is pushed through the anterior interdental space, the other through the posterior interdental space, and together they are returned to the vestibule through the central interdental space. The ends are twisted together, shortened to about 5 mm, and turned towards the gingival margin in the form of a hook. A rubber band is then fixed between the hooks linking the maxilla and the mandible, or the hook ends are twisted together.

Another simple wiring method is that of Gilmer. In both jaws a single wire ligature is passed around each tooth, emerging through the interdental spaces; for intermaxillary fixation the maxillary wire ends are twisted together with the mandibular ones. Other methods include inter-dental eyelet wiring-Ivy; and continuous oral multiple-loop wiring-Obwegeser (Fonseca *et al*., 1997).

Schuchardt's technique of arch wiring is stable and protects the periodontium: a semicircular 2 mm thick soft wire is connected to 6-8 perpendicular cross-wires and bent across the vestibular surface of the teeth just below their equator; the short cross-wires are turned over toward the occlusal plane of the teeth so as to prevent the archbar slipping to the gingival margin. The bar is then fixed to each tooth with single ligatures. Following this, the bar and wires are covered with self-polymerizing acrylic resin which fills the spaces between the wiring and the teeth, thus providing absolute stabilization. After application to the maxilla and the mandible, the remaining cross-bars are shortened and connected with rubber bands or additional wiring to establish intermaxillary fixation. Archbars may be preformed or custom made on a plaster model. For partially dentate jaws archbars with prosthetic saddles are prefabricated in the laboratory; other methods include orthodontic banded dental-arch wires, open cap splints, and cast metal splints (Booth *et al*., 1999).

Potential problems with intermaxillary fixation are well known and include disturbances in phonation, compromised oral airway, inadequate nutritional intake with weight loss, social inconvenience, temporomandibular joint articular cartilage thinning or ankylosis, and patient noncompliance with frequent removal of arch bars (Levy *et al*., 1991; Schmelzeisen *et al*., 1992; Tuovinen *et al*., 1994; Kuriakose *et al*., 1996).

2.3 - OPEN REDUCTION

Open reduction involves exposure of the fracture, through either the skin or the mucosa. Once opened, the fracture can then be reduced and directly fixed through the incision.

Thirty years ago, open reduction was reserved for cutaneously compound fractures, or certain unstable mandibular fractures. Currently with the availability of osteosynthesis, many fractures are treated by open reduction, allowing direct access for fixation. This greatly improves the precision of the reduction, as the fragments can be carefully examined and manipulated.

The move towards open reduction of fractures with semi-rigid internal fixation has resulted from the refinement of aseptic technique to minimize de novo infection, the advent of effective antibiotics for prophylaxis and treatment, and the realization that, although bone is usually not devitalized by open surgery, if it is, it behaves as a bone graft, acting as a template for new bone growth, rather than as a foreign body promoting infection.

The acknowledgement that open surgery on fractured bones was biologically feasible was hampered by there being no reliable and biocompatible metal from which to fashion plates and screws. This was overcome in 1929 with the development of the cobalt-chromium-molybdenum alloy, vitallium, and this material along with stainless steel and titanium has since provided non-corrosive biocompatible metals for osteosynthesis. Of these metals, titanium has become pre-eminent owing to its malleability, lack of memory and strength, along with a long history of biocompatibility in the human body when used for a wide variety of prostheses.

It later fell to workers such as Michelet to transfer orthopaedic steel metacarpal plates to use in rigid internal fixation of mandibular fractures via the intraoral approach. Michelet's (1973) monocortical miniplate technique was refined by Champy (1978), who designed steel miniplates specifically for use with the facial skeleton and carried out valuable research work with his colleagues in order to define a rationale for positioning plates along stress lines in the mandible. As a result of this work, Champy et al. (1978) identified an upper tension zone and lower compression zone.

Miniplate osteosynthesis is usually performed under general anesthesia with nasal intubation to permit control of the occlusion during osteosynthesis. The fracture site is exposed by periosteal elevation as far as is required to place the plate. Special attention is given to protecting the mental nerve when performing the incision and during reflection of the periosteum around the mental foramen (Michelet et al., 1973).

The great advantage of open reduction is the lack of requirement for maxillomandibular fixation, which is attractive to patients and surgeon.

The choice between open and closed reduction may be clear in some cases, but there are many in which both are equally acceptable. Currently, with good surgical technique and safe anaesthesia, open reduction offers the best opportunity to obtain effective reduction and immobilisation. In most cases this means a safer postoperative recovery and earlier return to normal function and discharge.

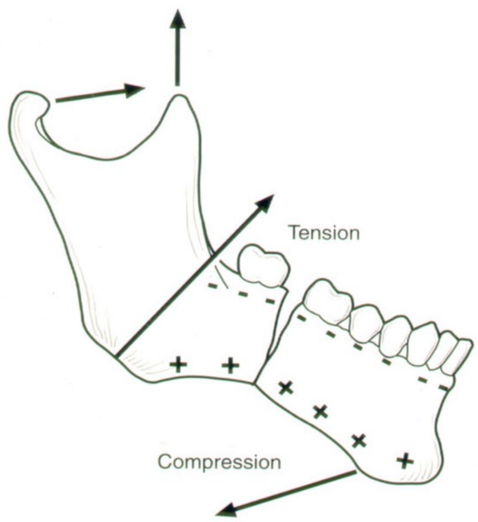

Figure 1 - Diagram of a fractured mandible to illustrate the tension forces along the alveolar border (---) and compression forces along the lower border (+++). The arrows indicate muscular tension (From Champy *et al*., 1978).

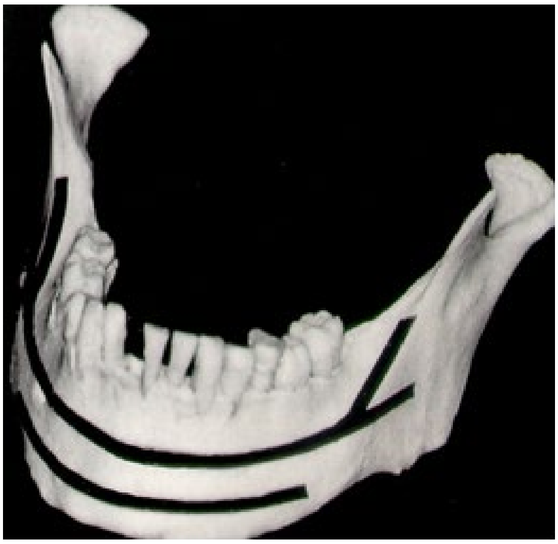

Figure 2 - Ideal lines for miniplate osteosynthesis for the mandible (From Champy *et al*., 1978).

2.4 - EXTERNAL PIN FIXATION (EPF)

External pin fixation (EPF) may be suitable in certain circumstances such as infected fractures or gunshot injury. Currently it is used in distraction osteogenesis.

In 1942 Converse and Waknitz developed EPF from a method of treating limb fractures into a practical treatment for mandibular fractures. Since World War II it has been extensively modified.

The EPF method consists of anchoring threaded pins in the bone fragments. The screws are applied transcutaneously at a distance from the fracture, and project from the skin, where they are connected to each other by a bar. Local forces are bourne by this external supporting bridge structure, thus the continuity of the mandible is maintained by the mechanical structure. In addition is possible to manipulate the fragments.

Compared to the internal fixation method, EPF is advantageous in that surgical exposure of the fracture gap is not required, and the operation requires local and general anesthesia. A particular advantage is the potential for non-invasive correction of fragment dislocations after fixation by adjustments to the external bar. However, EPF is not commonly used: it may be employed to treat external defects and comminuted fractures, such as those resulting from gun-shot injuries, and in emergency situations for temporary immobilization of mandibular fragments.

The reasons for its infrequent use currently are the visibility of the device and discomfort where the pins enter the skin. Moreover, the stability of the system may be insufficient to prevent relative movement in the fracture gap. In addition, the screws may work loose in time, produce ugly scars, or be infected.

2.5 - SURGICAL APPROACHES TO THE MANDIBLE FOR DIFFERENT METHODS OF INTERNAL FIXATION

Depending on the planned method of internal fixation and the site of the fracture, three different surgical approaches to the mandibular body, with slight modifications, are possible: intraoral, extraoral or combined access.

The intraoral approach is used predominantly for the application of miniplates, 3D plates, and, especially in the anterior part, for lower border interosseous wiring, lag screw osteosynthesis and compression plating. Disinfection of the oral cavity with chlorhexidine, and infiltration of a local anaesthetic with adrenaline 1:80.000 to control haemorrhage is advisable. The standard incision line lies in the buccal sulcus: in the body about 5mm below the attached gingival, and in the angle, region following the external oblique line. Most surgeons perform the incision through mucosa and periosteum in one step. In order to avoid postoperative suture dehiscence, it is advisable to incise the mucosa first and to continue the dissection of the underlying muscular attachments and the periosteum at right angles to the underlying bone. This thus gives a “two-layer” closure.

The fracture site is then exposed by subperiosteal dissection to allow placement of the plate. Special attention needs to be given to protecting the mental nerve, which is identified during the supraperiosteal dissection. If exposure of the neurovascular bundle is necessary an incision has to be made through the periosteum over the mental nerve. In edentulous mandibles the incision line is placed at the level of the alveolar ridge. To provide complete exposure of the symphyseal region, including the lower border, the use of the degloving technique is recommended. The flap is first reflected in the usual manner, the assistant firmly turns down the lower lip as the surgeon continues to elevate the periosteum. The symphysis is thus “degloved” and the whole of the symphysis and inferior border can be visualized. With some restrictions this technique may be extended to the posterior part of the mandible, when a wider retraction of the neurovascular bundle is required. This is performed by tracing the mental nerve superiorly while a bur is used to enlarge the mental foramen in a posterior and inferior direction. The degloving technique is only advised when performing lower border wiring or osteosynthesis using the intraoral approach.

The extraoral approach may be only required for the mandibular body/angle; the symphysis and parasymphysis regions usually can be approached intraorally. For the angle an incision should be made in a natural skin crease approximately two finger breadths below the lower mandibular border. The skin and subcutaneous tissue are incised; dissection of the platysma takes place at right angles to the muscle fibers. The incision should be just long enough to provide adequate exposure of the fracture site to perform the osteosynthesis.

In order to protect the marginal branch of the facial nerve when dissecting towards the lower border of the mandible the operator should remain deep to the investing layer of deep cervical fascia, at approximately the level of the submandibular gland.

Using the combined approach, the fracture site is exposed via an intraoral incision. In most cases, a straight plate, which will provide two holes on either side of the fracture, is used. Care must be taken in positioning screws to ensure they do not enter the fracture line, thus weakening the osteosynthesis, or penetrate structures such as tooth roots and the inferior dental neurovascular bundle. When treating mandibular angle fractures there are two acceptable surgical methods: the transoral and the transbuccal approaches. In the transbuccal approach the plate is placed along Champy's tension lines. The first screw hole is drilled through the outer cortex with generous saline irrigation to aid bone cutting and minimize over-heating. The holes are drilled and screws inserted transbuccally using a puncture incision extraorally above the plate, and a trocar is inserted transcutaneously for drilling and tightening of the screws. The sharp trocar and cannula supplied with the osteosynthesis kit is pushed through the cheek and the trocar removed. The cannula can now be manipulated over each screw placement and a special long drill piece placed through the cannula is used to drill the bone perpendicularly. The plate is then manoeuvred into position intraorally and screw placement effected again through the cannula, with a screw-holding driver.

A 7 mm screw is usually adequate to fix the plate to one fragment before the process is repeated in a screw hole over the second fragment. With the plate attached to underlying bone, any final adjustments can be made to bone or plate position prior to the drilling of holes and placement of the remaining screws.

At the end of the procedure, one fine monofilament suture is usually sufficient to close the transbuccal skin wound.

Alternatively, the use of a right-angle drill unit and screwdriver permits the fixation, especially of miniplates, even in unfavorable positions, without an extraoral approach.

The transoral approach fallows the same principles described above, however the plate is placed on the external oblique ridge without need for a trochar for screw placement.

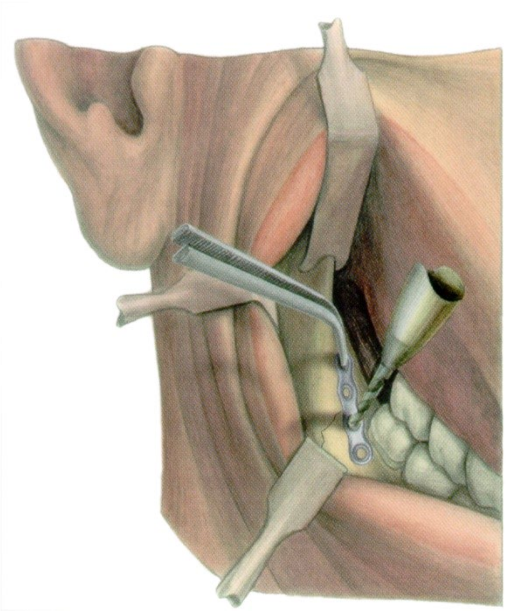

Figure 3 - Transoral approach with the plate placed on the external oblique ridge (From Harle *et al*., 1999).

