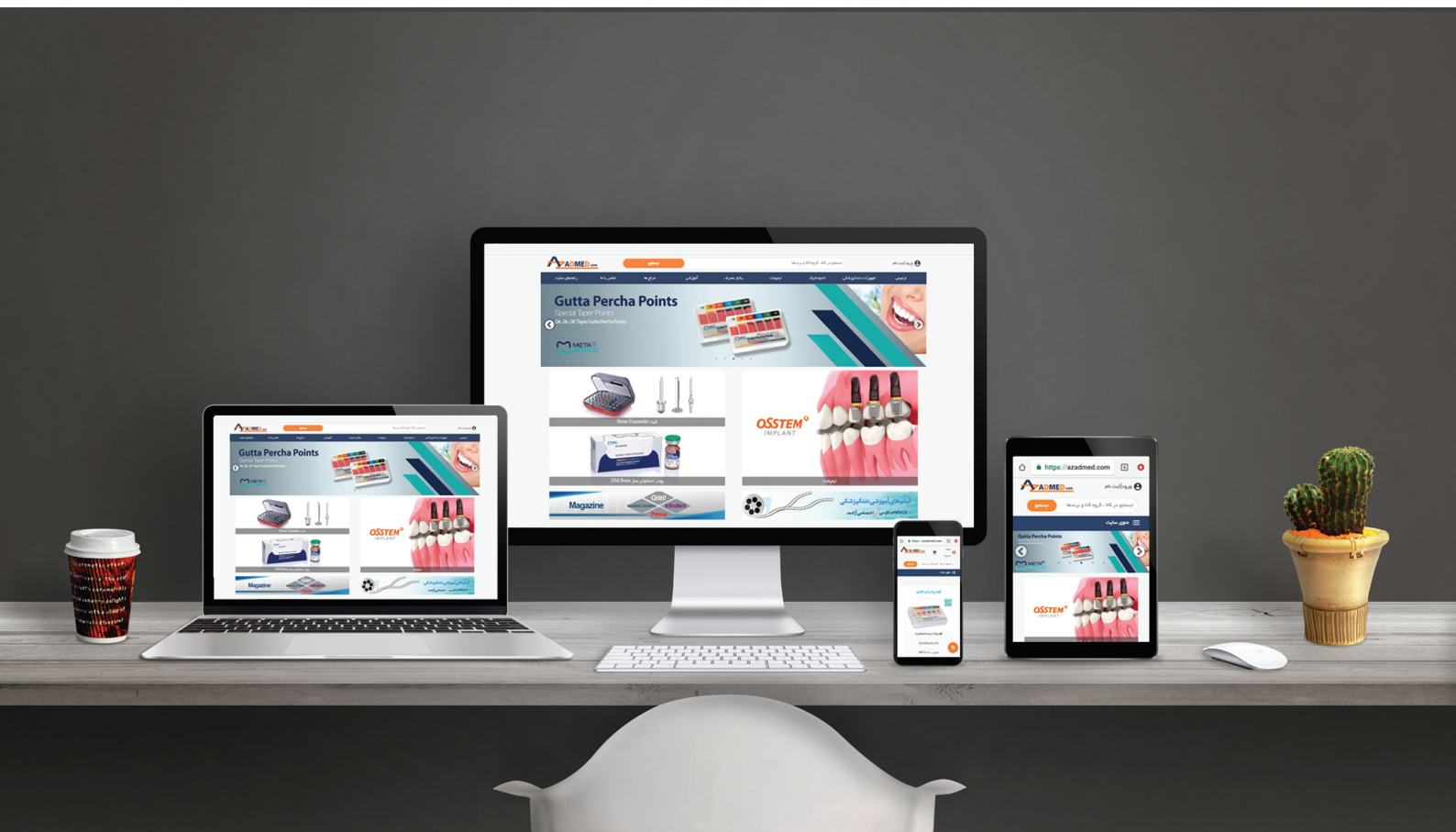




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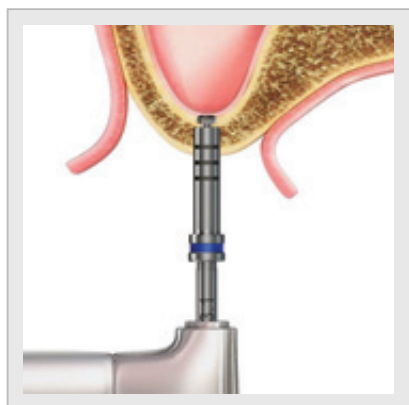
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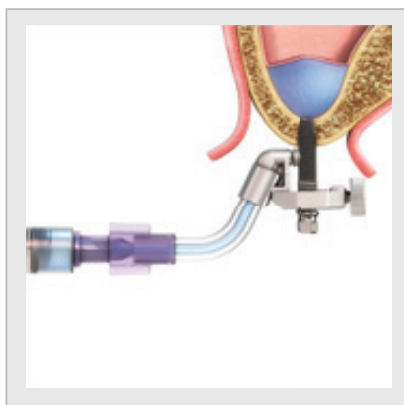
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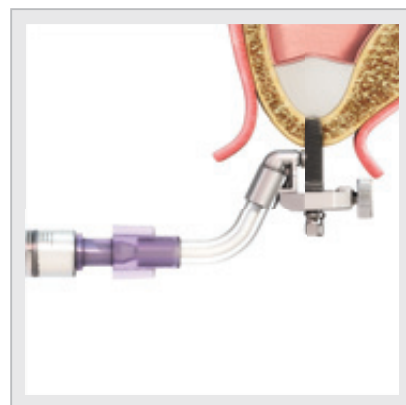
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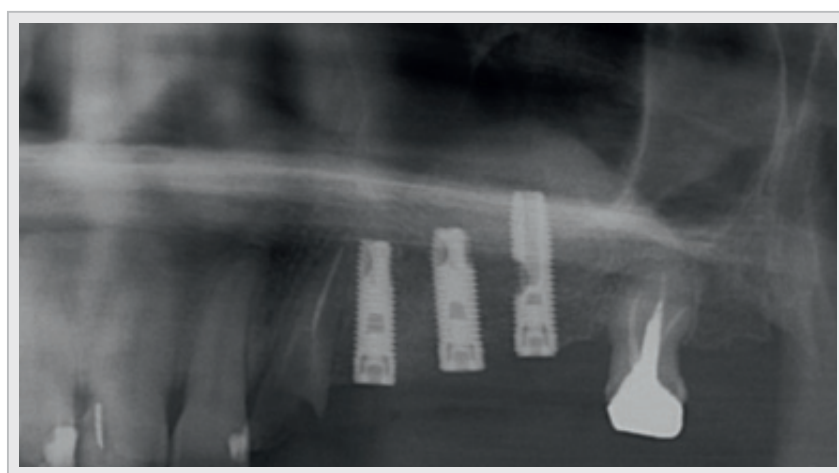
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What is the most severe
early complication concerning dental implants?

The placement of dental implants, although not without early complications—which are usually self-limited—has become a scheduled, routine and standardized surgical procedure. However, it is important that education in oral implantology adequately cover the immediate bleeding complications, especially in the floor of the mouth, that may arise and that, although infrequent, may be severe, sometimes even life-threatening, and require hospitalization for emergency treatment.

The interforaminal area in the mandible is quite often considered as the easiest region in which to insert dental implants, such as placing two implants to support an overdenture. However, the most serious bleeding accidents occur in this region owing to injury of the terminal branches of the sublingual or submental arteries if the lingual cortical plate is perforated during drilling or implant placement. This vascular injury can trigger massive internal bleeding in the mouth floor, which expands, causing protrusion and displacement of the tongue and sometimes subsequent obstruction of the airways, which may necessitate an emergency tracheotomy or even be fatal. Thus, the clinician should not treat placement of anterior mandibular implants lightly in the belief that placement in this region is easy.

In order to minimize the possibility of perforating the lingual cortical plate, some authors recommend placing implants that are not very long (10–12 mm) in the anterior region of the mandible. Tilting implants in a buccolingual direction, tipping the implant apex toward the vestibule, is another option. Perhaps the most important factor concerning minimization of the risk of these complications is that the surgeon carrying out the implant therapy should have extensive anatomical knowledge of this area, including the important anatomical structures located in the sublingual space.

Dr. Miguel Peñarrocha Diago
Co-Editor

03

Editorial

Dr. Miguel Peñarrocha Diago

06

About the *Journal of Oral Science & Rehabilitation*

08

Marco Tallarico et al.

Minimally invasive hydraulic elevation of the Schneiderian membrane and insertion of bone graft material using a novel self-tapping implant system: Radiographic and prosthetic aspects

16

Marco Annunziata et al.

Impact of argon plasma treatment on microbiological surface receptivity of titanium implants: An *in vitro* study

20

Erta Xhanari and Milena Pisano

Comparison of hard- and soft-tissue changes using a superimposition technique: A prospective case series study

26

Rubén Agustín Panadero et al.

Influence of fatigue on resistance and deformation of implant abutments used for provisional prosthetic restoration

34

Gaia Pellegrini et al.

Human pulps capped with PDGF: A pilot study

42

Fabio Camacho Alonso et al.

Importance of the axial reference plane in computed tomography for dental implant surgery: A cadaveric study

50

Giovanni Polizzi et al.

Immediate loading of variable-thread expanding tapered-body implants placed into maxillary post-extraction or healed sites using a guided surgery approach: An up-to-5 year retrospective analysis

62

Atsuko Imai et al.

An *in vitro* study on viscosity using an electromagnetically spinning sphere viscometer

68

Guidelines for authors

70

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Minimally invasive hydraulic elevation of the Schneiderian membrane and insertion of bone graft material using a novel self-tapping implant system: Radiographic and prosthetic aspects

Abstract

Objective

The objective of this article was to report the clinical and radiographic performance of a novel implant system that allows for hydraulic Schneiderian membrane elevation and simultaneous bone graft augmentation.

Case description

A 63-year-old female patient presenting with compromised fixed dental prostheses supported by failing teeth in her posterior maxilla underwent transcrestal sinus floor elevation using a novel implant system. Implant failure, any complications and bone gain measured using cone beam computed tomography (CBCT) were assessed.

Results

The residual alveolar ridge height was 3.2 mm. A 14.5 mm length implant was placed and followed for 20 months. Bone gain was 18.5 mm after a healing period of eight months. One year after implant loading, CBCT scans showed the stability of the grafted material.

Conclusion

Hydraulic elevation of the Schneiderian membrane using the iRaise sinus lift system (Maxillent, Herzliya, Israel) can be considered a valuable treatment option for the rehabilitation of atrophic edentulous posterior maxillae.

Keywords

Dental implant, sinus lift, Schneiderian membrane, atrophic maxilla, bone augmentation.

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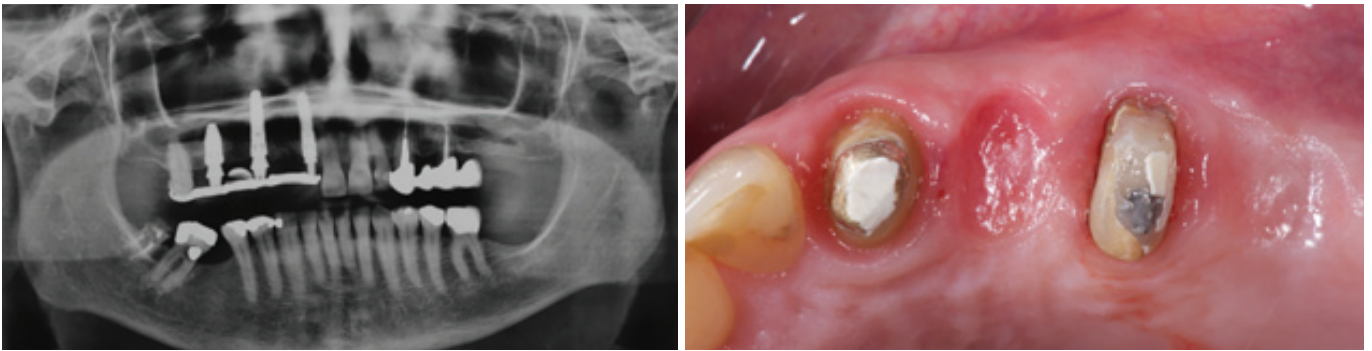
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Figs. 1 & 2



Introduction

In the posterior sextants of the maxilla, tooth loss is generally associated with alveolar bone loss and sinus pneumatization.¹ In addition, poor bone quality may have a negative influence on the survival rate of implants.² There is no consensus on treatment for the atrophic posterior maxilla, with the dilemma of whether to place short implants^{3,4} or tilted implants^{5,6} or to augment the floor of the maxillary sinus.^{7,8} In a recent review of the literature, Pjetursson et al. reported that the placement of dental implants in combination with maxillary sinus floor elevation using a lateral approach is a predictable treatment option showing high medium-term implant survival rates and low incidences of complications.⁷ However, the lateral approach to the sinus entails elevation of a large mucoperiosteal flap that affects postoperative recovery of the patient and the additional expense of the augmentation procedure.⁹ Schneiderian membrane perforations, nose bleeding, postoperative pain and swelling could be considered major risks.¹⁰ The elevation of the maxillary sinus floor through the alveolar crest (transalveolar) was first described by Tatum¹¹ and modified by Summers.¹² Subsequently, various modifications to the original technique have been reported, in order to improve the predictability and safety, such as the use of atraumatic lifting drills,¹³ membrane elevation via inflation of a balloon catheter,¹⁴ and the use of hydraulic¹⁵ or negative pressure.¹⁶

The aim of this clinical report was to present a novel self-tapping endosseous implant system (iRaise, Maxillent, Herzliya, Israel) developed for sinus augmentation. The advantage of this system is the ability to perform major sinus lift augmentation via a minimally invasive transcrestal approach and to simultaneously place an implant, with minimal patient discomfort and shortened treatment time.

Case presentation

A 63-year-old female patient presented with compromised fixed dental prostheses supported by failing teeth in her posterior maxilla (**Figs. 1 & 2**). The patient reported esthetic concerns and impairment of her masticatory function; consequently, she desired replacement of the prostheses. A cone beam computed tomography (CBCT) scan was performed to evaluate the amount of residual bone. On the right side, conventional implant placement was planned. However, on the left side, the distance from the maxillary crest to the sinus floor was 3.2 mm, requiring a bone augmentation procedure. After detailed consultation, various treatment options were discussed with the patient. Closed major sinus floor augmentation with a transcrestal approach using the iRaise implant system was planned for the maxillary left first molar position to support a screw-retained fixed dental prosthesis. An adjunctive implant was planned for the maxillary left first premolar position.

The day before the implant placement, the patient underwent intranasal spray therapy (thiamphenicol glycinate acetylcysteinate, 810 mg/4 mL) b.i.d. One hour before surgery, a single dose of antibiotic (2 g of amoxicillin and clavulanic acid) was administered prophylactically. A 0.2% chlorhexidine mouthwash was administered for 1 min prior to the implantation procedure.

Local anesthesia was administered (articaine with 1:100,000 epinephrine) and a small full-thickness mucoperiosteal flap was elevated. A 2 mm diameter round bur was used to mark the implant site. The osteotomy was prepared with a 2 mm twist drill 1 mm below the sinus floor. A periapical radiograph with a depth guide was performed in order to verify the drilling angle and depth, as well as the distance to the sinus floor. The implant recipient site was wide-

Fig. 1

Preoperative panoramic radiograph.

Fig. 2

Alveolar ridge before implant placement (occlusal view).

Fig. 3

Preoperative CBCT scan.

Fig. 4

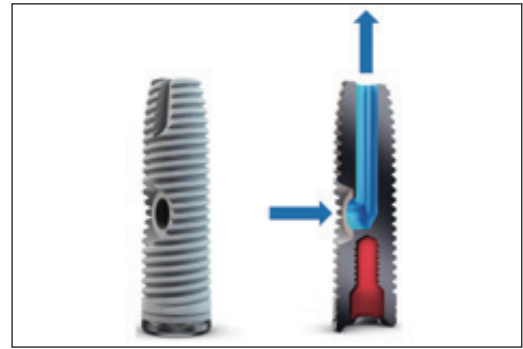
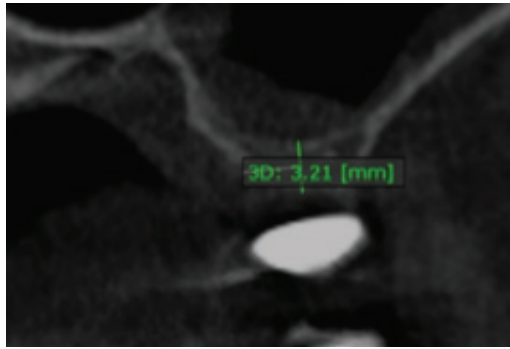
The iRaise sinus-lift system (Maxillent, Herzliya, Israel).

Fig. 5

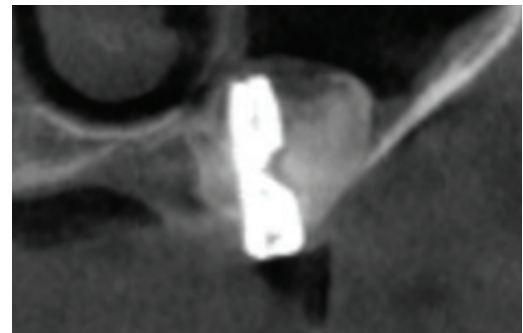
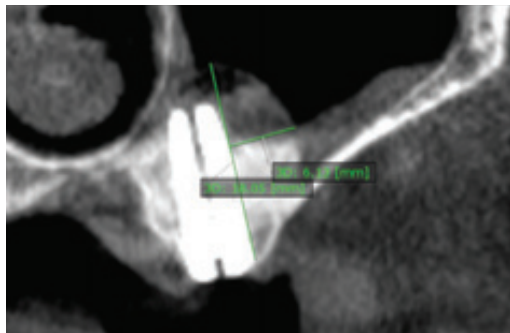
CBCT scan immediately after implant placement.

Fig. 6

CBCT scan six months after implant placement.



Figs. 3 & 4



Figs. 5 & 6



Figs. 7 & 8

Fig. 7

Definitive prostheses on the cast (occlusal view).

Fig. 8

Definitive prostheses on the cast (frontal view).

ned to allow the placement of a 5 mm diameter implant, according to the drilling protocol suggested by the manufacturer and reported in a previously published paper.¹⁷ The length of the implant was selected beforehand based on the residual bone height, measured using the preoperative CBCT scan, from the bone crest to the sinus floor, along the implant's planned axis. A 14.50 mm length implant (iRaise, Maxillent, Herzliya, Israel) was used according to a residual bone height of 3.21 mm (**Fig. 3**). The implant was first inserted into the osteotomy until it reached the end of the prepared site. The implant was then slowly advanced until the sinus floor was penetrated for approximately 1 mm. A periapical radiograph was performed in order to determine whether the implant had penetrated the sinus floor. A saline syringe with 2–3 cm³ of a 0.9% sterile saline solu-

tion was connected to the implant through the tubing port. With this system, the tube connector is easily assembled on the implant, allowing injection of fluids with a standard Luer lock connector. Saline solution was gently injected through the implant and into the sinus and slight bleeding was noted in the retracted saline solution upon stopping the injection. A syringe containing 2 cm³ of a flowable bone graft material (MBGP Gel, Biomat-lante, Vigneux-de-Bretagne, France) was subsequently connected to the same port. The material was slowly injected through the implant into the sinus (**Fig. 4**). After the grafting procedure had been completed, the hydraulic system was disconnected from the implant, and the implant was inserted to its entire length into the osteotomy and the grafted sinus cavity and left to heal according to a submerged protocol. An additional implant

Figs. 9 & 10



Figs. 11 & 12



was placed after completing the iRaise surgical sequence. A postoperative CBCT scan was taken with reduced voxel size, field of view and milliamperage settings (**Fig. 5**). After surgery, intranasal spray therapy (thiamphenicol glycinate acetylcysteinate, 810 mg/4 mL) was continued for ten days, an antibiotic (1 g of amoxicillin and clavulanic acid b.i.d.) for six days and a 0.2% chlorhexidine mouthwash (1 min b.i.d.) for two weeks. A soft diet was recommended for one week, while 1 g of paracetamol was prescribed in case of pain. The sutures were removed after one week, and oral hygiene instructions were emphasized.

