

A new concept on dental implant for high primary stability on low density bone and fresh extraction socket

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Abstract

Objective: this article presents a new dental implant proposal with special characteristics for complex clinical situations. **Material and methods:** all dental implants were installed by professionals with a minimum experience of ten years and following the manufacturer's recommendations. A survey containing the gender and age of the type of implant installed, type of socket (fresh or healed) and whether or not the use of simultaneous bone graft, trans or postoperative complications, clinical or radiographic data and the achievement of osseointegration was used to collect data. Two representative cases were documented and presented. **Results:** overall, 161 implants (109 CM, 52 EH; diameters: 3.5 - 4.5 mm, lengths: 10-13 mm) were installed in 91 patients (68% men, 32% women, mean age of 50 years), with 65% of implants in post-extraction socket and 53% associated with intra-alveolar grafts. The average value of insertion torque was 45 Ncm, allowing for immediate loading when clinically indicated. The overall survival rate was 99.37%. **Conclusion:** within the limitations of this study, the cases presented suggest the bone density or when immediate loading is indicated.

Key words – Immediate loading; Dental implants; Osseointegration; Implant surface; Implant design.

Introduction

Rehabilitative treatment with implants replacing teeth that have been lost. Its use in Dental Surgery due to its ability to restore masticatory and esthetic function and improve the patients' quality of life¹. However, some characteristics of the implants, such as microgeometry and surface nanoactivation, are critical for increasing the success of the surgical procedure, predictability, and speed of peri-implant bone repair. Therefore, optimal osseointegration depends on the characteristics of the material that constitutes the implant, the capacity of the implant to bear loads, the surgical technique used, and the bone type present at the insertion site, in addition to the individual local and systemic characteristics of the individual to be subjected to this type of treatment. In the long term, the conservation of the bone/implant interface also depends on the prosthesis design, occlusal loading, and maintenance of the peri-implant tissues free from Biofilm or Inflammation².

Implant macrogeometry directly affects its primary stability and, consequently, cases of low density bone presence or immediate or early loading procedures in fresh extraction sockets, with or without the use of connective tissue and/or bone grafts³. Evolutions have been proposed in the geometry of implants and their surface, seeking greater predictability and reduced treatment time, since implants with bioactive surfaces are related to a higher survival rate when compared to untreated implants³. Thus, the use of implants with a macrostructure that provides greater primary stability, and a microstructure that favors fast bone repair, is especially indicated in rehabilitation with dental implants in areas of low bone density, especially in immediate fresh extraction insertion techniques.

Within the evolution and development in Implantology, a new concept was proposed (Epikut Plus S.I.N. Implant System – São Paulo, Brazil) with hybrid macrogeometry (converging in cervical region, parallel in body, and conical in the apical region) and double threads with an inverted support format, in order to create high primary stability and an easy path for insertion, especially in sites with a large presence of medullary bone and/or implant insertion techniques associated with immediate or double loading causes these threads to intertwine and, consequently, provide an insertion

This article aimed to present data on a series of clinical cases that support the use of this new dental implant model.