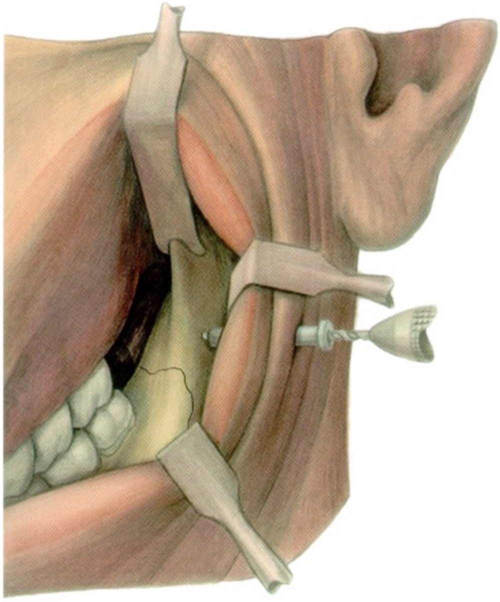

Figure 4 - Transbuccal approach with the plate placed on the buccal cortex (From Harle *et al*., 1999).

2.6 - FIXATION METHODS

2.6.1 - INTEROSSEOUS WIRING

Interosseous wiring is the direct skeletal fixation of two or more bone fragments with the aid of wire ligatures pulled through previously drilled holes. This technique for treatment of mandibular fractures was initially popularised in the mid-19th century. However, because of a disproportionately high complication rate caused by poor asepsis, the use of corrodable materials and insufficient stability, it was not routinely practiced until the 1950s (Iizuka et al., 1993; Nakamura et al., 1994). In an addition to the different techniques of intermaxillary fixation it became the treatment of choice to stabilize mandibular fractures.

The wire ligatures keep the fragments in exact anatomic alignment following reduction, but supplementary fixation of the fractured mandible with splints and intermaxillary fixation is required to maintain stability. The development of the modern plate and screw osteosynthesis systems has gradually replaced the use of interosseous wiring. Currently the technique is indicated for replacement of small fragments in grossly comminuted fractures, and for temporary stabilization of the fragments during plate and screw osteosynthesis. There may however be economic considerations; that dictate this approach.

The required instruments are two bone-holding forceps and a twist drill or Lindemann bur; curved forceps are also helpful.

Depending on the type of fracture, various shapes of wire ligature are advocated.

The wiring osteosynthesis is performed via either an intraoral or an extraoral route. The latter provides a good overview of the fracture sites in the distal part of the mandibular body, including the angle (Fonseca et al., 1997).

Wire osteosynthesis is most commonly used for angle fractures and placed at the superior border of the mandible, (the upper border wire). The wire is placed via an intraoral approach. Concomitant removal of an impacted third molar allows excellent access and easy placement of the wire. The wire is positioned across the fracture site through the cortical bone, and tightened after fracture reduction when control of the fragments is required inferiorly, the lower border wire technique is required.

After a standard submandibular approach, the periosteum is cut along the lower border of each fragment, and on both the lateral and the lingual surfaces is reflected upwards for about 1 cm. Fragments can be grasped and thus reduced with bone-holding forceps. When the occlusion secured by means of intermaxillary wiring and reduction has been performed holes are drilled approximately 6 mm distant from the fracture line, passing through the outer as well as the inner cortical layer. Continuous irrigation with Ringer's solution protects the bone from overheating. The use of a lingually placed spatula prevents damage to the soft tissue. Care must also be taken not to drill into the inferior dental canal following which an osteosynthesis wire is placed. It must be stressed that wire osteosynthesis is not stable on its own: Maxillomandibular fixation (MMF) is also needed.

Dym in 1992 described the bone screw-wire osteosynthesis technique, that has been shown to be a quick and effective treatment in controlling unfavorable mandibular angle fractures when used in open reduction procedures. It provides a more stable fixation than simple intraosseous wiring techniques because the wire is wrapped and tightened around a screw and cannot rotate and pivot around a point contact as can occur with a simple wire-hole technique.

Metal plate stabilization, either by a compression or noncompression technique, is now considered the state of art (Levy et al., 1991; Schmelzeisen et al., 1992).

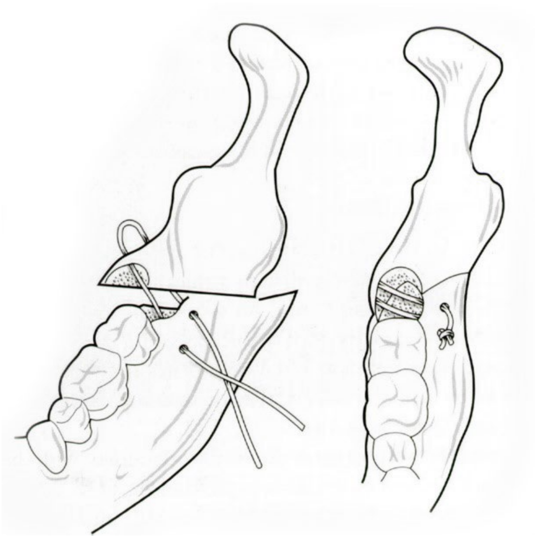

Figure 5 - Method of upper border wiring employed to reduce the edentulous posterior fragment following fracture and loss of the third molar (From Champy *et al*., 1978).

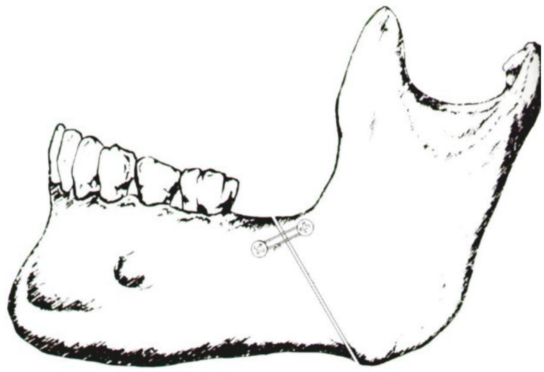

Figure 6 - Line drawing indicating sites of screw placement (From Dym *et al*., 1992).

2.6.2 - PLATE AND SCREW OSTEOSYNTHESIS

A number of mandibular fracture plating techniques exist, varying in component materials and plate configuration. “Dynamic compression” or “noncompression” plates are available. Dynamic compression plates create a compressive force across the fracture site through the use of eccentrically machined and beveled screw holes. Fracture site compression provides increased stabilization and promotes primary bone healing without the need for bone callous formation. Noncompression plates simply fix the fracture in the plated position, providing no additional compressive force to the fracture. Repair techniques that employ various plate combinations and plate positions are in use today as accepted methods of mandibular angle fracture management (Anderson et al., 1992; Fedok et al., 1998). The advantages of plating techniques include the rapid return to normal masticatory function and mouth opening, resulting in less disturbance to social function, reduced weight loss and less time lost from employment (Rix et al., 1991).

The mandibular fracture plates may be secured with screws that penetrate only one mandibular cortex (monocortical) or both cortices (bicortical).

The development of inert metals and antibiotics gave rise to enthusiasm for the use of bone plates in treating mandibular fractures. In particular where there was marked displacement with interposition of soft tissue, and in cases in which other means rendered the results uncertain. However, bone plates and screws made of vitallium and tantalum were too bulky to adapt to the bone. If the screws were inserted slightly off center, displacement of the fracture occurred.

The outstanding exception was the approach adopted by the AO/ASIF (Association for the study of Internal Fixation) using compression osteosynthesis. Orthopedic experience had shown that under compression the healing of a fracture is accelerated (Smith et al., 1996). Self-tightening compression plates and plates with spherical gliding holes-dynamic compression plate (DCP) were developed (Perren et al., 1969). The most favorable site for an osteosynthesis is the region of maximal tension caused by muscular pull. Although clinical experience demonstrated that compression plates led to excellent results in the treatment of fractured extremities, the systems could not be directly transferred for application to the mandible. The different anatomy meant that the bicortically fixed compression plate could only be inserted in the lower part of the mandible, to avoid injury to dental roots and the inferior alveolar nerve, but this is also the region of maximal functional compression and therefore from a biomechanical point of view unsuitable for performing osteosynthesis. The development of compression-plate osteosynthesis for mandibular fractures therefore required specially designed materials. Luhr, in 1968, first developed a self compressing plate (SCP) to stabilize edentulous fractures, and Spiessl introduced the DCP into maxillofacial traumatology. Subsequently eccentric dynamic compression plates (EDCP) were recommended and an SCP was developed (Niederdellmann et al., 1975).

Effective use of open reduction and internal fixation (ORIF) of comminuted fractures allows anatomic reduction of the comminuted segments as well as restoration of the pretraumatic occlusion. This permits restoration of facial proportion and symmetry, using the reconstructed mandible as an anatomic template and foundation (Smith et al., 1996).

ORIF should be considered for individuals who have severe swelling of the floor of the mouth, tongue, or pharynx that would predispose them to postoperative airway compromise if placed in maxillomandibular fixation (MMF). ORIF may also be indicated for patients with medical conditions inn which MMF may be contraindicated, such as psychiatric disorders, dyskinesias, and poorly controlled seizure disorders (Smith et al., 1996).

2.6.3 - COMPRESSION PLATES

A plate offers the greatest stability when loaded in its longitudinal direction and is weakest when loaded by the application of a bending force around an axis that lies parallel to the lower surface of the plate and perpendicular to its long axis. This means that the plate should be applied along the tension zone of a fractured bone with the intention of producing primary bone healing and rigid fixation (Ikemura et al., 1988).

Compression plates and screws are available in titanium, stainless steel or vitallium, with a thickness of 2.0 mm and widths of 6.5, 8 and 9 mm. All systems also include larger reconstruction plates with a thickness of 2.7 or 3 mm. It should be noted, that these later compression systems are rarely used currently.

Dynamic compression plates are designed with holes that can be used to create compression on both sides of the fracture. Each screw is eccentrically screwed into the end of the oval screw hole further from the fracture site. The compression caused by the application of this type of plate at the lower border of the mandible creates a gap within the fracture at upper border of the mandible. To compensate for this an additional tension band system in the alveolar region is required. This may consist of an additional two-hole tension band plate, a wire osteosynthesis at the upper border of the mandible, or the use of a miniplate fixed with monocortical screws above the DCP.

The use of an EDCP should neutralize the tensile forces within the alveolar region. The EDCP is designed with axial compression holes in the middle of the plate and, lateral to these, angled or vertical holes. In this way it is possible to provide compression to the lower part of the mandible together with axial moment in the alveolar part. An additional tension band is therefore unnecessary.

The standard AO/ASIF technique for treating fractures of the mandibular angle is to neutralize the functional forces by restoring the tension and compression trajectories in the mandible (Ellis et al., 1993; Jaques et al., 1997). The recommended method to restore these trajectories is by the application of two compression bone plates, one along the superior aspect of the buccal cortex (tension band plate) and one along the inferior aspect of the buccal cortex (stabilization plate). The tension band plate can be a smaller bone plate using monocortical screws; the stabilization plate has traditionally been a larger compression bone plate using 2.7 mm bone screws (Ellis, 1993; Ellis et al., 1993).

The application of any rigid compression plate is technically demanding and requires very exact repositioning of the fragments and precise adaptation of the plate to the bony surface (Ikemura et al., 1988; Ellis et al., 1996).

Meantime miniplate osteosynthesis has superseded the use of compression osteosynthesis. A few authors still recommend the latter, but others limit the indications to special situations such as the fractured atrophied mandible or infected comminuted fractures. Miniplate osteosynthesis is currently the “gold standard”.

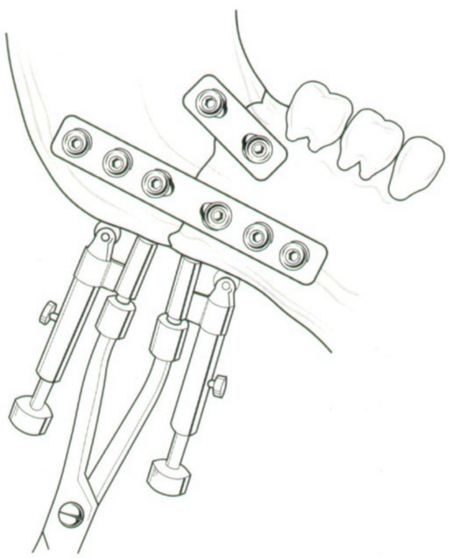

Figure 7 - Treatment of an angle fracture using a 6-hole dynamic compression plate (DCP) at the lower border after previous fragment compression using reduction forceps with connected side rollers. To avoid a gap in the upper part an additional 2-hole tension band plate is applied (From Booth *et al*., 1999).