Six months after implant placement, a CBCT scan was taken with the same parameters used for the postoperative scan, and the healing abutments were connected. The bone gain was 18.5 mm (**Fig. 6**). Definitive screw-retained metal-free restorations were delivered eight months after implant placement (**Figs. 7–9**). The occlusion was carefully checked. Recall appointments for oral hygiene maintenance and oral hygiene instructions were set for every four months after loading. The occlusion was evaluated at each visit. CBCT scans were performed one year after implant loading (20 months after implant placement) and compared with the previously taken CBCT scans (**Figs. 10–16**).

Discussion

The present case report is one of the first aimed at evaluating a novel implant system that allows for minimally invasive major sinus floor elevation at the time of implant placement. According to a recent Cochrane systematic review, if the residual alveolar bone height is 3–6 mm, a transcrestal approach to lifting the Schneiderian membrane and placing 8 mm implants may lead to fewer complications than would a lateral window approach and placing implants at least 10 mm long.¹⁹

In the case presented, the patient experienced minimal discomfort and was functionally restored in a shorter period than are patients treated with a two-stage sinus grafting technique. In investigating the transcrestal osteotome technique for sinus floor augmentation, some researchers have recorded high rates of patient satisfaction.^{7, 20, 21} Maxillary sinus floor elevation with a transcrestal approach is advocated as a minimally invasive procedure, owing to the minimal surgical flap required. Moreover, the lateral sinus wall remains intact, reducing postoperative morbidity.^{22, 23} This technique is widely documented in the literature

Fig. 9

Metal-free framework.

Fig. 10

Right lateral view of the definitive prosthesis taken one year after loading.

Fig. 11

Frontal view of the definitive prosthesis taken one year after loading.

Fig. 12

Left lateral view of the definitive prosthesis taken one year after loading.

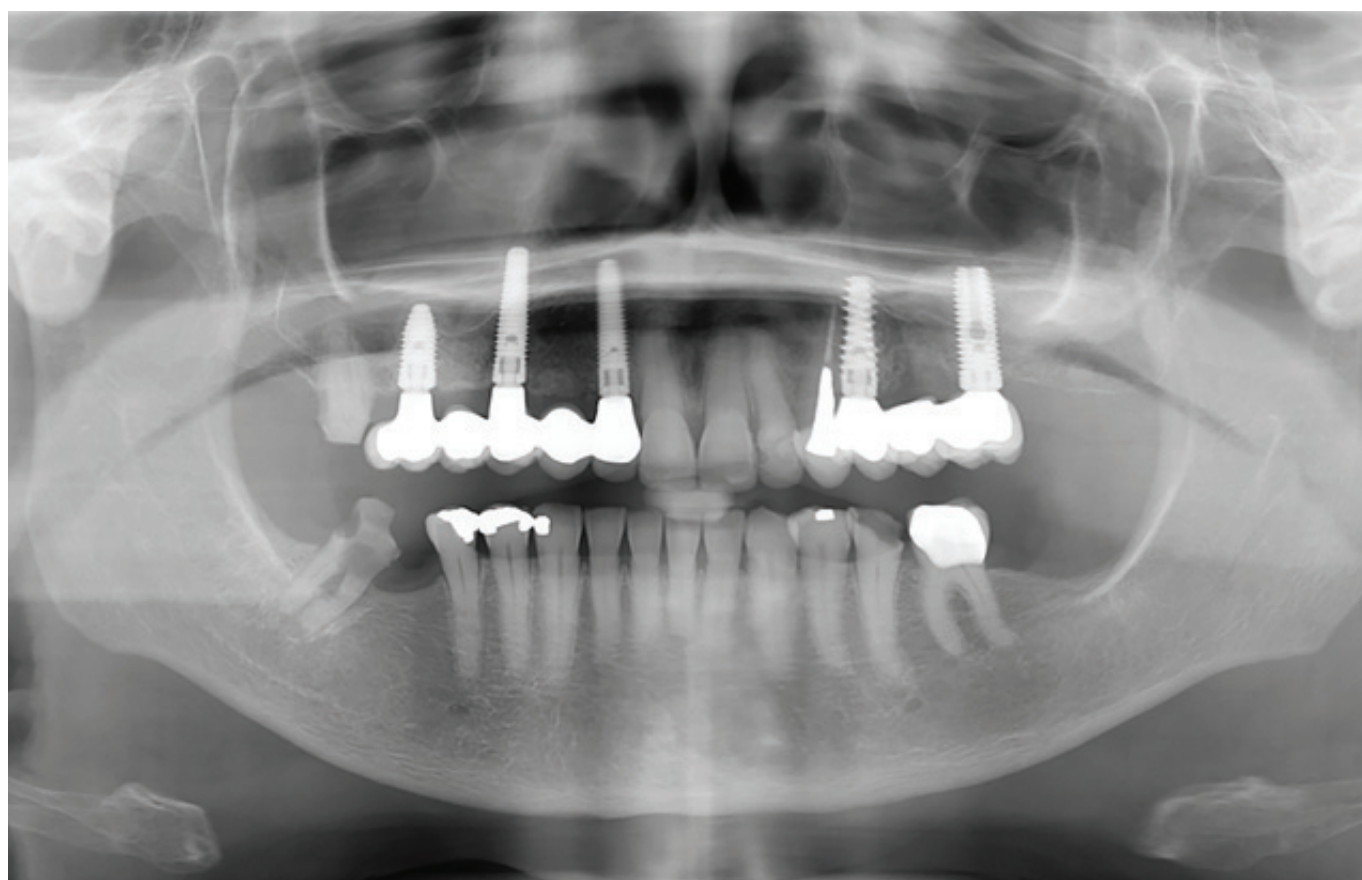
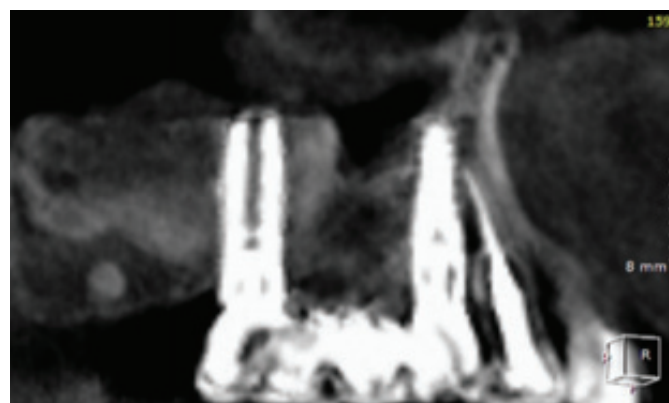
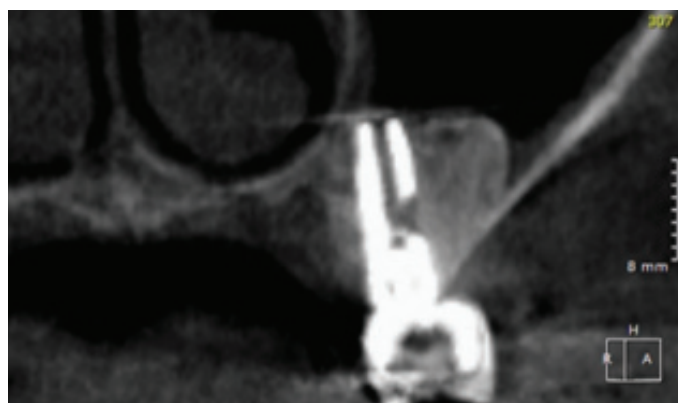


Fig. 13



Figs. 14 & 15

Fig. 13

Panoramic radiograph taken one year after loading.

Fig. 14

CBCT scan one year after loading (sagittal view).

Fig. 15

CBCT scan one year after loading (coronal view).

and supported by several longitudinal studies that attest to an average implant survival rate close to 92% in the medium term.^{7, 8, 24} Recent publications have shown that transalveolar sinus floor elevation is a reliable method for implant placement in the posterior maxilla, even at sites with ≤ 4 mm of residual alveolar bone height.^{17, 25–27} Nevertheless, implant survival rates may decrease with reduced residual bone height.^{18, 28}

The main concerns related to the transcresal approach, compared with the lateral surgical approach, are the absence of direct visualization

of the sinus cavity and Schneiderian membrane, the limited amount of bone augmentation achieved and the high risk of inadvertent perforation of the Schneiderian membrane during fracture of the sinus floor with osteotomes, or burs, with or without stop drills, without the possibility of repairing the torn membrane. Nevertheless, in an eight-year retrospective study on 1,100 participants with 1–5 mm of residual bone height who received 1,557 implants with minimally invasive hydraulic elevation of the Schneiderian membrane, an incidence of membrane perforation of less than 0.5 % was reported.¹⁵

Fig. 16

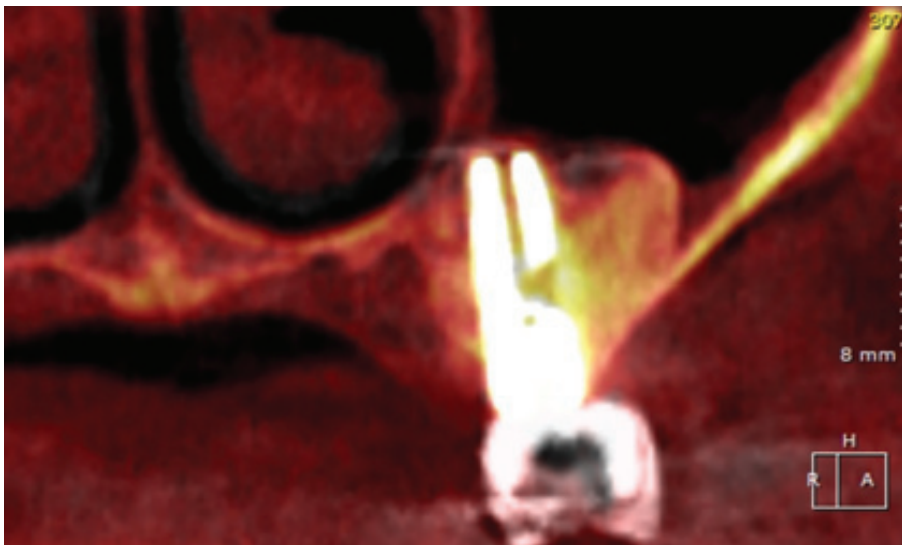


Fig. 16

Superimposition of the CBCT scans taken six months after implant placement (red) and one year after loading (gray) showing stability of the grafted material over time.

The iRaise implant system is a uniquely designed implant housing an L-shaped channel separate from the prosthetic connection and the oral cavity, thereby eliminating the possibility of bacteria migrating into the bone. Through this channel, saline is introduced to elevate the Schneiderian membrane. The iRaise system allows the clinician to perform a minimally invasive sinus augmentation procedure immediately. The hydraulic elevation of the Schneiderian membrane and the insertion of bone graft material are performed through the implant itself, resulting in fewer complications, shorter treatment time and greater comfort for patients, compared with the open sinus lift procedure.

Closed major sinus floor augmentation with a transcrestal approach can be accomplished using a novel system that allows for hydraulic elevation of the Schneiderian membrane, injection of a flowable bone graft material and simultaneous dental implant placement, with minimal patient discomfort. Long-term clinical studies on larger cohorts of patients are needed to confirm these preliminary results.

Competing interests

This was an investigator-initiated trial. The trial was supported partially by Maxillent.

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Impact of argon plasma treatment on microbiological surface receptivity of titanium implants: An *in vitro* study

Abstract

Objective

Pretreatment of dental implants by argon plasma has been suggested to increase their surface energy and enhance integration of both hard and soft periimplant tissue. However, no data are available on the risk of implant sterility loss after this process. This study aimed to test whether the treatment of implant fixtures by argon plasma in conditions compatible with clinical use produced an increased risk of microbiological contamination.

Materials and methods

Thirty (15 control and 15 test) sterile Grade 4 titanium implants were used. Test implants were removed from their original packages, pretreated in an argon plasma chamber for 12 min, and then immersed in a bacterial culture medium (Luria-Bertani broth) at 37°C for 72 h. Control implants were directly transferred to Luria-Bertani broth.

Results

When the culture broths were examined after the 72 h incubation, no traces of bacterial contamination were found for either controls or test implants.

Conclusion

Within the limits of this study, the data reported suggest that argon plasma technology could be used to pretreat implant fixtures immediately before their surgical placement without increasing the risk of microbiological contamination.

Keywords

Argon plasma, dental implant, microbiological contamination.

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Introduction

Argon plasma is widely employed as the final step of the manufacturing process of titanium implant fixtures before their sterilization by gamma rays. With this treatment, a spray of argon under pressure at room temperature is used to clean implants and remove microbiological and organic contaminants from the metal surface. At the same time, however, the atomic bombardment to which the titanium surface is subjected, causes its activation, that is, a state of excitation of the electronic mantle and the modification of its physicochemical and biological features.¹

The activation obtained during the manufacturing phase is temporary and will have ceased once the implant fixture is used clinically. It has been suggested that the reactivation of the titanium surface by argon plasma immediately before the implant positioning in the oral cavity could be advantageous in terms of the integration of both hard and soft periimplant tissue.

In vitro and animal studies performed in sterile environments have shown an increased surface energy and an enhanced early biomechanical fixation of dental implants pretreated by argon plasma.²⁻⁴ Furthermore, preliminary results have suggested that treatment of titanium abutments by argon plasma may enhance cell adhesion at the early stage of periimplant soft-tissue healing⁵ and marginal bone preservation over time.⁶ However, no data are available about the possible effect of this treatment on the implant surface receptivity toward environmental bacteria and on the risk of sterility

loss of the fixture just before its surgical placement. The aim of the present study was to test whether the treatment of implant fixtures by argon plasma in conditions compatible with clinical use produced an increased risk of microbiological contamination.

Materials and methods

Thirty (15 control and 15 test) sterile Grade 4 titanium implant fixtures with a sandblasted and acid-etched surface (ZirTi, average surface roughness of 1.3 μm ; Sweden & Martina, Due Carrare, Padua, Italy) were used for this study. Control implants were directly transferred with sterile tweezers from their original packaging into test tubes containing 5 ml of Luria-Bertani broth (Oxoid, Basingstoke, UK) and incubated at 37 °C for 72 h. Test implants were inserted into a metallic holder (**Fig. 1**) and pretreated in an argon plasma chamber (Plasma R, Diener electronic, Ebhausen, Germany) for 12 min at room temperature and then transferred to culture broth. In order to simulate the clinical practice and environment, the time between the removal of each fixture from its sterile package, or from the argon plasma chamber, and its immersion in the culture broth was standardized at 60 s and the transfer was performed in a nonprotective environment. Three independent experiments were carried out under the same conditions.

Fig. 1

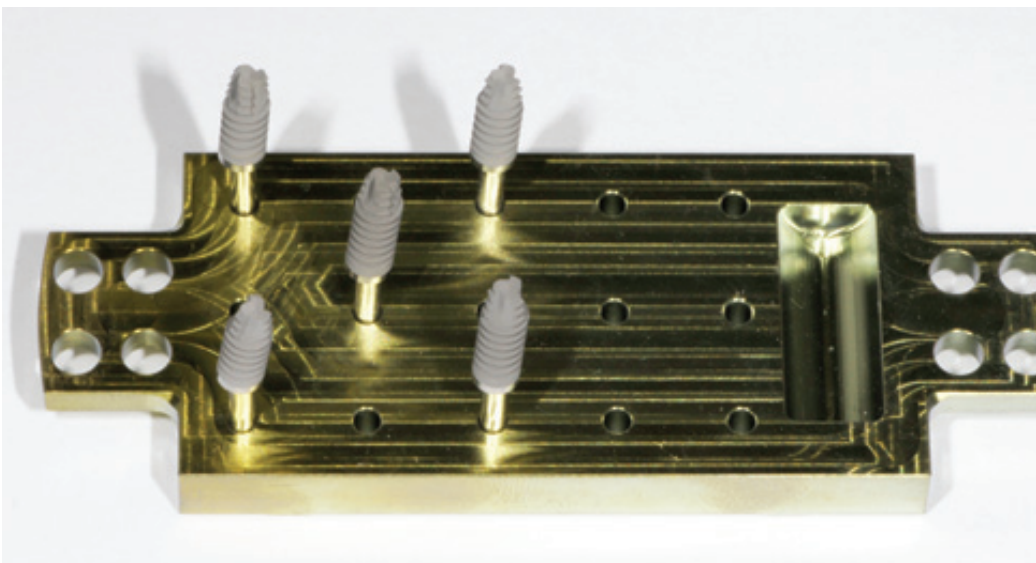


Fig. 1

Test implants inserted into a metallic holder before pretreatment in the argon plasma chamber.

Fig. 2

Culture broths examined after the 72 h incubation. No traces of bacterial contamination were found for either controls or test implants.

**Fig. 2**

Results

When the culture broths were examined after the 72 h incubation, no traces of bacterial contamination were found for either controls or test implants (Fig. 2).

Competing interests

The authors declare that they have no competing interests.

Conclusion

Within the limits of this study, the data reported suggest that argon plasma technology could be used to pretreat implant fixtures immediately before their surgical placement without increasing the risk of microbiological contamination. However, additional microbiological and preclinical studies should be performed to test the clinical applicability of this procedure.

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Comparison of hard- and soft-tissue changes using a superimposition technique: A prospective case series study

Abstract

Objective

This prospective case series study reports on a novel comprehensive method using digitized model casts and a superimposition technique to allow an objective evaluation of the hard- and soft-tissue parameters.

Materials and methods

Any patients requiring all-ceramic restoration of the anterior maxillary teeth were recruited and treated between January 2014 and December 2014. No inclusion or exclusion criteria were considered. Soft-tissue level changes were measured on the casts taken before and after treatment, using a novel digital technique.

Results

Eight patients with a total of 34 all-ceramic veneer restorations were treated. One year after delivery of the definitive restorations, no complications were observed (fracture, wear, chipping or debonding). Mean soft-tissue levels improved between bonding and the one-year follow-up examination. The mean height of the mesial and distal papillary changes was 0.64 ± 0.31 and 0.47 ± 0.28 , respectively.

Conclusion

The technique presented offers an objective evaluation of the hard- and soft-tissue changes, and it could complement previously established methods.

Keywords

Esthetic score, porcelain veneer, soft tissue, superimposition, CAD/CAM.

