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A New Horizon in Osseo-Compression Oral Implantology

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Abstract

Dental implants have been available in press-fit and threaded variations as well as one-piece and two-piece designs since the 1960's. Drawbacks to press-fit implants related to low insertion torque requiring a non-loading phase to allow integration and the surface of these implants being predominately under shear loading saw a transition to threaded designs. These threaded implants allowed better insertion torque allowing immediate loading when specific parameters were met. Modifications of surgical technique have allowed osseo-compression to be utilized to improve bone quality (density) and achieve higher insertion torques. This study shall discuss a one-piece non-threaded implant specifically designed to osseo-compress the bone surrounding the osteotomy at placement, while using the benefits of eliminating the connection between the implant and abutment head.

Purpose: The aim of this *in-vitro* study was to develop a polygonal and solid dental implant based on the concepts of fulcrum-lever force dissipation and circumferential-apical wedging to maximize primary stability for immediate loading. A threadless implant was designed with a Restorative Attachment and a Bone Engagement Zone as a one-piece implant without fixation screws that are normally seen in two-piece implant systems.

Material and Methods: Two human mandibles were chosen. osseo-compression, drill, and hybrid delivery methods were used to insert 30 prototype dental implants in D1 and D2 dense bone zones. Placements were recorded and evaluated with pre- and post-operative CBCT and photographs. Finite Element Analysis (FEA) and periotest were conducted before extraction to evaluate the primary stability, fatigue, and stress resistance.

Results: Regardless of the insertion protocol implemented, primary stability of the polygonal concept exceeded expectations during periotest evaluation. A significant amount of fine bone was harvested during osteotomy. FEA demonstrated exceptional structural strength due to strategic design features. The integrity of both bone and implants were maintained without any observable micro-fractures around the osteotomies.

Conclusion: With advancements in delivery technologies, osseo-compression implantology remains an effective alternative delivery method. The results demonstrated the 1P prototype design provided profound primary stability, a conservative osteotomy, and controlled ridge expansion while exhibiting autogenous bone self-harvesting capabilities in all three delivery methods.

Keywords: *Dental Implant; Fulcrum; Lever; Polygonal Design; One-Piece; Primary Stability; Osseo-Compression*

Introduction and Background

By the 1990's, Brånemark's concept made such an impact in clinical dentistry that mainstream clinicians and public acceptance rose significantly to the extent that it overshadowed all other protocols and systems, specifically one-piece implants. Inadequate clinical

documentation, inclination towards reports of failed cases, and a lack of university based implantology programs accelerated the isolation of those alternative approaches. Failure reports are not scientifically sufficient and conclusive enough to substantiate or refute any techniques or implant systems without proper investigation, hence there are discrepant reports of one and two-piece success rates [1-5]. However, growth in reception and subsequent demand for dental implant utilization have put forth considerations for shorter healing periods and better esthetics in the last two decades [6,7]. Therefore, one-piece systems are returning to the spotlight only after numerous published studies [8-23] have found that one-piece and immediate loading implants superior in terms of implant-bone interface (IBI), surgical protocol, and elimination of potential structural drawbacks of two-piece implants placed in a two-stage protocol. Regardless of the how many pieces the system is, primary stability and long-term success is the driving force behind the dramatic evolution in implant design. The focus has been to place a foreign device into the body as minimally invasive as possible with biocompatibility between the implant material and host bone, achieving initial stability allowing immediate loading of the implants. To achieve such tour de force, multiple components are scrutinized within surgical and biomechanical perspective [24].

Whether 1-stage, with or without immediate loading or 2-stage, a prosthetic abutment and an anchoring implant body, as the standard pieces, are accompanied by an expensive array of armamentarium and complicated protocols in all 2-stage- two-piece implants. With this approach, the implant is inserted into the bone surgically (first stage) followed by a healing screw. After months of osseous healing, a healing abutment is attached (second stage) for soft tissue healing and development of permucosal seal while the patient awaits another appointment for the final restoration [25,26]. At the second stage, a minute yet redundant uncover surgery may be required to expose implant-abutment interface (IAI), although submerged healing is not a prerequisite of osseointegration [12].

In the case of 1-stage protocol with two-piece implants, the hard and soft tissues heal at the same time eliminating the second stage surgery and appointment using a healing abutment at implant placement. Finally, immediate loading requires attachment of the prosthetic abutment and provisional restoration, at the time of implant insertion, eliminating the need for healing abutments or screws [25]. The implant is subjected to loading in multiple directions during the course of the treatment as healing occurs. Considering the very low shear strength of the bone during the first year of osseointegration, consecutive tightening and un-tightening of the restorative components of two-piece implants may potentially increase the risk of loss of IBI and the already achieved primary implant stability [27].

Conversely, both major elements (fixture and abutment) of the one-piece implant are manufactured as one unit and practitioners require less than half of the armamentarium. A one-piece implant provides unparalleled surgical advantages in terms of surgical simplicity. It is accomplished in a 1-stage surgical procedure and often inserted immediately after extraction or flapless with minimal osteotomy, substantially decreasing surgical trauma and post-operative edema, to provide for an uneventful and accelerated healing phase with less post-operative issues for the patient. Furthermore, it is associated with less bone grafting, sinus augmentation and nerve transpositioning [28]. Regardless this permits elimination of a prolonged treatment period and unnecessary supplementary surgeries making the treatment more comfortable and less traumatic for patients that may already apprehensive.

Biological width in natural dentition is comprised of a connective tissue attachment and a junctional epithelium, respectively 1.07 mm and 0.97 mm on average for a total of approximately 2 mm, by which probing depth is determined [29]. Similar to the tooth, biologic tissue encapsulates the implant by generating a band of soft tissue to provide for the integrity of the periodontium and protection from external factors such as mechanical and biological agents [30]. Bone resorption occurs when the epithelium forges a defensive distance as an attempt to isolate the external factors by proceeding beyond them apically [31]. It has been suggested that the location and presence of microgaps at the implant abutment interface (IAI) and abutment-crown interface (ACI), are directly related to crestal peri-implant bone loss and stage two uncover surgery of the two-piece implants [32-37]. These studies found that exposure of the implant to the oral environment during uncovery surgery allows introduction of bacteria to the newly established biological width eliciting an inflammatory response and subsequent bone resorption at the crestal region. In a one-piece system, the microgap is excluded at the IAI and the ACI location falls coronal to the biological width, thus the risk of microgap-induced bone resorption is significantly reduced [35,38]. In another

study comparing the one-piece and two-piece implants, the effects of micromovement and the size of microgaps at the crestal bone were analyzed and concluded that the more components utilized in an implant system, the higher is the rate of crestal bone loss regardless of the size of the microgap [39].

Heat generation and dissipation are regarded as major concerns during implant surgery as well as intraoral abutment preparation [40,41]. Osteotomy preparation is an inevitable direct assault to the buccal bone. The resultant surgical trauma can be classified into mechanical and thermal injury from which the bone must recover by utilizing renewed blood supply in order to produce osseointegration at the IBI [42]. The amount of prepared bone, depth of osteotomy, and heat generated during drilling are associated with implant success, especially at the crestal regions due to the presence of denser bone and insufficient blood supply [43-45]. Moreover, during abutment preparation, frictional heat easily conducts through the metal implant rapidly and may jeopardize osseointegration. Research has defined a thermal threshold of 47°C for 1 minute to avoid subsequent heat-induced cortical bone necrosis and impaired healing. Practitioners are strongly advised to utilize precautionary methods such as frequent coolant irrigation and short working intervals (intermittent contact) [46]. When compared to a two-piece implant, a one-piece requires possibly more abutment preparation by which excessive heat is generated fostering apprehensions amongst clinicians. However, Omer., *et al*. reported proper water irrigation as beneficial, serving to enhance the cooling capacity of one-piece implants significantly and to prevent thermal induced injuries to adjacent hard and soft tissue [47]. In another study on two-piece implants, abutment preparation recorded a maximum temperature change of 2°C and 4.7°C, with diamond and tungsten burs respectively, using a standard turbine and water irrigation system [48]. Intermittent contact of the bur with the implant abutment intraorally will also allow the irrigant to keep the metal in the acceptable temperature range during restorative preparation.

"Stress treatment theorem", according to Misch, "is the key to implant treatment plans." Unlike the natural dentition, implant lacks the viscoelastic shock absorbing periodontal ligaments while fixated in the bone rigidly; and therefore, the surrounding bone and implant system are at high risks of fatigue and fractures under parafunctional forces. The width, length, and crestal cross-sectional shape of a transosseous structure, implant or tooth, become pertinent in diffusing these forces. The greater the width, the lesser transmitted stress to the bone. The length of the location determines the length, and the cross-sectional shape resists and directs lateral and occlusal loads at the crest [45]. However, in addition to bone width and height limitations as the greatest obstacles to reckon with when choosing the right implant, no implant cross-sectional design comes close to mimic that of a natural tooth. Therefore, from a biomechanical perspective, one of the detrimental aspects in achieving adequate implant-bone approximation, stress distribution, and osseointegration of an implant is its design. Over-all geometry, prosthetic platform and abutment shape, macro- and microgeometries, and material composition define what is referred to as the implant "design" [49-53].

Improper transition and dissipation of multi-axial functional loading and bending moments is menacing to implant success and marginal bone level preservation. The implants geometry and bone-implant contact percentage (BIC%) greatly influences load distribution [8]. Exact reproduction of the manner by which a natural tooth distributes stress and load to the adjacent bone is improbable by dental implants. However, geometrical similarity between a natural tooth and a tapered implant leads one to speculate that they may abide by similar principles when distributing forces [54]. It has been suggested that a tapered (conical) design has proven significantly superior to parallel-walled designs, in achieving and maintaining primary stability even in D4 bone zones without any soft or hard tissue complications [55-62]. Although parallel-walled implant scores 20 - 30% higher in providing surface area for osseointegration and lowering stress in cortical bone in a few studies [49,62,63]. Tapered implants compensate for deficiencies by obtaining much higher values in maximum insertion torque, maximum removal torque, and resonance frequency analysis [57,60,61].

The coincidental release of Brånemark's work at the time of a technological revolution triggered a movement that lead to a multidimensional expansion in implantology in terms of materials and techniques. The material of choice has been titanium since 1940's, when Bothe., *et al.* observed the very first "bone fusing" [64]. Titanium ubiquity is directly related to its chemical and mechanical properties. Anti-corrosive in biological fluid, high strength-to-weight ratio, and machinability are unrivaled qualities that lend titanium "the

gold standard" title [65]. Although commercially pure Titanium (cpTi) has proven its clinical success, few alloys have been developed to compensate for its deficiencies. As any metal is bound to corrode, Ti-6Al-4V corrosion toxicity was found to produce adverse local and immunological reactions. Yet, the most common commercial dental implants are manufactured from Ti-6Al-4V [66,67]. However, the binary titanium zirconium (TiZr) alloy poses as an integral and improved alternative in that it offers better strength without compromising biocompatibility and osseointegration [68,69].

In conjunction with material, surface topography or roughness is a pivotal complement to osseointegration. Generally, the main idea behind texturing the implant is to maximize surface area and BIC, thus, it is indicated in regions with poor bone quality [70]. So far, three levels have been defined: macro, micro, and nano [71]. Macro-level indeed produces favorable results in respect to primary stability; however, it is associated with ionic leakage and peri-implantitis. Nano-level has been advocated in the past few years as it encourages protein absorption and guides osteoblast adhesion to the titanium surface [72]. Achieving nano-level roughness with current technology has been deemed difficult and expensive. Moreover, only a few studies have been conducted and many parameters are still unknown in respect to biological quantification and mechanism of action [71]. On the other hand, Micro level yields the maximum bone-implant fixation as well as higher resistance to shear via configuration such as semi-spherical indentations of 1.5 um in depth and 4 um in diameter [73-75].