2.6.4 - MINIPLATE OSTEOSYNTHESIS

The seminal works of Michelet and later Champy started a quiet revolution in maxillofacial surgery that resulted in the adaption of orthopaedic bone plating techniques for use in the facial skeleton.

Initially rigid steel metacarpal plates were used to fix bone fragments after direct exposure and reduction of facial fractures. This coupled the benefits of an anatomically accurate reduction of facial bones with a rigid osteosynthesis at the fracture site. There was an immediate improvement in patient safety, because of the unrestricted airway. The technique also allowed for an improved diet and immediate function. The widespread use of rigid internal fixation has acted as a spur to many instrument manufacturers to produce increasingly sophisticated systems and there is now a very wide range of plates which have moved away from rigid towards semi-rigid fixation techniques.

Displacement of fragments of the mandibular body is predominantly the result of the activity of the muscles of mastication. From a biomechanical view point an ideal method of osteosynthesis should therefore neutralize these unfavorable forces (Haug *et al*., 1996). The mechanical characteristics of the material used for this purpose should on the one hand contain these forces, and on the other not be so rigid that stress shielding occurs and delays healing. These prerequisites are met by miniplate osteosynthesis first described by Michelet (1973) and popularised by Champy *et al*. (1978) and based on the ideal lines of osteosynthesis. It consists of the use of small malleable plates made of stainless steel or titanium which are placed in a defined osteosynthesis line. The fixation is performed with self-tapping monocortical screws; postoperative intermaxillary fixation is unnecessary, such fixation being semi-rigid in contra-distinction to the rigid fixation afforded by the A/O compression plate system.

Based on a mathematical model of the mandibular body and taking into account the reactive biting forces applied to the mandible and performing different experimental evaluations, they were able to define the strains created within the bone by muscular activity. Moments of flexion were found at the upper part of the mandible, increasing progressively from the front teeth to a maximum of approximately 600 N in the angle; there are also torsion moments between the canines, which increase in strength towards the midline to 1000 N. The adult human man may generate between 300 and 400 N maximal bite force.

The most widely used material for semi-rigid internal fixation is now titanium, which its excellent biocompatibility, malleability and lack of memory.

In the United Kingdom, plates placed to fix fractures of the facial skeleton internally tend to be left in situ, unless they give symptoms or became infected. However, between 10% and 20% (Langdon *et al*., 1998) of plates placed ultimately require removal, and for this reason manufacturers are currently striving to manufacture a resorbable plate and screw system, constructed from materials such as polygalactide. The problems of constructing plates and screws robust enough to undergo placement and capable of maintaining their strength long enough before resorption to ensure fracture healing, but at the same time not exciting an excessive inflammatory reaction, are proving hard to overcome.

2.6.5 - THREE-DIMENSIONAL TITANIUM MINIPLATES

In 1913 Lambotte recommended an aluminium geometrically closed quadrangular plate secured with bone screws at the lower border of the mandible for the treatment of fractures of the mandibular body via an extraoral approach. He found that, provided the fragments were properly repositioned, this specially designed plate osteosynthesis offered sufficient stability without further immobilization; furthermore, this system was superior to that in use at the time using wire osteosynthesis. However, it did not gain the popularity because of the lower biocompatibility of the material and because treatment methods using close reduction were preferred.

More recently, 3D titanium plates and screws have been developed by Farmand (1993). Their shape is based on the principle of the quadrangle as a geometrically stable configuration for support. Because stability is achieved by the geometric shape, as compared to standard miniplates, the thickness of these plates is reduced to 1 mm. The basic form is a quadrangular 2x2 hole plate with square or rectangular segments; 3x2 or 4x2 hole plates are also available. The plates are adapted to the bone according to Champy’s principles and secured with monocortical self-tapping screws.

The use of three-dimensional plates for mandibular fracture treatment is relatively new, and only a few series are presented in the literature. Wittenberg (1994) in a prospective study, reported the stabilization of 20 fractures of the angle - 12 associated with additional fractures of the mandibular body. All patients had a stable occlusion after fracture healing; in 5 cases, in addition to the osteosynthesis, light intermaxillary elastic bands were placed for 2-3 days.

In the late 1980s, microsystems for internal fixation of maxillofacial fractures were introduced because of a growing demand for smaller systems and the improved technical ability to produce them. Microdimensioned osteosyntheses titanium plates (1.0 mm and 1.5 mm) have the advantage that they can anatomically fix small bone pieces. However, the application of microsystems is limited to regions of the craniomaxillofacial region, where loading forces are minimal, especially the thin midfacial region and the cranium. The application of this microsystems to mandibular angle fractures is not recommended (Haug *et al*., 1995; Schortinghuis *et al*., 1999).

2.6.6 - LAG SCREW FIXATION

Lag screw fixation (LSF) for mandibular fracture treatment was introduced in 1970 by Brons and Boering. This method is based on the principle that an axial tensile stress within the screw is turned into a compressive one acting on the fracture surface. This is caused by driving the screw through both fragments; however, the screw thread only engages in the fragment remote from the screw head. When the screw is tightened the fragments converge until complete axial compression of the fracture surface is produced, the near fragment being supported by the screw head (Booth *et al*., 1999).

The lag screw technique for the mandibular angle requires screws up to 40 mm in length (Ellis *et al*. (a), 1991). If there are areas of comminution, the lag screw technique should be abandoned because it has little chance of success (Ellis *et al*. (b), 1991).

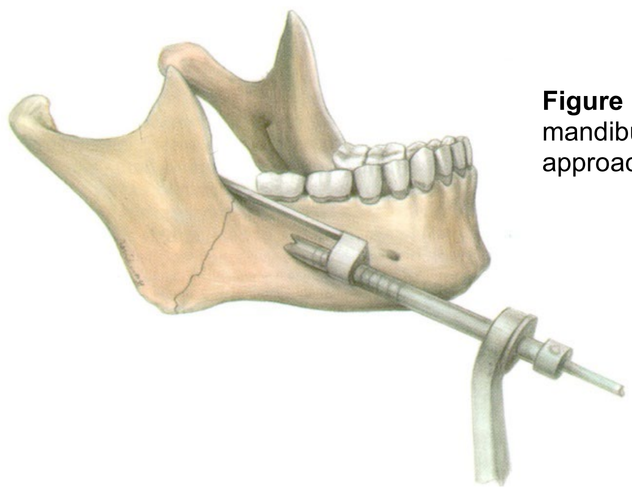

Figure 8 - Placement of a lag screw in a mandibular angle fracture from an inferior anterior approach (From Harle *et al*., 1999).

Indications for its use depend on the purpose and the particular situation. Reliable cortical anchoring of the screw thread is essential and a strong cortical surface for the screw head is necessary. Fractures in the symphysis region, fractures of the angle, and specific fracture types such as sagittal fractures may be treated by this method (Haug et al., 1996).

In symphyseal fractures the mandible is composed of strong cortical bone which serves as an excellent buttress. Moreover, there is no neurovascular bundle in this area and the fracture site is readily accessible.

In fractures of the angle the lag screw may be installed on the tension side of the fracture, which is biodynamically advantageous (Niederdellmann, 1987). The mandibular angle fractures must amenable to this technique are those that run in an oblique fashion from anterior to posterior. The external oblique line of the mandible is used as a bony buttress (Niederdellmann, 1987), and usual approach is via the transbuccal technique.

Sagittal fractures can occur in the body region of the mandible, and lag screw osteosynthesis is maybe appropriate for these fractures.

The main advantages of the lag screw fixation method compared to plate fixation are, axial compression of the fragments with good adaptation of the fracture surfaces, the reduction may be more anatomically accurate, as in some cases it is difficult to perfectly adapt a bone plate to the complex contours of the mandible (Ellis et al. (a), 1991., Kallela et al., 1996).

Lag screw osteosynthesis is a very sensitive technique, any deviation from the standard lag screw procedure will affect the stability of the result. Disadvantages are: that it is technically demanding and third molars must be removed as they often interfer with screw placement.

Complications during lag screw surgery may occur if the strength of the bony buttress, the instruments, or the fixation materials have been overestimated. In particular, the long distance to be drilled or tapped in the paramedian mandibular region may result in tool failure; subsequently, when the fragments are removed, the thread may strip and the screw fixation method can no longer be employed (Ellis et al. (b), 1991).

2.7 - PLATES AND SCREWS - SURGICAL PLACEMENT

There are many commercially available systems, the one currently in use in our Unit is the Leibinger system. This is a titanium 2 mm osteosynthesis miniplate system. The distance between the holes have been standardized, as are those with an intermediate spacing section. Monocortical screws are used, from 5 to 15 mm in length. Their diameter is 2 mm: the corresponding drill has a diameter of 1.5 mm, to allow self tapping application. The screw heads are designed to allow insertion at a 30-degree slant with respect to the plate surface. Screws 7 mm or greater in length are normally used in the mandible.

The plates can be adapted to the bone surface using two bending pliers with a guiding pin. It is important that the plate is fixed by at least two screws in each fragment. In dentate patients the occlusion is secured resulting in exact anatomic repositioning of the fragments. This is performed ideally by temporary MMF, in simple fractures an assistant may be used to manually hold the patient in occlusion. The bent plate is applied to the bone surface along the osteosynthesis line and the first hole is prepared through the hole of the plate furthest from the fracture site. The drill is angled perpendicular to plate’s surface, although a 30-degree angulation is possible. The penetration of the bur must be strictly monoaxial: this is achieved by a single continuous movement through the external cortical layer only. Eccentric drilling or repeated insertions of the drill produce an unfavorable conical or oversized hole, diminishing the grip of the screw. The average cortical thickness is 3 mm, so only in a cylindrical hole are the necessary three screw threads secured to provide adequate anchorage for the self-tapping screw. During drilling with a low-speed handpiece continuous liquid cooling is necessary to avoid thermal necrosis. A decrease in resistance during drilling indicates penetration into cancellous bone. The first screw is then inserted and tightened; care is required as excessive tightening results in microfractures within the hole. The screw nearer the fracture is then inserted. The distance between the holes of the plate is 4 mm, so the screw is placed 2 mm from the fracture line. It is therefore recommended that the drill be inclined slightly away from the fracture to ensure a secure hold for the screw. In some cases, it is helpful to use a spaced plate. Finally, the holes in the other fragment are drilled and the screws inserted in the same order.

To stabilize fractures of the angle a plate is adapted as high as possible on the oblique line; it is more convenient to twist the plate over its plane so that the distal part can be fixed from the medial aspect and the anterior part can be fixed on the lateral aspect of the external cortical layer. In some cases, rounding of the crest of the oblique line with a bone cutter facilitates adaptation of the plate. The wound edges are sutured with absorbable material (Booth et al., 1999). Alternatively, the plate may be placed laterally on the buccal cortex, utilising the transbuccal approach as previously described.

2.8 - POSTOPERATIVE COMPLICATIONS

The treatment of mandibular angle fractures is plagued with the highest postsurgical complication rate of all mandibular fractures (Ellis *et al*., 1994).

Infection is the most common complication of mandibular fractures. Cellulitis, abscess formation, necrotizing fasciitis and Ludwig's angina can also occur (Kaban *et al*., 1997).

Infection, may predispose to malunion, non-union, chronic osteomyelitis, pain, acquired skeletal deformities, and extended/multiple hospitalisations (Cawood, 1985; Stone *et al*., 1993; Fedok *et al*., 1998; Joos *et al*., 1999). Infection rates vary between different authors, and range from 5% to 30% (Childress *et al*., 1999).

2.8.1 - ALLEVIATION OF PAIN

Pain and swelling are predominantly caused by the initial trauma, but these are also features associated with operative procedures involving the mandible. Pain is prominent among the subjective after-effects of a mandibular fracture and is caused particularly by movement between the fragments. A short time interval between trauma and fracture stabilization is therefore integral to the prevention of pain. If a fracture cannot be treated operatively immediately after admission, temporary intermaxillary fixation using for example eyelets, Ernst or Gilmer ligatures, or the application of a bridle wire, is recommended, to effect temporary immobilisation.