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Introduction

Esthetic outcomes and patient satisfaction have become the main focus of interest in esthetically sensitive areas.^{1,2} The level and thickness of the soft tissue, as well as its color and texture, are decisive for the natural appearance of an implant-supported restoration.³

Over the last 20 years, the evaluation of the success of tooth- and implant-supported restorations has shifted from judging only the survival rate of the restoration itself to additionally assessing whether an esthetic appearance similar to the adjacent teeth has been achieved. Today, the main concern is whether the surrounding bone architecture and soft-tissue texture and color can precisely and biomimetically emulate nature.⁴ Assessment of esthetically successful treatment outcomes is validated clinically by several objective periodontal and esthetic parameters.^{5–7} However, there is still a lack of clinical comparative studies in the current literature regarding objective outcome evaluation from an esthetic perspective.^{8–13}

In 2004, the International Team for Implantology presented a treatment guide to provide clinicians with practical and evidence-based clinical instructions for implant restorations in the esthetic zone.¹⁴ Successful tissue integration and pleasing esthetic outcomes after the application of this treatment protocol have been reported in retrospective¹⁵ and prospective¹⁶ case series studies. Jemt proposed an index, termed the Papilla Index, to assess the size and volume of the interproximal papillae adjacent to a single tooth. The index defines five distinct levels, ranging from the complete absence of papillary tissue (index score of 0) to hyperplastic papillae (index score of 4).¹⁷ Meijer et al. published the Implant Crown Aesthetic Index, which stipulates criteria related to the implant restoration itself and those associated with the surrounding soft tissue.⁵ Fürhauser et al. proposed an index, termed the Pink Esthetic Score (PES), focusing essentially on the soft-tissue aspects associated with an anterior single implant-supported restoration.⁶ Seven distinct soft-tissue parameters are considered: the presence or absence of mesial and distal papillae, the level and curvature of the line of emergence of the implant restoration from the mucosa at the facial aspect, the facial soft-tissue convexity (in analogy to a root eminence), and the color and texture of the facial marginal periimplant

mucosa. Each parameter score can range from 0 to 2, which results in a maximum score of 14. Finally, Belser et al. proposed a five-variable index, termed the White Esthetic Score (WES), focusing on the visible part of the implant restoration itself and usable in combination with the previously reported PES.¹⁵

The aim of this prospective case series study was to propose a novel comprehensive method using digitized model casts and a superimposition technique to allow an objective evaluation of the hard- and soft-tissue parameters for both tooth- and implant-supported restorations.

Materials and methods

Any patients requiring all-ceramic restoration of the anterior maxillary teeth were recruited and treated between January 2014 and December 2014. All of the patients were treated in a private dental center in Rome, Italy, by the same clinician (EX). No inclusion or exclusion criteria were considered. Initial photographs and radiographs were taken (**Fig. 1**). Diagnostic casts were obtained from polyvinyl siloxane impressions (Aquisil Putty DECA and Aquisil Ultra LV/XLV Regular Set, DENTSPLY International, Milford, Del., U.S.) taken with customized light-curing acrylic impression trays (Elite LC Tray, Zhermack, Badia Polesine, Italy) fabricated from preliminary casts. A diagnostic wax-up was performed (**Fig. 2**) and used to fabricate a silicone guide. Acrylic duplication of the wax-up was performed directly in the patient's mouth, using the silicone guide (direct mock-up; **Fig. 3**) in order to test the function and esthetics of the envisioned restorations. Dental preparation was carried out according to a minimally invasive approach (**Fig. 4**) based on the silicone guide, to avoid over-reducing areas of the teeth. A new cast was obtained for the fabrication of the all-ceramic veneer restorations. The all-ceramic veneer restorations were bonded according to a previously published technique.¹⁸ One year after delivery of the definitive restorations (**Fig. 5**), a new polyvinyl siloxane impression was taken for each patient to allow direct comparison with the pre-treatment scenario. Pre- and post-treatment model casts were poured using a conventional single-pouring technique. Vacuum-mixed, low-expansion (0.09%) Type IV dental stone was vibrated into the impression (CAM-base, Dentona, Dortmund,

Fig. 1

Preoperative views revealing worn maxillary anterior teeth.

Fig. 2

Diagnostic wax-up.

Fig. 3

Direct acrylic mock-up.

Fig. 4

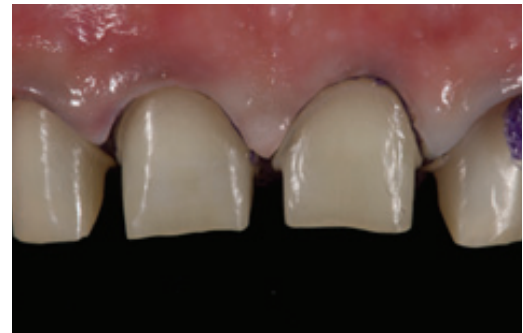
Minimally invasive tooth preparation.

Fig. 5

One-year postoperative intra-oral view.



Figs. 1 & 2



Figs. 3 & 4



Fig. 5

Germany). The stone casts were allowed to set for 2 h before separation from the impressions.

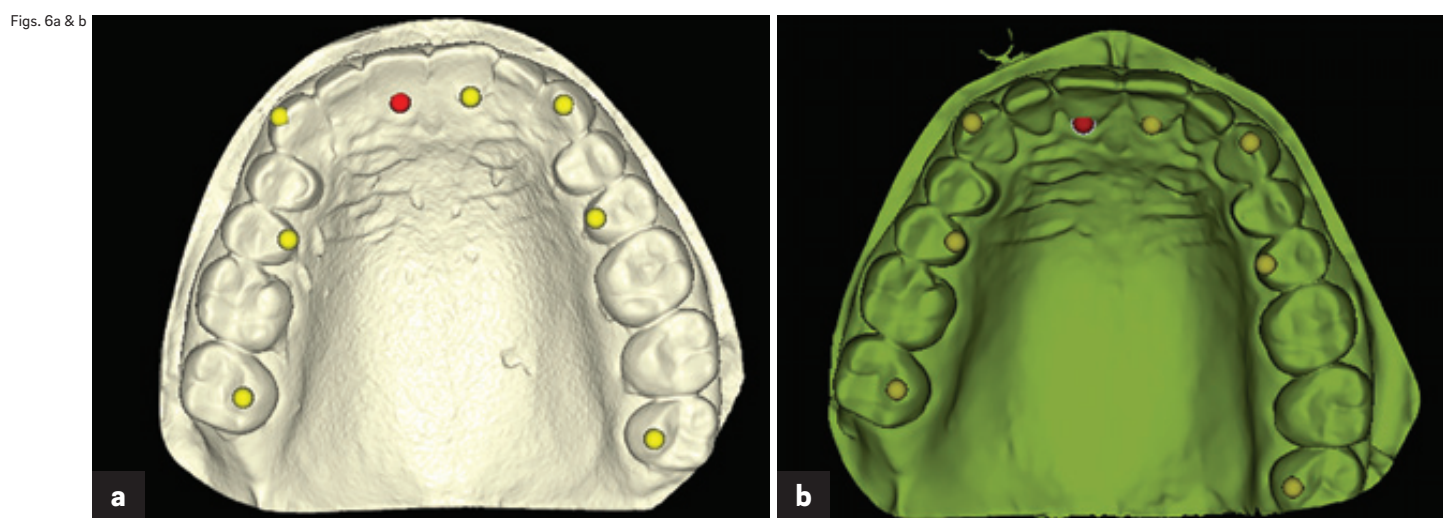
The model casts were then scanned using both a cone beam computed tomography (CBCT) scanner (CRANEX 3D, SOREDEX, Tuusula, Finland) with a 1 mm copper filter and a dental scanner based on conoscopic holography technology (NobelProcera Scanner, Nobel Biocare, Kloten, Switzerland), coupled with dedicated software (NobelProcera).

The DICOM and STL files were imported into NobelClinician Software (Nobel Biocare) to perform the superimposition of the two data sets. The DICOM and STL data were automatically matched based on the adjacent teeth and manually checked for a complete match using SmartFusion technology (Figs. 6a & b). The hard- and soft-tissue dif-

ferences between the two digitized model casts were calculated on 2-D sections taken along the long axes of the restored teeth and along the papillae (Figs. 7a–d).⁹ An independent assessor, not previously involved in the study, scanned and measured all of the model casts.

Results

Overall, eight patients (two men and six women) with a total of 34 all-ceramic veneer restorations placed in the esthetically sensitive area of the maxilla (between the canines) were followed for at least one year after delivery of the final restorations. Of these, 16 replaced the central incisors, 14 the lateral incisors, and four the canines. One

**Figs. 6a & b**

Corresponding points in the DICOM (a) and STL (b) data during superimposition.

year after delivery of the definitive restorations, no complications were observed (fracture, wear, chipping or debonding). Mean soft-tissue levels improved between bonding and the one-year follow-up examination. The mean height of the mesial and distal papillary changes was 0.64 ± 0.31 and 0.47 ± 0.28 , respectively.

Discussion

The present clinical study examined a new objective technique to assess the hard- and soft-tissue changes in natural and artificial dentition. The present technique is not intended to replace previously established methods developed to evaluate the esthetic success of a dental treatment. Conversely, the superimposition of CAD model casts may complement techniques that use subjective methods, such as standardized clinical photographs.

The main limitation of the present technique is the spatial resolution of the scanners and that it does not evaluate color. Nevertheless, the study cast evaluation involved a PES/WES evaluation, facilitating the objective appreciation of crown outline, as well as hard- and soft-tissue changes. Esthetics are subjective and linked to the patient, but this technique aims to evaluate the thickness and level of the hard and soft tissue, which is also useful in pre- and postoperative comparison (e.g., bone reconstruction and socket preservation).

The results of the present study showed a mean soft-tissue increase at the level of both the mesial and distal papillae between the pre- and post-treatment situations. A possible explanation

could be the re-establishment of the correct contact points and the renewed instructions on proper oral hygiene.

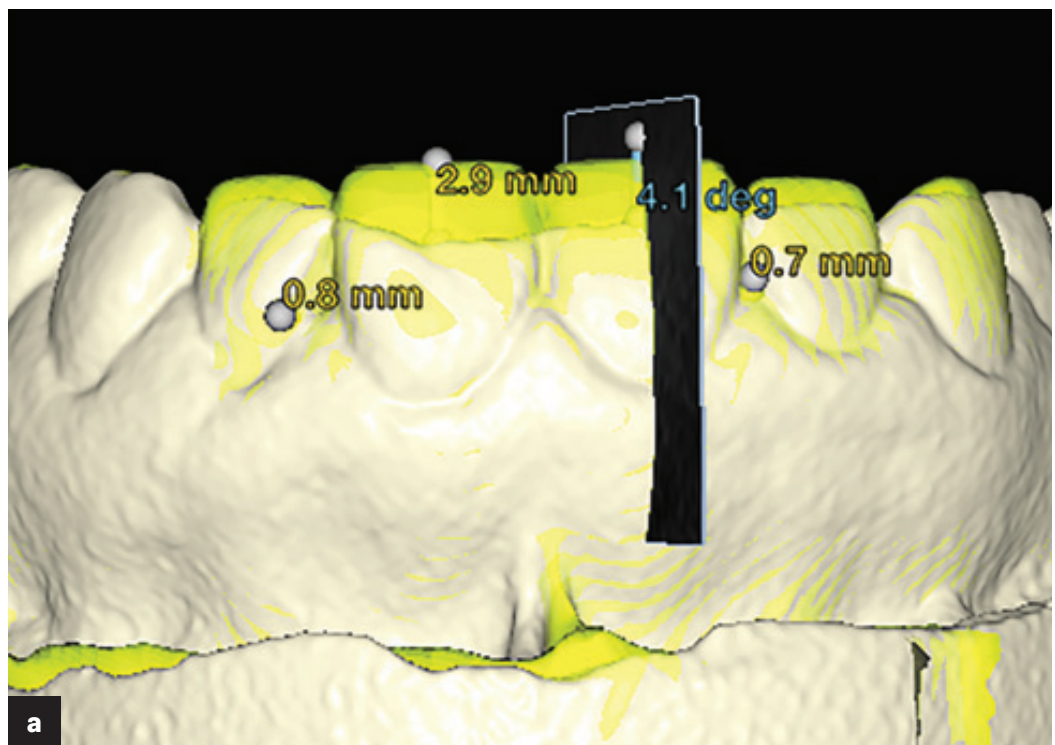
All of the reference studies^{5–7} use subjective indexes and require the capture of a series of photographs to compare the differences between follow-up examinations. If clinical photographs are to provide an accurate record of pre- and postoperative patient appearance, the relative positions of the patient and camera must be kept constant. Perspective distortion may be an unacceptable drawback, especially in comparison of pre- and post-treatment clinical photographs.¹⁹

CBCT scanning ensures a comprehensive, high-precision scan of both impressions and plaster casts, delivering accurate 3-D models, which can be used immediately or stored for later use. The scanned 3-D model can be exported as a DICOM set or superimposed onto CBCT data to provide an artifact-free model of the patient's dentition, including the bone, crowns and soft tissue. The DICOM and STL files can be superimposed too, helping the clinician with clinical and treatment planning, as well as allowing for pre- and post-treatment comparison. A straightforward DICOM to STL conversion is easily possible.

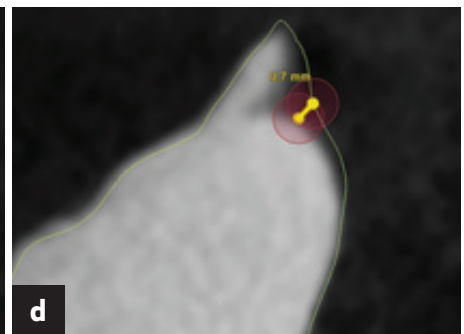
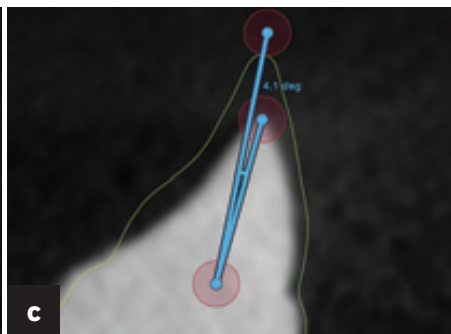
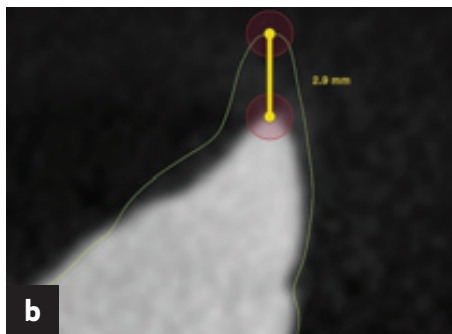
Conoscopic holography scanning technology is a valid option for the laboratory digitization of model casts.²⁰ This technology projects and reflects light beams from the shape of a complex scanned object along the same linear pathway. This collinearity measures steep angles and deep cavities for precision scanning. Furthermore, it allows, in a few minutes, a full simultaneous digitization of a model cast in a single work session without any manual user intervention.

Figs. 7a–d

Hard- and soft-tissue measurements of the differences between the two digitized model casts, calculated on 2-D sections (a) taken along the long axes of the restored teeth (b & c) and along the papillae (d).



Figs. 7a–d



Superimposition of digitized data using a voxel-based registration method has already been explored in the literature.^{21–25} The main advantage is the generation of digital archive of patients for several purposes, including esthetic analysis.

Competing interests

The authors declare that they have no competing interests related to this study.

Conclusion

The technique presented offers an objective evaluation of the hard- and soft-tissue changes over time. This technique could complement previously established methods.

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Influence of fatigue on resistance and deformation of implant abutments used for provisional prosthetic restoration

Abstract

Objective

One of the most difficult challenges for implant-supported prosthetic restorations is the management and maintenance of periimplant soft-tissue esthetics, especially in the anterior region. In order to do this effectively, there are diverse techniques for tissue management, the most significant being fixed provisionalization, which can be immediate or delayed. The aim of this study was to analyze fracture resistance of provisional implant-prosthetic abutments (titanium, PEEK and methacrylate) and to determine whether previously fatiguing the abutments influenced fracture resistance.

Materials and methods

Forty implant-prosthetic abutments underwent static load testing; 20 of these were subjected to fatiguing before load testing. Forty internal hex connection implants supported the 40 abutments: ten titanium provisional abutments, ten castable methacrylate provisional abutments, ten PEEK resin provisional abutments and ten titanium definitive abutments.

Results

The group that showed the greatest fracture resistance was the nonfatigued definitive titanium abutments, with values over 1,000 N. The abutments that showed the lowest fracture resistance were the fatigued castable methacrylate provisional abutments, with a mean value of 192.8 N.

Conclusion

Fatiguing the abutments did not significantly influence their fracture resistance or elastic behavior. All of the abutments studied fulfilled the mechanical requirements for survival in the mouth.

Keywords

Dental implant, provisional/definitive implant abutment, fatiguing, immediate loading.

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Introduction

In the field of dentistry, implant dentistry is one area that has undergone extensive development in recent years, owing to the high demand for this treatment and constant innovation and research into new materials and attachments. Implant placement has become the first treatment choice for replacing missing teeth, particularly single teeth, because of the excellent clinical results confirmed by long-term research.¹ Nowadays, esthetics is an important factor in judging the final outcome of dental treatment. In the case of implant dentistry, various factors influence esthetics. It is not enough to place a natural-looking restoration with correct proportions and adequate color, for a successful outcome will also depend on management of the periimplant soft tissue.² This is not always straightforward, as the soft tissue is governed by multiple factors: the periodontal biotype, alveolar bone crest level, angle of implant insertion, depth of implant platform and level of the first point of bone-to-implant contact.³ Given this scenario, achieving optimal esthetic results is a complicated process. A diverse range of techniques are available for soft-tissue management. From the prosthodontic perspective, provisional prostheses are useful to help model the surrounding tissue and create a harmonious profile before placing the definitive restoration.⁴ Furthermore, provisional restorations help improve communication with the patient, as they offer the opportunity to view future outcomes.²

For all these reasons, dental professionals need to be aware of the different materials available on the market, as well as their physical and chemical properties, for the correct fabrication of both provisional and definitive prostheses that will achieve optimal esthetics and good peri-

implant health.^{3–11} Provisional restoration can be useful as a diagnostic tool too, as it allows the dentist to assess the final outcome in advance and provides an opportunity to obtain the patient's feedback and opinion. Its main function is to guide and shape the soft tissue during healing and maturation, allowing the tissue to develop more quickly and suggest the definitive gingival shape.^{12–29}

This study was designed with the following objectives:

- to analyze the deformation and fracture resistance of implant-supported provisional abutments made of different materials (titanium, PEEK and methacrylate)
- to determine whether fatiguing prior to static load testing influenced fracture resistance and deformation of the abutments.

Materials and methods

Materials

Forty Kohno internal hex connection implants (Sweden & Martina, Due Carrare, Italy) were used (4.25 mm in diameter and 11.5 mm in length). Forty abutments were screwed on to the implants, 30 of which were provisional and ten definitive ($n = 40$). The abutments were divided into four groups (**Table 1**): castable methacrylate provisional (CMP) abutments with a titanium base; PEEK (polyether ether ketone) provisional (PP) abutments with a machined titanium base; Grade III titanium provisional (TP) abutments; and Grade IV titanium definitive (TD) abutments.