By far, the most common dental implants are root-form type due to their predictability and simplified surgical placement compared to platform type implants and subperiosteal implants. According to Misch's terminology, root-form implants are classified based on design into cylinder (press-fit), screw (threaded), or a combination design [25]. These models govern the transmission and conversion of occlusal load to the bone and different types of forces: compressive, shear, and tensile. Therefore, strategic engineering designs become more important than ever to counter and prevent the destructive shear and tensile forces [27]. While press-fit type implants benefits from macro- and microgeometries (e.g. surface topography, semi-spherical indentations) to obtain microscopic bond to the bone load on these implants is predominately shear with little compressive loading due to the implant surface being parallel to the load. Conversely, threaded type affixation is by means of microscopic elements of threads on the body of an implant whereby the threads are angular or perpendicular to the load which is predominately compressive in nature [25]. The best-known macro- and microgeometry designs and textures for osseointegration play major role in maintaining structural integrity of bone and implant as well as enhancing quality of bone-implant fixation.

It is pertinent to mention that simply designing a perfect implant does not diminish the need to examine the cause(s) of implant failure, although science has yet to designate an exact reason for rejection [76]. However, consensus is when establishment and/or maintenance of osseointegration is jeopardized or impaired, at early stages of bone healing, implant mobility is rendered as the epitome of unsuccessful implant surgery [77-79].

To date, geometrical studies on implant design have not investigated alternative shapes other than circular or oval in cross section of bone engagement. The aim of this *in-vitro* study was to develop a one-piece, threadless, tapered, and hexagonal (in cross-section) implant design for immediate loading. Utilizing the concept of fulcrum-lever force dissipation and wedging circumferentially and apically for primary stability while enhancing the clinical and functional aspects through osseo-compression during placement. The results of the present study would make it possible to explore alternative possibilities other than common implant devices, delivery methods, and protocols in implantology.

Methodology, Results, and Materials

Methodology

In this study, the term "hybrid" refers to a combination of osseo-compression and drill methods. Also, "regular and irregular hex" refer to the cross-sectional shape of the implant prototypes. Regular hex is a symmetrical hexagon geometrically; while in the later, only two parallel planes of hexagon are equally and slightly longer than the other four planes in cross-section. Two human mandible specimens

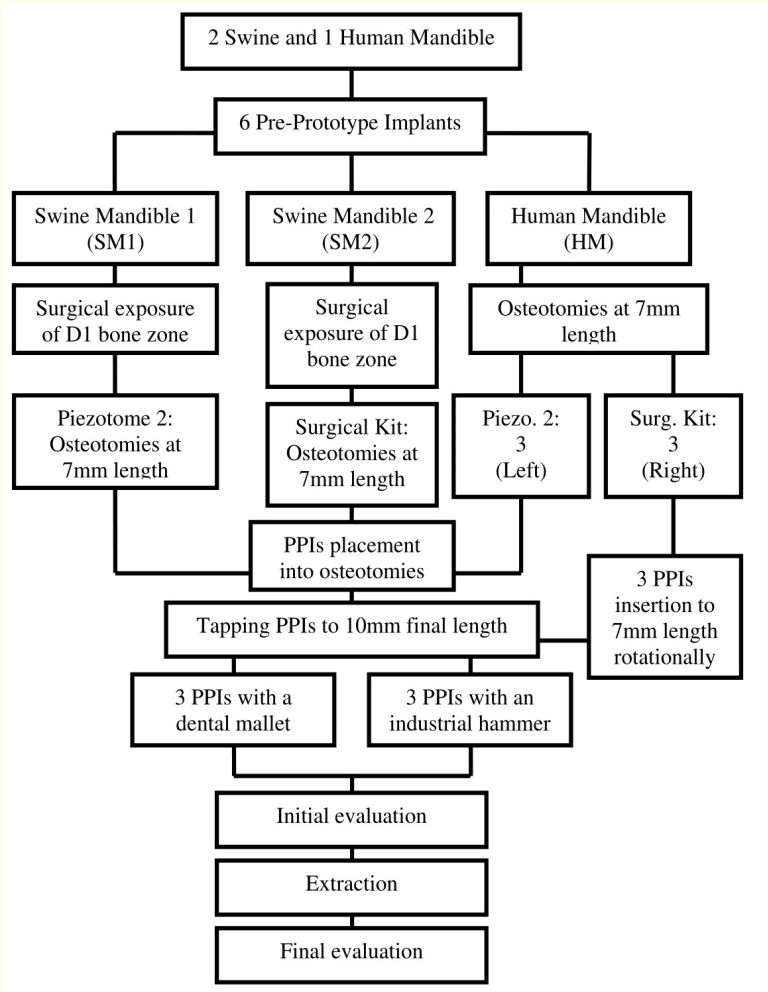
(Skulls Unlimited International Inc., Oklahoma City, OK, USA) were chosen to perform All-On-6 substructures. The condition of each specimen was as follows: one fully edentulous (FEM) and one with extracted sites (EM). osseo-compression, drill, and hybrid delivery methods were used to insert 30 prototype dental implants in D1 and D2 bone zones. Initial anatomical landmarks were examined via pre-operative CBCT. Surgical kit drills were utilized to prepare osteotomies with respect to anatomical structures such as mental and inferior alveolar nerves. All the prototype implants were fabricated from Titanium Grade IV according to specific chemical compositions (Table 1) and mechanical properties (Table 2). A total of 30 prototype dental implants were divided into 2 groups. In group 1, 15 Regular Hex Polygon Prototypes (RHPP) (Figure 3) and the FEM specimen were dedicated to the drill and hybrid methods. It was decided to utilize two delivery methods for placement of RHPPs for further analysis. In group 2, 15 Irregular Hex Polygon Prototypes (IHPP) (Figure 4) and the EM specimen were dedicated to the osseo-compression method only. Although all implants were 16 mm in total length with a 10 mm osseous engagement zone, RHPPs greatest width marked at 4.39 mm and IHPPs greatest width were 4.20 mm. Figures 5 and 6 demonstrate dimensional specifications for both prototypes.

Chemical Composition	Maximum Allowed Values (%)	Tolerance
Nitrogen	0.05	+/- 0.02
Carbon	0.08	+/- 0.02
Hydrogen	0.015	+/- 0.002
Iron	0.50	+/- 0.10 (% < 0.25) +/- 0.15 (% > 0.25)
Oxygen	0.40	+/- 0.02 (% < 0.20) +/- 0.03 (% > 0.20)
Titanium	Remainder	-

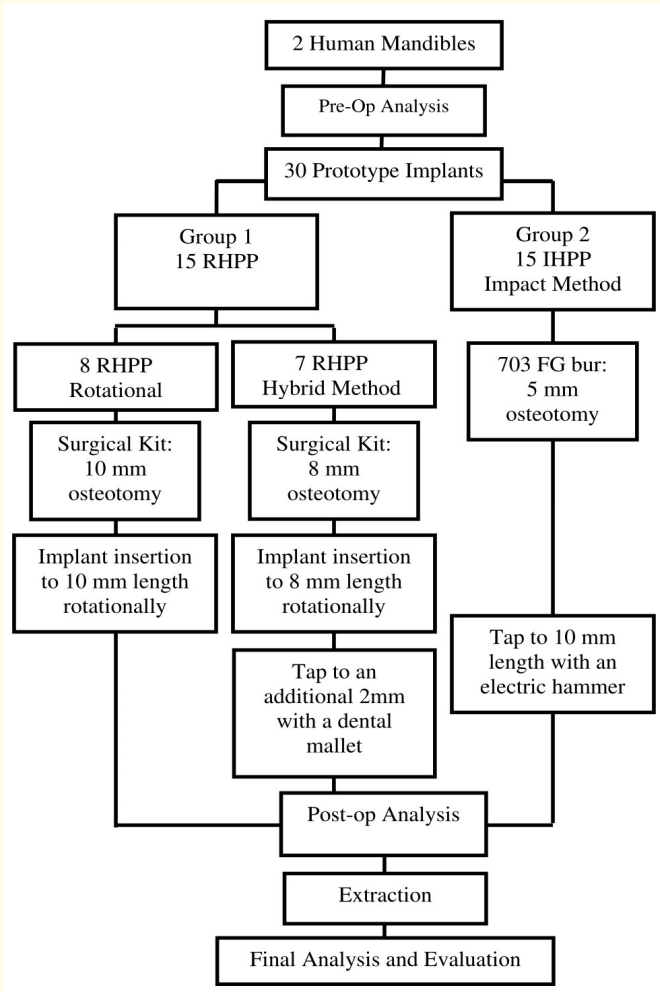
Table 1: *Chemical Composition of Titanium Grade IV.*

Mechanical Properties	Minimum allowed values (%)
Tensile strength	680 MPa (N/mm^2)
Yield strength (0.2%)	520 MPa (N/mm^2)
Elongation at yield	15%
Necking	25%