2.8.2 - WOUND DEHISCENCE

Cawood (1985) noted that dehiscence occurred most commonly in the posterior region. In his study, gingival margin incisions were frequently used for angle and body fractures wherever possible to avoid suture lines lying close to the plane. In the anterior region, however, a muco-gingival incision suffices because the plates lie inferior to the incision line, low on the labial cortex of bone. In modifying the exposure of the fracture site, no early intraoral wound dehiscence or infection occurred. This implies that the siting of the incision line is one factor in reducing of the complication wound dehiscence.

Wound dehiscence is more frequently found if there has been an undue delay between the sustaining of the trauma and the time of operation (Booth et al., 1999).

Pre-existing mucosal tears and poor oral hygiene are other possible factors contributing to wound dehiscence (Cawood, 1985). In such cases, suture removal and wound toilet with 1.5% hydrogen peroxide is advisable. The wound is then dressed with an iodoform Vaseline pack, a secondary suture is not necessary.

2.8.3 - INFECTION

Criteria that have been used for the diagnosis of infection include, pain, swelling, erythema, a purulent extra-or intraoral discharge, leukocytosis, elevated erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), (Iizuka et al., 1991). The clinical signs of infection precede radiological signs, such as bone resorption or loosening of screws in most cases (Iizuka et al., 1991).

Infection occurs when there is a significant bacterial insult. It occurs more readily if the patient’s host defence mechanisms are reduced, rendering the patient more susceptible to infection. Stone (1993) hypothesized that for infection to occur, a combination of at least two of the following elements must be present: fracture mobility, foreign body in the wound, compromised medical status, and poor surgical technique.

Postoperative infections with abscess formation are commonly observed in those patients whose treatment was delayed for some days following trauma and who received no prophylactic antibiotics (Booth et al., 1999). For the prevention of infection perioperative antibiotic coverage is recommended, in association with early treatment. Surgical factors other than degree of contamination may also influence infection rates. Operative procedures that last longer than 3 hours, and procedures necessitating the insertion of foreign bodies (implants), may increase infection rates (Peterson, 1990; Stone et al., 1993).

The antibiotic chosen by the surgeon must be effective against the bacteria that are most likely to cause infection following a particular surgical procedure. Penicillin is the first choice in terms of antibiotic prophylaxis, clindamycin is used as alternative antibiotic if the patient is allergic to penicillin.

Use of appropriate antibiotics in the treatment of mandibular fractures decreases the rate of infection. Zallen and Curry (1975), in a randomized prospective study of antibiotic use in compound mandibular fractures, found infection rates of 50% in cases treated without antibiotics and 6% in cases treated with antibiotics. Higher infection rates occurred with both open and closed reductions when antibiotics were not administered (Kaban et al., 1997).

It is clear that the vast majority of postoperative infections are caused by endogenous bacteria. Thus, the most likely contaminating organisms following transoral approaches are aerobic gram-positive cocci; anaerobic gram-positive cocci, and anaerobic gram-negative rods. If the surgical procedure is to be done transcutaneously, the most likely organisms that would cause infection are colonizing staphylococci from the skin (Peterson, 1990).

After acute abscess formation incision and drainage generally lead to normal bone healing (Brown et al., 1989; Koury et al., 1992). Usually, the plates can be retained in situ. In cases of delayed often chronic infections, usually resulting from inadequate immobilization of the fragments, with incorrectly applied plates, the osteosynthesis material should be removed if it does not ensure immobilization (Nakamura et al., 1994). When bony union is insufficient, intermaxillary fixation ± bone grafting becomes necessary.

Some patients (diabetics, transplant patients, patients on long term steroid therapy, those with HIV) are immunocompromised and are more likely to suffer postoperative infections. Reduction of infectious complications in these patients may be achieved with the appropriate use of perioperative, high-dosage antibiotic administration, also optimisation of underlying condition; reduction time to surgery; and by minimising trauma to the tissues. The antibiotic must be delivered before the surgical procedure is started and maintained at a high plasma level throughout the period of surgery. The effectiveness of these principles has been well established in the contemporary surgical literature (Peterson, 1990).

2.8.4 - OSTEOMYELITIS

Osteomyelitis is an inflammatory condition of bone involving the medullary cavity, haversian systems, and adjacent cortex. To establish the diagnosis of an intraosseous mandibular infection bone samples should be obtained and evaluated microscopically. Even when osteomyelitis is present, a positive bone culture may be difficult to obtain, possibly because the organisms are walled of deep in the bone sample. Therefore, histologic examination is required for the definitive diagnosis (Koury et al., 1994).

Osteomyelitis of the fracture site is the most serious form of infection, but this complication is rare. The cause is often inadequate immobilization of the fragments.

Decreased vascular supply has been shown to predispose bone to osteomyelitis (Topazian et al., 1981). Furthermore, management of these patients may be compromised by their poor attendance in the outpatient clinic.

Koury et al. (1994) proposed a protocol for the management of this condition. Technetium-99m methylene diphosphonate (99mTc) and Indium 111 (111In) radionuclide scans, bone cultures, and microscopic examination were used to document the diagnosis of osteomyelitis. The infections were treated with antibiotics, incision and drainage, and decortication. Reconstruction plates that were large enough to provide four holes in each bone segment were used for rigid internal fixation of the fractures with simultaneous reconstruction of the osseous defects.

The results of this study indicate that the protocol of simultaneous debridement, reduction, and rigid internal fixation is a satisfactory method for treatment of mandibular fractures complicated by osteomyelitis.

2.8.5 - NON-UNION

When an infection occurs, the most common significant negative outcome is a non-union. Fracture mobility, repeated trauma, infection, wide fracture gap, soft tissue interposition, poor reduction, mandibular atrophy, decreased blood supply and systemic disease can cause non-union (Kaban et al., 1997). Non-union remains a risk when infection occurs, even if new fixation is applied and loose hardware is removed.

There appears to be no clear data from valid studies on whether an infected wire osteosynthesis or an infected plate is more likely to result in nonunion (Assael, 1994).

In cases of pseudoarthrosis, after removal of the plates the bone ends should be exposed and the eburnated bone removal with bone burr. The bone defect must be reconstructed with cancellous bone or iliac bone grafts: it is preferable to bridge the defect with two parallel miniplates or one reconstruction plate.

2.8.6 - DELAYED UNION

Delayed union is a rare complication, 0.1% to 2.4% (Childress et al., 1999). It generally occurs after incorrect fracture reduction or plate fixation, and osteomyelitis at the fracture. In the early postoperative period reoperation - with removal of the plates, proper reduction of the fragments, and repetition of the osteosynthesis with longer plates - is recommended.

2.8.7 - MALOCCLUSION AND MALUNION

Malunion is any degree of malocclusions associated with a fracture. Valentino et al. (1994) divided malunions into three categories: those corrected with occlusal equilibration, those requiring orthodontic's, and those requiring osteotomy.

Malunion occur when segments heal with improper alignment and result in malocclusions and facial deformity. The incidence of malunion ranges from 0 to 4.2% (Kaban et al., 1997).

This complication is associated with poor reduction, inadequate immobilization, delayed healing, poor patient compliance, and fixation. Large errors of occlusion necessitate a re-osteosynthesis. If the error is minimal, it can be compensated by selective occlusal grinding after bony union is completed. This complication is avoided by precise occlusal fixation during surgery (Shetty et al., 1995).

2.8.8 - DAMAGE TO DENTAL ROOTS

Injuries to the apices of the teeth may result from application of the osteosynthesis plate at too high a level. This complication is seen significantly more often in the posterolateral regions, where the positions of the root apices are not so easily appreciated through the cortical bone. Injury to the root tips is unlikely to occur if the drill holes are made below the alveolar crest at the distance approximately twice the height of the root crown (Harle et al., 1999).

The outer cortex of the body of the mandible has an average thickness of 3.3 mm, is particularly strong and offers a good anchorage for the osteosynthesis screws. The cortical bone is thinnest in the mental region and posteriorly is reinforced laterally by the external oblique line, which runs from the coronoid process to the molar region, cross sections of the mandible show the thickest cortex to be towards the upper border; behind the third molar.

Near the alveolar process the thickness of the bone is variable; the anatomy of the tooth roots and the structure of the bone do not allow screw fixation in this region.

2.8.9 - DAMAGE TO THE INFERIOR ALVEOLAR NERVE

Sensory disturbance in the distribution of the inferior alveolar nerve may occur. In most series this complication was either noted, or ascribed to the injury, therefore occurring prior to osteosynthesis (Tuovinen et al., 1994). Cawood (1985) noted iatrogenic damage to the inferior alveolar nerve in 8% of 50 cases studies, associated with a fracture in the vicinity of the mental foramen.

In a study done by Tuovinen (1994) preoperative mental nerve disfunction was noted in 26.9% of cases. In the immediate postoperative period, sensory disturbance was noted in 40.1% of patients, 3 months postoperatively in 10.4%, and after 12 months in 1.4%.

Careful protection of the mental nerve with an elevator while inserting the plate is recommended (Jaques et al., 1997).

2.8.10 - TOOTH IN THE FRACTURE LINE

There is still controversy about the need to remove teeth within the fracture line. Although in the past extraction, especially of third molars, was regularly performed, several studies (Neal et al., 1978; Lindqvist et al., 1986; Ardary, 1989; Ellis et al., 1994) have shown higher infection rates after adopting this policy.

The literature has consistently shown that the presence of third molar is associated with 2-to-3-fold increased risk of angle fractures in patients with fractured mandibles (Lee et al., 2000), and that fractures occur more frequently in the dentate regions of the mandible. It has been hypothesized that the presence of third molars decreases bone mass in the angle region, thereby increasing the risk for angle fractures.

Removal of teeth may require loss of bone, which in turn will reduce the bony contact between the fragments; in addition, a tooth in the fracture line may provide good support when the fragments are reduced.

However, certain guidelines, based on the observations of the various authors reviewed, may be useful (Shetty et al., 1989):

1-Intact teeth in the fracture line should be left in situ if they show no evidence of severe loosening or inflammatory change.

2-Impacted molars, especially complete bony impactions, should be left in place to provide a larger repositioning surface. This also allows the effective application of the tension band principle. Exceptions are partially erupted molars with a history of pericoronitis or those associated with a follicular cyst.

3-Teeth that prevent reduction of fractures should be removed.

4-Teeth with crown fractures may be retained provided that emergency endodontic therapy is carried out. All teeth with fractured roots must be removed.

5-Teeth with exposed root apices may adversely affect healing. Hemisection should be considered as an alternative to the extraction of molars.

6-Teeth that appear nonvital at the time of injury should be treated conservatively, keeping in mind their potential for recovery and their importance in simplifying fracture treatment and subsequent prosthodontic rehabilitation.

7-The condition of the alveolus and the periodontium is decisive for uneventful fracture healing. Optimal healing is doubtful when there is extensive periodontal damage, with broken alveolar walls, resulting in the formation of a deep pocket. Primary extraction is preferred in such situations.

2.8.11 - STRESS SHIELDING

Stress shielding is an osteoporotic process in the area of bone shielded from normal functional forces by the plate, which has been reported in the healing of long bones. This may be less of a concern when a semi-rigid fixation plating technique is used (Brown et al., 1989).

2.8.12 - REMOVAL OF OSTEOSYNTHESIS MATERIAL

The matter of whether osteosynthesis material used for internal fixation should be removed remains controversial. After an extensive literature review regarding carcinogenesis, toxicity, hypersensitivity, corrosion and stress protection, Haug (1996) found no indication that hardware made of commercially pure titanium and Ti-6Al-4V should be removed after fracture healing. This was supported by clinical experience. Routine removal increases complication rates and has significant cost implications.

Luhr (1982) also stated that vitallium implants could remain in situ.

2.9 - TREATMENT OF INFECTED MANDIBULAR FRACTURES

When treating infected mandibular fractures, two goals exist: 1) resolution of the infection and 2) achievement of bony union. Those advocating maxillomandibular or external fixation believe elimination of the infection must occur before bone union occurs. Those using internal fixation believe that the best manner to eliminate the infection is to rigidly immobilize the segments and that, by doing so, bony union will occur irrespective of whether an infection is present. Thus, a dichotomy exists in the treatment of such fractures (Koury et al., 1992).

When deciding whether to treat a fracture with plate and screw osteosynthesis, the clinician must weigh the risk of exposing the fracture site and placing a plate against the benefits of absolute rigidity. In the past two decades, research has provided much information about this dispute. To answer the questions about the viability of the treatment options, a review of the biological research is necessary.

2.9.1 - FOREIGN-BODY EFFECT OF IMPLANT

In orthopedics and oral and maxillofacial surgery, many authors have emphasized the “foreign-body effect” of a metal implant. Difficulty exists in accurately determining the biological influence of a foreign body, because when an implant is placed, surgical trauma is inevitably inflicted. If an infection then develops, it is difficult to determine whether the implant or the surgical trauma and contamination caused the infection.