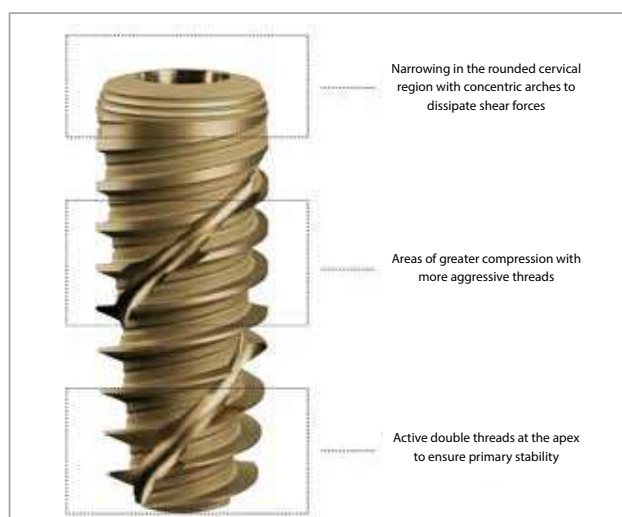
Material and Methods

Characteristics of the implants tested

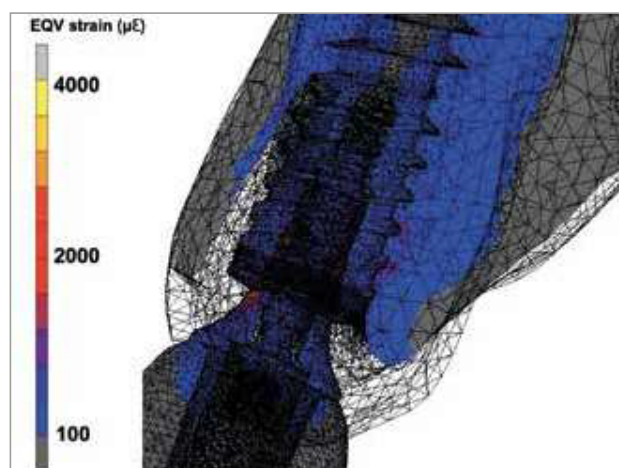
The hybrid macrogeometric concept aims to divide the implant into three distinct parts, with specific functions to increase its clinical efficiency, and the apex have active threads to allow anchorage and high primary stability, especially in fresh extraction sockets. In the implant body is the largest compression area generated by the threads with inverted support format, which tend to compress the bone trabeculae in the apical direction and form a wedge effect, when the cervical region has a narrowing of 0.2 mm in rounded and microchannels to promote better dissipation of occlusal loads that can lead to bone resorption or excessive bone remodeling in this region, especially when affected by shear forces, which are proven to be more harmful to the maintenance of the bone/implant interface, as previously demonstrated in pre-clinical and clinical trials (**Figures 1 and 2**)⁴⁻⁵.

Another important aspect related to challenging cases, such as immediate or early loading, and fresh extraction sockets is related to the use of surface treatment with bioactive and super-hydrophilic characteristics that accelerate the healing process and improve the quality of peri-implant bone tissue⁶. The implants used in this series of cases have surface treatment performed through thermal double acid etching with superficial microroughness of 0.9 μm to 1.2 μm , coated with reabsorbable hydroxyapatite with a homogeneous

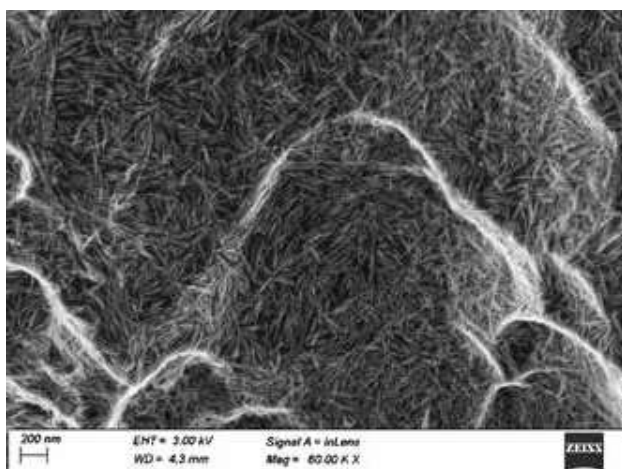
thickness of 20 nm (HANano, Promimic – Gothenburg, Sweden), with characteristics and benefits previously described⁷⁻⁸. **Figure 3** shows the scanning electron microscopy of the HANano coating of the new implant, where it is possible to note the presence of hydroxyapatite nanocrystals with shape and size similar to those of human bone tissue, and this interaction leads to the presence of neoformed bone between the threads in almost its entirety (**Figure 4**).



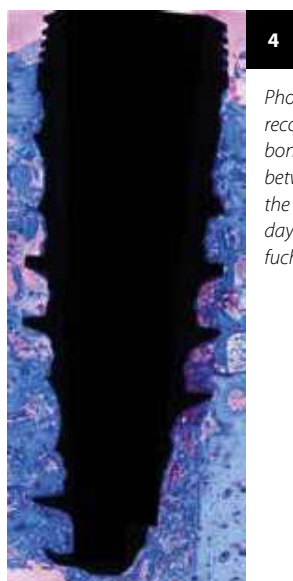
1 Illustrative image demonstrating the hybrid macrogeometric characteristics related to increased primary stability and better dissipation of forces in the cervical region.



2 Assessment by finite element analysis of the distribution of deformations in the Epikut implant, inserted in an extraction socket with 100 N loading. Buccal-palatine section showing the Morse taper prosthetic connection and alveolar bone structures.