Table 2: *Mechanical Properties of Titanium Grade IV.*



Flow Chart 1: *Over-all Pilot Study Design.*



Flow Chart 2: *Over all Main Study Design.*

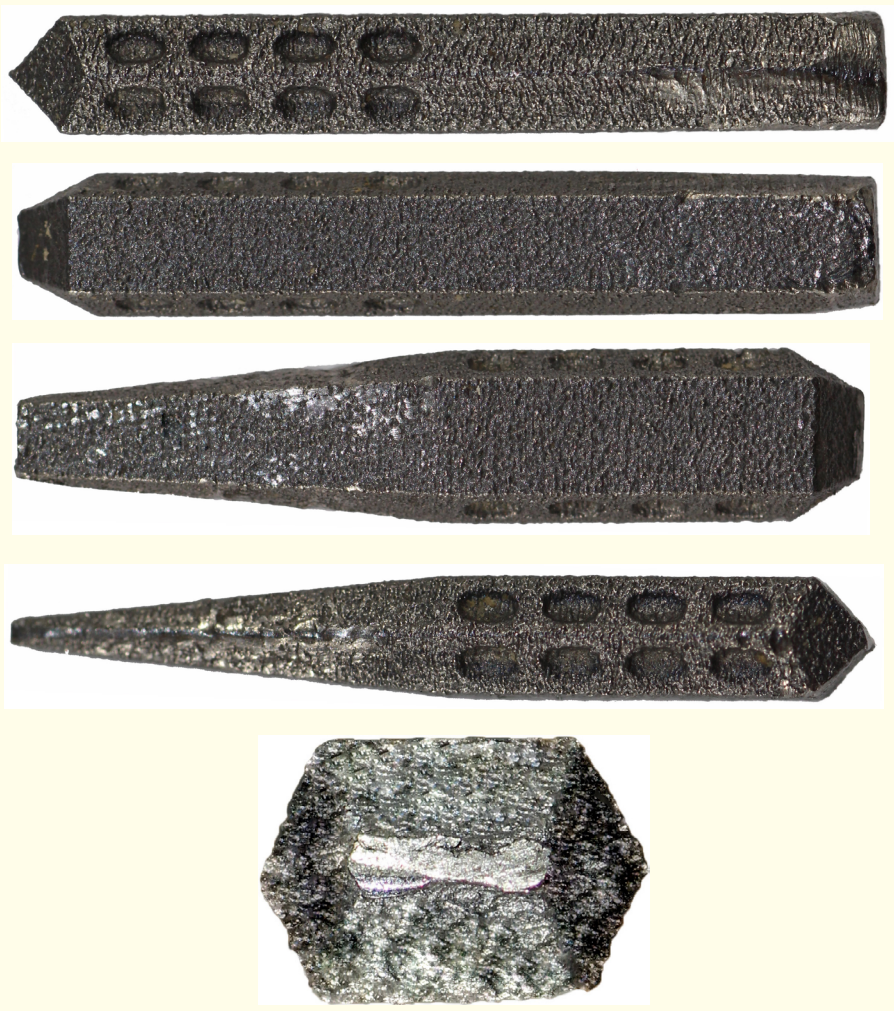


Figure 1: *Straight and Tapering Pre-Prototype Implants.*

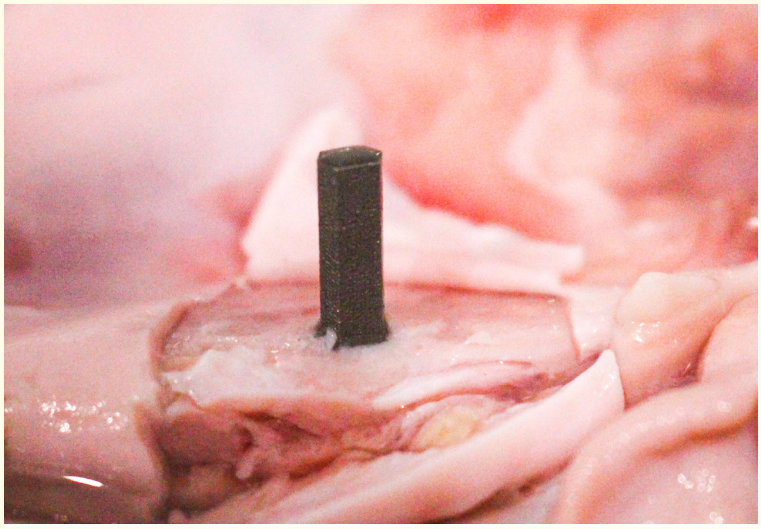


Figure 2: *Fully seated PPI in SM 2.*

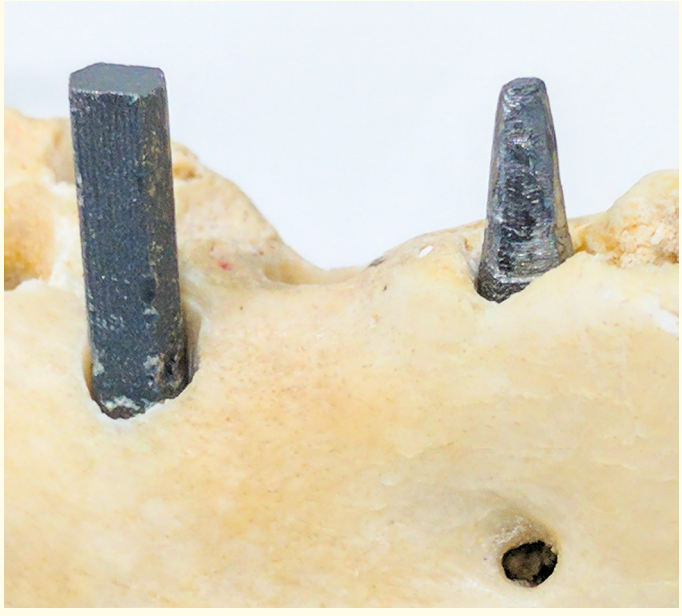


Figure 3: *Fully seated PPIs in HM.*

Figure 4: *Bone particles with in PPI reservoirs.*

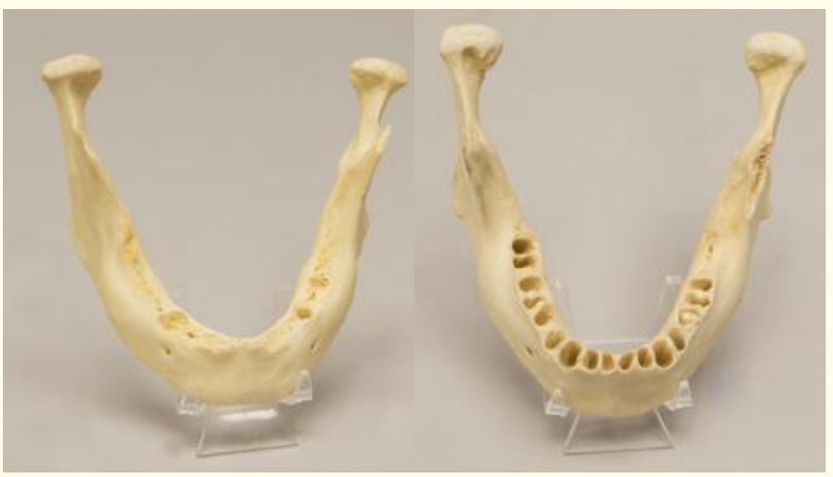


Figure 5: *Mandible Specimens: IHPP group (Left) and RHPP group (Right) Pre-Op.*

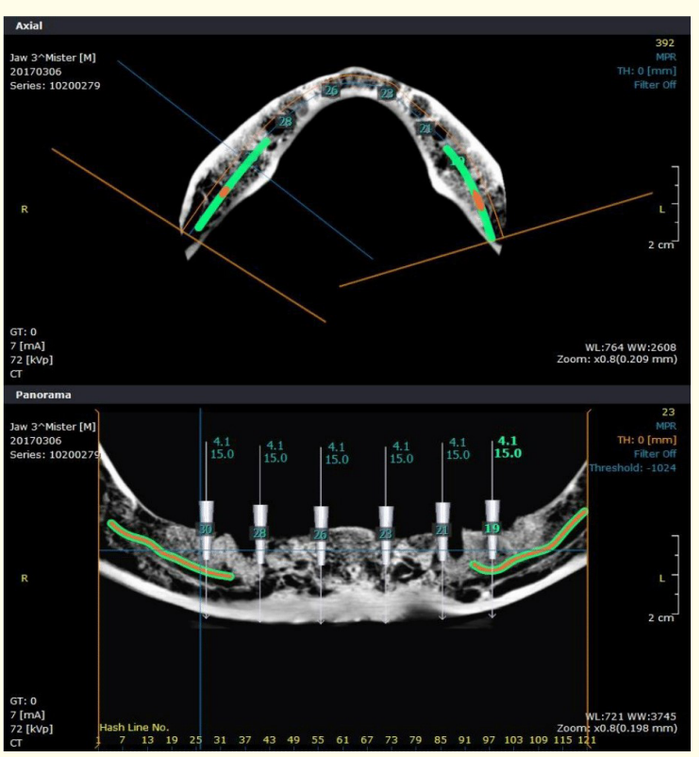


Figure 6: *Anatomical Landmarks: IHPP group Pre-Op Analysis.*

Group 1: RHPP – Hybrid method

8 mm vertical osteotomy preparations were made for placement of seven RHPPs. A precision drill was used to penetrate crestal bone for guiding holes. Then, a 2.4 mm diameter tapered-tip pilot drill was used to prepare 8mm deep vertical initial osteotomies. This step was

followed by osseous preparation with a 3.8 x 8 mm and 4.25 x 8 mm conical drills to a final depth of 8 mm. RHPPs were initially driven to 8 mm length of osseous engagement zone using a surgical handpiece at 45 N/cm (Figure 7). Then, they were tapped in an additional 2 mm with a dental mallet to achieve osseo-compression.

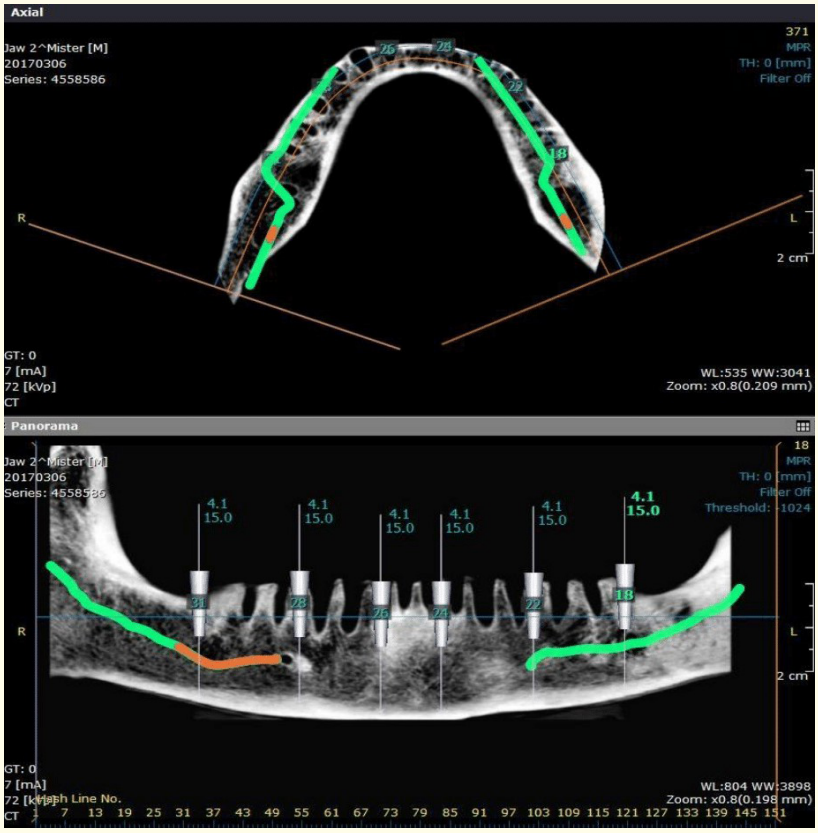


Figure 7: *Anatomical Landmarks: RHPP group Pre-Op Analysis.*

Group 1: RHPP – Drill method

10 mm vertical osteotomy preparations were made for placement of eight RHPPs. A precision drill was used to penetrate crestal bone for guiding holes. A 2.4 mm diameter tapered-tip pilot drill was next used to prepare 10 mm deep vertical initial osteotomies. This step was followed by osseous preparation with 3.8 x 10 mm and 4.25 x 10 mm conical drills to a final depth of 10 mm. RHPPs were rotationally driven to 8 mm depth of osseous engagement zone using a surgical handpiece at 45 N/cm. They were tightened further with a ratchet wrench to a final depth of 10 mm.

Group 2: IHPP – Osseo-compressive method

A 703FG bur and a surgical stent were used to penetrate crestal bone vertically for a 5 mm deep pilot hole. The prototypes were tapped to the final length of 10 mm using an industrial grade electric hammer guided by a carrier.

All placements were studied with post-operative CBCT studies and digital photographs. Additionally, Periotest was conducted to measure initial instability and resistance to micromovement of all the implants before extraction and evaluating the amount of autogenous bone graft collected during each delivery method.

Materials - Topography and Design

All prototypes were 16mm long, one piece and hexagonal design in cross section of the Bone Engagement Zone (BEZ). A gradual taper mimics the shape of a root of the natural dentition from the Crestal Zone (CZ) to the apical terminus of the implant; such that, the implant is thicker and wider at the BEZ than at the apical end portion (Figure 3 and 4).

By design, this prototype is divided into multiple zones each serving multiple purpose(s). The 6mm Restorative Zone (RZ) is comprised of 3 mm Attachment Zone (AZ) and 3 mm Prosthetic Margin Zone (PMZ). Whereas, 3o taper is evident from the top of the RZ to the platform switch in IHPPs (Figure 6), RHPPs experience such taper only at the PMZ and its AZ remains parallel to the long axis of the device (Figure 5). Geometrically, the RZ is designed to accommodate for multi-unit restorations and delivery systems to engage an external hex at the most coronal 3 mm of the prototype. The PMZ in collaboration with the initial 2 mm of the Implant Body Zone (IBZ) provides the 5 mm Machines Surface Zone (MSZ), which aids to prevent plaque accumulation. The 2 mm Crestal Zone (CZ) represents the transition zone from the PMZ to IBZ at the crest of the ridge. A total of 36 semi-spherical indentations, which acted as autogenous bone graft reservoirs in this study, are engraved onto the 6mm Harvesting Zone (HZ) linearly, 6 on each plane and 1 mm deep at the most concave point. All of the planes and beveled corners converge harmoniously into a chisel-like apical end portion from the 2 mm Fulcrum Zone (FZ). The 10 mm BEZ is referred to as the IBZ and FZ collectively (Figure 8).

