Design and biomechanical comparison between classic- and new-generation of zygomatic implants – Experimental study

ABSTRACT

Purpose: The present experimental study aims to show the evolution of zygomatic implant design from a well-known manufacturer (S.I.N. Implant System, São Paulo, Brazil) since its classic zygomatic dental implant to the modern zygomatic dental implant. A biomechanical comparison of the two previously mentioned types of zygomatic implants has been performed through dynamic fatigue evaluation tests in accordance with ISO 14801 standards.

Materials and Methods: Classic- and new-generation of zygomatic implants have been subjected to dynamic fatigue loading tests performed in accordance with ISO 14801:2007 and ISO 14801:2016 standards.

Results: The “% of Reference Load versus Number of Cycles” curves show that classic-generation zygomatic implants can resist up to 30,0% of reference load during $5 \times 10^6$ mechanic loading cycles, whereas the new-generation zygomatic implants can resist up to 66,6% of the reference load during $5 \times 10^6$ mechanic loading cycles. Whereas classic-generation zygomatic implants only show rupture in the screw region of the implant, new-generation zygomatic implants show either implant or screw rupture.

Conclusions: The new-generation zygomatic implants have shown promising biomechanical properties in dynamic loading tests. They can support twice the amount of reference load (66,0% against 30,0%) when compared with classic-generation zygomatic implants.

KEYWORDS

Zygomatic implant, design, biomechanical comparison, new generation of zygomatic implants

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INTRODUCTION
The use of zygomatic implants for the rehabilitation of edentulous patients was firstly described by Per-Ingvar Brånemark in 1998 and opened a new field within the implant dentistry area that has been particularly active in the last 20 years. Migliorança and colleagues have recently published an extensive systematic review and meta-analysis about the subject describing, from the historical point-of-view, the main zygomatic implant techniques developed in the past two decades, where the paradigm shift has been the change in the zygomatic implant insertion from an intrasinus to an extrasinus path, allowing an easier and less morbid procedure. However, where this historical review has been completed with respect to zygomatic implant techniques, little has been done regarding the evolution of zygomatic implants as implant materials, which led the authors of this study to do a design and biomechanical comparison between a classic and a new generation of zygomatic implants from the same developer.

ZYGOMATIC IMPLANTS DESIGN
CLASSIC-GENERATION DESIGN
The classic-generation zygomatic implant (S.I.N. Implant System, São Paulo, Brazil) was available in 13 different lengths, ranging from 32 to 62 mm. It was an implant with universal external hexagon connection, made of grade IV titanium, being surface treated by a double acid attack in all the implant, sterilized by gamma radiation and coming with a mounter and cover-screw. It has an angled head of 45°, which compensates for the angulation between the zygomatic bone and the maxilla and between two zygomatic implants, when placed in the same quadrant. The apical diameter was Ø4.0 mm and the cervical diameter was Ø4.4 mm; presented in Figure 1.

NEW-GENERATION DESIGN
The new-generation zygomatic implant (S.I.N. Implant System, São Paulo, Brazil) is available in 13 different lengths, ranging from 32 to 62 mm. It is an implant with universal external hexagon connection, made of grade IV titanium, being surface treated by a double acid attack in the apical and cervical regions, sterilized by gamma radiation and coming with a mounter and cover-screw. It has an angled head of 45°, which compensates for the angulation between the zygomatic bone and the maxilla and between two zygomatic implants, when placed in the same quadrant. The apical diameter became Ø3.85 mm with a length of 10 mm, this change aiming to enable the placement of implants in smaller zygomatic bones; presented in Figure 2. The cervical diameter became Ø4.5 mm with micro-screw threads in a length of 3 mm; this change aiming to increase the primary stability of the implant at the level of the alveolar ridge, most of the time very atrophic and without consistency. Keeping the bone around the implant head, a greater area of osteointegration is achieved and, as a consequence, peri-implant soft tissue coverage will be improved, increasing resistance to occlusal forces. Resorption of the thin palatal bone rapidly leads to oro-antral fistula followed by implant loss.
MATERIALS AND METHODS
Classic- and new-generation of zygomatic implants from S.I.N. Implant System, São Paulo, Brazil have been subjected to dynamic fatigue loading tests performed in accordance with ISO 14801:2007 and ISO 14801:2016 standards, respectively. For the dynamic fatigue evaluation of the old-generation zygomatic implants (ISO 14801:2007 standards), the measuring parameters were the following: Brasvalvulas equipment_model BME1500-160/AT, reference load of 2901.02 N (18.86 N.m), test frequency of 15 Hz, minimum/maximum load R ratio of 0.1, tightening torque of 20 N.cm, L distance of 13 mm, number of run out cycles of 5´10^6, polyacetal specimen holder, ambient air at room temperature. Maximum load (N), maximum moment (N.m) and the number of cycles for implant rupture were recorded to evaluate the zygomatic implant tolerance limit.