Forty specimens were fabricated, each consisting of an implant set in a 5 cm diameter nylon cylinder with epoxy resin (Exakto-Form, bredent, Senden, Germany). In order to simulate implant

Table 1

Group	Abutment type	Connection
CMP	Castable methacrylate provisional abutments with a machined titanium base	Anti-rotational
PP	PEEK provisional abutments	Anti-rotational
TP	Grade III titanium provisional abutments	Anti-rotational
TD	Grade IV titanium definitive abutments	Anti-rotational

Table 1

Specimen distribution by abutment type

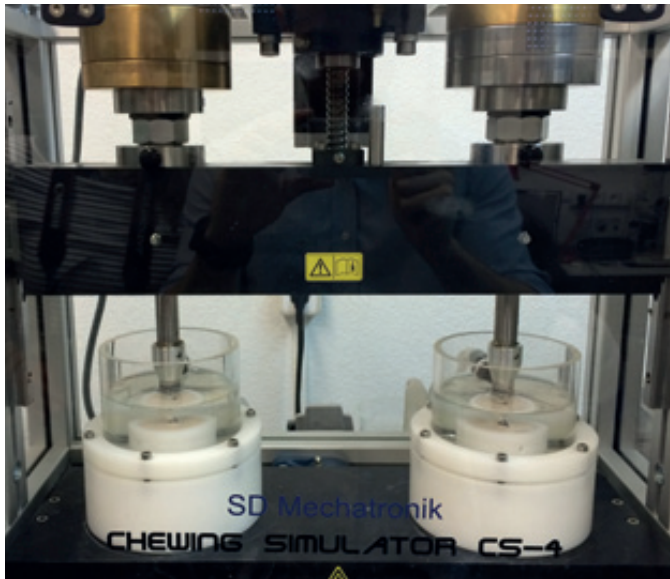
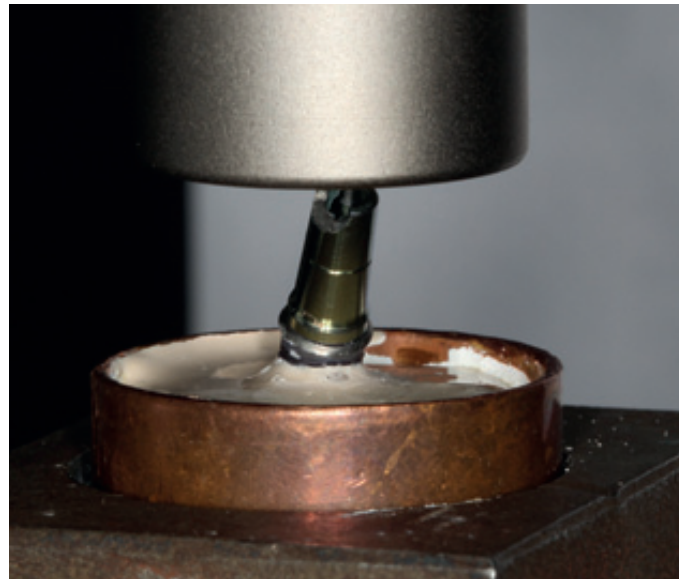


Fig. 1

Cyclic loading of implant-supported abutments.

Fig. 2

Static load testing of implant-supported abutments.



Figs. 1 & 2

position conditions in the alveolar ridge in the premaxilla, specimens were placed in the cylinder at an angle of 30° to the direction of the load. The abutments were screwed on to the implant–cylinder complex using a dynamometric torque wrench, applying a torque of 30 N, as recommended by the manufacturer.

Method

Before specimens underwent static load testing, they were subjected to dynamic loading. This fatiguing process was performed using a chewing simulator (CS-4, SD Mechatronik, Rosenheim, Germany; **Fig. 1**). Loading was applied to the upper part of the abutment (angled at 30°) with an impact force of 80 N and a frequency of 2 Hz. Each specimen was subjected to 60,000 cycles at an application speed of 40 mm/s. They then underwent thermocycling (Thermocycler 2000, Heto-Holten A/S, Allerød, Denmark) for 6000 cycles with temperature changes between 5°C and 55°C every 30 seconds.

Static compression load testing was used to evaluate the abutments' fracture resistance. The testing was performed using a static load testing machine (AG-X plus, Shimadzu, Kyoto, Japan). A load cell of 5,000 N was used at a crosshead speed of 0.5 mm/min (**Fig. 2**).

Statistical analysis consisted of preliminary descriptive analysis of the force (fracture resistance) and deformation variables (mean, standard deviation, range and median). Comparisons were made adopting a nonparametric approach. Significance was set at 5% ($p = 0.05$).

Results

The results obtained registered the force in Newtons (N) required to produce the fracture of each specimen (**Tables 2 & 3**). Fracture of the prosthesis was understood as the first mechanical failure that the specimen underwent, whether this was the maximum load that produced a clearly observed fracture or the maximum load before the test machine registered a decrease in load even if the fracture was not visibly obvious. Fracture resistance values for two specimens (not subjected to fatiguing) were discarded owing to failure to fulfill the study procedure. The same also occurred with two specimens subjected to fatiguing.

Table 4 shows the descriptive data by group for fracture resistance in specimens not subjected to fatiguing. The group that presented the highest resistance to fracture was the TD group and the group that showed the least resistance was the PP group, with mean values of 1,106.7 N and 329.4 N, respectively. The groups that presented the lowest resistance to fracture were CMP and PP, obtaining values of between 300 N and 400 N. Fracture resistance levels were heterogeneous, as the Kruskal–Wallis test confirmed that there was no homogeneity in the distribution of resistance across the four groups ($p = 0.006$).

When the Mann–Whitney test was applied to identify differences between pairs of groups, CMP showed lower resistance than TP ($p = 0.032$) and TD ($p = 0.016$), with the differences being statistically significant. PP restorations obtained lower resistance than the TP ($p = 0.016$) and TD

Table 2

Specimen	CMP	PP	TP	TD
1	370.0	355.0	878.7	937.2
2	359.3	198.0	1089.0	No data
3	192.0	382.0	1403.0	1022.0
4	579.5	254.0	571.0	854.5
5	352.9	485.0	No data	1613.0

Table 2

Fracture resistance (N) for implant-prosthetic abutments not subjected to fatiguing.

Table 3

Specimen	CMP	PP	TP	TD
1	No data	304.8	675.3	1289.0
2	173.6	340.9	904.9	1578.0
3	194.5	282.6	810.3	1521.7
4	No data	432.8	566.5	1397.7
5	210.3	340.8	485.9	1086.3

Table 3

Fracture resistance (N) for implant-prosthetic abutments subjected to fatiguing.

Table 4

	CMP	PP	TP	TD
N	5	5	4	4
Mean	370.7	329.4	985.4	1106.7
Standard deviation	137.8	103.6	350.3	344.4
Minimum	192.0	198.0	571.0	845.5
Maximum	579.5	458.0	1403.0	1613.0
Median	359.3	355.0	983.9	979.6

Table 4

Descriptive data by group for abutments not subjected to fatiguing (N).

Table 5

	CMP	PP	TP	TD
N	3	5	5	5
Mean	192.8	340.4	688.6	1373.5
Standard deviation	18.4	57.3	171.7	196.2
Minimum	173.6	282.6	485.9	1086.3
Maximum	210.3	432.8	904.9	1578.0
Median	194.5	340.8	675.3	1397.7

Table 5

Descriptive data by group for abutments subjected to fatiguing (N).

Table 6

Specimen	CMP	PP	TP	TD
1	1.509	0.977	3.937	1.599
2	2.362	1.463	1.899	No data
3	3.991	2.349	3.530	1.379
4	1.811	2.313	1.349	0.733
5	2.645	2.694	No data	1.316

Table 6

Deformation data (mm).

Table 7

Deformation data (mm).

Specimen	CMP	PP	TP	TD
1	No data	2.330	0.867	0.825
2	0.794	2.222	3.796	0.845
3	1.449	2.006	2.258	0.978
4	No data	2.345	3.978	0.921
5	1.897	1.476	1.967	0.978

Table 7

Table 8

Descriptive deformation data by group for abutments not subjected to fatiguing (mm).

	CMP	PP	TP	TD
N	5	5	4	4
Mean	1.3	1.6	1.9	1.3
Standard deviation	0.3	0.7	1.1	0.4
Minimum	0.9	0.6	1.2	0.7
Maximum	1.6	2.3	3.5	1.6
Median	1.4	1.4	1.6	1.3

Table 8

Table 9

Descriptive deformation data by group for abutments subjected to fatiguing (mm).

	CMP	PP	TP	TD
N	3	5	5	5
Mean	1.4	2.1	2.6	0.9
Standard deviation	0.6	0.4	1.3	0.1
Minimum	0.8	1.5	0.9	0.8
Maximum	1.9	2.3	4.0	1.0
Median	1.4	2.2	2.3	0.9

Table 9

groups ($p = 0.016$), with the differences being statistically significant. The performance of the TP group was similar to that of the TD group ($p = 0.886$). CMP and PP were also homogenous, but with a significantly lower resistance than the other two groups ($p = 1.000$).

In a comparison of the statistical data for fracture resistance of restorations subjected to fatiguing (**Table 5**), the group that showed the highest resistance was the TD group (1,373.5 N). The groups with the lowest resistance were PP and CMP; both groups obtained values of between 200 N and 350 N. Fracture resistance levels were heterogeneous, and the Kruskal–Wallis test confirmed that there was no heterogeneity in the distribution of resistance across the four groups ($p < 0.001$).

When resistance distribution was compared between pairs of groups of fatigued specimens,

statistically significant differences were identified for all comparisons. Unlike the groups not subjected to fatiguing, no group of fatigued specimens presented a homogenous distribution of resistance when paired comparisons were made.

CMP restorations showed lower fracture resistance than the rest of the groups, with the differences being statistically significant (PP: $p = 0.036$; TP: $p = 0.036$; TD: $p = 0.036$). The PP group also showed lower resistance than TP ($p = 0.008$) and TD specimens ($p = 0.008$), with the differences being statistically significant.

In making a comparative analysis between the specimens subjected to fatiguing and those that were not fatigued, a slight decrease in fracture resistance was observed among all of the provisional restorations subjected to fatiguing (CMP, PP and TP). However, the TD group showed

stable performance despite cyclic loading, such that its performance was not affected by fatiguing. The Mann–Whitney test was applied to evaluate differences between fatigued and non-fatigued specimens and a p -value of 0.401 was obtained, indicating that resistance to fracture was similar between the two groups (fatigued/nonfatigued). Likewise, within the individual groups, no significant differences were found between fatigued or nonfatigued subgroups (CMP: $p = 0.143$; PP: $p = 1.000$; TP: $p = 0.190$; TD: $p = 0.286$), although the CMP and TP groups did show a certain tendency toward difference, but this did not reach statistical significance.

In data analysis of the deformation that the restorations suffered up to the point of fracture or mechanical failure (in mm; **Tables 6 & 7**), deformation values for specimen 2 in the TD group and specimen 5 in the TP group (not fatigued) were discarded from analysis owing to various technical failures in the study procedure. The same occurred with two specimens (1 and 4) in the CMP group (subjected to fatiguing).

In deformation data analysis of groups not subjected to fatiguing (**Table 8**), it was found that the group that presented the highest deformation values was the TP group. The group with the least deformation was the TD group. The PP and CMP groups showed similar median values, but a dispersed range of values. The Kruskal–Wallis test showed that there were no overall significant differences ($p = 0.187$). The Mann–Whitney test found that the only significant difference occurred between the CMP and TD groups, the TD group showing the lowest deformation values (CMP–PP: $p = 0.421$; CMP–TP: $p = 1.000$; PP–TP: $p = 0.556$; CMP–TD: $p = 0.032$; PP–TD: $p = 0.190$; TP–TD: $p = 0.114$).

As for deformation data analysis of specimens subjected to fatiguing (**Table 9**), the TD and CMP groups underwent the least deformation. The PP and TP groups showed similar median values, but the range of values was more widely dispersed in the TP group. The group that underwent the greatest deformation was the TP group. When homogeneity was analyzed between groups, the Kruskal–Wallis test found a p -value of 0.022, indicating homogeneity between the groups. The Mann–Whitney test for paired groups only identified statistically significant differences between the TD and PP groups, with the TD group obtaining lower deformation values (CMP–PP: $p = 0.071$; CMP–TP: $p = 0.143$; PP–TP: $p = 0.841$; CMP–TD: $p = 0.571$; PP–TD: $p = 0.008$; TP–TD: $p = 0.056$).

In order to determine whether fatigue influenced deformation, specimens subjected to fatiguing were compared with those not subjected to fatiguing, but no significant differences were found (CMP: $p = 0.143$; PP: $p = 1.000$; TP: $p = 0.905$; TD: $p = 0.286$).

Discussion

Nowadays, many patients regard dental esthetics as one of the principal requirements of dental treatment. In the case of implant dentistry, a range of factors influence esthetic outcomes, including color, contour, the natural appearance of the definitive prosthesis, and most importantly, the topography and appearance of the peri-implant soft tissue.² Soft-tissue management is not straightforward, as multiple factors affect the final outcome, in which the provisional prosthesis plays a key role.^{2,4} Given the importance of provisionalization as a part of dental implant treatment, the present study set out to evaluate the resistance to fracture of implant-supported provisional prostheses of different materials (titanium, PEEK resin and methacrylate) subjected to fatiguing. While definitive prostheses have been extensively studied, little research has investigated fracture resistance and the influence of fatigue on provisional abutments *in vitro*.

The present study protocol was designed to fulfill the test geometry specified in ISO 14801:2007 for testing single-post endosseous dental implants, in that the implant made a 30° angle with the test machine's load cell.^{30–39} This geometry has been used in most other studies of similar characteristics to the present one.^{34–37} The material used to set the implant in the cylinder–epoxy resin—was chosen for its elastic modulus > 3 GPa, also required by ISO 14801:2007, and because this material has been used in similar studies too.^{30–37} All of the abutments were tested without placing restorations on them, as was the case in Truninger et al., in which the abutments were subjected to load testing without bearing restorations.³⁵ Likewise, Rack et al. tested abutments without placing restorations on them, but soldered a steel sphere of 10 mm in diameter to the coronal part of the abutment so that the force applied would be evenly distributed throughout the abutment structure.³³

The choice of test design was based on Agustín-Panadero et al., who studied provision-

al abutments subjected to static loading.⁵ Various authors have proposed similar variables to the present test design in terms of specimen design and distribution, as well as crosshead speed and movement.^{30–35} The crosshead speed in compression testing in this study was 0.5 mm/min, a speed established from the literature review conducted in preparation for the study to ensure use of the same speed used in the majority of other similar studies (standardization being important when it comes to comparison of studies).^{30–36} However, pure compression studies do appear to be adequate for researching the fracture resistance of implant-prosthetic structures. The ideal procedure in a study of these characteristics is to subject specimens to dynamic loading—artificial aging of the specimens—before performing the static load testing. For this reason, the present study divided the specimens ($n = 40$) into two subgroups and subjected half to a prior fatiguing process to simulate the aging of the abutments. Like compression testing, the fatiguing process must meet criteria established in ISO 14801:2007.³⁹

The literature contains several studies that have subjected specimens to aging prior to testing.^{27, 28, 30, 34–39} Stimmelmayer et al. used the same test machine (Mechatronic), the same specimen distribution and frequency parameters (1.2 Hz), as well as impact speed (10 mm/s), as the present work³⁶ to determine the fracture resistance of fatigued zirconia abutments. Artificial aging or dynamic loading reproduces conditions in the mouth to which the implant-prosthetic abutments are exposed, reducing their fracture resistance evaluated by static load compression testing.^{27, 28, 30, 34–39} Several studies have observed that the use of substances that simulate saliva, creating a moist environment, generates environmental conditions that negatively affect the fatigued implant abutment.^{27, 28} Steinebrunner et al. carried out fatigue testing of implant-prosthetic abutments submerged in artificial saliva, imitating intra-oral conditions in order to evaluate the influence of the fluid medium.²⁸ A control group was made up of specimens subjected to fatiguing in ambient air. The results showed that the artificial saliva acted as an aggressive environment, affecting the implants' fracture resistance.²⁸ The oral environment is clearly an important factor to consider when evaluating dental implants' mechanical properties and that the present study did not simulate oral condi-

tions by exposing specimens to artificial saliva can be considered a significant limitation.

To date, few studies have provided scientific evidence in relation to provisional abutments, while definitive abutments have been extensively studied. The range of fracture resistance values obtained in similar studies is 714–906 N.^{28, 34, 35} The data obtained in the present study for the definitive abutments (TD), whether subjected to fatiguing or not, and the TP abutments not subjected to fatiguing fall within this range and even exceed them. Sanino and Barlattani obtained values of 906 N in static load testing of definitive titanium abutments.³⁴ Truninger et al. evaluated the fracture resistance of zirconia abutments, using titanium abutments as a control group, and obtained a mean value of 714 N.³⁵ It is important to consider the fracture resistance levels cited in the literature that implant-prosthetic abutments must support in the oral environment under normal conditions. Ferrario et al. affirmed that the occlusal load that a single tooth must support in the anterior region is 150 N; this study included 52 patients who used a bite force transducer to register occlusal force.³⁸ In this scenario, the present results confirm that all of the abutments analyzed, whether subjected to fatiguing or not, fulfilled the requirements for survival in the anterior region.

Conclusion

The Grade IV titanium definitive abutments obtained the highest fracture resistance and deformation values. The nonfatigued PEEK resin provisional abutments and fatigued castable methacrylate provisional abutments obtained the lowest fracture resistance values. The Grade III titanium provisional abutments showed the highest deformation values. Fatiguing did not influence fracture resistance significantly or the abutments' elastic performance. All of the abutments tested fulfilled the mechanical requirements for survival in the oral environment.

Competing interests

The authors declare that they have no competing interests related to this study. No financial support was received for this study.

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Human pulps capped with PDGF: A pilot study

Abstract

Objective

Growth factors have shown the potential to promote odontoblast-like cell differentiation and induce the formation of reparative dentin. The aims of this pilot study were to develop a regenerative approach to pulp capping using platelet-derived growth factor (PDGF) BB and to describe histologically the pulp tissue response.

Materials and methods

Two third molars (Site A and Site B) were treated. Class I cavities were prepared and the exposed pulps were capped with cotton pellets embedded in a PDGF solution. Teeth were extracted after 40 days and processed for routine histological examination. The hard bridge formation and the pulp reaction were evaluated.

Results

In Site A, incomplete and thick dentin bridge formation was observed. The pulp tissue close to the remaining exposed pulp was moderately disorganized, with many fibroblasts and few inflammatory cells. In Site B, an incomplete dentin bridge covered part of the defect. The pulp was overall normal, but a limited area showing a clot-like tissue with many fibroblasts and few inflammatory cells close to the dentin bridge interruption was observed.

Conclusion

PDGF-BB did not elicit an inflammatory response and did not induce extensive dentin matrix deposition. It thus appears to be a safe pulp capping agent.

Keywords

Histology, human platelet-derived growth factor, pulp capping, wound healing.