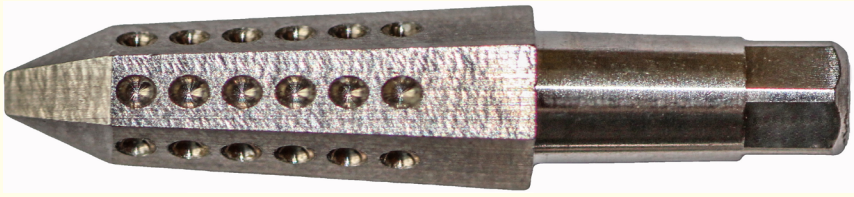


Figure 8: *RHPP Implant.*

Finite Element Analysis

The Bone Engagement (BEZ) and Restorative Zone (RZ) of the RHPP and IHPP were subjected to a series of comparative behavior for fatigue failure. Four types of spherical titanium alloy coping (Ti-6Al-4V Gr. 5) were attached to each RZ to ensure the uniform transfer of applied load while stimulating prosthetic crowns of various lengths. Additionally, load was applied at a 30o angle to better approximate standard masticatory force vectors in a worst-case scenario. Four IHPPs and one RHPP implants were embedded onto separate bases. The objective was to evaluate the differences in the FEA and the maximum load that the best configuration test could tolerate during a fatigue test in multiple scenarios. Table 3 illustrates the testing conditions for each implant in details. The list of implants that were tested as follows: (Figures 9-12).

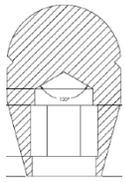
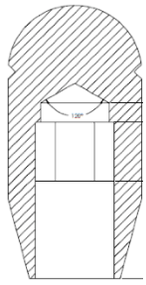
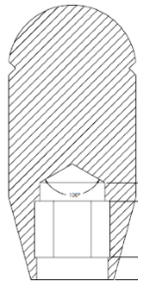
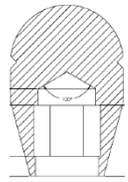
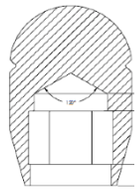
Implants	IHPP Conf. 1	IHPP Conf. 2	IHPP Conf. 3	IHPP Conf. 4	RHPP Conf. 5
Coping attachment design	 Short-1	 Long-1	 Long-2	 Short-1	 Short-2
RZ coverage	2.5 mm	5 mm	2.5 mm	5 mm	2.5 mm
BEZ coverage (BIC%)	7 mm (70%)	7mm (70%)	10 mm (100%)	7 mm (70%)	7 mm (70%)
Load direction in respect to FZ	Parallel	Parallel	Parallel	Perpendicular	Parallel

Table 3: *Testing Conditions of each implant configuration test.*

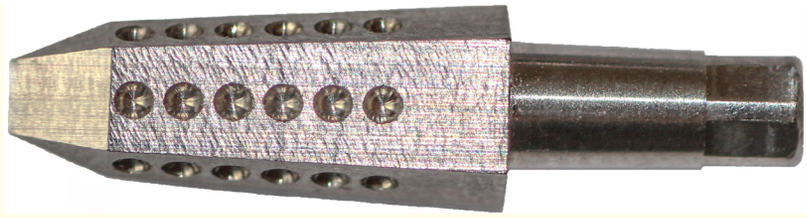


Figure 9: *IHPP Implant.*

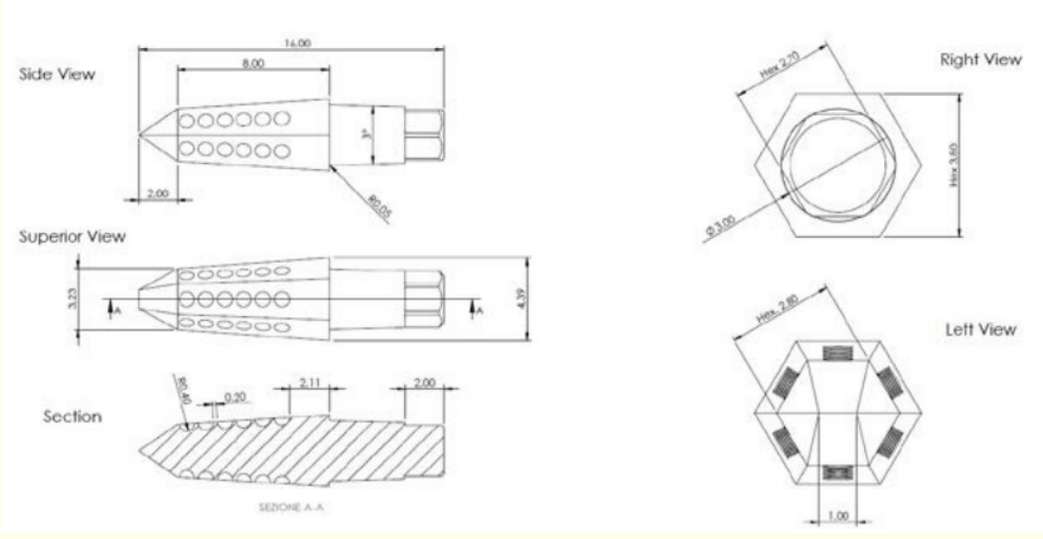


Figure 10: *RHPP Implant Dimensional Specifications.*

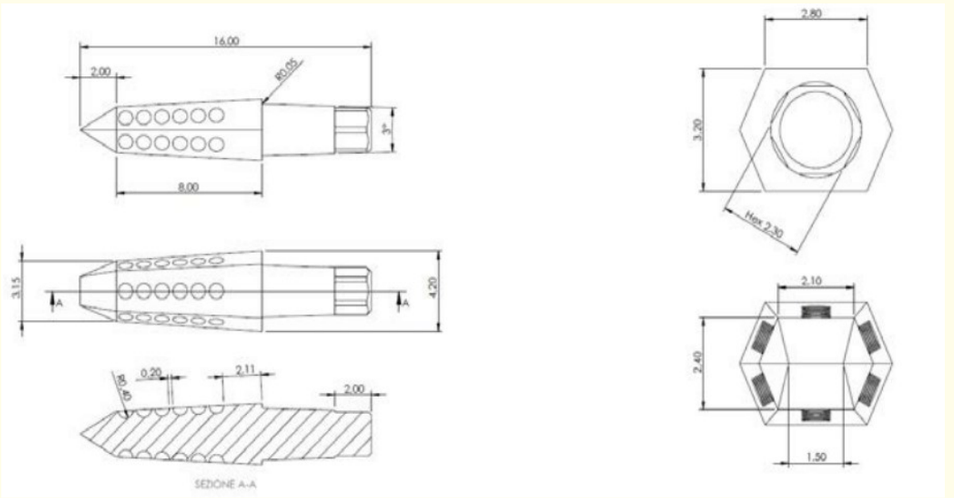


Figure 11: *IHPP Implant Dimensional Specifications.*

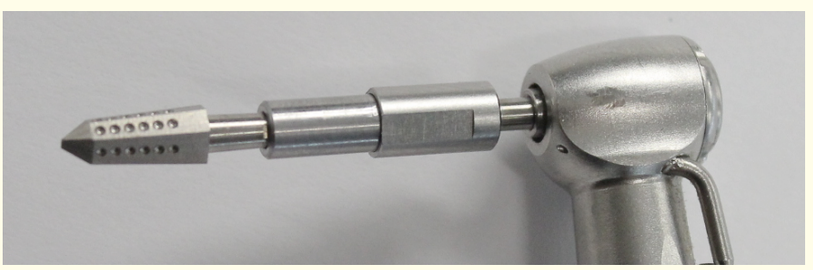


Figure 12: *RHPP Implant Insertion Assembly.*

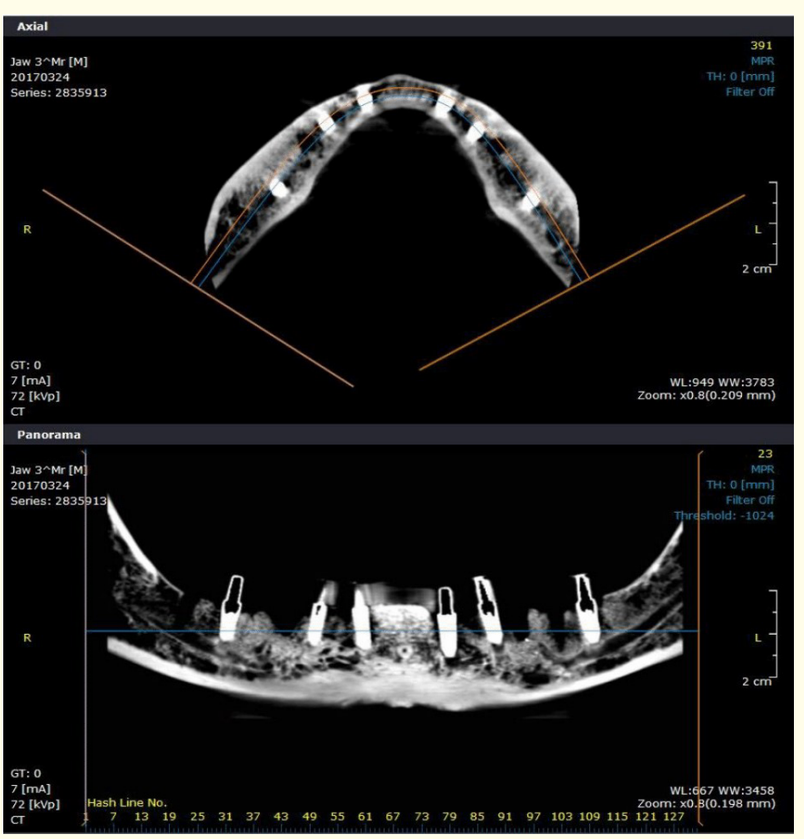


Figure 13: *Anatomical Landmarks: IHPP Group Post-Op Analysis.*

1. IHPP Implant Configuration 1 Test with support.
2. IHPP Implant Configuration 2 Test with support.
3. IHPP Implant Configuration 3 Test with support.
4. IHPP Implant Configuration 4 Test with support.
5. RHPP Implant Configuration 5 Test with support.

The Mathematical calculation model of the implants was obtained by means of tetrahedral solid elements. The structural analysis was conducted in a linear elastic field. Therefore, a linear increase in maximum stress in bone was expected. The interface between the titanium alloy coping and the RZ was considered continuous.

Load and Constrains Application Method

The structural analysis is conducted by applying a unit load at an intensity of 1N in accordance with standard requirements. Linear elastic analysis allows applying the principle of superposition for determining the limit load of static resistance and fatigue resistance. In case of the implants that do not have pre-angled components, the UNI EN ISO 14801:2017 standard requires that the load applied has a straight line of action, forming an angle of 30° with the axis of the implant. The fixture must be embedded onto a base so that the nominal bone level is distant 3 mm from the connecting section to stimulate bone resorption. The test scheme indicated by the standard is reported in figure 14. The figures 15 to 19 show the main dimensions for application of the loads and constraints on all configurations.