2.9.2 - IMPLANTS PLACED INTO CLEAN VERSUS CONTAMINATED WOUNDS

The closest approximation of the risk assumed solely by the addition of an implant to the body is seen when placement occurs with minimal soft tissue and vascular trauma during a sterile elective procedure.

The rate of infection is higher in open (contaminated) fractures when compared with close (noncontaminated) fractures (Koury et al., 1992).

2.9.3 - EFFECT OF MOBILITY ON INFECTION

Internal fixation has been recognised as the optimum treatment for infected mandibular fractures, partly because the biological reaction to mechanical influences plays an important role in local infection. Many studies (Friedrich and Klaue, 1977) have shown that instability promotes infection, and stability helps prevent it.

2.9.4 - EFFECT OF INFECTION ON BONE HEALING

Friedrich and Klaue (1977) have shown that bone union can take place in the face of infection both experimentally and clinically.

2.9.5 - INFECTION FOLLOWING OSTEOSYNTHESIS

Although several authors (Johansson et al., 1988) have stated that implants must be removed to resolve infection in the mandible, clinicians have shown resolution without removal as long as the fixation was stable. On the other hand, when plates or screws were loose, infections persisted until the loose, implants were removed (Cawood, 1985).

2.9.6 - OVERVIEW

Review of the literature led to the following conclusions regarding placement of miniplates into contaminated wounds: 1) the risk of infection following open reduction may be no greater than when a device is not placed; 2) bony union can occur in the face of infection as long as immobilization of the fractured segments is maintained; 3) resolution of infection can occur even when a plate is present; 4) if resolution of an infection does not occur in a fracture treated with internal fixation, one must verify that the fixation is rigid; 5) if resolution of an infection does not occur in a fracture treated with stable internal fixation, one can usually leave the plate for 8 to 12 weeks to achieve bone union, and then remove it to allow rapid resolution of the infection (Koury et al., 1992).

CHAPTER 3 - STATEMENT OF THE PROBLEMS

Fractures of the mandibular angle represent between 23% (Pape et al., 1983) and 42% (Wald et al., 1988) of all mandibular fractures. This site is also associated with the highest incidence of infective complications following treatment, (Ikemura et al., 1988; Ardary 1989). However, such information is rarely categorised in a way that permits comparison of infection rates following miniplate osteosynthesis at the mandibular angle with those at other facial fractures sites. Those figures that are discernible from the literature range from 5%-25% (Tuovinen et al., 1994; Ellis et al., 1994). Following a retrospective audit of 100 consecutive facial fractures treated with miniplate osteosynthesis, our own experience demonstrated a 19% infection rate when mandibular angle fractures were examined in isolation. This complication rate is unacceptably high.

Many aetiological factors have been proposed to explain the high incidence of infection at this site. These include the retention or extraction of partially erupted third molars in or from the fracture line, a higher proportion of open injuries, and increased bone density resulting in relatively reduced vascularity.

Whilst the debate still continues as to the role of the partially erupted third molar in the genesis of infection, the other two variables are essentially beyond influence, and as such, less important. There is another factor that may influence infection rates at this site, namely the technique employed to effect miniplate osteosynthesis following fracture reduction. There are two main approaches, both of which were advocated in Champy's original paper from 1978. The trans-oral route, in which the plate is placed on the external oblique ridge, and the trans-buccal approach, in which the plate or plates are placed more inferiorly on the buccal cortex, utilising a trochar passed through the cheek.

Retrospective analysis of Maxillofacial Unit – University College London Hospitals data suggests that there is a higher infection rate when trans-oral external oblique ridge plates are used. We are unaware of any published data that specifically investigates this putative relationship between the incidence of infection and the site of plate placement to effect osteosynthesis at the mandibular angle. Both approaches are considered appropriate techniques in the management of mandibular angle fractures. Previous studies have compared internal fixation using one or two plates without difference in outcome (Ellis et al., 1994).

CHAPTER 4 - AIMS OF THE STUDY

1. It is our contention that the mucosal cover afforded to plates placed on the external oblique ridge is relatively poor when miniplate osteosynthesis is used to treat fractures at the mandibular angle. We postulate that flaps heal poorly and/or breakdown when the wound margin is placed over an alloplastic surface. This results in impaired healing and a high rate of infective complications.

2. It is our contention that the better soft tissue coverage afforded by the trans-buccal approach would reduce the rate of this particular complication in fractures of the mandibular angle.

CHAPTER 5 - MATERIAL AND METHODS

5.1 - PATIENTS

Twenty-four dentate patients (age range 16-39, mean= 27.2 years, SD= 6.92 years, F:M= 4:20) with fractures of the mandibular angle were included in this study as they presented or were referred for treatment at the Maxillofacial Unit at University College of London Hospitals.

5.2 - SURGICAL TECHNIQUE

All had pre-operative radiographs consisting of an orthopantomogram and PA mandible. Each was randomly allocated to either the transbuccal or transoral treatment group. Each underwent open reduction and internal fixation, by either senior registrar or consultant maxillofacial surgeons using the Leibinger titanium 2mm osteosynthesis miniplate system. All third molars in the fracture line were left in-situ unless such teeth had sustained a root fracture, were grossly mobile, or had been affected by pericoronitis (Shetty *et al*., 1989). All patients were given our standard antibiotic prophylaxis regime:

1g amoxycillin intravenous infusion (I/V) at induction plus 500mg I/V 3 hours post-operatively. If penicillin allergy 300mg clindamycin I/V at induction plus 150mg I/V 3 hours post-operatively.

Time taken to perform the procedure was recorded. Closure was performed using interrupted 3 ‘0’ catgut, without the placement of a wound drain.

5.3 - FOLLOW-UP

Patients were reviewed at fortnightly intervals for the first month, at 3 months following surgery and then as required. Patients were informed of possible infective complications and asked to return appropriately. Post-operative radiographs consisting of an orthopantomogram and PA mandible were taken immediately post-operatively, and again at 3 months.

During this period patients were observed for clinical and radiographic signs of infection. Patients deemed to have suffered an infective complication would be those who presented with any or a combination of the following:

1- Erythematous swelling and/or discharge of pus in the buccal sulcus or swelling overlying the angle of the mandible appearing after the effects of the initial trauma/surgery have settled, (i.e. after 7 days).

2- Intra-oral wound dehiscence with plate exposure.

3- Radiographic evidence of loosening of screws, osteomyelitis, fracture non-union.

4- Persistent infection requiring plate removal.

5.4 - SCORING SYSTEM FOR INTRAORAL WOUND INFECTIONS

We used the following scoring system, and overt infection was defined as a score of 8 or more.

Scoring system for intraoral wound infections		
Swelling[1]	0 - 3	
Pain[2]	0 - 4	
Erythema[3]	0 or 5	
Purulent exudate	0 or 10	
Isolation of pathogenic bacteria from the wound[4]	0 or 10	
Temperature[5]	0 or 10	
Wound dehiscence	0 or 10	
Total		

[1]Swelling: visual assessment will be used;
0: no swelling
1: minor swelling
2: moderate swelling
3: great swelling
[2]Pain: verbal analogue scale will be used;
0: absent
1: mild
2: moderate
3: severe
4: excruciating pain
[3]Erythema: 5 given for the presence of extraoral erythema.
[4]Swabs taken only when there is pus and pathogenic bacterial refers to significant growth.
[5]Temperature: 10 is given when the temperature is 37.5Cº or more (measured orally).

Information was recorded on an individual patient proforma. On completion, data was analysed and subjected to non-parametric statistical analysis.

Patients presenting with infective complications were managed initially with antibiotics, and if necessary, plate removal and wound debridement.

5.5 - INCLUSION CRITERIA

All patients presenting with one or more facial fractures which included a displaced fracture of the mandibular angle. Diabetic patients were included, but noted.

5.6 - EXCLUSION CRITERIA

Patients who at presentation had clinical evidence of pre-existing infection at the fracture site.

Patients undergoing immuno-suppressive therapy.

Patients requiring re-operation for post-operative malocclusion.

CHAPTER 6 - STATISTICAL ANALYSIS

Non-parametric tests are sometimes known as assumption-free tests because they make no assumptions about the type of data on which they can be used. Most of these tests work on the principle of ranking the data, that is, finding the lowest score and giving it a rank of 1, then finding the next highest score and giving it a rank of 2, and so on. This process results in high scores being represented by large ranks, and low scores being represented by small ranks. The analysis is then carried out on the ranks rather than the actual data. This process in an ingenious way around the problem of using data that breaks the parametric assumptions. However, this ingenuity comes at a price: by ranking the data we lose some information about the magnitude of difference between scores and because of these non-parametric tests are less powerful than the parametric counterparts (Field, 2000).

The Mann-Whitney test is used for testing differences between means when there are two conditions and different subjects have been used in each condition.

The Mann-Whitney test works by looking at differences in the ranked positions of scores in different groups. Therefore, the first part of the output summarizes the data after it has been ranked. The Mann-Whitney test relies on scores being ranked from lowest to highest: therefore, the group with the lowest mean rank is the group with the greatest number of lower scores in it. Similarly, the group that has the highest mean rank should have a greater number of high scores within it. Therefore, this initial table can be used to ascertain which group had the highest scores, which is useful in case we need to interpret a significant result (Field, 2000).

There are many variations on the Mann-Whitney test; in fact, Mann, Whitney and Wilcoxon all came up with statistically comparable techniques for analysing ranked data. The form of the test commonly taught is that of the Mann-Whitney test. However, Wilcoxon developed a different procedure, which can be converted into a z-score and, therefore, can be compared against critical values of the normal distribution.

Statistical Package for the Social Sciences (SPSS) provides both statistics and the z-score for the Wilcoxon statistic and is the statistical package used to analyse the results in this study.

SPSS has a column for each variable and in each column, there is the value of Mann-Whitney's U statistic, the value of Wilcoxon's statistic and the associated z approximation. The important part of the table is the significance value of the test, which gives the two-tailed probability that the magnitude of the test statistic is a chance result. This significance value can be used as it is when no prediction has been made about which group will differ from which. However, if a prediction has been made then we need to calculate the one-tailed probability (Field, 2000).

In this study, age and time of surgery were sufficiently normally distributed to allow the t-test to be used for comparison between infection and non-infection groups (tables 1 and 2, figures 9 and 10).

The first tables (tables: 3,5,7,9,11,13,15) tell us the average and total ranks in each condition.

The second tables (tables: 4,6,8,10,12,14,16) provides the actual test statistics for the Mann-Whitney test.

CHAPTER 7 - RESULTS

Twenty-four dentate patients with fractures of the mandibular angle were included in this study.

Age showed borderline significance at the 10% level (ρ= 0.11), where as time of the surgery had no significant relationship with infection (ρ= 0.62).

The other variables were also subject to statistical analysis in relation to infection.

Gender (ρ value= 0.337; exact ρ value= 0.575) - tables 3 and 4 , past medical history (ρ value= 0.418; exact ρ value= 0.620) - tables 5 and 6, 3rd molar (ρ value= 0.448; exact ρ value= 0.653) - tables7 and 8, smoking (ρ value= 0.169; exact ρ value= 0.383) - tables 9 and 10, substance abuse (ρ value= 0.655; exact ρ value= 0.833) - tables 13 and 14 and fracture site (ρ value= 0.858; exact ρ value= 0.910) - tables 15 and 16 showed no statistical relationship to infection.

Alcohol showed borderline significance in relation to infection (ρ value= 0.032; exact ρ value= 0.178) - tables 11 and 12. This is at odds with previously reported data (Renton et al., 1996). This probably reflects the small sample size.

From the 24 patients treated in this study 4 (16.6%) developed infection.

Of the 14 patients treated via transbuccal approach only one had infection, a rate of 4.2% of all the patients treated and 7.1% of the transbuccal cohort.

Of the 10 patients treated via transoral approach 3 presented infection, a rate of 12.5% of all the patients treated and 30% of the transoral cohort.