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Introduction

The dental pulp provides nutrition and sensory properties to dentin and has reparative capacity to react to injury. When the injury results in odontoblast death, a new generation of odontoblast-like cells may differentiate from progenitor cells within the pulp and secrete a reparative dentin matrix.¹ Pulp capping is a common procedure that induces reparative dentin formation after pulp exposure due to cavity preparation, caries removal or trauma. Calcium hydroxide, zinc oxide eugenol cements, composite resins, mineral trioxide aggregate (MTA) and glass ionomer cements are used in clinical daily practice.^{2, 3} However, several concerns have been listed regarding the use of these materials for pulp capping, including cytotoxic effects,⁴ the lack of adequate bleeding control after acid etching⁵ and the new hard-tissue formation at the expense of pulp chamber width, causing narrowing of root canals.⁶ Although calcium hydroxide is the most widely used pulp capping agent to encourage hard-tissue bridging, the material is not able to effectively induce new tissue formation.⁷ Bridge formation remains unpredictable, with varying thickness and numerous tunnel defects,⁸ suggesting that it may be of insufficient quality to protect the pulp against bacterial microleakage along the restoration margins. Several articles have addressed the use of MTA for pulp capping and demonstrated a hard-tissue barrier beneath the MTA; however, pulpal soft tissue enclosed within the hard-tissue barrier and unpredictable dentin bridge formation were observed.^{9, 10}

Recently, a growth factor delivery approach has been introduced to induce reparative dentin formation in noninflamed mechanically exposed pulps.^{11, 12} Rutherford et al. examined histologically the reparative dentin formation of pulp treated with osteogenic protein-1 (bone morphogenetic protein [BMP] 7) in monkeys.¹³ They reported that BMP-7 has the potential to induce the formation of reparative dentin and related the amount of newly formed dentin to the amount of implanted protein. Nakashima observed histologically the induction of tubular dentin formation in teeth capped with BMP-2 and -4 in monkeys.¹¹ An *in vivo* study has demonstrated with histomorphometric analysis the role of transforming growth factor- β in promoting odontoblast-like cell differentiation and the secretion of extracellular matrix.¹⁴ The effects of enamel matrix protein on pulp capping have been evaluated histologically and immunohistochemically in

animal¹³ and human studies.^{15, 16} After application of enamel matrix protein, the damaged pulp showed at first a reparative process with formation of a scar and moderate inflammatory infiltrate. Subsequently, neogenesis of normal dental pulp occurred and odontoblast-like cells produced reparative dentin.¹⁷ In the literature, there is converging evidence that reparative processes recapitulate early developmental events that lead to dental tissue formation.¹⁸ However, the effects of platelet-derived growth factor (PDGF) on reparative processes after pulp capping have not been defined. PDGF is a potent mitogenic, chemotactic agent. It stimulates cells of mesenchymal origin to produce protein¹⁹ and promotes angiogenesis and the regeneration process of several tissues, such as bone, cementum and periodontal ligament.²⁰ PDGF also regulates cell proliferation and dentin matrix protein production in dental pulp culture.^{21, 22} In their histochemical and immunohistochemical study, Yokose et al. evaluated the effects of three PDGF dimers (PDGF-AA, -BB and -AB) on odontoblast differentiation of dental pulp cells.²³ The authors reported the different effects of the PDGF dimers on dentin formation during the repair process in damaged dental pulp. They observed that PDGF-AB and -BB stimulated the differentiation of odontoblastic cells, increasing the number of mature odontoblastic cells. In contrast, PDGF-AA exerted inhibitory effects on odontoblast differentiation.²³ These findings suggest a role of PDGF-BB in dentinogenesis in the dental pulp and in differentiation of odontoblasts during repair processes after injury to the mature pulp. The aims of this preliminary human study were to develop a regenerative approach to pulp capping using PDGF-BB and to describe histologically the pulp tissue response.

Materials and methods

After a thorough explanation of the experimental rationale, clinical procedure and possible risks, written informed consent was obtained from both subjects to be entered in the study. The study conformed to the principles outlined in the Declaration of Helsinki of 1975, as revised in 2013, on experimentation involving human subjects and was approved by the Ethics Committee of the Department of Human Morphology and Biomedical Sciences "Città Studi", Milan, Italy. Before treatment, all patients gave written informed consent. Two completely erupted third molars that needed to be extracted for orthodontic treat-

ment were selected from two patients (one tooth from each patient) with the following inclusion criteria: (a) no systemic diseases or metabolic bone disorders; (b) not pregnant; and (c) no history of malignancy, radiotherapy or chemotherapy for a malignancy in the past five years. Furthermore, in order to standardize the age-related prognostic factor, subjects aged between 18 and 39 were enrolled.²⁴ The experimental teeth were clinically and radiographically examined and presented superficial enamel decay; however, the teeth were asymptomatic, without periapical lesions and responded positively to the cold stimulus test performed by applying HYGENIC ENDO-ICE F frozen gas (Coltène/Whaledent, Mahwah, N.J., U.S.) for 5 s to the buccal surfaces.

Procedures employed

Forty days before the extraction, after local and intraligament anesthesia with lidocaine containing 1:80,000 epinephrine to control pain and bleeding from the exposed pulp, the selected molars were isolated with a rubber dam and disinfected with topical antiseptic. Class I cavities on the occlusal surfaces of the experimental teeth were prepared by means of diamond burs (1 mm in diameter) and the pulps were exposed. On one tooth (Site A), a perforation of 1 mm × 1 mm (evaluated at the level of the pulp chamber) was performed; and on the other tooth (Site B), the perforation was 3 mm × 3 mm.

After rising with sterile water to remove the debris, establishing hemostasis with a sterile cotton pellet soaked in saline solution and drying with a sterile cotton pellet, the pulp was capped with sterile cotton embedded in a PDGF-BB solution and covered with zinc oxide cement (CAVIT, 3M ESPE, Seefeld, Germany). During the days after capping, the patients completed a questionnaire on pain occurrence. After 40 days, the experimental teeth were tested for pulp vitality by applying HYGENIC ENDO-ICE F and were carefully extracted without root separation or crown fracture.

Histological analysis

Immediately after extraction, the teeth were immersion fixed in a 10% formalin/0.1 M phosphate-buffered saline (pH 7.4) for 24 h at room temperature. The dental crown was separated from the roots using a round bur in a low-speed

handpiece and then decalcified for 30 days in a solution containing formic acid (625 cm³ in 625 cm³ of distilled/purified water) and sodium citrate (250 g in 125 cm³ of distilled/purified water). Decalcification of dental tissue was verified by radiograph. After rinsing under running water for 48 h, the sample was routinely dehydrated in increasing concentrations of ethanol (from 50 to 100%), immersed in xylol for 12 h and then embedded in paraffin. Serial buccolingual sections were obtained from 4 to 5 mm and then hydrated in xylol and decreasing concentrations of ethanol (from 100 to 70%) and finally immersed in distilled water. Sections were stained with hematoxylin and eosin (H&E) to evaluate the tissue morphology and with Masson's trichrome stain to distinguish the connective matrix from cells. The sections were viewed and photographed under a light microscope (Eclipse E600, Nikon, Tokyo, Japan) equipped with a calibrated digital camera (DXM 1200, Nikon). Multiple central sections were used to perform an overall assessment for each tooth. The hard-tissue bridge formation (continuity, morphology, localization and thickness) and the dental pulp reaction (inflammatory cell response and tissue disorganization) were described.

Results

Both patients (A and B) who completed the study were female, nonsmokers, and 23 and 26 years old, respectively. A total of two teeth were analyzed. After the experimental pulp capping, the patients did not report any symptoms or analgesic intake. At the extraction appointment, both teeth were vital and both cavities still closed with CAVIT. At the histological evaluation, the thickness (mm) of the newly formed hard tissue was measured at three different points of the bridge: alongside the dentinal wall (on the mesial side and distal side) and in the center. **Table 1** shows the mean thickness of the newly formed bridge.

Site A

In all of the sections, the drill-created cavity contained debris and bacteria along all of the cavity walls (**Fig. 1**). An incomplete dentin bridge lined the pulp exposure site and was formed by well-organized tubular reparative dentin, with a clear predentin layer and odontoblastic-like cells (**Fig. 2**). No extensive dentin matrix deposition

Table 1

	M [†]	Center	D [‡]
Site A	209	190	–
Site B	–	338	92

[†] M = mesial side.

[‡] D = distal side.

Table 1

Thickness (mm) of the newly formed bridge measured at three different points. The thickness was not evaluated in sites where the bridge was absent.

Fig. 1

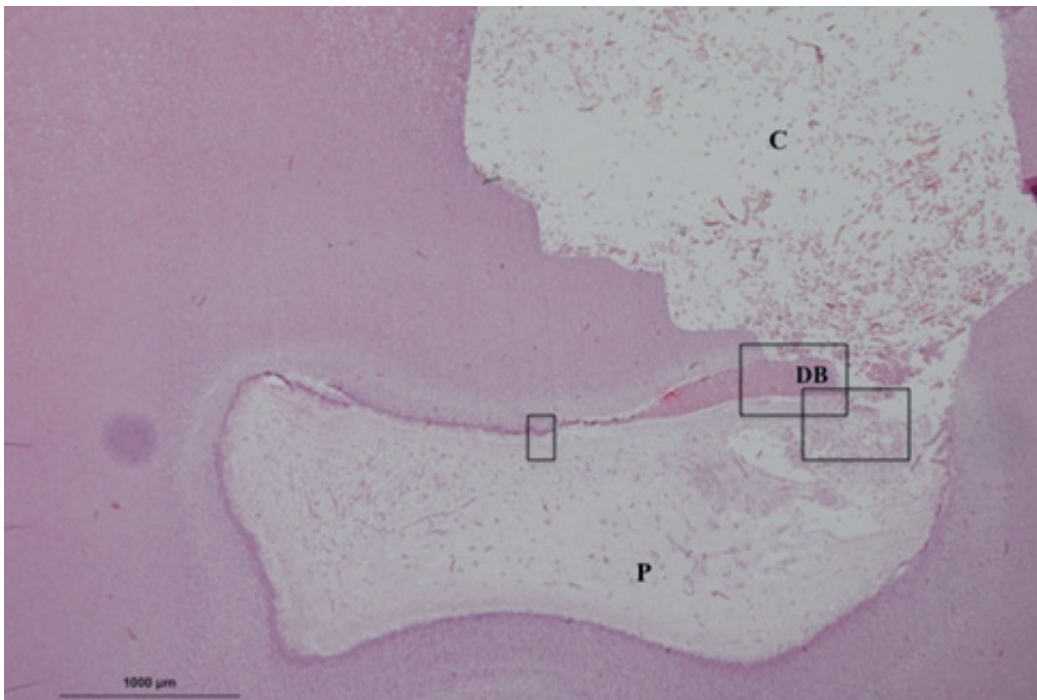


Fig. 1

Photomicrograph of Site A. Buccolingual section. The drill-created cavity (C) containing much debris is separated from the pulp (P) by a thick and incomplete dentin bridge (DB). The newly formed hard tissue starting from the original dentin tissue covers only half of the exposed pulp. H&E staining (at original 20× magnification).

Figs. 2 & 3

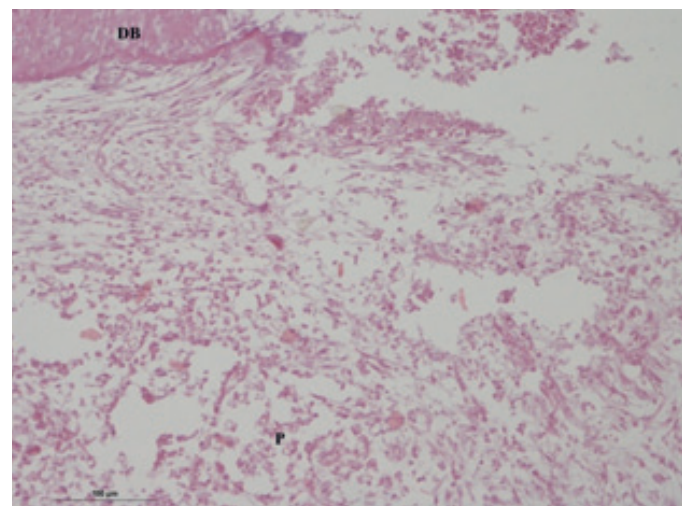
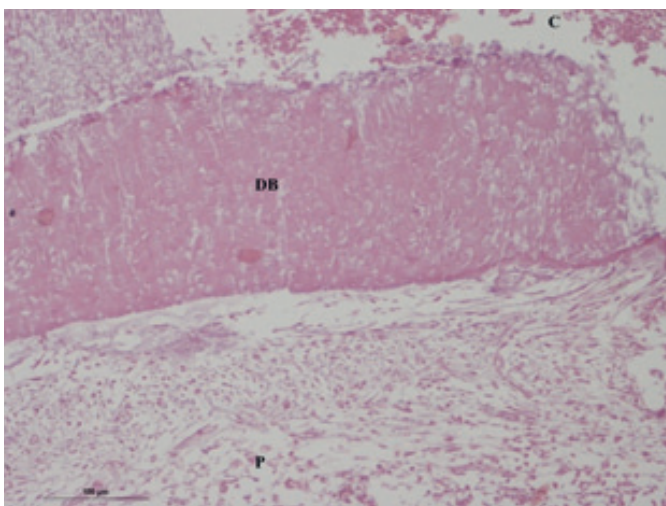
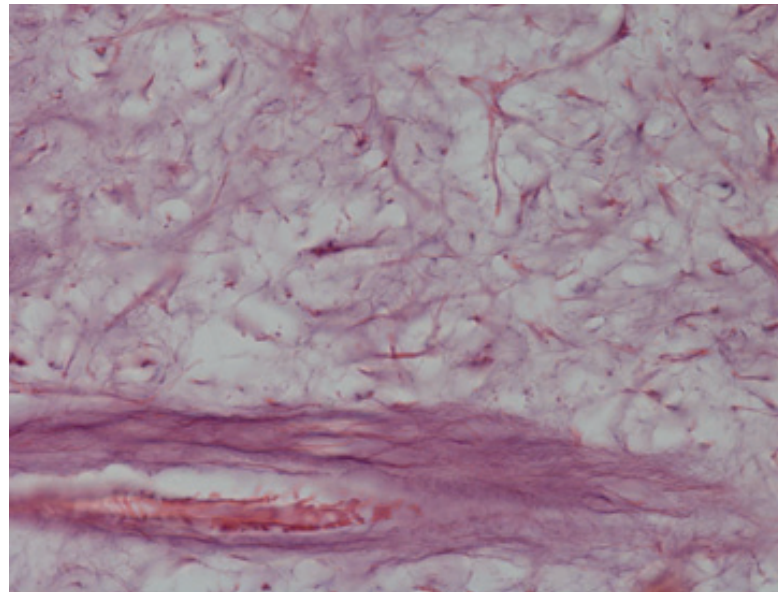
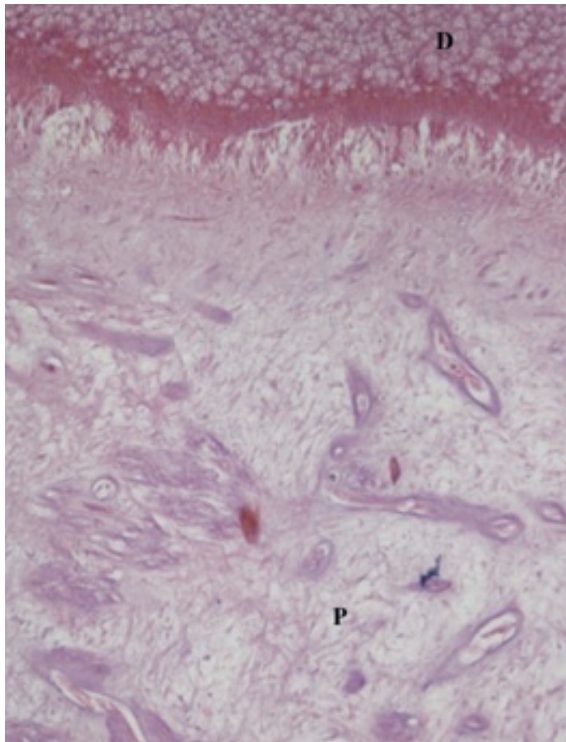


Fig. 2

Detail of **Figure 1**. The dentin bridge (DB) is formed by tubular and well-oriented reparative dentin. The pulp (P) appears slightly disorganized with few scattered inflammatory cells. C = cavity. H&E staining (at original 100× magnification).

Fig. 3

Detail of **Figure 1**. The pulp tissue (P) close to the newly formed dentin (DB) and surrounding the remaining defect appears disorganized, with many fibroblasts and few scattered inflammatory cells. H&E staining (at original 200× magnification).



Figs. 4 & 5

Fig. 4

Detail of **Figure 1**. The pulp tissue (P) adjacent to the reactive area and under the original dentin (D) appears healthy and well organized, with no signs of necrosis or abscess. H&E staining (at original 100× magnification).

Fig. 5

Detail of **Figure 1**. Photomicrograph of the pulp in the area adjacent to the reactive tissue. No extravasated red blood cells, suffering pulp or inflammatory cells are detectable. H&E staining (at original 400× magnification).

obliterating the pulp chamber was observed. The general state of the pulp close to the remaining defect was moderately disorganized. This area contained many fibroblasts, some extravasated red blood cells and few inflammatory cells (**Fig. 3**). No signs of abscess were observed. The pulp tissue adjacent to the reactive area appeared normal, with no signs of inflammation or necrosis (**Figs. 4 & 5**).

Site B

Debris occurred along and over the cavity walls, but without touching the pulp tissue (**Fig. 6**). The hard bridge formation was moderate and incomplete, leaving a small area of communication between the capping material and the dental pulp. The reparative dentin was tubular and well oriented (**Fig. 7**), without invading the pulp space. The general state of the pulp was normally organized without inflammatory cells beneath the dentin bridge formation. Only a limited area of tissue disorganization and pulp reaction similar to that observed in Site A was adjacent to the hard-barrier interruption and separated the normal pulp tissue from the contaminated drill-created cavity (**Fig. 8**). No tunnel-like defect appeared in any section. The hard-tissue thickness was greater in the central portion, and the thickness at the distal side was not calculated because of the interruptions (**Table 1**).

Discussion

The present pilot study was designed to evaluate the response of noninflamed mechanically exposed human pulps after capping performed using PDGF-BB. In Site A, an area of moderate disorganization was evident below the remaining pulp exposure site. In Site B, only a limited area of slight reaction was observed at the lateral side of the defect, close to the dentin bridge interruption. No signs of abscess or inflammatory infiltrate in the connective tissue were detected in either sample. The pulp was overall normal and asymptomatic, despite the use of nonsealing cement. Tubular reparative dentin and an adjacent well-organized odontoblast-like cell layer were detected in both samples. No extensive dentin matrix deposition obliterating the pulp chamber was found. In the literature, tunnel defects are often described throughout the newly formed dentin bridges of teeth capped with calcium hydroxide.⁸ In the present study, in both samples, the reparative dentin was compact and without defects. Since the aim of the present study was to assess the response of noninflamed pulp tissue after PDGF-BB treatment, no control samples were evaluated to compare the amount of newly formed dentin matrix. Also, the experiment was conducted on a limited number of cases and thus did not allow for statistical analysis. In the treated teeth, access to the pulp chamber was of two different sizes to assess the response of capped pulp tissue to varying extents of such a traumatic event.

Fig. 6

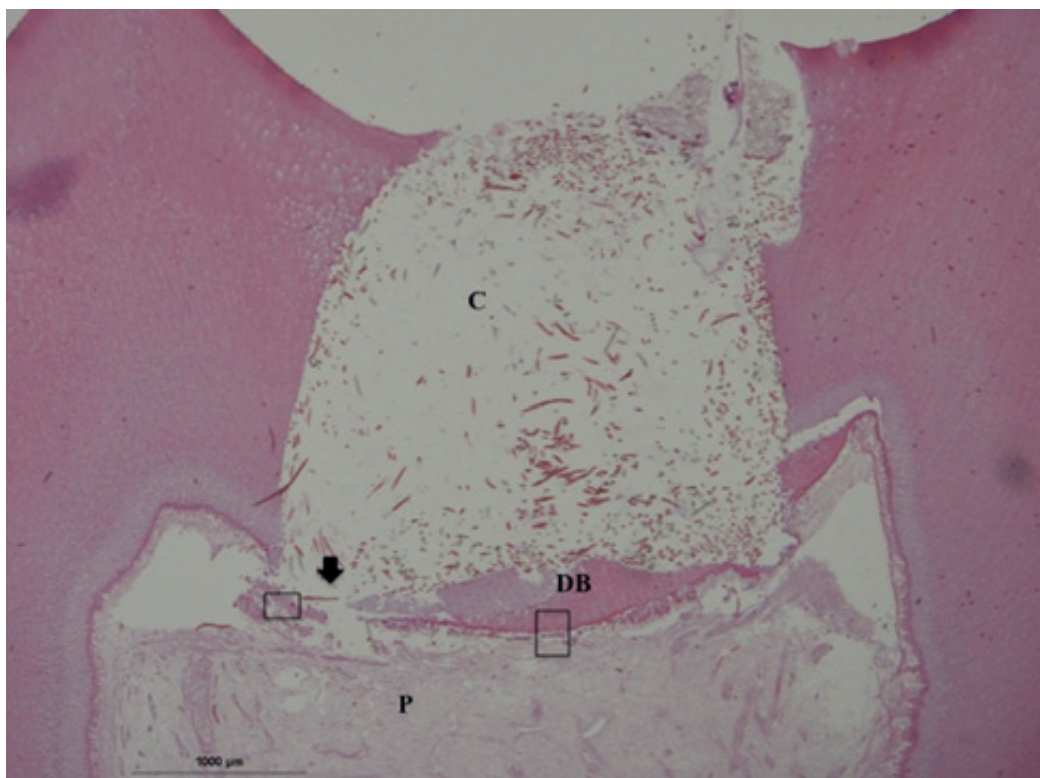


Fig. 6

Photomicrograph of Site B. Buccolingual section. Within the cavity (C), debris is visible. Between the cavity and the pulp (P), the dentin bridge (DB) runs horizontally from the cut surfaces, covering most of the exposed dental pulp. This hard tissue is very thin on the right side close to the original dentin tissue, is the thickest in the central area of the defect and is incomplete on the left side (black arrow). The dental pulp presents no inflammatory response and has an organized structure, but for the area close to the dentin bridge interruption, where a disorganized and fibrous clot-like tissue is observed. H&E staining (at original 20x magnification).