3 Scanning electron microscopy (SEM) of the HANano surface with 60,000 x magnification. Note the topography of the implant surface after double acid etching covered by the deposition process of hydroxyapatite with a constant thickness of 20 nm.



4 Photomicrograph of histological image reconstruction. Presence of newly formed bone occupying almost all of the space between the implant threads, especially in the cervical and apical regions after 28 days. Coloration: toluidine blue and acid fuchsin. Magnification: 10 x.

Applied Therapy

Analysis of the insertion torque and survival rate

In this research, a standardized questionnaire was used containing the following items: gender and age of patients, type of implant inserted, type of socket (fresh or healed) and whether or not the use of simultaneous bone graft, trans or postoperative complications, clinical or radiographic data and the achievement of osseointegration was used to collect data. All implants were inserted by professionals with at least ten years of prior experience in Implantology and following the manufacturer's recommendations.

Exclusion Criteria

Patients who presented systemic alterations such as diabetes, osteoporosis or metabolic disorders were excluded, in addition to smokers and patients who had previously undergone bone regeneration, radio or chemotherapy. Data were compiled and tabulated by a single evaluator.

Results

161 implants were placed in 91 patients (68% men, 32% women), and 109 implants had prosthetic coupling of the type morse taper (CM) and 52 of the type external hexagon (HE), with diameters of 3.5 mm and 4.5 mm, and lengths ranging from 10 mm to 13 mm. The mean insertion torque value was 45.18 Ncm. The mean age of patients was 50 years. The percentage of implants placed in fresh extraction sockets was 65% and implants inserted associated with intra-alveolar grafts corresponded to 53%.

Description of clinical cases

For greater transparency of this case report, they were described in accordance with the case report guidelines (CARE - www.carestatement.org), which states that a

report of clinical cases must present diagnostic evaluation, therapeutic intervention, follow-up, and results, without the need for a control group, focusing on a comprehensive description of the technique and the results obtained.

Clinical case 1

A 22-year-old male patient attended the dental care with an esthetic complaint regarding the tooth loss of element 21 (**Figures 5**), due to a trauma that occurred in his childhood. The clinical examination revealed the absence of teeth and, for a more assertive diagnosis, a cone beam computed tomography (CBCT) was requested, identifying a moderate horizontal bone resorption in the region, thus enabling the implantation and probable provisionalization of the missing element. Due to the partial bone availability, its insertion was proposed using the guided surgery technique.

The tomography and the intraoral scanning were exported to the Implant Studio (3Shape, Denmark) virtual planning software (**Figures 6**) for the prescription of the implant measurement, determination of the proper bone positioning and establishment of the ideal emergence profile. Previously, a provisional of the missing element was performed based on the dental anatomy of the contralateral tooth.

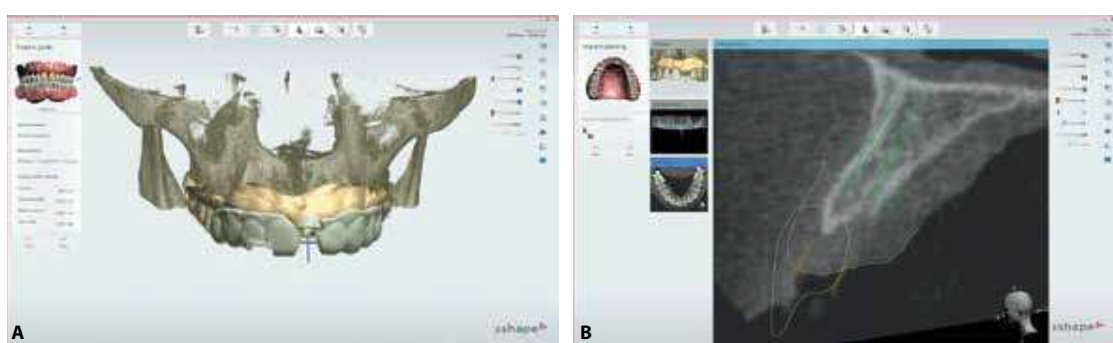
The patient was anesthetized with 4% articaine (DFL - Rio de Janeiro/RJ) and a full-thickness flap incision was performed (**Figures 7**). Next, the surgical guide was inserted to assess its adaptation through the inspection windows of the guide's dental support. The instrumentation of the surgical socket was performed using the drills from the guided surgery kit (S.I.N. Implant System - São Paulo, Brazil), observing the exchange of drill stems (**Figure 8**) in the washers installed in the surgical guide. Once the instrumentation was completed, the implant was inserted with a nanoactivated surface (Epikut Plus, S.I.N. Implant System - São Paulo, Brazil), with 3.5 mm in diameter and 13 mm in length, with a primary lock of 60 Ncm, enabling immediate provisionalization After