For the dynamic fatigue evaluation of the new-generation zygomatic implants (ISO 14801:2016 standards), the measuring parameters were the following: CENIC 017 testing machine for evaluation of bending fatigue, reference load of 706.3 N (6.36 N.m), test frequency of 15 Hz, minimum/maximum load R ratio of 0.1, tightening torque of 20 N.cm, L distance of 11 mm, number of run out cycles of 5´10^6, polyacetal specimen holder, ambient air at room temperature. Maximum load (N), maximum moment (N.m) and the number of cycles for implant rupture were recorded to evaluate the zygomatic implant tolerance limit.

The fatigue load setting predicted in the 2007 version of ISO 14801 standard doesn’t present any procedure for selecting the worst condition of the sample and has unclear side restricts, whereas the 2016 version of ISO 14801 standard both clarifies the procedure for selecting the worst condition of the sample and also the lateral restrictions involved in the testing as can be seen in following Figure 3.

In order to normalize the methodological differences between the two versions of ISO 14801 that cause variations in the value of reference load for both zygomatic implants, the authors present the traditional “Load versus Number of Cycles” curve in the form of “% of Reference Load versus Number of Cycles” for both zygomatic implants, thus allowing a direct comparison of the biomechanical performance of the two types of zygomatic implants, regardless of the version of ISO 14801 used for the assessment.

![Figure 3. Schematic of test set-up for systems with pre-angled connecting parts. a) ISO 14801:2007 standards used for the evaluation of classic-generation zygomatic implant. b) ISO 14801:2016 standards used for the evaluation of new-generation zygomatic implant.](image-url)
RESULTS

The results obtained in the dynamic fatigue evaluation tests performed for the classic- and new-generation zygomatic implants are presented below, respectively, in Figures 4 and 5. The “% of Reference Load versus Number of Cycles” curves show that classic-generation zygomatic implants can resist up to 30.0% of reference load during $5 \times 10^6$ mechanic loading cycles, whereas the new-generation zygomatic implants can resist up to 66.6% of reference load during $5 \times 10^6$ mechanic loading cycles, which means a two-fold increase in the zygomatic implant resistance to biomechanical loading. Another difference between classic- and new-generation zygomatic implants, is that in the former the fractures are associated to low cycle fatigue (below 10$^4$ mechanic loading cycles), whereas in the latter, the fractures are associated with high cycle fatigue (above 10$^4$ mechanic loading cycles), as can be observed in both Figures 4 and 5.

Higher test loads and moments have resulted in fracture/rupture of the zygomatic implants, as can be shown in Figure 6. Whereas classic-generation zygomatic implants only show rupture in the screw region of the implant, new-generation zygomatic implants show either implant or screw rupture. Considering that the material used for both dental implants is a titanium Ti6Al4V alloy, one can infer that the superior biomechanical properties of new-generation zygomatic implants when compared to classic-generation zygomatic implants must be attributed to implant design, namely the length and thickness of the zygomatic implant.7

The fact that classic-generation zygomatic implants consistently show a rupture in the screw region of the implants, when new-generation zygomatic implants present ruptures in either the screw or the implant itself, shows that in the more recent zygomatic implants, the mechanical loading is more successfully distributed by all the area of the implant than the earlier versions of zygomatic implants, where the screw region seems to be the weak point of the overall implant.7,8,9

In either case, the dynamic fatigue evaluation tests are always limited when compared to in vivo evaluations, once they do not account for the intraoral medium that contacts with the dental implants throughout years and decades, eventually causing variations in the levels of temperature, electrolyte concentration, pH, enzymes, proteins and cells in the surroundings of the implant that slowly weaken the implant’s biomechanical resistance and reduce its lifespan.

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Figure 4. “Percentage of Reference Load versus Number of Cycles” curve for classic generation zygomatic implant

Figure 5. “Percentage of Reference Load versus Number of Cycles” curve for new-generation zygomatic implant

Figure 6. “Percentage of Specimens that failed under the dynamic fatigue test performed with ISO 14801 standards a) Classic-generation zygomatic implants. b) New-generation zygomatic implants
CONCLUSIONS
The new-generation zygomatic implants have shown promising biomechanical properties in dynamic loading tests. They can support twice the amount of reference load (66.0% against 30.0%) when compared with classic-generation zygomatic implants. Considering that dynamic fatigue evaluation tests simulate better the in vivo performance of dental implants than static fatigue evaluation tests, one can expect that new-generation zygomatic implants will have superior performance upon application.

In face of the results here presented, it is undeniable that zygomatic implants design and biomechanical resistance has shown a significant evolution throughout the last 20 years, which has helped to increase the percentage of rehabilitation success rate among edentulous patients, together with the advances in zygomatic implant techniques attained in the same period.

Future studies comprising a comparison with other commercially available zygomatic implants should give a more complete insight on the biomechanical potential of these new-generation zygomatic implants. In addition, in vivo performance evaluation of these systems must be attempted in order to confirm these promising preliminary data.

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CONFLICT OF INTEREST
The author declares that there is no conflict of interest regarding the publication of this article.

REFERENCES