	Infection	N	Mean	Std. Deviation	Std. Error Mean
AGE	0	20	26.20	6.58	1.47
	1	4	32.25	7.23	3.61
TIME	0	20	72.00	30.32	6.78
	1	4	80.00	20.00	10.00

Table 1 - Group Statistics: Age and Time of surgery

		Levene's Test for Equality of variances		**t-test for Equality of Means**						
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
AGE	Equal variances assumed	.306	.586	-1.655	22	.112	-6.05	3.66	-13.63	1.53
	Equal variances not assumed			-1.550	4.0	.195	-6.05	3.90	-16.82	4.72
TIME	Equal variances assumed	.882	.358	-.501	22	.621	-8.00	15.96	-41.09	25.09
	Equal variances not assumed			-.662	6.1	.532	-8.00	12.08	-37.35	21.35

Table 2 - Independent Samples Test: Age and Time of surgery

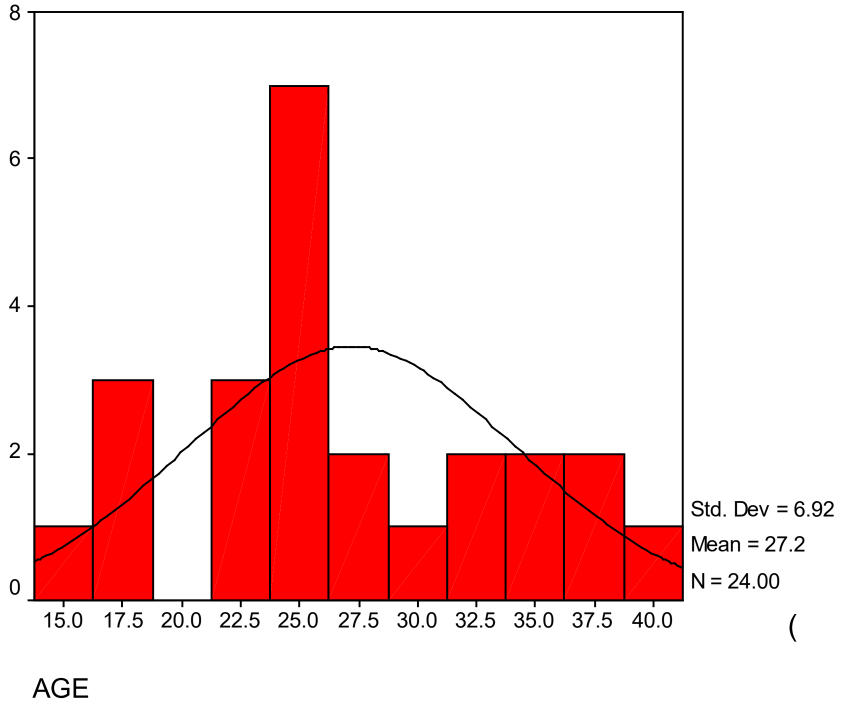

Figure 9 - Age distribution

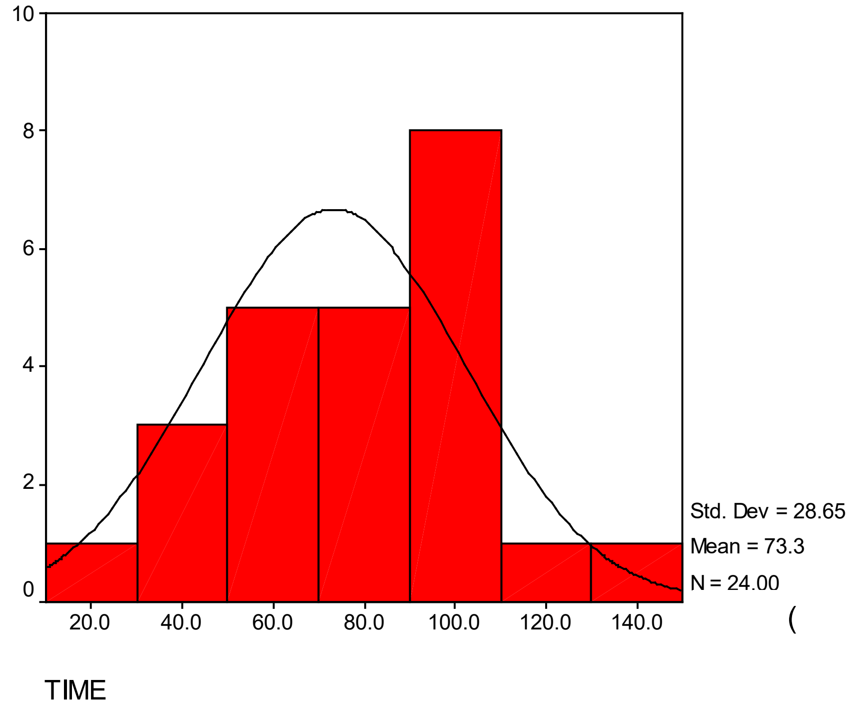

Figure 10 - Time of surgery distribution

	Gender	N	Mean Rank	Sum of Ranks
INFECTION	male	20	12.90	258.00
	female	4	10.50	42.00
	Total	24		

Table 3 - Ranks: Gender

	INFECTION
Mann-Whitney U	32.000
Wilcoxon W	42.000
Z	-.959
Asymp. Sig. (2-tailed)	.337
Exact Sig. [2*(1-tailed Sig.)]	.575

a) Not corrected for ties.
b) Grouping Variable: Gender

Table 4 – Test Statistics: Gender

	Past medical history	N	Mean Rank	Sum of Ranks
INFECTION	no	21	12.79	268.50
	yes	3	10.50	31.50
	Total	24		

Table 5 – Ranks: Past medical history

	INFECTION
Mann-Whitney U	25.500
Wilcoxon W	31.500
Z	-.811
Asymp. Sig. (2-tailed)	.418
Exact Sig. [2*(1-tailed Sig.)]	.620

a) Not corrected for ties.
b) Grouping Variable: Past medical history

Table 6 - Test Statistics: Past medical history

	3rd molar	N	Mean Rank	Sum of Ranks
INFECTION	left in situ	16	12.00	192.00
	extracted	8	13.50	108.00
	Total	24		

Table 7 - Ranks: 3rd molar

	INFECTION
Mann-Whitney U	56.000
Wilcoxon W	192.000
Z	-.758
Asymp. Sig. (2-tailed)	.448
Exact Sig. [2*(1-tailed Sig.)]	.653

a) Not corrected for ties.
b) Grouping Variable: 3rd molar

Table 8 - Test Statistics: 3rd molar

	Smoking	N	Mean Rank	Sum of Ranks
INFECTION	no	7	10.50	73.50
	yes	17	13.32	226.50
	Total	24		

Table 9 - Ranks: Smoking

	INFECTION
Mann-Whitney U	45.500
Wilcoxon W	73.500
Z	-1.376
Asymp. Sig. (2-tailed)	.169
Exact Sig. [2*(1-tailed Sig.)]	.383

a) Not corrected for ties.
b) Grouping Variable: Smoking

Table 10 - Test Statistics: Smoking

	Alcohol	N	Mean Rank	Sum of Ranks
INFECTION	no	12	14.50	174.00
	yes	12	10.50	126.00
	Total	24		

Table 11 - Ranks: Alcohol

	INFECTION
Mann-Whitney U	48.000
Wilcoxon W	126.000
Z	-2.145
Asymp. Sig. (2-tailed)	.032
Exact Sig. [2*(1-tailed Sig.)]	.178

a) Not corrected for ties.
b) Grouping Variable: Alcohol

Table 12 - Test Statistics: Alcohol

	Substance abuse	N	Mean Rank	Sum of Ranks
INFECTION	no	23	12.59	289.50
	yes	1	10.50	10.50
	Total	24		

Table 13 - Ranks: Substance abuse

	INFECTION
Mann-Whitney U	9.500
Wilcoxon W	10.500
Z	-.447
Asymp. Sig. (2-tailed)	.655
Exact Sig. [2*(1-tailed Sig.)]	.833

a) Not corrected for ties.
b) Grouping Variable: Substance abuse

Table 14 - Test Statistics: Substance abuse

	Fracture site	N	Mean Rank	Sum of Ranks
INFECTION	left	13	12.35	160.50
	right	11	12.68	139.50
	Total	24		

Table 15 - Ranks: Fracture site

	INFECTION
Mann-Whitney U	69.500
Wilcoxon W	160.500
Z	-.179
Asymp. Sig. (2-tailed)	.858
Exact Sig. [2*(1-tailed Sig.)]	.910