this step, the provisional crown was captured using a titanium provisional cylinder 3.5 mm wide, with a 3 mm transmucosal profile, using a composite resin (Admira Fusion, VOC - Cuxhaven, Germany). A free gingival graft was removed from the patient's palate region (**Figures 9**) and, after deepthelialization, it was inserted and stabilized in the region to make up for the aesthetic deficiency of the area, consequently increasing the volume of the keratinized range (**Figures 10**). Occlusal

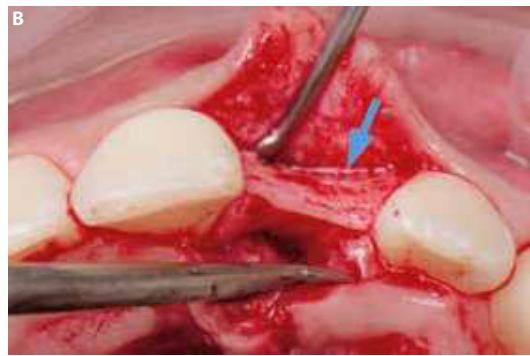
sutures and adjustments were established and, after patient guidance and care, the patient was released. There were no complications in the postoperative period and, after five months of healing, the provisional crown was removed (**Figures 11**) and periapical radiography (**Figure 12**) to verify the osseointegration and peri-implant tissue contours, in addition to the release to carry out the final rehabilitation of the case.



5 Frontal and occlusal initial view of the clinical case.



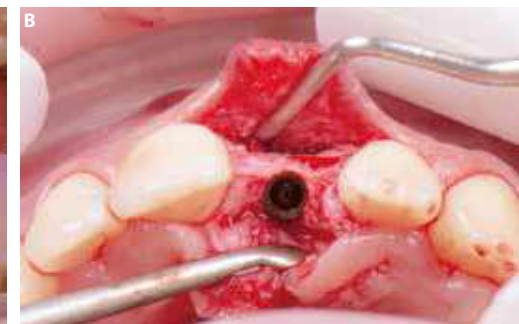
6 3D implant placement planning associated with surgical guide construction using Implant Studio software (3Shape, Denmark).



7 **A.** Incision. **B.** Tissue detachment in the surgical area. Observe the moderate horizontal resorption of bone tissue (blue arrow).



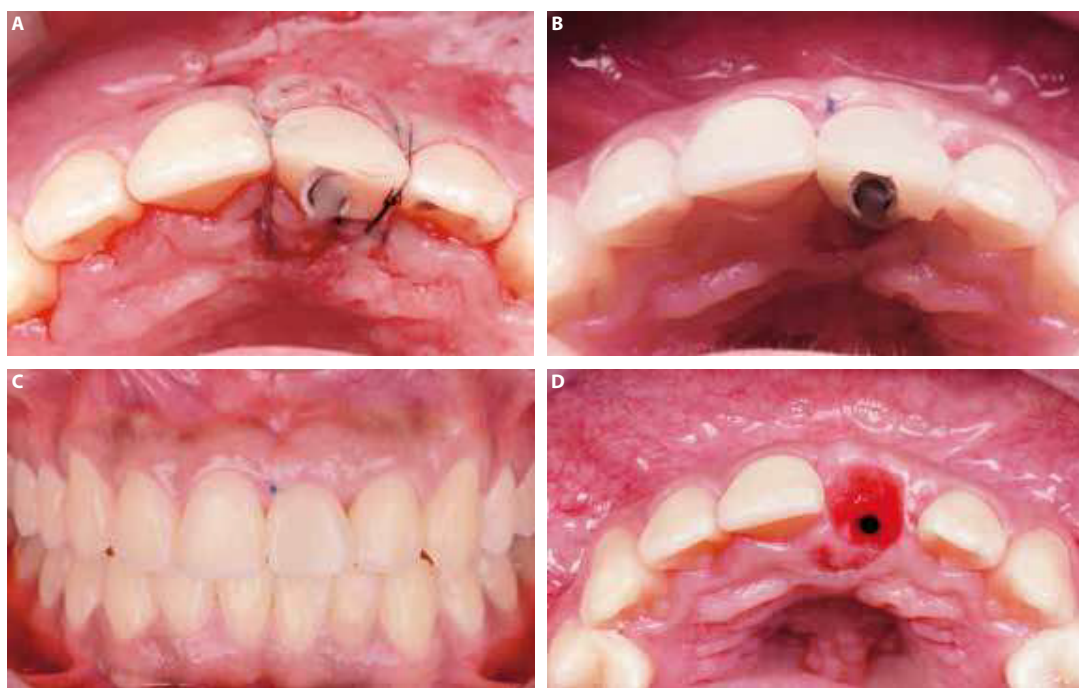
8 **A.** Drilling of the surgical socket. **B.** Staggering of drills. Blue arrows show the change of drivers to perform the drilling procedures