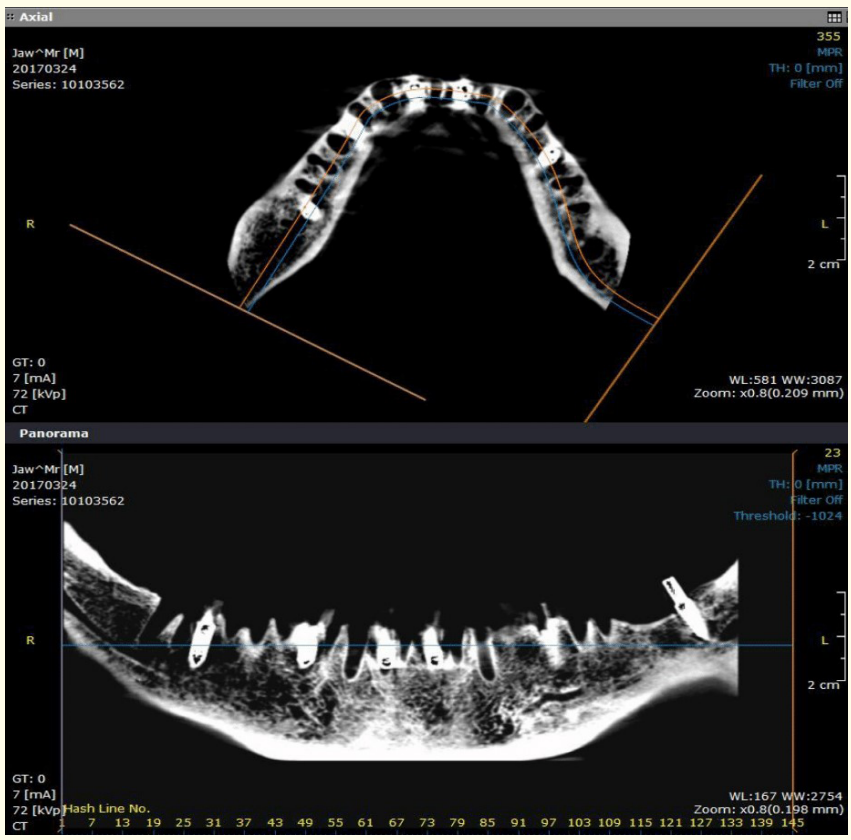


Figure 14: *Anatomical Landmarks: RHPP Group Post-Op Analysis.*

Figure 15: *Mandible Specimens: IHPP group (Left) and RHPP group (Right) Post-Op.*

Figure 16: *Extraction.*

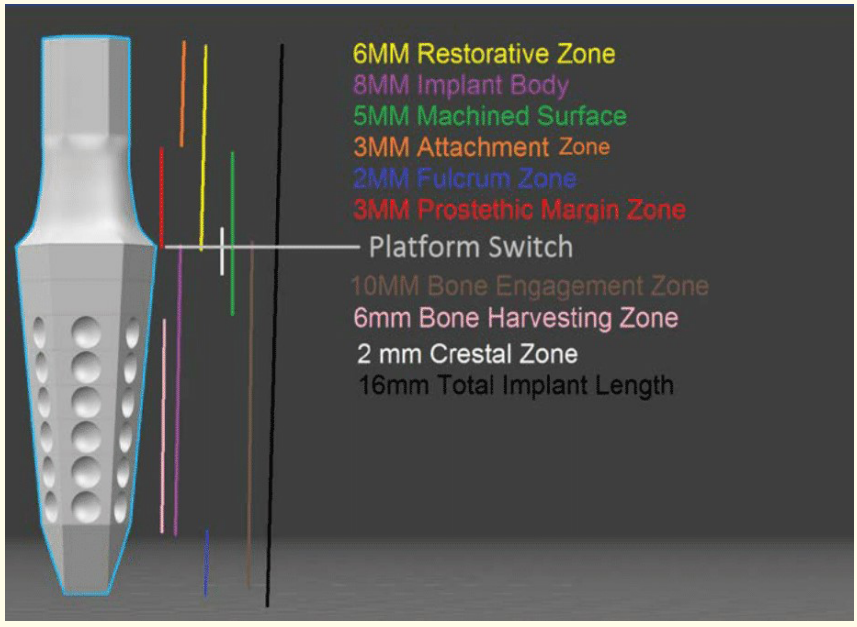


Figure 17: *Prototype Zones.*

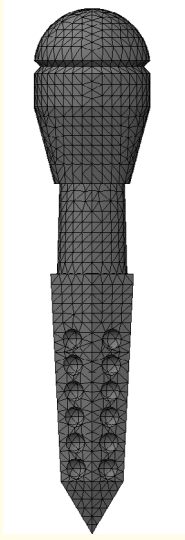


Figure 18: *IHPP Implant Configuration 1 test with support – Mesh of the mathematical model with tetrahedral elements.*

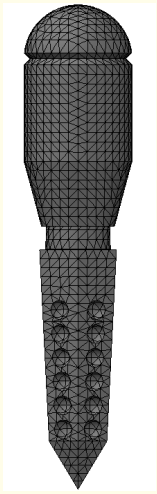


Figure 19: *IHPP Implant Configuration 2 test with support – Mesh of the mathematical model with tetrahedral elements.*

Method adopted to test the static resistance

Comparing the Von Mises equivalent stress with the yield strength reported in table 5 tests the static resistance.

Element type		BEZ	RZ and Coping
Material		Gr. 4 Titanium	Ti-6Al-4V Gr. 5
Properties of the material	Modulus of elasticity [GPa]	110	110
	Poisson's ratio	0.34	0.34
	Breaking strength [MPa]	550	860
	Yield strength [MPa]	480	790
	Elongation at break %	15	15
	Fatigue resistance LA [MPa] per 1·107 cycles	425	300

Table 5: *Mechanical properties of the material used.*

Result of the static resistance structural tests

A series of illustrations showing the stress condition of the IHPPs and RHPP implants (Figures 20-24). In alphabetical order, the conditions represent:

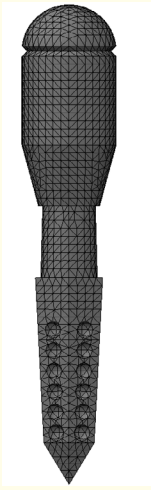


Figure 20: *IHPP Implant Configuration 3 test with support – Mesh of the mathematical model with tetrahedral elements.*

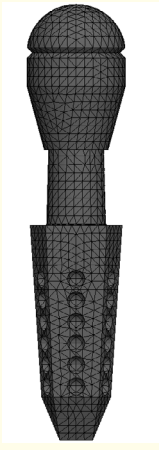


Figure 21: *IHPP Implant Configuration 4 test with support – Mesh of the mathematical model with tetrahedral elements.*

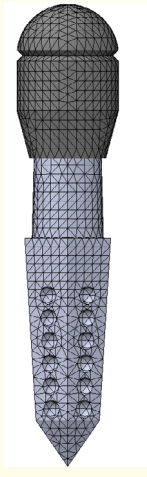


Figure 22: *RHPP Implant Configuration 5 test with support – Mesh of the mathematical model with tetrahedral elements.*

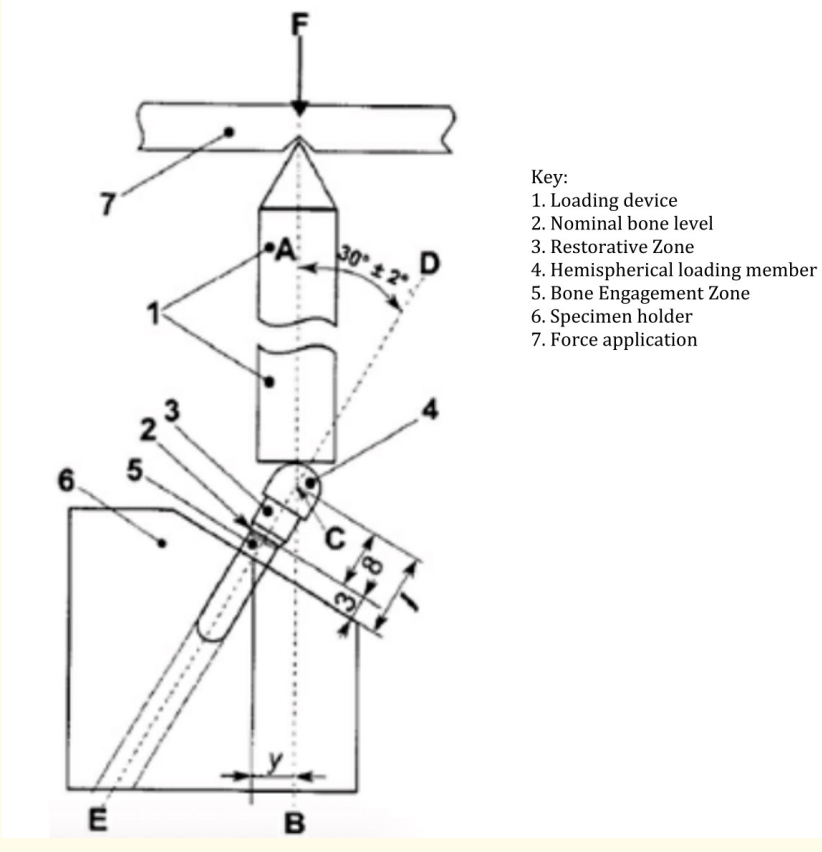


Figure 23: *Test scheme indicated by the UNI EN ISO 14801:2017.*

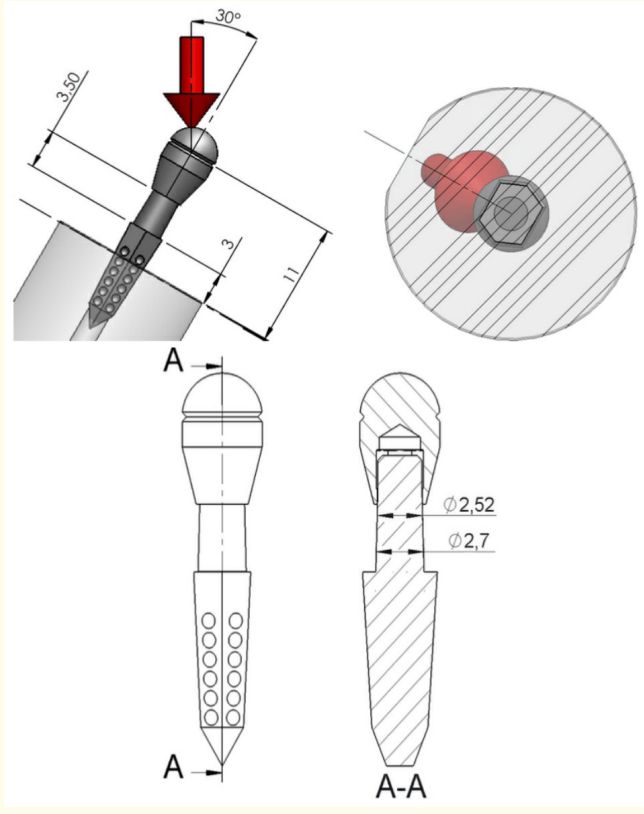


Figure 24: *IHPP Implant Configuration 1 test with support – Main dimensions for the structural analysis (Dimensions in millimeters).*

1. Von Mises equivalent stresses on the external threading of the BEZ and RZ.
2. Equivalent Von Mises stresses on the implant.
3. Detail of Von Mises equivalent stresses on the implant.
4. Equivalent Von Mises stresses on the implant.
5. Detail of Von Mises equivalent stresses on the implant.