Fig. 7

Detail of **Figure 6**. The reparative dentin (DB) is tubular and well organized. Odontoblast-like cells (O) are between the dental pulp (P) and the predentin (PD) tissue. The pulp is well organized and without inflammatory cells. H&E staining (at original 400x magnification).

Figs. 7 & 8

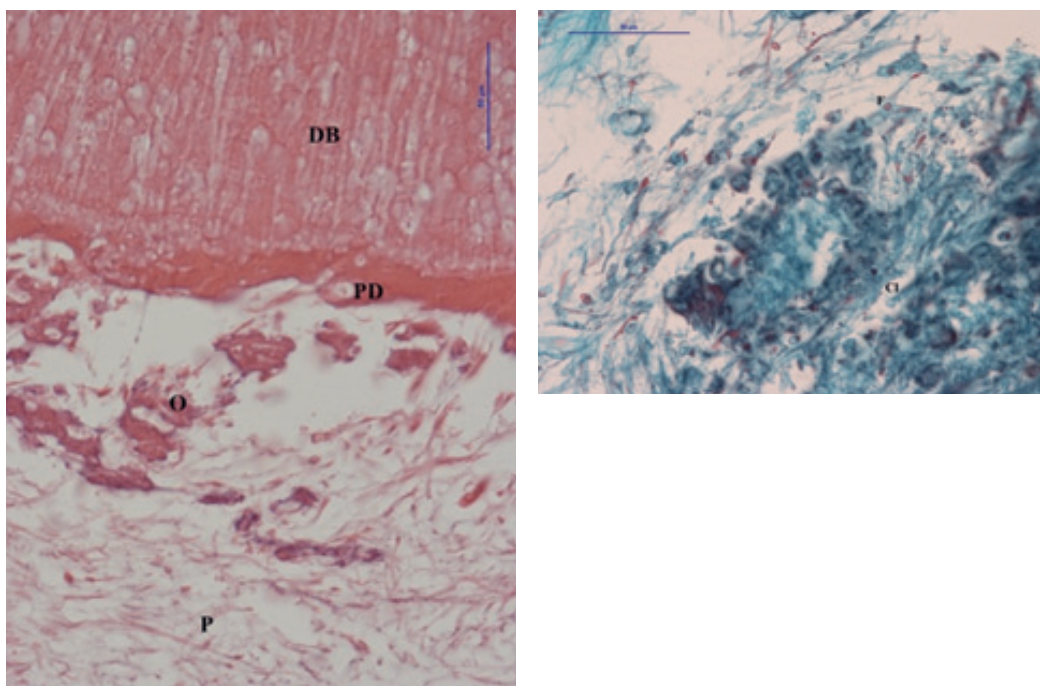


Fig. 8

Detail of **Figure 6**. In correspondence with the dentin bridge interruption, the pulp is not in direct contact with the cavity. A disorganized clot-like tissue (Cl) with many fibroblasts (F) and few inflammatory cells is apparent between the cavity and the pulp in close contact with bacteria and debris. Masson's trichrome staining (original 600x magnification).

These preliminary findings indicate that PDGF-BB does not elicit pulpal inflammatory response, nor induce extensive dentin matrix deposition, suggesting that this growth factor could be safely applied in human pulp capping. According to previous human models that proved the efficacy of growth factors in noninflamed exposed pulp,¹⁵ this study was performed on healthy and freshly exposed pulps. However, Rutherford and Gu demonstrated the failure of a treatment strategy utilizing BMP-7 proteins for management of inflamed pulpal wounds.²⁵ Despite this, it may be supposed that the therapeutic activity of PDGF-BB is mainly due to the promotion of tissue regeneration than to the resolution of the inflammatory process. Further studies should thus investigate the efficacy of PDGF in promoting newly formed dentin bridges in inflamed pulps and compare this treatment with a biological agent to the gold standard pulp capping agent (MTA).⁹ The role and mechanism of action of PDGF in healing of damaged dental pulp and dentin bridge formation are not completely understood. PDGF plays a role in cell chemotaxis, proliferation and differentiation at each stage of wound healing.^{19,20} In periodontics, clinical studies have been conducted since PDGF demonstrated an important role in regeneration of cementum, periodontal ligament and alveolar bone.²⁶ In a clinical trial, Nevins et al. evaluated the healing and regeneration of infrabony periodontal defects treated with highly purified recombinant human PDGF-BB and a β -tricalcium phosphate scaffold and demonstrated the efficacy of PDGF-BB in accelerating and improving periodontal soft-tissue healing and bone regeneration.²⁷ In addition, clinical trials have suggested the promotion of bone turnover during the repair process of tooth-supporting osseous defects.²⁸

A histochemical and immunohistochemical study has evaluated the effects of three PDGF dimers (PDGF-AA, -BB and -AB) on odontoblast differentiation of dental pulp cells.²³ The authors observed dentin formation during the repair process in damaged dental pulp. They also observed that PDGF-AB and -BB stimulated the differentiation of odontoblast cells, increasing the number of mature odontoblast cells. In contrast, PDGF-AA exerted inhibitory effects on odontoblast differentiation.²³ These findings suggest a role of PDGF-BB in dentinogenesis in the dental pulp and in differentiation of odontoblasts during repair processes after injury to the mature pulp. The importance of PDGF in the

dental pulp regenerative process is due to the role that this growth factor plays during embryonic development. PDGFs and platelet-derived growth factor receptors (PDGFRs) play a role in gastrulation,²⁹ development of the cranial and cardiac neural crests,³⁰ and formation of the palate.³¹ Studies have shown that PDGF- α and PDGFR- α are expressed in developing mouse molars, regulate epithelial-mesenchymal interaction during mammalian tooth morphogenesis, and have a critical function in differentiation of dental pulp cells and in the development of dental cusps.^{31,32}

Conclusion

Within its limitations, this study suggests that PDGF-BB appears to be a safe pulp capping agent. PDGF-BB may stimulate dentinogenesis, promoting differentiation of odontoblasts after dental pulp injury. It appears that differentiated odontoblasts produce tubular and compact reparative dentin, without tunnel defects, and do not obliterate the pulp chamber.

Competing interests

The authors declare that they have no competing interests.

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Importance of the axial reference plane in computed tomography for dental implant surgery: A cadaveric study

Abstract

Objectives

The aims of the study were to assess the accuracy of dental computed tomography (CT) scans and to compare the discrepancies obtained when either the occlusal plane or the basal plane was used as the axial reference plane.

Materials and methods

Thirty-nine mandibles from adult cadavers were examined. Eighteen tomographic slices were performed for each mandible, using the occlusal and the basal planes as axial reference planes. The radiographic measurements obtained using the two reference planes were compared with bone measurements taken using a digital calibrator.

Results

Discrepancies, which varied between 0.03 mm and 1.47 mm, were found between measurements taken from CT scans and measurements taken directly from the bone. When the distribution of discrepancies was considered in relation to the axial reference plane used, it was found that when the basal plane was used, a higher percentage of discrepancies of over 0.5 mm occurred (99.44%) than when the occlusal plane was used (44.44%), with the difference being statistically significant ($p = 0.001$).

Conclusion

The discrepancies between CT radiographic measurements and direct bone measurements should be taken into consideration in order to achieve satisfactory dental implant treatments. With regard to positioning the patient when CT scans are taken, use of the occlusal plane as axial reference will produce the most accurate measurements.

Keywords

Axial reference plane, occlusal plane, basal plane, computed tomography, dental implantology.

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Introduction

Edentulous patients seeking dental treatment to restore function and esthetics have traditionally received removable complete or partial dentures. However, the use of removable dentures may give the patient a sense of insecurity, reduced masticatory function and taste capacity, as well as low self-esteem.¹ For these reasons, approaches to treatment have turned toward dental implants, which produce marked improvements in patients' quality of life and high treatment success rates.^{2,3}

An adequate radiographic technique that will provide a sufficiently accurate assessment of the bone dimensions is of great help when planning the surgical intervention. Intra-oral and panoramic radiographs give information in two dimensions, visualizing bone morphology in a buccolingual direction, but lack the third dimension. Both techniques are only useful for a primary preoperative evaluation to obtain preliminary information about the available bone height.⁴ Three-dimensional information is obtained using computed tomography (CT).

In edentulous mandibles, the location and course of the mandibular canal remain relatively unchanged in the cranial and caudal borders of the mandible, although some atrophy at the lingual and buccal external borders may occur.⁵ Recently, some anatomical structures in the jawbone, which are difficult to detect using conventional radiography, have been explored using CT.⁶⁻⁹ Investigations of mandibular accessory foramina and canals have drawn attention to anatomical variations of perimandibular neurovascularization.¹⁰⁻¹³

Although there is a wide range of dental CT equipment marketed as providing exact bone data at a 1:1 scale, several studies have shown discrepancies between radiographic CT measurements and clinical measurements taken directly from the bone.^{4,14-16} Furthermore, depending on the positioning of the patient when the CT measurements are taken, these discrepancies between radiographic measurement and measurements taken from real bone can increase even further.^{17,18} In 2008, Cucchiarelli et al. compared the discrepancies between radiographic measurements with CT and measurements taken directly from 15 edentulous maxillae, using two different axial reference planes.¹⁹ The study showed distortions with regard to the real bone measurements, and these discrepancies were different for each of the two axial reference planes used.

The aims of the present *ex vivo* study were to assess the accuracy of dental CT scans and to compare the discrepancies obtained when either the occlusal plane or the basal plane was used as the axial reference plane.

Materials and methods

Mandibles

A total of 39 normal and dry mandibles from adult cadavers aged 35–83 (mean age of 50) were examined following state regulations, the study protocol having been approved by the Murcia (Spain) City Hall Health Service. Thirty of these mandibles were edentulous and the other nine retained teeth. In order to homogenize the study, multiple exodontias were performed on the nine mandibles that retained teeth.

Marking the occlusal plane

The occlusal plane was marked on the nine mandibles that retained teeth before the exodontias were performed. This was done by marking a line parallel to the teeth from the incisal edge of the central incisor to the vestibular cusps of the second molar (**Fig. 1a**). Once the occlusal plane had been marked, the teeth were extracted.

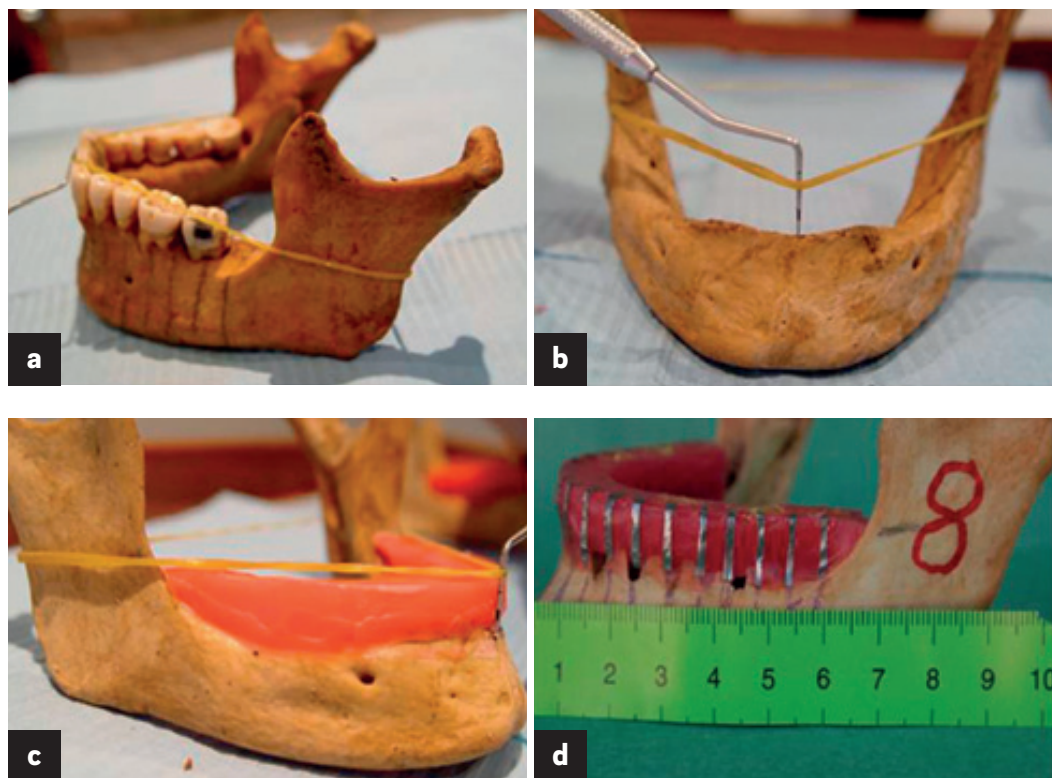
For the 30 edentulous mandibles, the occlusal plane was established in the anterior region by measuring a height of 1 cm (the usual height of the mandibular incisal crowns) and in the posterior region by dividing the retromolar trigone into three parts: upper, middle and lower. Thereafter, a meeting point between the upper third and the middle part was chosen; this point usually measured 1 cm in height (**Fig. 1b**).²⁰

Once the occlusal planes of the mandibles had been established, a Moyco wax piece (Thompson Dental Manufacturing, Montgomeryville, Pa., U.S.) was molded to follow the previously established plane. After placing the wax simulation of the occlusal plane (**Fig. 1c**), this was divided into 18 parts using 2 mm lead strips. These strips were placed 6 mm apart so that they corresponded to the 18 tomographic slices performed for each mandible (**Fig. 1d**).

Lastly, Fox planes were attached to the wax on each of the 39 mandibles (to be used as a guide for delimiting the occlusal plane radiographically) and each assembly was placed into a polymethyl methacrylate (PMMA) box for radiographic study.

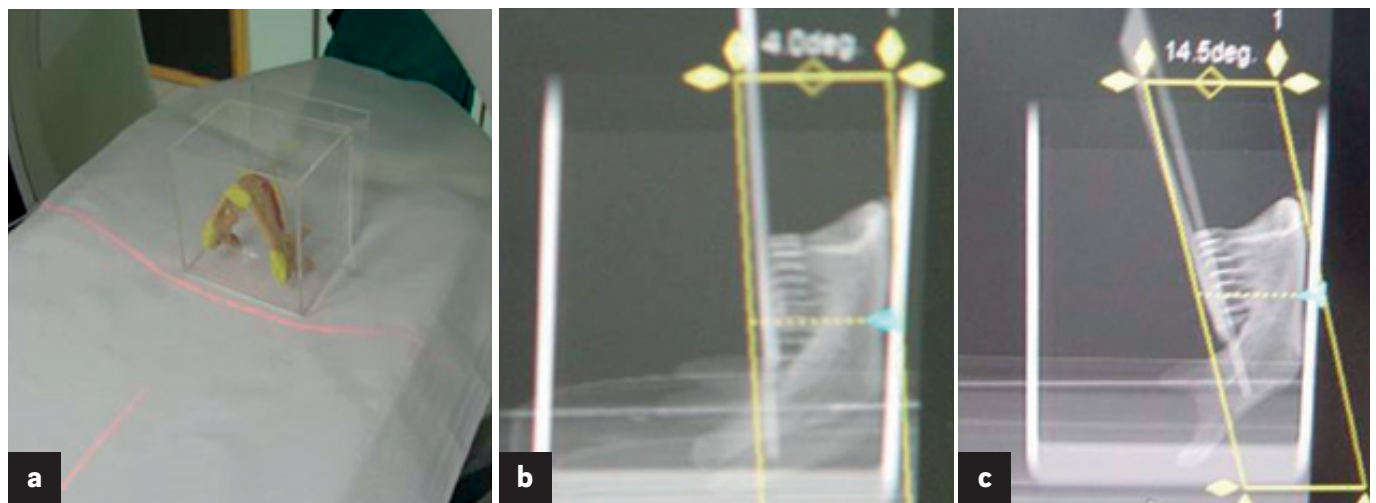
Figs. 1a–d

Marking the occlusal plane:
(a) marking mandibles with teeth intact before multiple exodontias were performed; (b) marking edentulous mandibles; (c) placing the wax piece to simulate the occlusal plane; (d) wax piece divided into 18 parts with lead strips corresponding to the 18 tomographic slices taken of each mandible).



Figs. 1a & b

Figs. 1c & d



Figs. 2a–c

Figs. 2a–c

Basal plane: (a) positioning of mandibles in PMMA boxes to support the lower edge against the container's anterior wall; (b) use of the occlusal plane as the axial reference plane; (c) use of the basal plane as the axial reference plane.

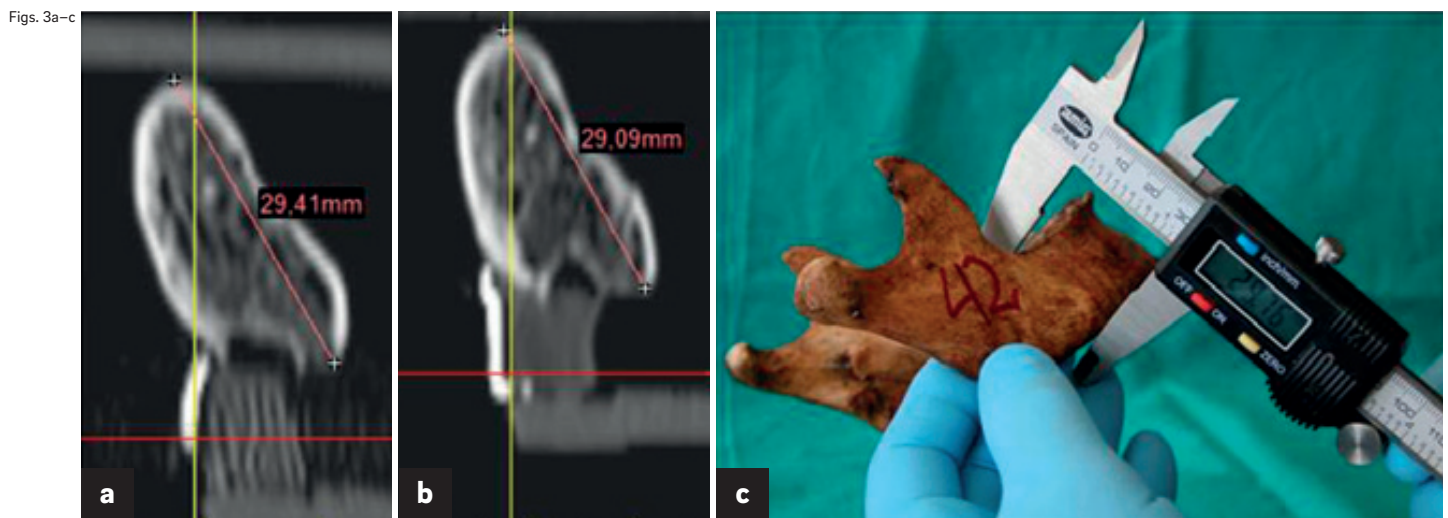
Basal plane

In order to establish a good axial reference from the basal plane, all of the mandibles were positioned in PMMA boxes to support the lower edge (basal plane) against the container's anterior wall (**Fig. 2a**).