9 **A.** Insertion of the Epikut 3.5 mm x 13 mm implant. **B.** Positioning the implant from the occlusal view.



10 **A.** Connective tissue to be used in the grafting procedure. **B.** Conclusion of the surgical procedure with the immediate provisional in place.



11 **A.** Occlusal view of the immediate postoperative period. **B.** Occlusal imaging after 30 days. **C.** Front view after 60 days. **D.** Occlusal view of health and tissue gain after emergence profile conditioning.



12 Periapical radiography showing good bone/implant contact.

Clinical Case 2

A 58-year-old female patient presented a main complaint of mobility with pain in the upper right second premolar (**Figure 13**). An infraosseous fracture caused by a deep carious lesion was detected through probing and clinical examination. After radiographic and tomographic examinations, extraction was performed with immediate implant insertion using the Epikut Plus 3.5 mm x 13 mm implant with initial stability of 32 Nem (**Figures 14 and 15**). After positioning the implant, an intra-alveolar graft was placed using a xenogenous biomaterial (Bio-Oss Collagen, Geistlich Pharma - Switzerland) followed by insertion of a PEEK healing abutment (S.I.N. Implant System - São Paulo, Brazil), in order to maintain the peri-implant contour (**Figure 16**). The 90-day healing period was then awaited (**Figure 17**), performing the removal of the healing abutment (**Figure 18**) followed by transfer molding with customization of the emergency profile area using flow resin (**Figure 19**), in order to carry out the molding and submit it to the laboratory where a metal-ceramic crown was manufactured directly on the implant head (**Figure 20**).



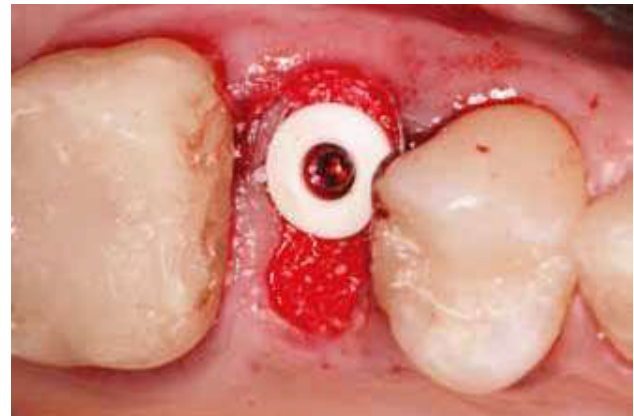
13 Initial panoramic radiography. Detail for the radiolucent image in the distal region of unit 1.5, showing a deep carious lesion.



14 Photograph of the Epikut Plus implant with 3.5 mm in diameter and 13 mm in length, demonstrating its thread profile in inverted support and hybrid macrogeometry.



15 Implant insertion after minimally invasive extraction and preparation of the bone socket according to the manufacturer's recommendations.



16 Occlusal photograph demonstrating the socket filled with the biomaterial and the use of a PEEK healer to maintain peri-implant tissue volume.