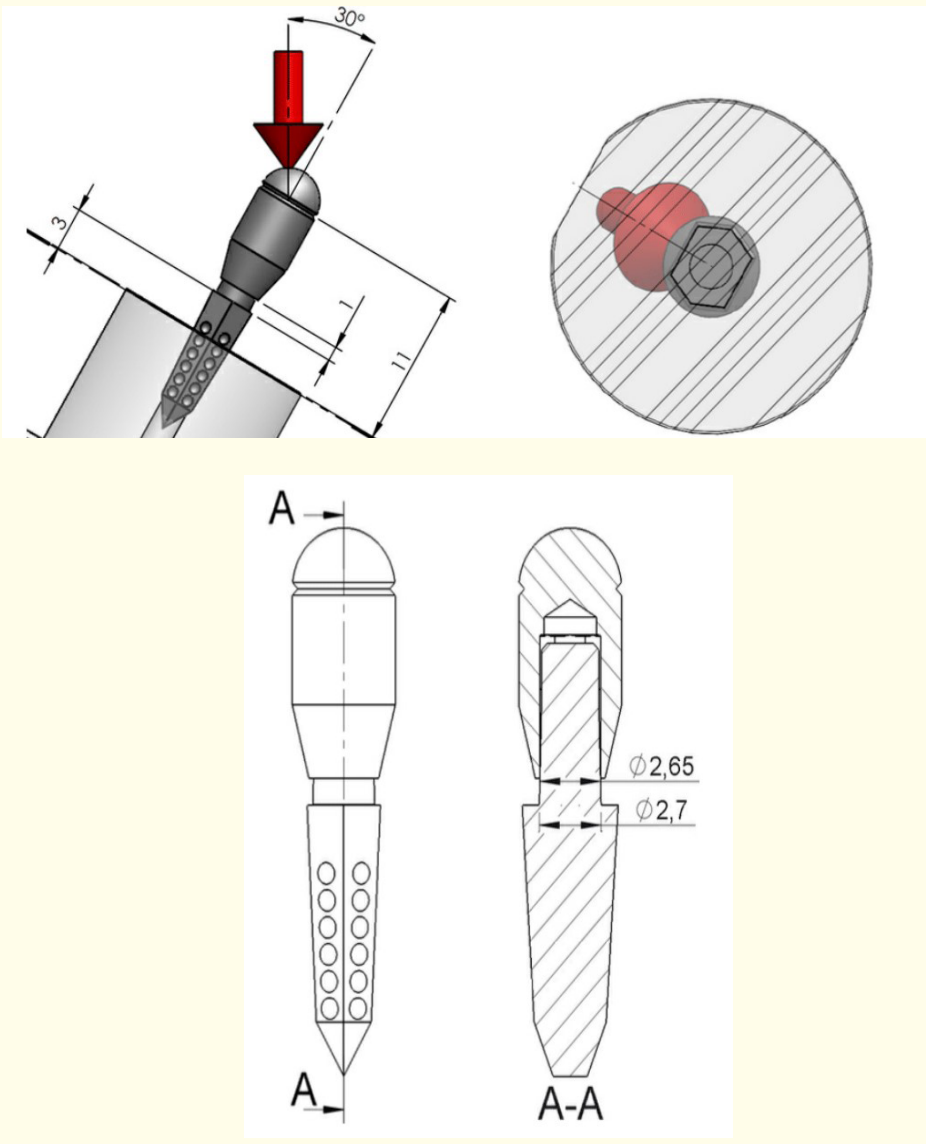


Figure 25: *IHPP Implant Configuration 2 test with support – Main dimensions for the structural analysis (Dimensions in millimeters).*

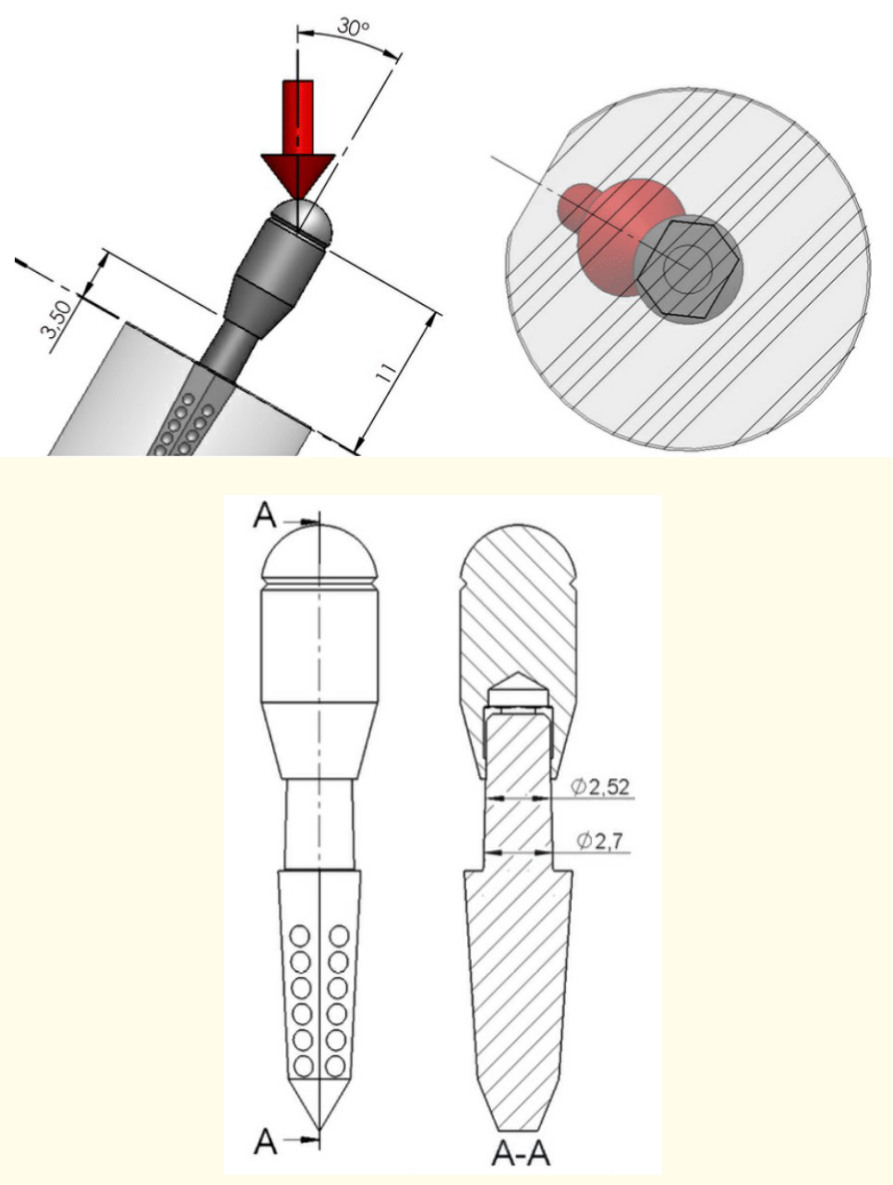


Figure 26: *IHPP Implant Configuration 3 test with support – Main dimensions for the structural analysis (Dimensions in millimeters).*

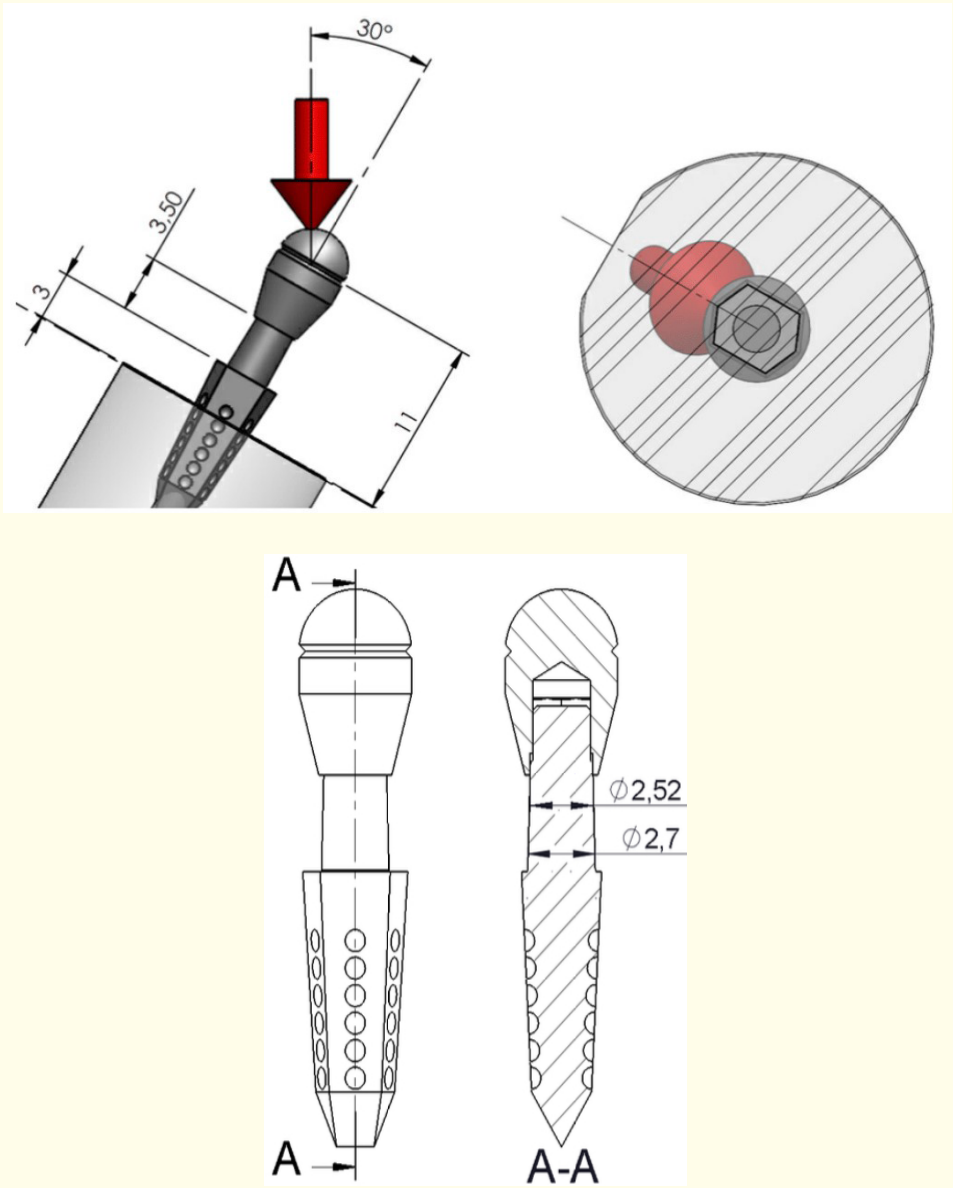


Figure 27: *IHPP Implant Configuration 4 test with support – Main dimensions for the structural analysis (Dimensions in millimeters).*

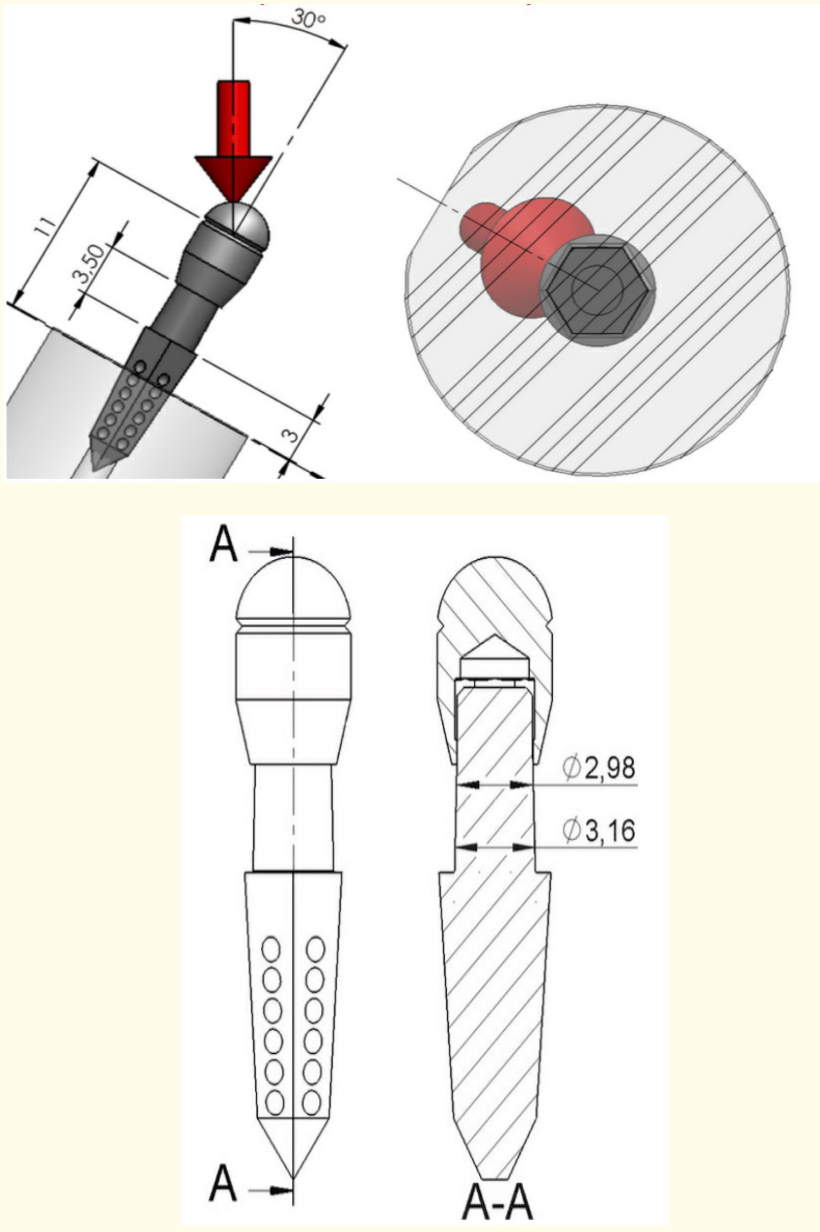


Figure 28: *RHPP Implant Configuration 5 test with support – Main dimensions for the structural analysis (Dimensions in millimeters).*