a) Not corrected for ties.
b) Grouping Variable: Fracture site

Table 16 - Test Statistics: Fracture site

CLINICAL PICTURES - TRANSORAL APPROACH

Figure 11 - Initial X-ray, fracture at the right angle of mandible

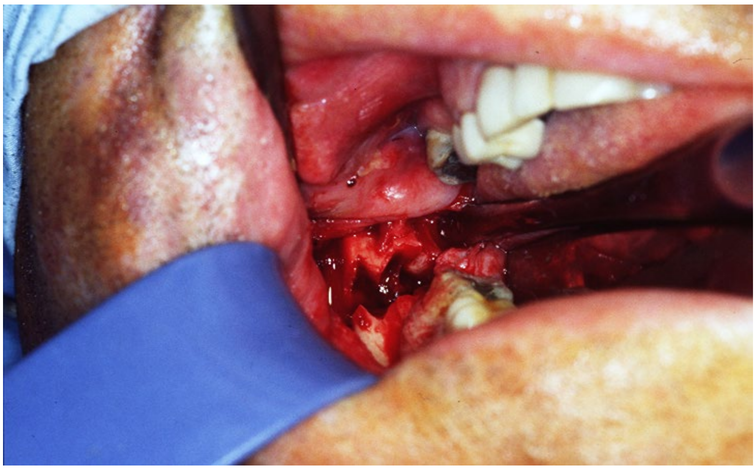

Figure 12 - Fracture line with displaced fragments

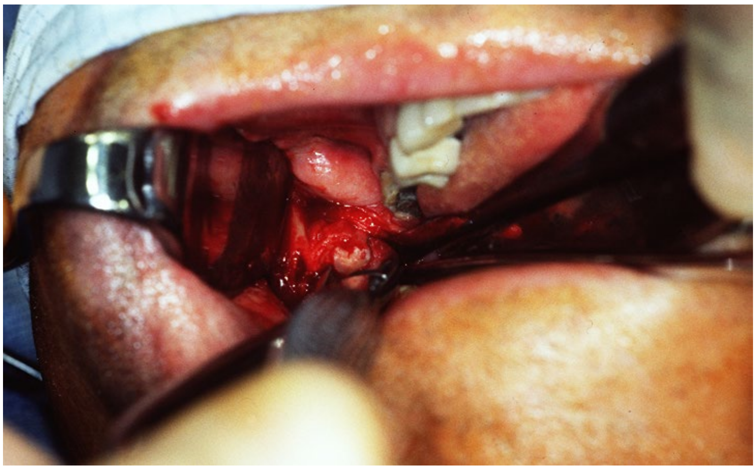

Figure 13 - 3rd molar with mobility in the line of fracture

CLINICAL PICTURES - TRANSORAL APPROACH

Figure 14 - Extraction of the 3rd molar

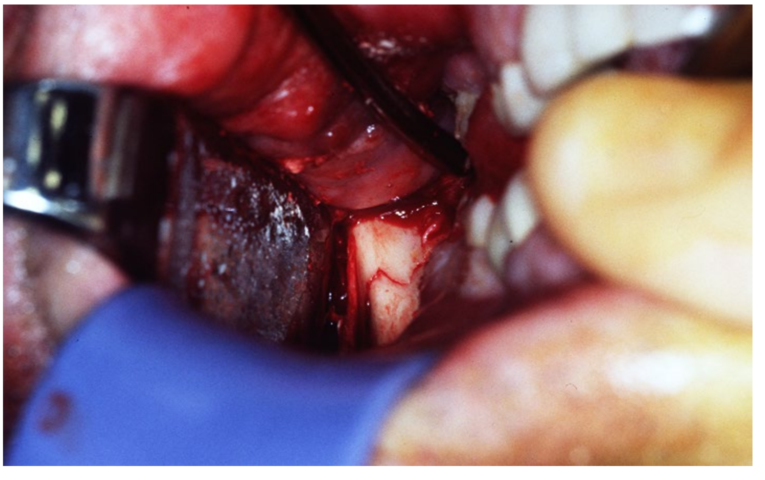

Figure 15 - Fracture reduced

Figure 16 - 4 hole miniplate placed in the external oblique ridge

CLINICAL PICTURES - TRANSORAL APPROACH

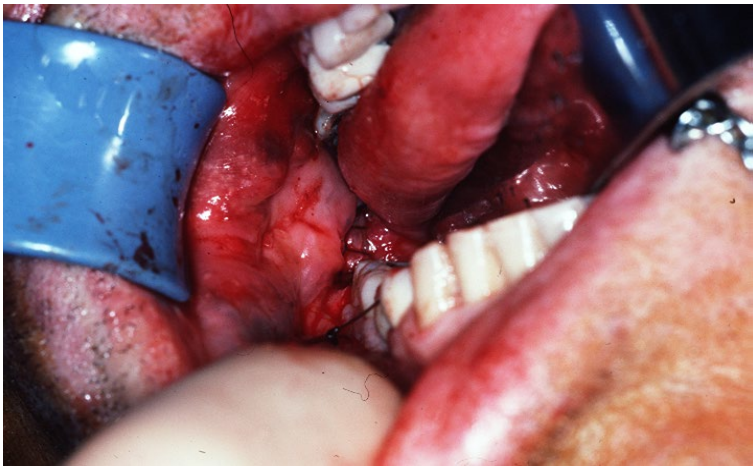

Figure 17 - Closure with 3.0 catgut

Figure 18 - Occlusion tested

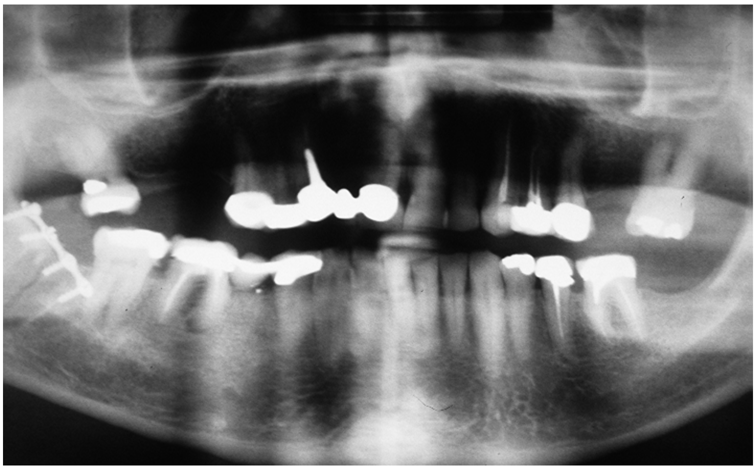

Figure 19 - Final X-ray

CLINICAL PICTURES - TRANSBUCCAL APPROACH

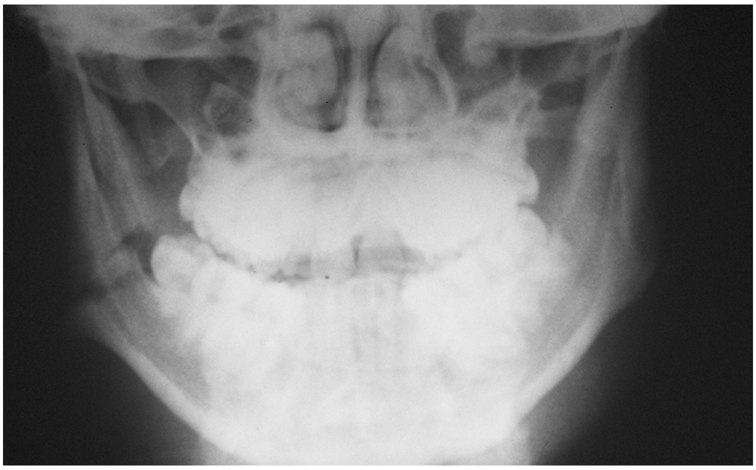

Figure 20 - Initial X-ray, fracture at the right angle of mandible

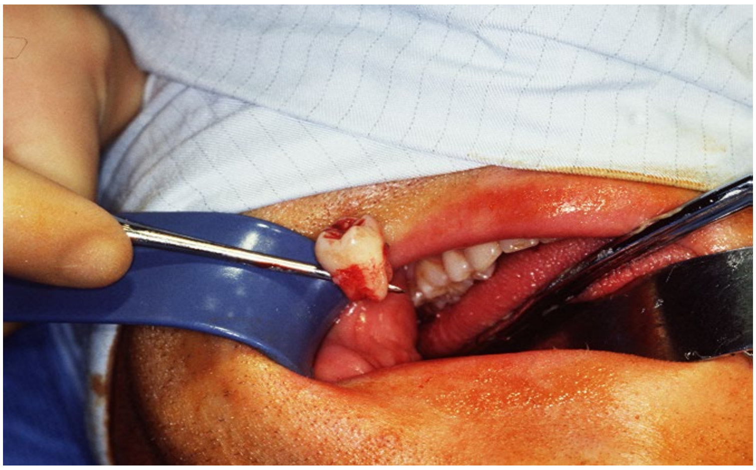

Figure 21 - Extraction of the 3rd molar with mobility

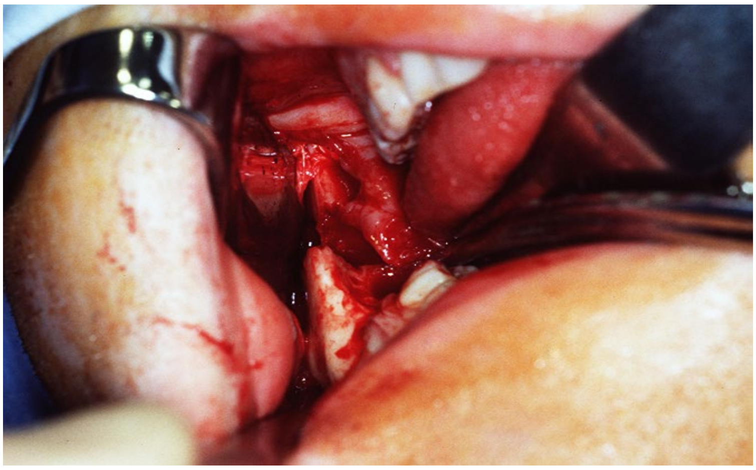

Figure 22 - Fracture line with displaced fragments

CLINICAL PICTURES - TRANSBUCCAL APPROACH

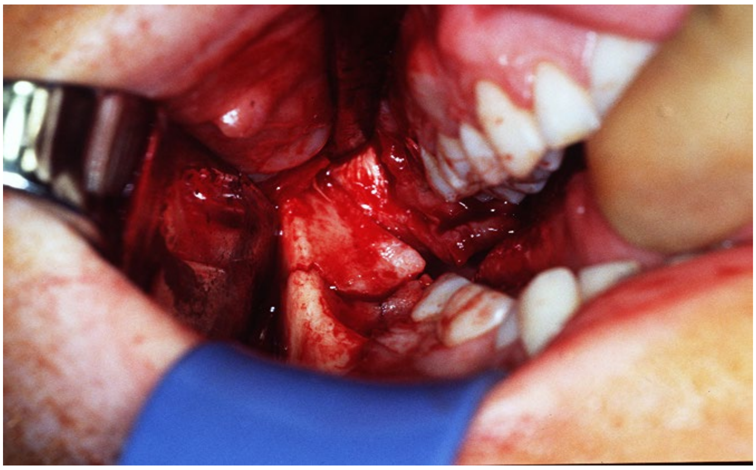

Figure 23 - Fracture reduced

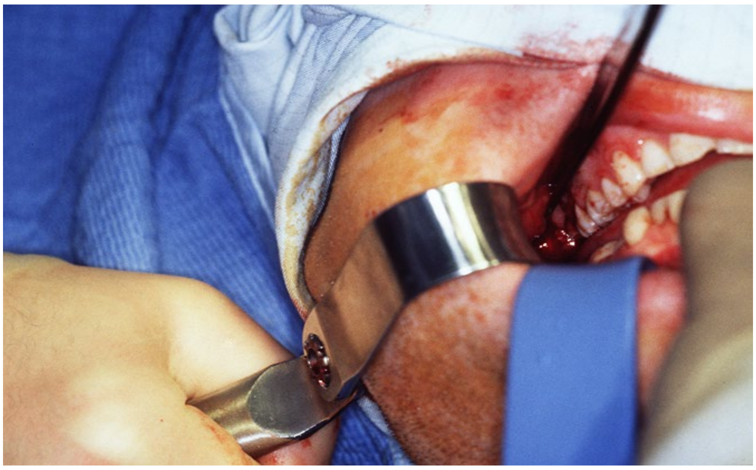

Figure 24 - Transbuccal approach use of trochar

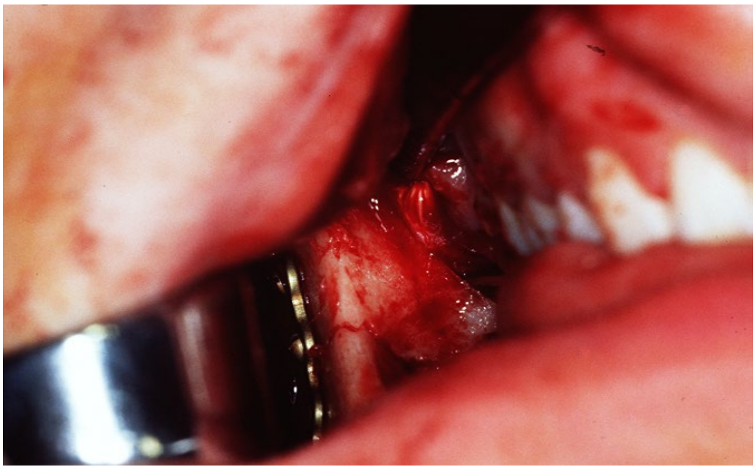

Figure 25 - 4 hole miniplate placed in the buccal cortex

CLINICAL PICTURES - TRANSBUCCAL APPROACH

Figure 26 - Closure with 3.0 catgut

Figure 27 - Occlusion tested

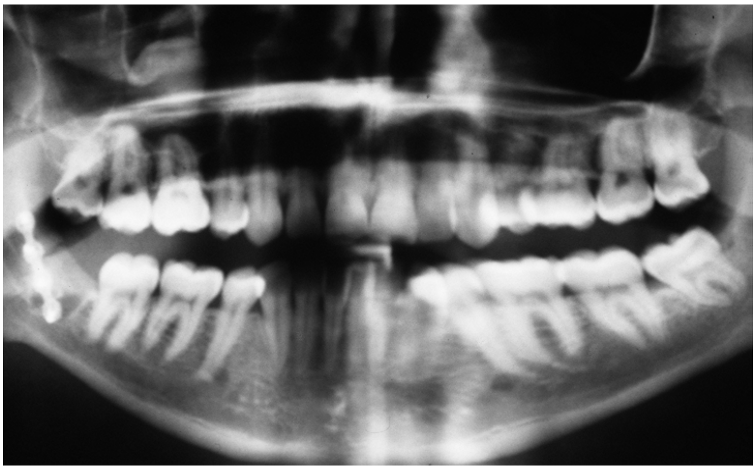

Figure 28 - Final X-ray

CHAPTER 8 - DISCUSSION

Fractures of the mandibular angle represent between 23% and 42% of all mandibular fractures (Pape et al., 1983; Wald et al., 1988). This site is also associated with the highest incidence of infective complications following treatment.

In this study age showed a trend toward a significant relationship with infection, the 24 patients had an age range between 16-39 years, M:F ratio (20-4). This demonstrates that the study comprises a cohort primarily composed of young males. This merely representing the demography of this particular condition, rather than an association perse between age/sex and infection.

The presence of the 3rd molar in the line of fracture showed no significant impact on infection rates. A third of the cases in this study requiring third molar removal. According to our protocol all third molars in the fracture line were left in-situ unless such teeth had sustained a root fracture, were grossly mobile, or were previously affected by pericoronitis.

Gender, past medical history and smoking showed no significant impact on infection rate. Although 16 of the 24 patients were smokers (66.6%). The lack of relationship between infection and smoking found there is odds with previous reports of the literature (Booth et al., 1999). This again probably reflects the relatively small sample size.

In this study we have defined alcohol abuse as a consumption of alcohol exceeding 21 units/week for females and 28 units/week for males (as per National Governmental Guidelines).

In this study 10 males and 2 females exceeded these limits. However, we were unable to demonstrate a statistically significant relationship between excessive alcohol consumption and infective complications. This is not consistent with the findings of other authors, and again represents the small sample size.

Ellis and Walker (1994) described that approximately 60% of patients with mandibular fractures gave a history of chronic alcohol consumption, nonintravenous, and/or intravenous drug abuse.

Substance abuse showed no significance impact on the infection in this study, but this variable should always be considered. The results of a study done by Passeri et al.

(1993) show that intravenous drug users had a 30% rate of complication (including infection, malunion, malocclusion and neurosensory dysfunction), and chronic non-intravenous drug users and alcoholics had complication rates of 19% and 15.5% respectively. Those individuals who did not abuse substances had a complication rate of only 6%.

Surprisingly, the number of fractures per patient was not associated with risk of postoperative infection as found by previous authors (Stone et al., 1993).

The mechanism of injury in this study was predominantly assault, represented in 16 of the patients, (66.6%). According to the British Association of Oral and Maxillofacial Surgeons Survey of Facial injuries study (Hutchison et al., 1997) the aetiological profile reveals falls (40%), assaults (24%), other accidents/sports injury (21%), road traffic accident (5%) as the cause of facial trauma. Therefore, our figure for assault as the aetiological factor of 66% is much higher than the aforementioned study; but again, this may reflect the relatively small sample size.