17 Occlusal photograph after 90-day scar repair, demonstrating good peri-implant health.



18 Peri-implant tissue appearance after the removal of the healing abutment to perform the transfer molding.



19 Customization of the transfer coping using flow resin.



20 Final appearance of the metal-ceramic prosthesis inserted.

Discussion

Favorable results from implant procedures depend on many variables, including patient characteristics, surgical technique and implant design⁹. Another important feature is the insertion torque value, also known as shear strength measurement, to assess bone density during implant surgery¹⁰. Insertion torque is a mechanical parameter influenced by the surgical procedure, implant design, and bone quality. A high final insertion torque means the implant is firmly embedded to the bone and mechanically stable in its definitive insertion position. The stability measured at the time of implant insertion is called primary stability; after conclusion of the osseointegration process, it is called secondary stability. The average torque obtained in the analyzes of the present study was 4518 Ncm, which led to a high rate of post-surgical survival of implants inserted in different clinical situations. Traditionally, a high primary stability is associated with the expectation of good secondary stability, which would ensure the probability of implant success and osseointegration¹¹.

The macrostructure of the implant strongly influences its primary stability. Conical or hybrid implants, as in the concept described here, have been shown to generate greater primary stability and insertion torque values. And these characteristics of the design of this new implant, especially the body with threads with more aggressive compressive action and the apex shape featuring active double threads, result in greater efficiency in the distribution of stresses resulting from

masticatory loads, which contributes to an optimized bone response and greater predictability of achieving osseointegration. On the other hand, cylindrical implants with V-threads obtain primary stability, mainly by the lateral compaction of the bone trabeculae, in an osteotomy with a smaller diameter than the implant body¹¹⁻¹². In this sense, in bones with low density, the trabeculae would accumulate in medullary spaces and would not promote the desirable stabilization of the implant.

Implants with narrow diameters such as those used in these case reports are sometimes questioned about their mechanical resistance to fatigue, which leads to greater care regarding their clinical indication. The Epikut implant (S.I.N. Implant System - São Paulo, Brazil), used in the present study, was evaluated in an experimental trial¹³ of accelerated fatigue (step-stress) comparing it with two other implants with similar geometric characteristics, the Nobel Active (Nobel Biocare - Gothenburg, Sweden) and the BLX (Straumann - Basel, Switzerland). As a result, all implant systems used showed a high probability of survival (> 95%, CI: 85-100%) in stipulated loads of 80 N and 120 N, with no significant difference between them. The Weibull modulus ranged from 6 to 14. The failure mode predominantly involved fracture of the abutment and/or abutment screw, whereas no implant was fractured. The authors concluded that all implant systems exhibited a high probability of survival under masticatory forces and failures were restricted to the abutment and the abutment fixation screw.

In the clinical cases presented here, the hybrid implant, with optimized macrogeometry, was shown to favor high primary stability in the implant in the anterior and fresh extraction premolar regions, while the fact that the work was performed using digital planning and surgical guide in case 1 greatly facilitated the stabilization of the implant in its ideal prosthetic position. Although case 2 was planned virtually, it was performed without a guide, which shows that this modality of procedure, when properly performed, also leads to clinical success. In addition, the nanometer-scale surface of Epikut (S.I.N. Implant System) seems to have influenced the rapid bone neoformation around the implant, reaching secondary stability in a reduced time, which allowed the performance of clinical procedures for definitive rehabilitation in less time.

Although the analyzes of the survival index and mean torque presented here, together with the clinical case report, were favorable to the indication of the use of this new implant concept, randomized controlled clinical follow-ups are necessary and are being conducted to prove the benefits of this long-term implant.

Conclusion

Within the limitations of this study, the post-surgical survival rate and the high mean torque value obtained suggest the efficiency of using this new implant proposal for cases of low bone density or when immediate implantation is indicated.

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Clarification note

We, the authors of this paper, have not received research financial support given by organizations that may have benefited or not from this study publication. We, or our family members, have not received consulting fees or were not paid as evaluators by organizations that may have benefited or not from this study publication, we do not own stocks or investments in organizations that may also have benefited or not from this study publication. We are not paid presentation fees from profitable-driven organizations that may have benefited or not from this study publication, we are not employed by the commercial entity that has sponsored this study and we also do not own patents or royalties, nor do we work as specialized advisors or carry out activities for entities with a financial interest in this area, except for the co-author Fábio). B. Bezerra, who is Director of Research and Development at the company S.I.N. Implant.

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