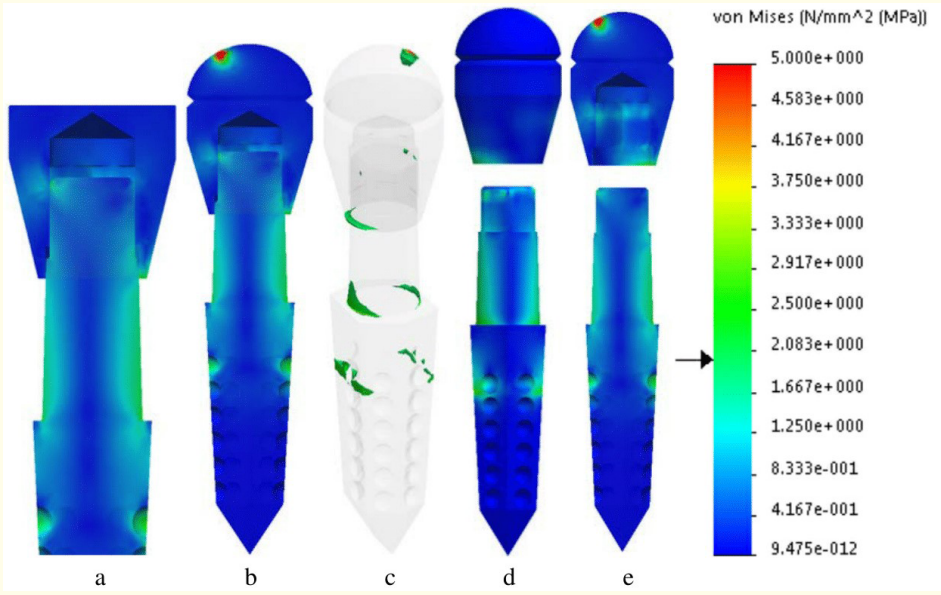


Figure 29: *Static resistance of IHPP Implant Configuration 1 test with support.*

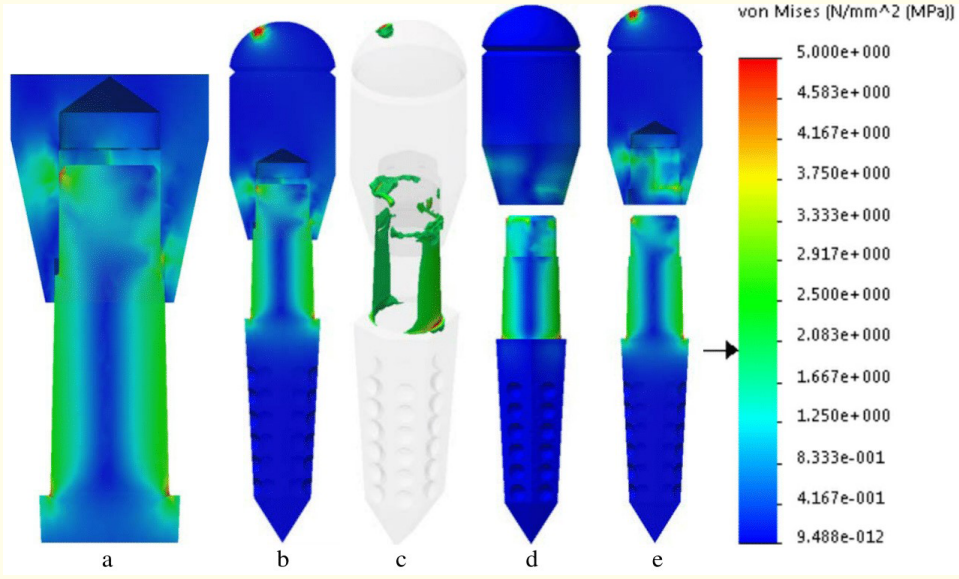


Figure 30: *Static resistance of IHPP Implant Configuration 2 test with support.*

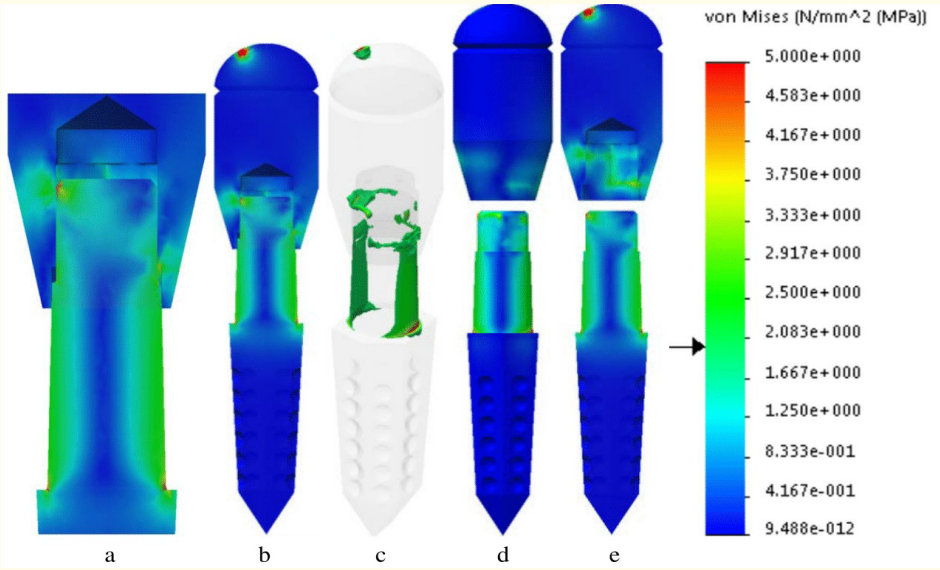


Figure 31: *Static resistance of IHPP Implant Configuration 3 test with support.*

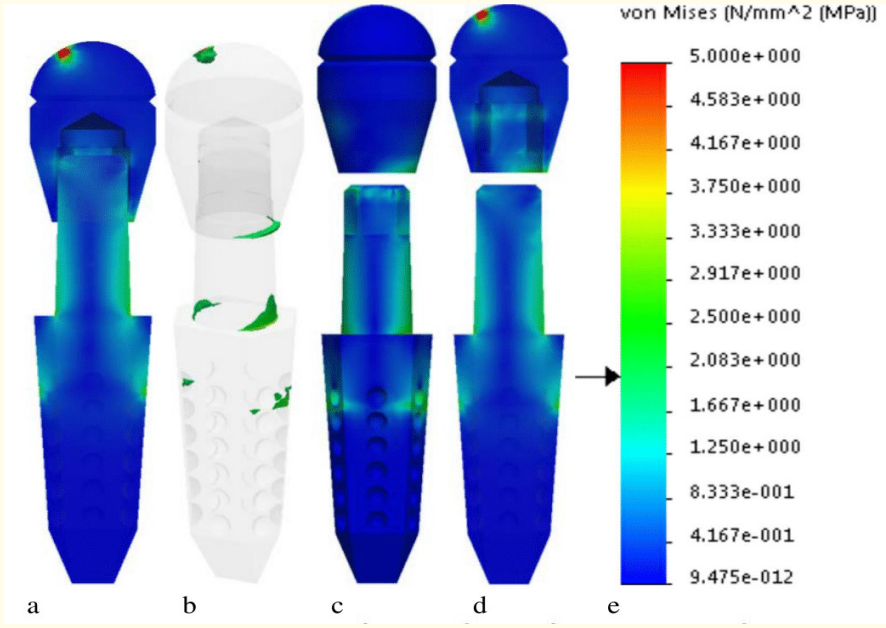


Figure 32: *Static resistance of IHPP Implant Configuration 4 test with support.*

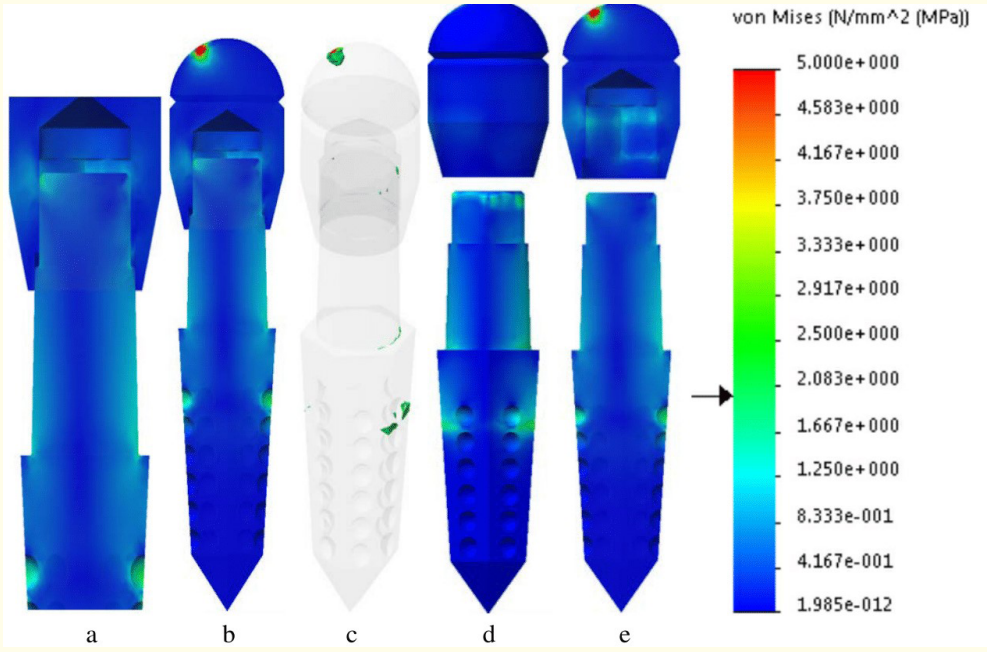


Figure 33: *Static resistance of RHPP Implant Configuration 5 test with support.*

Result of the fatigue resistance structural tests

The fatigue load limit was calculated by applying the procedure described earlier. The results that emerged are shown in the table 6. Which illustrates the fatigue load limit for each implant configuration, setting a limit value of nodes that does not exceed 0.5% and 5% of the total.

Implant with support	Fatigue load limit per N=5·106 [N]	
	With maximum percentage of nodes outside the test = 0.5%	With maximum percentage of nodes outside the test = 5%
IHPP Config. 1 test	273	535
IHPP Config. 2 test	276	605
IHPP Config. 3 test	196	404
IHPP Config. 4 test	281	577
RHPP Config. 5 test	374	767

Table 6: *Fatigue load limits for each implant with 0.5% and 5% limit value of nodes.*

Periotest

The Restorative Zone of (RZ) of the RHPP and IHPP were subjected to the Periotest to assess the mobility of the implant after insertion and subsequently the quality of primary stability. A Periotest M handpiece, type 3218, Medizintechnik Gulden Germany, was used. This device measures the damping characteristics of the periodontium and, indirectly, tooth/implant mobility. During a measuring cycle of this

device, an electrical motor activated a percussing rod to tap an implant surface approximately 16 times over a period of 4 seconds. Its output measurements in the form of a Periotest Value (PTV) ranges from -8.0 to +50.0, which correlate to Miller's Mobility Index (Table 7). The smaller the PTV, the higher is the stability of the implant. Table 8 illustrates the PTV and its interpretations in correlation to implant mobility clinically, according to the manufacturer guideline values.