Dental CT

The CT equipment used was a Toshiba Multi CT scan Aquilion 16 TSX-101A/6A (Toshiba America

Medical Systems, Tustin, Calif., U.S.). Thirty-six sagittal tomographic slices were performed for each mandible, 18 taking the occlusal plane as the axial reference plane (**Fig. 2b**) and 18 using the basal plane (**Fig. 2c**). The exposure parameters were set at 57 Kv, 56 s and 1.0–3.2 mA, and a rectangular collimator was used. The radiographic images were processed using SIMPLANT software (Materialise Dental, Madrid, Spain). All of the measurements were scored independently by two oral surgeons. When measuring the sagittal tomographic slices, the observers were



Figs. 3a–c

Measurements taken from the mandibles: **(a)** radiographic measurement of a sagittal tomographic slice using the occlusal plane as the axial reference plane; **(b)** radiographic measurement of a sagittal tomographic slice using the basal plane as the axial reference plane; **(c)** bone measurement taken using a digital calibrator.

blinded as to which axial reference plane, occlusal (**Fig. 3a**) or basal (**Fig. 3b**), had been used. Lastly, the observers' mean scores were calculated.

Direct mandibular measurements

These measurements were taken using a digital calibrator (AMIG T304B.W-1220, AMIG, Amorebieta-Etxano, Spain). The interedges (apical-coronal distance in mm) were measured perpendicularly from the base of the mandibular body to the alveolar ridge, along each of the lines corresponding to the tomographic slices (**Fig. 3c**).

Statistical analysis

The data were analyzed using SPSS statistical software (Version 12.0; SPSS, Chicago, Ill., U.S.). Descriptive statistics were obtained for each variable. The associations between the different qualitative variables were studied using Pearson's chi-squared test. Student's *t*-test for two independent samples was applied to quantitative variables, in each case determining whether variances were homogeneous. Statistical significance was set at $p \leq 0.05$.

Results

In comparing measurements taken from the 18 tomographic slices of each mandible with measurements taken directly from the bone when the occlusal plane was used as the axial reference plane, discrepancies were found in all of the tomographic slices assessed. These discrepan-

cies were positive in nine (50%) of the slices, while in the remaining nine (50%), the measurements taken from the CT scans were lower than the measurements taken from the bone. In six of the 18 slices analyzed (33.33%), the discrepancies observed showed statistically significant differences ($p \leq 0.05$; **Table 1**).

When the basal plane was used as the axial reference plane, discrepancies were also found between measurements taken from tomographic slices and clinical measurements of the mandibles in all 18 slices analyzed. These discrepancies were negative in all cases. In 17 of the slices (94.44%), the discrepancies showed statistically significant differences ($p \leq 0.05$; **Table 2**).

In this sense, with regard to positioning the patient when the CT scans were taken, use of the occlusal plane as axial reference produced the most accurate measurements (**Fig. 4**).

When the distribution of discrepancies in millimeters found in each of the 18 tomographic slices was compared in relation to the axial reference plane, a higher percentage (99.44%) of discrepancies greater than 0.5 mm were produced when the basal plane was used than when the occlusal plane was used (44.44%), with the difference being statistically significant ($p = 0.001$; **Table 3**).

Discussion

Ever since the first dental implants were introduced by Brånemark et al. in 1969, dental practitioners and researchers have sought methods that might improve the accuracy of surgical implant placement.²¹ CT has been widely used for preop-

Sagittal tomographic slices	Radiographic measurements (n = 39) Mean $\pm$ SD [†]	Bone measurements (n = 39) Mean $\pm$ SD	Discrepancies Mean $\pm$ SD	p-value
Cut 1	25.04 $\pm$ 4.03	24.96 $\pm$ 3.93	0.16 $\pm$ 1.33	0.250
Cut 2	25.03 $\pm$ 4.11	25.16 $\pm$ 3.98	-0.13 $\pm$ 1.33	0.085
Cut 3	25.74 $\pm$ 4.24	25.98 $\pm$ 4.19	-0.24 $\pm$ 1.37	0.106
Cut 4	26.82 $\pm$ 4.17	27.31 $\pm$ 4.05	-0.48 $\pm$ 1.45	0.498
Cut 5	28.41 $\pm$ 4.35	29.17 $\pm$ 4.35	-0.76 $\pm$ 1.75	0.389
Cut 6	30.64 $\pm$ 4.39	30.61 $\pm$ 4.31	0.03 $\pm$ 1.39	0.611
Cut 7	31.31 $\pm$ 4.31	30.29 $\pm$ 4.36	1.02 $\pm$ 1.48	< 0.001
Cut 8	31.34 $\pm$ 4.57	30.09 $\pm$ 4.43	1.24 $\pm$ 1.76	< 0.001
Cut 9	31.59 $\pm$ 4.77	30.11 $\pm$ 4.74	1.47 $\pm$ 1.81	< 0.001
Cut 10	31.55 $\pm$ 4.84	30.24 $\pm$ 4.62	1.31 $\pm$ 1.71	< 0.001
Cut 11	31.32 $\pm$ 4.64	30.17 $\pm$ 4.45	1.15 $\pm$ 1.61	< 0.001
Cut 12	30.87 $\pm$ 4.53	29.83 $\pm$ 4.55	1.03 $\pm$ 1.43	< 0.001
Cut 13	29.78 $\pm$ 4.63	29.51 $\pm$ 4.65	0.27 $\pm$ 1.77	0.330
Cut 14	28.13 $\pm$ 4.82	28.29 $\pm$ 4.91	-0.31 $\pm$ 1.87	0.524
Cut 15	26.61 $\pm$ 4.75	27.02 $\pm$ 4.75	-0.41 $\pm$ 1.75	0.345
Cut 16	25.64 $\pm$ 4.49	25.94 $\pm$ 4.71	-0.29 $\pm$ 1.45	0.144
Cut 17	25.21 $\pm$ 4.56	25.37 $\pm$ 4.78	-0.17 $\pm$ 1.31	0.251
Cut 18	25.11 $\pm$ 4.38	25.64 $\pm$ 4.64	-0.52 $\pm$ 1.48	0.500

[†] SD = standard deviation.

Table 1

Discrepancies between radiographic measurements (mm) and measurements taken directly from the bone (mm) using the occlusal plane as the axial reference plane (Student's t-test).

Fig. 4

Bar graph comparing discrepancies between radiographic measurements (mm) and measurements taken directly from the mandibles (mm) using both axial reference planes studied.

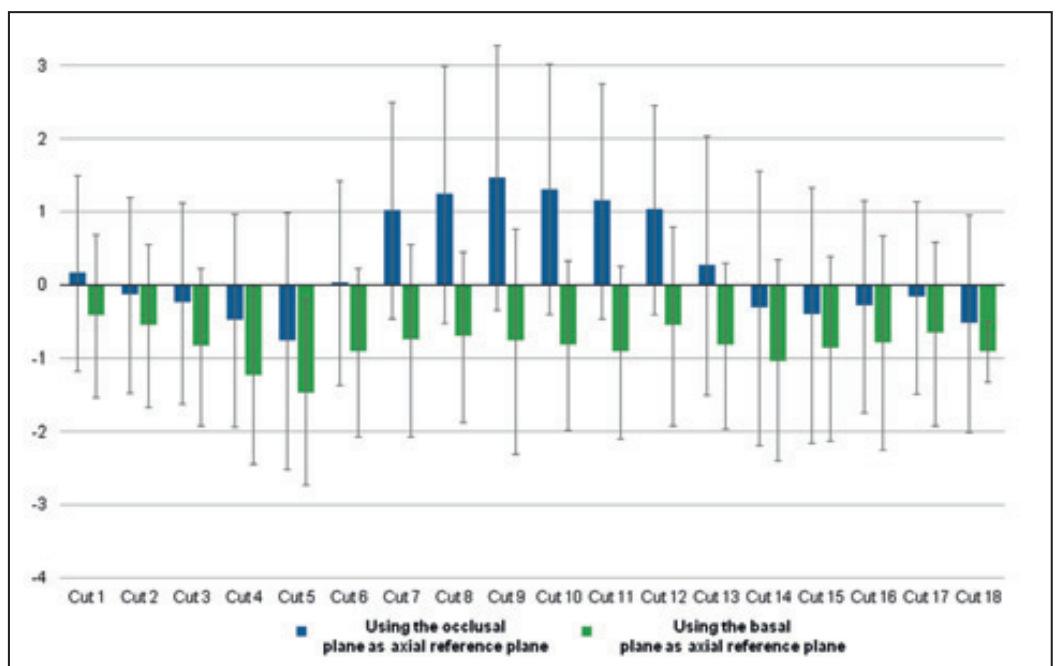


Table 1

Fig. 4

Table 2

Sagittal tomographic slices	Radiographic measurements (n = 39) Mean $\pm$ SD [†]	Bone measurements (n = 39) Mean $\pm$ SD	Discrepancies Mean $\pm$ SD	p-value
Cut 1	24.53 $\pm$ 3.88	24.96 $\pm$ 3.93	-0.42 $\pm$ 1.11	0.064
Cut 2	24.61 $\pm$ 4.02	25.16 $\pm$ 3.98	-0.55 $\pm$ 1.11	0.001
Cut 3	25.13 $\pm$ 4.15	25.98 $\pm$ 4.19	-0.84 $\pm$ 1.07	< 0.001
Cut 4	26.07 $\pm$ 4.08	27.31 $\pm$ 4.05	-1.23 $\pm$ 1.21	< 0.001
Cut 5	27.71 $\pm$ 4.22	29.17 $\pm$ 4.35	-1.46 $\pm$ 1.26	< 0.001
Cut 6	29.67 $\pm$ 4.30	30.61 $\pm$ 4.31	-0.92 $\pm$ 1.15	< 0.001
Cut 7	29.53 $\pm$ 4.21	30.29 $\pm$ 4.36	-0.75 $\pm$ 1.31	< 0.001
Cut 8	29.38 $\pm$ 4.35	30.09 $\pm$ 4.43	-0.71 $\pm$ 1.16	< 0.001
Cut 9	29.34 $\pm$ 4.47	30.11 $\pm$ 4.74	-0.77 $\pm$ 1.53	< 0.001
Cut 10	29.41 $\pm$ 4.55	30.24 $\pm$ 4.62	-0.82 $\pm$ 1.15	< 0.001
Cut 11	29.25 $\pm$ 4.36	30.17 $\pm$ 4.45	-0.92 $\pm$ 1.18	< 0.001
Cut 12	29.26 $\pm$ 4.37	29.83 $\pm$ 4.55	-0.56 $\pm$ 1.36	0.001
Cut 13	28.67 $\pm$ 4.62	29.51 $\pm$ 4.65	-0.83 $\pm$ 1.13	< 0.001
Cut 14	27.26 $\pm$ 4.83	28.29 $\pm$ 4.91	-1.03 $\pm$ 1.37	< 0.001
Cut 15	26.14 $\pm$ 4.89	27.02 $\pm$ 4.75	-0.87 $\pm$ 1.26	< 0.001
Cut 16	25.14 $\pm$ 4.94	25.94 $\pm$ 4.71	-0.79 $\pm$ 1.46	< 0.001
Cut 17	24.71 $\pm$ 4.83	25.37 $\pm$ 4.78	-0.66 $\pm$ 1.25	0.004
Cut 18	24.73 $\pm$ 4.84	25.64 $\pm$ 4.64	-0.91 $\pm$ 0.41	< 0.001

[†] SD = standard deviation.

Table 3

	Occlusal plane (n = 18) n (%)	Basal plane (n = 18) n (%)	p-value
Discrepancies			0.001
≤ 0.5 mm	10 (55.56)	1 (5.56)	
> 0.5 mm	8 (44.44)	17 (94.44)	

Table 2

Discrepancies between radiographic measurements (mm) and measurements taken directly from the bone (mm) using the basal plane as the axial reference plane (Student's *t*-test).

Table 3

Distribution of discrepancies in millimeters observed in each of the 18 sagittal tomographic slices in relation to the axial reference plane used (Pearson's chi-squared test).

erative assessment of dental implant treatments.²² It provides good images of the thickness of vestibular cortical bone and interalveolar distances, as well as of important anatomical features in jaws.²³ When used for imaging the mandible, the main advantage of CT scans over periapical or panoramic radiographs is that they provide a relatively accurate assessment of the alveolar

crestal bone height and width and its spatial relationship with the mandibular canal.²⁴ However, although there is a wide range of dental CT equipment marketed as providing accurate bone data at a 1:1 scale, several studies have shown discrepancies between the radiographic measurements taken using CT and clinical measurements taken directly from the bone.^{14, 25} In 1996, Covino et al.

used ten rectangular acrylic blocks (prepared with titanium–molybdenum alloy) as markers spaced from 1 to 10 mm, respectively.¹⁴ A plastic sphere was prepared with ten sets of titanium markers spaced at variable intervals of 1–10 mm. Each object was scanned three times at slice thicknesses of 3.0 mm and slice thicknesses of 1.5 mm with 0.5 mm overlap, positioned in the CT scanner in two different positions in relation to the scanning beam (perpendicular and parallel). The authors concluded that when CT was carried out with slices every 3.0 mm, if the procedure was not performed correctly, significant errors would occur, but if the slices were less than 1.5 mm, even if the CT procedure were performed erroneously to some extent, the results would not show much variation and would be more precise. In 2004, Hanazawa et al. compared data obtained by means of a modified CT system and a conventional CT device with real measurements taken directly from cadaver mandibles, finding discrepancies in 90% of the measurements taken with the modified CT system compared with the direct measurements and in 87.5% of those taken with the conventional CT device, the discrepancies being approximately 1 mm.²⁵

These radiographic discrepancies can lead to iatrogenic lesions during implant treatment, which are of particular concern in posterior mandibular regions, where they can produce lesions of the mandibular canal. In this regard, Klinge et al., who studied sensitivity and accuracy in locating the mandibular canal using cadaverous mandibles, observed that when the accuracy in determining mandibular canal position was evaluated, comparing the extent of error with the true value, the error was up to 1 mm in 94% of the CT measurements, but 39% with tomography, 17% with panoramic radiography and 53% using intra-oral radiography.²³ Similar discrepancies between mandibular canal positions determined radiographically using CT and measurements taken directly from the bone have been observed by other authors.^{15, 16, 26}

Similarly, numerous authors have observed small variations between the precision of three-dimensional preoperative imaging and the final surgical positions of the dental implants, with variations ranging between 0.7 mm and 1.0 mm,^{2, 27} due to the discrepancies between CT measurements and the real dimensions. In this way, the results of the present study, in which discrepancies varied between 0.03 mm and 1.47 mm, coincide with the discrepancies observed by these authors.

Acquiring a good CT scan is of primary importance for visualizing the different bony structures, and the quality and accuracy of the scan are influenced by various factors. The skill of the operator has a major influence. Adequate positioning of the patient will minimize error, and the choice of the appropriate equipment settings is important for achieving good contrast. Discrepancies between radiographic and real measurements can increase according to patient positioning for CT scanning.^{17, 18} However, although many authors have observed discrepancies between radiographic measurements using CT and real bone measurements, these authors used a single axial reference plane, which in many cases was not specified.^{28–31} Currently, there are very few articles that examine the discrepancies obtained with various axial reference planes. Cucchiarelli et al.'s comparison of the discrepancies between radiographic measurements with CT and measurements taken directly from 15 edentulous maxillae showed distortions with regard to the real bone measurements.¹⁹ It was found that the use of the horizontal plane showed 19.20% magnification, as opposed to the use of the occlusal plane, which showed 16.5% magnification. In this regard, Abrahams made a general study of mandibles using CT and concluded that the best axial reference plane is the occlusal plane.³² Although the present study found discrepancies when both the occlusal plane and the basal plane were taken as the axial reference plane, the discrepancies were greater when the basal plane was used.

Conclusion

The present study found that there are slight discrepancies between radiographic measurements taken using CT and real bone measurement. These must be taken into consideration in order to perform satisfactory implant treatments. With regard to patient positioning for the CT procedure, use of the occlusal plane as axial reference will produce the most accurate measurements.

Competing interests

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that may have influenced its outcome.

Acknowledgments

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Immediate loading of variable-thread expanding tapered-body implants placed into maxillary post-extraction or healed sites using a guided surgery approach: An up-to-five-year retrospective analysis

Abstract

Objective

Transitioning from failing dentition to complete-arch implant rehabilitation may involve temporarily rendering the patient edentulous. In order to avoid the use of a removable prosthesis, immediate implant placement and immediate loading with a fixed provisional prosthesis have been proposed. The aim of this study was to retrospectively assess the clinical and radiographic performance of variable-thread expanding tapered-body implants placed into maxillary post-extraction or healed sites using computer-assisted template-guided surgery with a specially designed radiographic stent.

Materials and methods

Data from 160 implants placed in 27 consecutive patients were evaluated up to five years (mean of 29 months). Outcomes were implant and prosthetic survival and success rates, biological and mechanical complications, marginal bone remodeling, sulcus bleeding index, plaque score and gingival index.

Results

At the last follow-up, one implant had failed, resulting in an overall implant cumulative survival rate of 99.4%, and all of the prostheses were *in situ*. Marginal bone remodeling was statistically significantly higher in the healed sites (-0.67 ± 0.97 mm; $n = 105$) than in the post-extraction sites (0.42 ± 0.99 mm; $n = 55$; $p = 0.026$). Two implants showed excessive marginal bone remodeling (> 3 mm) at the last follow-up (1.25%). Good soft-tissue parameters were found around all of the other implants.

Conclusion

The expanding tapered-body implants placed into healed and post-extraction maxillary sites using computer-assisted template-guided surgery and immediately loaded showed a good survival rate and good periodontal parameters.

Keywords

Immediate loading, tapered-body implant, guided surgery.