We also found associated injuries were present in 41.6% of all mandibular angle fracture patients, the majority of these were involved in vehicular accidents, similar figures have been previously reported by Fridrich et al., 1992, Smith 1991, and Fedok et al., 1998.

No cases of malunion, non-union or facial deformity occured. However, a number of patients had a relatively small duration of follow-up, range (3-4 months), it may be too early to discount such complication in this group. Koury et al., 1994; Kearns et al., 1994 reported a series with follow-up of 26 months and found a complication rate of 11.5%.

In our study timing of surgery showed no significant impact on infection rate, however several authors have recommended that fractures are reduced and stabilized with in 48 hours. To reduce the chance of infection tracking into the fracture (Schierle et al., 1997; Booth et al., 1999). Naturally, earlier surgery also limits the discomfort to the patient. Late treatment, when the healing process has begun, is associated with poor outcome as it is increasingly difficult to reduce the fracture properly (Booth et al., 1999). In general, most mandibular fractures in the dentate area should be operated on within 48 hours. This particularly applies if the oral mucosa is lacerated.

Internal semi-rigid fixation affords patients early postoperative movement and a return to function. Early function without maxillomandibular fixation permits better oral hygiene and nutritional intake; access to an oral airway which is of paramount importance in a frequently polytraumatized patient population; reduced prevalence of temporomandibular joint ankylosis associated with long-term maxillomandibular fixation; and better patient communication (Fedok et al., 1998). Plate placement in a biplanar orientation is superior to monoplanar plate placement when applied to either a monocortical or a bicortical plating technique (Fedok et al., 1998).

Of the 24 patients treated in this study 4 developed infection, ie an infection rate of 16.6%. If we compare this figure with the previous one from the Maxillofacial Unit Audit of 19%, this is a decrease of 2.4%.

Of 14 patients treated via the transbuccal approach only one developed infection, representing an infection rate of 4.1% of all the patients treated and 7.1% of the transbuccal cohort.

Of the 10 patients treated via the transoral approach 3 presented infection, representing an infection rate of 12.5% of all the patients treated and 30% of all the transoral cohort.

In this study there are trends towards better results with the transbuccal approach versus transoral approach, which may result from a better placement of the plate, better soft tissue covers for the plate, and better bone stock, permiting more secure plate fixation, and therefore immobilisation.

We are aware of not other research that specifically relates the position of plates placement in miniplate osteosynthesis for mandibular angle fractures. From the above results we are confident that with larger numbers we will be able to demonstrate a significantly lower complication rate when the transbuccal approach is adopted over the transoral approach.

CHAPTER 9 - CONCLUSION

In this study we have shown that the key to success is: fixation of the plate in the region of optimal stress; good mucosal coverage; suppression of infection related to the presence of the mandibular third molar; and systematic prescription of antibiotics.

The results in relation to demographic variables were consistent with other authors findings. The small number of patients included in this study, don't allow us to draw hard and fast conclusions from them.

We found a post-operative and three-month orthopantomogram and PA mandible a useful manoeuvre to adequately assess the healing process, quality of bone and position of the plates.

A three-month follow-up was adopted in this study. However, it may be more reasonable to follow these patients for 1 year to detect later complications ie non-union, malocclusion and facial deformity. However, we appreciate the difficulties that can arise from long term follow-up in this patient group. However, study had an unusual follow-up profile, with 100% return rate to the outpatient appointments.

The protocol used for the extraction of third molar in the fracture line seems to be reasonable and should be considered in the surgical approach to this kind of fracture.

In this study there were trends towards better results with the transbuccal approach versus transoral approach, using one four-hole 2 mm titanium miniplate.

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CHAPTER 11 - APPENDIX

APPENDIX - 1

CLINICAL PROTOCOL

A comparison of infective complications associated with the two techniques employed in miniplate osteosynthesis for fractures of the mandibular angle

Nicholas Hyde and Fernando Duarte

Introduction

Fractures of the mandibular angle represent between 23%[1] and 42%[2] of all mandibular fractures. This site is also associated with the highest incidence of infective complications following treatment, (Ikemura et al 1988[3] and Ardary 1989[4]). However, such information is rarely categorised in a way that permits comparison of infection rates following miniplate osteosynthesis at the mandibular angle with those at other facial fractures sites. Those figures that are discernible from the literature range from 5%[5]-25%[6]. Following a retrospective audit of 100 consecutive facial fractures treated with miniplate osteosynthesis, our own experience demonstrated a 19% infection rate when mandibular angle fractures were examined in isolation. This complication rate is unacceptably high.

Many factors have been proposed as aetiological factors to explain the high incidence of infection at this site. These include the retention or extraction of partially erupted third molars in or from the fracture line, a higher proportion of open injuries, and increased bone density resulting in relatively reduced vascularity.

Whilst the debate still continues as to the role of the partially erupted third molar in the genesis of infection, the other two variables are essentially beyond influence, and as such, less important. There is another factor that may influence infection rates at this site, namely the technique employed to effect miniplate osteosynthesis following fracture reduction. There are two main approaches, both of which were advocated in Champy's original paper from 1978[7]. The transoral route, in which the plate is placed on the external oblique ridge, and the transbuccal approach, in which the plate or plates are placed more inferiorly on the buccal cortex, utilising a trochar passed through the cheek.

Retrospective analysis of our own data suggests that there is a higher infection rate when transoral external oblique ridge plates are used. We are unaware of any published data that specifically investigates this putative relationship between the incidence of infection and the site of plate placement to effect osteosynthesis at the mandibular angle. Both approaches are considered appropriate techniques in the management of mandibular angle fractures. Previous studies have compared internal fixation using one or two plates without difference in outcome[6].

Hypothesis

It is our contention that the mucosal cover afforded to plates placed on the external oblique ridge is relatively poor when miniplate osteosynthesis is used to treat fractures at the mandibular angle. We postulate that flaps heal poorly and/or breakdown when the wound margin is placed over an alloplastic surface. This results in impaired healing and a high rate of infective complications.

It is our contention that the better soft tissue coverage afforded by the transbuccal approach would reduce the rate of this particular complication in fractures of the mandibular angle.

Material and Methods

We will enrol sequentially 50 dentate patients with fractures of the mandibular angle as they present or are referred for treatment at the Maxillofacial unit at UCL. All will have pre-operative radiographs consisting of an orthopantomogram and PA mandible. Each will be randomly allocated to either the transbuccal or transoral treatment group. Each will then undergo open reduction and internal fixation, by either staff grade, senior registrar or consultant maxillofacial surgeons using the Leibinger titanium 2mm ostheosynthesis miniplate system. All third molars in the fracture line will be left in-situ unless such teeth have sustained a root fracture, are grossly mobile, or are affected by pericoronitis[8]. If any of these conditions apply, they will be removed at the time of surgery. All patients will be given a standard antibiotic prophylaxis regime:

1g amoxycillin I/V at induction plus 500mg I/V 3 hours post-operatively. If penicillin allergy 300mg clindamycin I/V at induction plus 150mg I/V 3 hours post-operatively.

Time taken to perform the procedure will be recorded. Closure will be performed by using interrupted 3 ‘0’ catgut, without the placement of a wound drain.

Patient will then be reviewed at fortnightly intervals for the first month, at 3 months following surgery and then as required. Patients will be told of possible infective complications and asked to return appropriately. Post-operative radiographs consisting of an orthopantomogram and PA mandible will be taken immediately post-operatively, and again at 3 months.

During this period patients would be observed for clinical and radiographic signs of infection. Patients deemed to have suffered an infective complication would be those who present with any or a combination of the following:

1- erythematous swelling and/or discharge of pus in the buccal sulcus or swelling overlying the angle of the mandible appearing after the effects of the initial trauma/surgery have settled, (i.e. after 7 days).

2- intra-oral wound dehiscence with plate exposure.

3- radiographic evidence of loosening of screws, osteomyelitis, fracture non-union.

4- persistent infection requiring plate removal.

We will use the fallow scoring system, and infection is classified as a score of 8 or above.

Scoring system for intraoral wound infections		
Swelling[1]	0 - 3	
Pain[2]	0 - 4	
Erythema[3]	0 or 5	
Purulent exudate	0 or 10	
Isolation of pathogenic bacteria from the wound[4]	0 or 10	
Temperature[5]	0 or 10	
Wound dehiscence	0 or 10	
Total		

[1]Swelling: visual assessment will be used;
0: no swelling
1: minor swelling
2: moderate swelling
3: great swelling
[2]Pain: verbal analogue scale will be used;
0: absent
1: mild
2: moderate
3: severe
4: excruciating pain
[3]Erythema: 5 given for the presence of extraoral erythema.
[4]Swabs taken only when there is pus and pathogenic bacterial refers to significant growth.
[5]Temperature: 10 is given when the temperature is 37.5Cº or more (measured orally).

Information would be recorded on an individual patient proforma. On completion, data would be analysed and subjected to non-parametric statistical analysis.

Patients presenting with infective complications would be managed initially with antibiotics, and if necessary, plate removal and wound debridement.

Inclusion Criteria

All patients presenting with one or more facial fractures which include a displaced fracture of the mandibular angle. Diabetic patients will be included but noted.

Exclusion Criteria

Patients who at presentation have clinical evidence of pre-existing infection at the fracture site.
Patients undergoing immuno-suppressive therapy.
Patients requiring re-operation for post-operative malocclusion.

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CHAPTER 11 - APPENDIX

APPENDIX - 2

PATIENT INFORMATION

PATIENT INFORMATION SHEET

UCL/UCLH JOINT COMMITTEES ON THE ETHICS OF HUMAN RESEARCH

Please read this form carefully. Please ask if you do not understand or would like more information.

GENERAL INFORMATION GUIDELINES

Title of research project:

Infective complications in mandibular miniplate osteosynthesis

Name of Investigator: Dr. Fernando Duarte
Supervisors: Mr. Nicholas Hyde, Senior Registrar in Maxillofacial Surgery UCLH
Professor Malcolm Harris, Head of the Department of Oral and Maxillofacial Surgery, EDI & UCLH

We would like your help in a study designed to allow us to decide which of two standard methods for treating your broken jaw is the best. It will involve you being randomly allocated to one of two groups.
It is current practice reduce the gap between both ends of your fractured jaw and hold it together with a small metal plate while it heals. There are currently two well recognised ways of doing this but no one knows which carries the lowest level of infective complications.

In order to find out which of these two approaches is the best we need to do this study. You will be assigned to one of the two treatment groups after you have had your initial investigations. The only difference between the groups being the site on the jaw where the metal plate used to treat your fracture is placed. In both methods you will have an incision inside your mouth, but in one of them you will have an extra very small incision through your cheek which heals with minimal scarring. There is no difference between the two techniques in terms of post-operative pain, swelling, or recovery time.
During your recovery period you will be followed up in our out-patient department, and we will monitor your progress with clinical observations and X-rays. The post-operative follow-up is the same whether or not you agree to take part in the study.

If you do not wish to participate in this study you are free to refuse and it will not affect your care.

Your personal information will be treated as confidential and kept secure.
You will be kept informed of all relevant facts arising as the project progresses.

The expected duration of the study is 3 months.

Participation in this project does not involve any restriction on your activities or drug administration.

You may ask questions of the investigator on any matters relating to participation in the proposed research project.

An ethics committee reviews all proposals for research using human subjects before they can proceed. This proposal was reviewed by the Joint UCL/UCLH Committees on the Ethics of Human Research.

CHAPTER 11 - APPENDIX

APPENDIX - 3

INFORMED CONSENT FORM

CONSENT FORM FOR RESEARCH ON PATIENTS

UCL/UCLH JOINT COMMITTEES ON THE ETHIC OF HUMAN RESEARCH

Please read this form carefully and ask if you do not understand or would like more information.

CONSENT BY THE PATIENT

Title of Research: Infective complications in mandibular miniplate osteosynthesis

Name of Investigator: Dr Fernando Duarte

I……………………………………….................…… (Full name) of…………….……………….

…………………………………………………………….…………………………(Address)

hereby fully and freely consent to participate in the above research project.

I agree that my general practitioner may be notified of my participation in the research project and that he may release information on my past history. I have informed the investigator of any drug I am presently taking.

I understand and acknowledge that the investigation is designed to promote medical knowledge.

I understand that I may withdraw my consent at any stage in the investigation.

I acknowledge the purpose of the investigation, the nature and purpose of which has been detailed to me during a personal interview and has been explained to me by:

Dr Fernando Duarte – Department of Oral and Maxillofacial Surgery

Signed…………………………………………………………….………. Date………………….

DECLARATION BY THE INVESTIGATOR

I confirm that I have informed the above-named patient during a personal interview and explained the nature and effect of the procedures to her consent have been given freely and voluntarily.

Signed……………………………………………………………………………………….

Name…………………………………………………………………………………………