Miller index	Clinical Finding	Periotest Value
0	No discernable movement	-8.0 to +9.0
1	Palpable movement	+10 to +19
2	Obvious movement	+20 to +29
3	Movement on tip pressure	+30 to +50

Table 7: *PTVs compared with Miller Mobility Index.*

Values	Mobility interpretation
-8.0 to 0.0	Good osseointegration; the implant can be loaded
+0.1 to +9.9	Clinical examination is required; loading of the implant might or might not be possible, depending on implant type and clinical situation
+10.0 or higher	Osseointegration is insufficient, the implant cannot be loaded

Table 8: *Guideline values in correlation to PTV.*

The device was held buccally in a horizontal position, +/- 25°, and directed perpendicularly to the long access of the implants at a distance between 0.6 and 2.5 millimeters to the center of the RZ end tip. The PTVs were taken three times for each implant and the average value was recorded. Additionally, the positions of placements were divided into anterior and posterior position in respect to D1 and D2 bone zones, for which the total average value was calculated individually for further analysis.

PerioTest Results

The recorded mean PTVs of all 30 implants are presented in table 9.

	Group 1: 15 RHPP		Group 2:15 IHPP Impact Method	
	8 RHPP Rotational	7 RHPP Hybrid Method		
Anterior Placement D1	-6.4	-6.9	-6.3	-6.4
	-6.1	-7.1	-5.8	-4.7
	-6.6	-6.7	-7.1	-4.2
	-5.2	-7.5	-5.5	-5.1
Average D1	-6.075	-7.05	-6.175	-5.1
Posterior placement D2	-5.4	-6.5	-4.9	-3.5
	-3.7	-5.9	-3.9	-2.9
	-4.3	-6.1	-5.2	-3.8
	-4.2		-3.6	
Average D2	-4.4	-6.16	-4.4	-3.4

Table 9: *The mean PTVs of all the implants.*

Results and Discussion

The present *in-vitro* study analyzed thirty titanium, solid, one-piece, threadless, and cross-sectionally hexagonal implant design during and after insertion. During delivery, the biomechanics and protocol facilitation aspects of the device, which utilized the concepts of fulcrum-lever force dissipation and wedging circumferentially and apically, were assessed. While the quality of primary stability and fixation was evaluated after implant insertion. Engineered and intended for immediate loading, the implants were delivered into two human mandibles D1 bone zones by means of conventional rotational, osseo-compression, and hybrid placement methods.

The concept of osseointegration has come a long way since Brånemark introduced it in the 1970's. Since then, geometric designs and surface characteristics have been continuously modified and incorporated into a variety of implant designs for the sole purpose of achieving better primary stability. How bone and implant interact essentially defines the long-term success in implant treatment. Profound osseointegration depends on the quality of initial rigid fixation at the time of implant placement, primary stability, and bone apposition onto implant surfaces during and after the healing process (secondary stability) [80]. On the other hand, biomechanical factors implemented in implant designs and prudent treatment planning demand close considerations to minimize the potential risks of failure. Having the mentioned criteria in mind, a unique one-piece implant system was designed to provide for enhanced primary stability, conservative osteotomy, and controlled ridge expansion with improvement to the bone quality via osseo-compression.

Inspired by an industrial chisel, the one-piece implant design discussed can be easily differentiated by its shape and design, when compared to other common implant systems. The polygon design, hexagonal in cross-section, delivers six slightly rounded line angles and flat planes with six semi-spherical indentations on each. These macrogeometries are present from the Crestal Zone (CZ) and are continuous along the tapering Bone Engagement Zone (BEZ) to finally merge together at the Fulcrum Zone (FZ) creating a miniature chisel. The objective behind such design was to produce a facilitating effect during and an antirotational effect after implant insertion within the osteotomy via harvesting the power of fulcrum-lever and wedging concept.

The FZ, a V-shaped tip coupled with a pair of auxiliary flat planes on either ends, stands as the primary wedge, anchorage, and fulcrum. Together with the tapering BEZ, the lever and the secondary wedge, they act harmoniously to decrease the amount of load necessary to insert the implant into the osteotomy [81]. During implant placement, this design allows operators to press-fit and/or rotate and guide the implant into freshly extracted socket or prepared osteotomy with enhanced control. Taking both the threadless and tapered design into account, a one-piece design provides ease of implementation, in terms of fewer protocol steps, accessibility and prevents inadvertent bone loss that threaded implants may cause during insertion into hard to access D3 and D4 regions [25]. In comparison to parallel-walled implants, previous studies have confirmed that tapered designs offer enhanced primary stability, particularly in soft quality bone types, due to higher compressive force on the cortical bone regions [55,56,82,83]. These findings were confirmed in this clinical study as none of the prototypes exhibited micromovement that may be accountable for poor stability.

The implant is designed to serve as an exceptional anti-rotational lock. Twelve flat planes of the BEZ and FZ with different areas and angulations appose bone surfaces and direct bone remodeling with growth creating an accurate negative impression of the implant, as compression loads, by which rotational load is resisted during parafunctional activities [81]. The crestal bone had conformed precisely to the CZ circumference without any evident gaps clinically. The corners were embedded into cortical bone rendering rotational movement impossible. Close approximation of bone-implant at the CZ seals the entrance preventing fibrous tissue and pathogens at early stage of healing from invading the crestal area between the implant and surrounding bone thereby enhancing primary stability [81,84,85]. Two studies [86,87] have reported an angled geometry at the crest module of a design reduces the risks of bone resorption via imposing compressive component to adjacent bone. Additionally, it is hypothesized that such tapering design prevents surgical complications such as dislodgement into facial cavities.

Whereas other common implant systems may have only a few spherical indentations, the Bone Harvesting Zone (BHZ) holds a total of thirty-six along the BEZ that transfer occlusal load into the bone and resist strain and stress [81]. It was discovered in our study that these indentations also served as reservoirs of autogenous bone harvested during insertion. Aside from their intended purpose, the BEZ and FZ macrogeometries shaved the osteotomy wall during placement and produced autogenous bone while the implant was being seated. A significant amount of bone particles were harvested and collected during all three delivery methods by which the need for bone graft could potentially be decreased. In conjunction with precise bone-implant contact, bone-harvesting capability of this design promotes profound primary stability during bone healing and aid subsequent long-term fixation.

In the one-piece implant systems, the prosthetic abutment and implant body are milled as a single unit. A prosthetic crown may be retained on the abutment portion either by a screw or cement [25]. Screw-retained crowns (SRC) have become most common due to retrievability and inconsequential retention and resistance-form [88,89]. Although SRC have been the a popular choice, studies have reported that an inclination is on the rise towards cement-retained crowns (CRC) [90,91]. In natural tooth restorations, the type of luting agent mandates the quality of resistance to dislodgment under compressive and shear forces [88]. Rosenthal., *et al*. [91] proved high compressive strength cements are the best candidates to counter such forces thereby applicable for implant-supported crowns. The hex abutment design observes the same retention and resistance-form as natural tooth preparation, plus provides an anti-rotational component. In despite of the proportionally smaller surface areas, the parallel walls and angled-hex designs can accommodate dimensionally larger crowns than natural tooth preparations [92,93]. In another study, Kwan., *et al*. [88] demonstrated that CRCs of common hex abutment designs well-resisted displacement under off-axial load, which mimics physiologic load.

The other possible cause of affinity towards the traditional CRC is the possible structural drawbacks of the screw system. Although recent screw designs and concepts have reduced the rate of screw failure in the two-piece SRC designs dramatically [45], the resultant complications call its value into question. On the other hand, the screw-less CRC one-piece implant conveniences both operators and patients as the hex abutment provides for the prosthetic crown attachment and eliminates possible uncover surgery.

Load distribution is greatly influenced by multiple aspects of the implant, bone, and force vectors. Finite Element Analysis (FEA) was designed in the late 1970's to predict functionality and feasibility of different implant designs in laboratory settings and predict their behavior and effects in real-life clinical cases. Therefore, some margin of error accompanies such theoretical analysis [6]. In this *in-vitro* study, the results of FEA were divided into the BEZ, the fixture, and the RZ, the abutment. Four types of titanium alloy attachments were used that slightly differed in vertical height and the amount of the RZ they covered. Efforts were made to stimulate realistic clinical scenarios as closely as possible by designing multiple implant configuration tests.

In the static resistance structural test, the implant configurations 1, 2, 4, and 5 tests demonstrated even load distribution vertically and laterally throughout the RZ and the initial 1/3 of the BEZ. The load was completely dissipated and neutralized before reaching the embedded 2/3 of the BEZ (Figures 15, 16, 18, 19). In the mentioned configuration tests, the Von Mises equivalent stress never exceeded 2.083e. The epicenters were at spherical head-RZ, RZ-BEZ, and BEZ-Base interfaces. IHPP implant configuration tests experienced identical load distribution patterns with almost similar stress resistance magnitudes. It was assumed that the minimal difference was due to the difference in the design of titanium coping attachment, which provided stability and support in resisting load. Therefore, the same principle might be duplicable clinically. The more embodiment of the RZ by prosthesis, the more occlusal load resisted and less transferred to the crestal bone. However, in IHPP implant configuration 3, where the BEZ was fully embedded, major stress of 4.583e was experienced at the BEZ-RZ interface diagonally opposite of load application area. A possible explanation could be a combination of the design of this interface, which is near a butt joint, and higher bending movement aided by the least stable coping. In this particular scenario, the base and the BEZ-RZ interface were equi-level, while the load source and the platform switch were the furthest apart when compared to other configuration tests. The long coping that covered the minimum amount of the RZ collaboratively provided a longer moment arm and

consequently more bending movement. Additionally, load application parallel or perpendicular to the FZ tip did not make significant difference in terms of fatigue load limit, load dissipation pattern, and stress resistance tolerance in IHPP implant configurations 1 and 4.

In fatigue load and structural static resistance tests, RHPP implant configuration 5 test with a short coping demonstrated the best result (Figure 19 and Table 6). It tolerated 374-N with 0.5% and 767-N with 5% maximum nodes outside of the test. Load distribution pattern was more spread uniformly, while the epicenters located at RZ-BEZ and BEZ-Base interfaces. Although the over-all magnitude of stress equaled the other configuration tests, the area under the most stress was significantly the smallest in the RHPP configuration 5 test. The greatest constraint related to the BEZ-Base interface at the level of first spherical indentation of the BEZ.

Methods for assessing implant mobility or stability are either subjective or objective. An objective evaluation becomes highly important when the examiner-dependent nature of the subjective method may be convoluted by bias [94]. Periotest is a quantitative, noninvasive, and reproducible method that has been reported reliable to evaluate primary stability of implants upon delivery and subsequent appointments [95-98]. In this study, the Periotest device measured PTVs consistently from -7.5 to -2.9 as the most to least stable implant (Table 8). The placements were divided into anterior and posterior in respect to their mandibular position. The average PTV of the anterior position group was determined to be greater than their posterior counterparts. The highest values on average belonged to Group 1 Hybrid method, RHPP implants. Additionally, our evaluation during explantation determined that the polygon implant provided sturdy primary stability within D1 and D2 bone where industrial pliers had to be used to remove the implant from the bone.

A major limitation of this study, however, was the small sample size of implants examined. Prospective clinical research is needed to determine the exact micromovement and heat generation statistical figures as well as the long-term effects of load distribution around implants and abutments in respect to marginal bone preservation.

Conclusion

Within limitations of this study, we demonstrated that:

1. A polygon-shaped (in-cross section) and tapered design enhances primary stability and provides for anti-rotational lock.
2. Fulcrum-Levered force dissipation concept facilitates and simplifies common protocols in implantology.
3. The tapering design prevents dislodgement into oral cavities.
4. Overall design provides clinicians with enhanced control and maneuverability during insertion.

Disclosure

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Dr. Kianor Shahmohammadi: the inventor of the implant designs and related parts.

Approval

For this *ex-vivo* study, neither approval from an institutional review board nor an ethics review committee was necessary.

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