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Introduction

Transitioning from a failing dentition to complete-arch implant rehabilitation may involve temporarily rendering the patient edentulous.¹ In such cases, interim complete removable dental prostheses have been used after extraction of the hopeless teeth and during the osseointegration period. However, many patients object to a complete removable dental prosthesis for psychological, functional or esthetic reasons, and request fixed provisionalization throughout all phases of the rehabilitation process.^{2,3} In order to avoid the use of a removable prosthesis, immediate implant placement and immediate loading with a fixed interim prosthesis have been proposed for the rehabilitation of hopeless dentition.⁴ Indeed, immediately loaded implants placed into post-extraction sockets have recently been demonstrated to provide a reliable option for replacing failing residual teeth.⁵ Although immediate loading may place implants at a higher risk of complications,⁶ comparable survival rates have been reported for the two loading protocols.⁷ Furthermore, immediate loading combined with implant placement in post-extraction sites may result in improved esthetic outcomes owing to preservation of osseous and gingival architecture, offer reduced treatment time, and provide the patient with the convenience of an immediate tooth replacement.⁸ The risk of implant failure can be minimized by proper patient selection, well-trained operators, high primary implant stability and lack of micromovements.⁹

Computer-aided design (CAD) technology allows for the transfer of patient data to a 3-D implant planning program for virtual implant placement.¹⁰ The virtual planning is then used to generate a custom-made surgical template (computer-aided manufacturing—CAM) with metallic sleeves to precisely guide each dental implant into the position planned virtually. In addition, implant-supported fixed acrylic resin prostheses can be fabricated in advance and immediately delivered to the patient. These aspects of minimally invasive and simplified surgery, along with reducing the treatment time and postoperative discomfort, are beneficial to the patient.¹¹ Favorable clinical results of computer-assisted template-guided surgery have been shown in several studies;^{12–15} however, deviations in 3-D position between virtual planning and actual final position of the implant in the patient's jaw and technique-related perioperative complications have to be taken into account.^{16–20}

In 2009, Cantoni and Polizzi described a step-by-step technique involving a specially designed two-piece radiographic stent that allows the patient to retain hopeless teeth until the day of the surgery, making easier the transition from failing dentition to implant-supported prostheses.²¹ The present study aimed to retrospectively assess the survival rate of variable-thread expanding tapered-body implants (NobelActive, Nobel Biocare, Zurich, Switzerland) placed into maxillary post-extraction or healed sites using template-guided surgery in combination with a specially designed radiographic stent.²¹ This study followed the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.²²

Materials and methods

This retrospective study evaluated data collected from 27 consecutive patients of both sexes (19 females, 8 males), aged 18 years or older (range of 38–84; mean of 60.6), presenting with failing maxillary dentition, confirmed by clinical and radiographic examination, and with a preference for a complete-arch implant-supported fixed dental prosthesis or an intolerance to a complete removable dental prosthesis. All of the implants were placed without elevation of a flap in maxillary post-extraction sockets or healed sites using computer-assisted template-guided surgery (NobelGuide, Nobel Biocare) between September 2009 and October 2012. The patients were clinically followed for a minimum of two years (range of two to five years; mean of 29 months). All of the patients were treated in a single specialized implant rehabilitation center. Two clinicians performed all of the surgical (GP) and prosthetic (TC) procedures, and two dental laboratories manufactured all of the restorations. One independent examiner (EP) conducted a retrospective chart analysis of the 27 consecutively implanted patients with compromised dentition in the maxilla.

Patients were informed about the clinical procedures, materials to be used, benefits, potential risks and complications, as well as follow-up evaluations required for the clinical trial, and gave their written consent to take part in this study. All of the procedures were conducted in accordance with the Declaration of Helsinki of 1975 for biomedical research involving human subjects, as amended in 2008. The patients were not admitted to the study if any of the following exclusion criteria were present: general contraindications to

Fig. 1

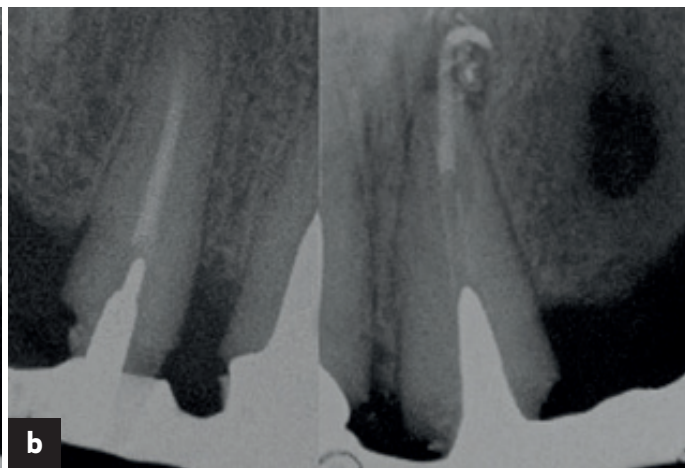
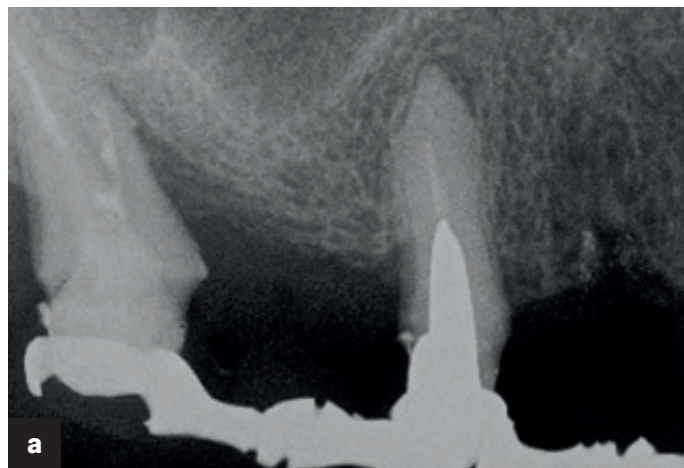
Initial clinical situation of a female patient with hopeless teeth in the maxilla.

Figs. 2a & b

Initial radiographic situation of a female patient with hopeless teeth in the maxilla.



Fig. 1



Figs. 2a & b

implant surgery; subjected to irradiation in the head and neck area less than one year before implantation; untreated periodontitis; poor oral hygiene and motivation; uncontrolled diabetes; pregnant or nursing; substance abuse; psychiatric problems or unrealistic expectations; severe bruxism or clenching; immunosuppressed or immunocompromised; treated or under treatment with intravenous amino-bisphosphonates; lack of opposite occluding dentition or prosthesis in the area intended for implant placement; active infection or severe inflammation in the area intended for implant placement; and need of bone augmentation procedures at implant placement.

Diagnostic protocol

The patients' medical histories were recorded and preoperative photographs (**Fig. 1**) and radiographs, including periapical (**Figs. 2a & b**) and panoramic radiographs, were obtained for initial screening and evaluation. Before implant placement, all of the patients underwent a cone beam computed tomography (CBCT) scan (New Tom VGi, Quantitative Radiology, Verona, Italy) according to a double-scan protocol.¹⁰ A two-piece radiographic guide was used for the diagnostic study and the virtual implant planning according to previously described procedures (**Fig. 3**).²¹ In

Fig. 3



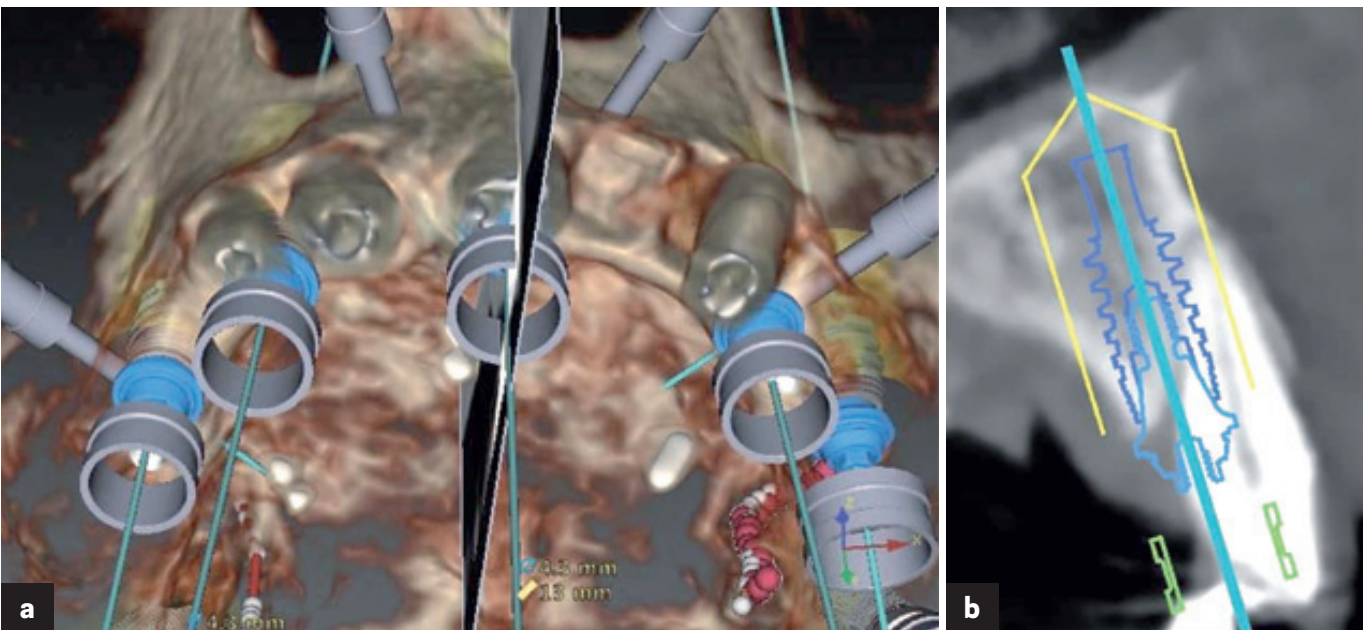
Fig. 3

Two-piece radiographic stent used for the CBCT scan.

Figs. 4a & b

Implant planning with teeth still in place. (a) Occlusal view. (b) Cross-sectional image.

Figs. 4a & b



order to predictably obtain a surgical template with the same fitting dimensions as the originally scanned radiographic guide, the NobelGuide calibration procedure was performed for each patient according to the manufacturer's instructions, using a specific calibration object. Finally, the two data sets were converted with the NobelGuide software to preview the patient's anatomy and to plan treatment (**Figs. 4a & b**). Once planning had been completed, the surgical template was ordered.

Surgical and prosthetic protocols

Antimicrobial prophylaxis with amoxicillin 1 g (Zimox, Pfizer, Rome, Italy) or clindamycin 600 mg, if allergic to penicillin, was administered b.i.d. for six days, starting 2 h before surgery. Prior to the start of surgery, patients rinsed with a 0.2% chlorhexidine mouthwash for 1 min. Oral premedication with flurazepam monohydrochloride 15 mg (Flunox, Teofarma, Pavia, Italy), octatropine methyl bromide 40 mg and



Fig. 5a

Figs. 5a & b

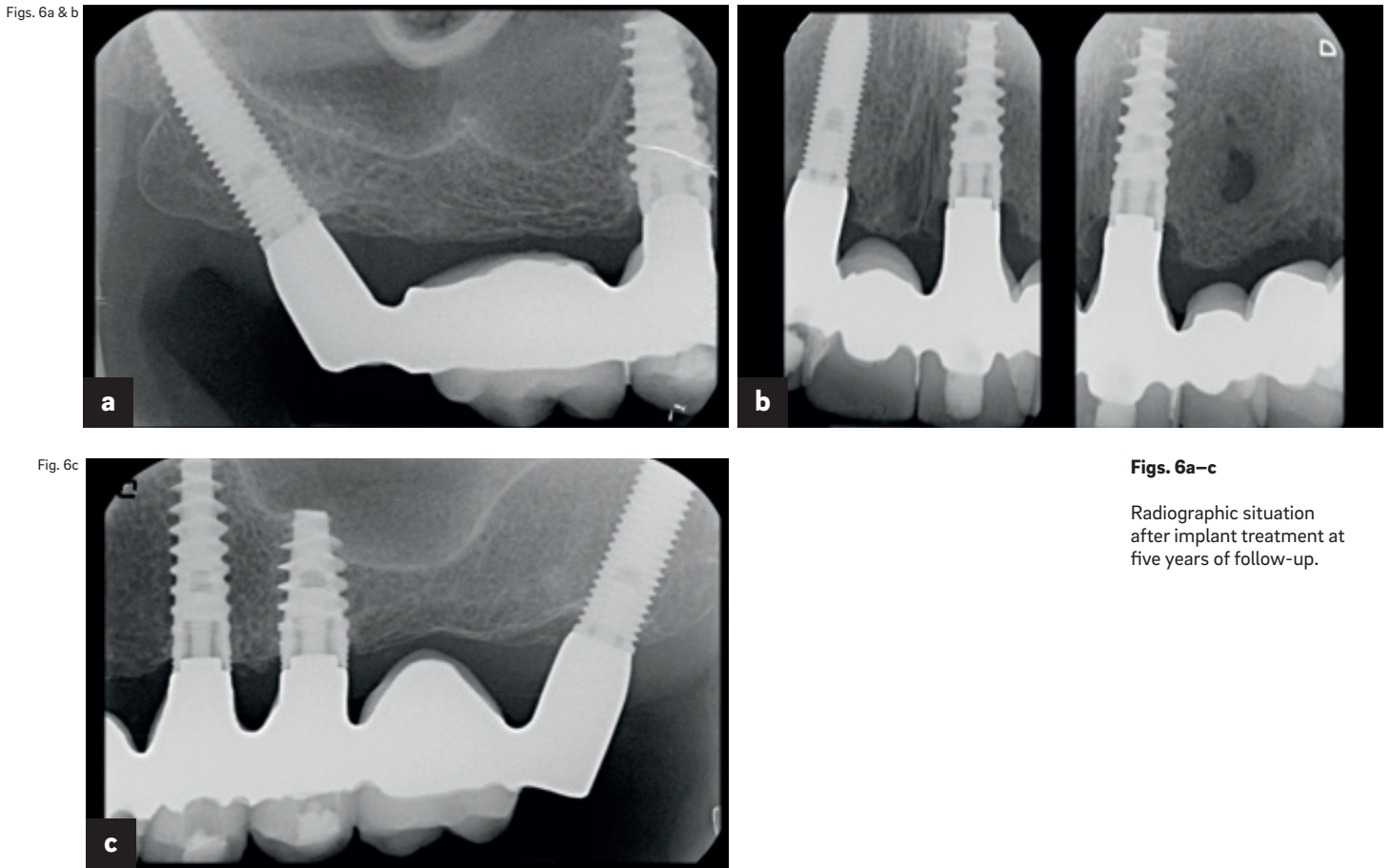
Clinical situation after implant treatment at five years of follow-up. **(a)** Frontal view. **(b)** Lateral view.



Fig. 5b

diazepam 5 mg (Valpinax, Crinos, Milan, Italy) was given prior to surgery. Local anesthesia was induced by infiltration of the buccal and palatal regions of the surgical area with a 4% articaine solution with 1:200,000 epinephrine (Ubistesin, 3M Italia, Bergamo, Italy). Conscious sedation with midazolam 0.05–0.15 mg/kg IV (Ipnovel, Roche, Monza, Italy) was performed; ranitidine 100 mg IV (Ranidil, Menarini, Florence, Italy) and ondansetron 4 mg IV (Zofran, GlaxoSmithKline, Brentford, U.K.) were also administered for gastroprotection and prevention of nausea and vomiting. A single post-operative dose of dexamethasone 8 mg IV (Decadron, Visufarma, Rome, Italy) and ketorolac 30 mg IV (Toradol, Recordat, Rome, Italy) was also given.

Hopeless teeth were atraumatically extracted with the aid of a periotome (PT2, Hu-Friedy, Chicago, Ill., U.S.) and the sockets debrided. In cases of multiple-rooted teeth, a rhizotomy was performed, starting from the center of the tooth, followed by careful extraction of the individual roots to prevent damage to the alveolar walls. Upon completion of the extraction, the integrity, depth and inclination of the alveolar socket were checked with a periodontal probe. The surgical templates were positioned using the silicone surgical index derived from the mounted casts, and precise fit was visually and manually assessed. The surgical template was then stabilized with three to five preplanned anchor pins. All of the implants were placed through metallic sleeves in a fully guided surgery approach. Im-



Figs. 6a–c

Radiographic situation after implant treatment at five years of follow-up.

plant sites were prepared according to the manufacturer's guidelines. Furthermore, a guided screw tapping was performed for half the depth of the osteotomy site, in order to provide an accurate and passive pressure-free seating of the implant into the prepared osteotomy. The bone tap was performed as the last step immediately prior to implant placement. Care was taken not to overheat the bone during the tapping procedure. The bone taps were removed from the site through counterclockwise rotation. Both tapping and implant placement were performed at 20 rpm. In the healed sites, the implant platform was positioned at the bone level, while in immediate post-extraction sockets, the platform was placed 1 mm deeper, below the buccal bone crest, engaging at least 3 mm of the bone apical to the root apex to achieve adequate primary stability of at least 35 N cm (range of 35–70 N cm; mean and standard deviation of 57.1 ± 13.4 N cm).

The residual gap between the buccal bone plate and the implant surface was filled with a mixture of autogenous bone and freeze-dried deproteinized bovine bone (Geistlich Bio-Oss,

Geistlich Pharma, Wolhusen, Switzerland). In extraction sockets presenting severe buccal bone dehiscence, the socket was sealed with a collagen membrane (Geistlich Bio-Gide, Geistlich Pharma) or with a connective tissue graft and left to heal without implant placement.

All of the implants were immediately loaded with a metal-reinforced, screw-retained acrylic resin provisional restoration without any cantilever. All of the restorations were prefabricated on a master cast poured from the surgical template, with the implant replica on-site. Non-engaging titanium temporary abutments were connected at the implant or abutment level. The provisional restoration was placed in the mouth and assessed for passive fit around the abutments. If any tension was detected, more space was provided by adjusting the provisional restoration. Once the prosthesis had been completely seated, a preliminary occlusal adjustment was performed. Using a disposable syringe filled with a cold-cure acrylic resin, the abutments were then connected to the temporary restoration by injecting the resin into the space between the abutments and the framework, having the pa-

tient close into occlusion. When the cold-cure acrylic resin had fully set, the provisional restoration was unscrewed from the mouth. The restoration was then refined, polished and screwed into the patient's mouth approximately 2–3 h later. A final check of the occlusion and of the interproximal spaces was then performed. The screw access holes were closed with PTFE and temporary filling material. Periapical radiographs of all of the implants were then obtained. All of the patients received postoperative instructions and prescriptions. In addition, an oral antiseptic and soft brushing were recommended for the first two weeks. Patients were recalled for clinical (**Figs. 5a & b**) and radiographic (**Figs. 6a–c**) examination and oral hygiene checks at two and four weeks, three, six and 12 months, and then yearly up to five years after implant placement. On average, the provisional fixed restorations were removed after six months and replaced with titanium or zirconia CAD/CAM screw-retained prostheses, with acrylic or ceramic esthetic material.

Outcomes

The primary outcomes were implant and prosthetic survival and success rates assessed 15 days after prosthesis delivery and then yearly up to five years after surgery, according to Pasparyidakos et al.²³ This investigation's prosthetic survival and success rates were defined as follows: a successful implant-supported dental prosthesis was a prosthesis that remained in function and the esthetic evaluation of which by both the dentist and patient was satisfactory at delivery and during the study period; a surviving implant-supported dental prosthesis was a prosthesis that remained in function even though not all success criteria were fulfilled and any discrepancies were regarded as correctable; and a failed implant-supported dental prosthesis was a prosthesis that had been removed, fractured beyond repair, or could not be classified as a successful or surviving dental prosthesis.

The secondary outcomes were any biological (pain, swelling, suppuration, etc.) and/or mechanical complications (fracture of the framework and/or the veneering material, screw loosening, etc.) occurring during the entire follow-up period, marginal bone level (MBL) changes, and periodontal parameters.

The distance from the most coronal margin of the implant collar to the most coronal point of bone-to-implant contact was defined as the

MBL. The MBL around the implants was evaluated on intra-oral digital radiographs taken with the paralleling technique using a film-holder (Rinn XCP, DENTSPLY, Elgin, Ill., U.S.) at implant placement (baseline) and then annually. The radiographs were accepted or rejected for evaluation based on the visibility of the implant threads. All readable radiographs were displayed in an image analysis program (Scion Image 4.0.2 for Windows, Scion Corporation, Frederick, Md., U.S.) on a 24-in. LCD screen (iMac, Apple, Cupertino, Calif., U.S.) and evaluated under standardized conditions (according to ISO 12646:2004). The software was calibrated for each image using the implant diameter. Measurements of the mesial and distal bone crest level adjacent to each implant were made, with accuracy of 0.01 mm, and averaged at the implant level. Marginal bone remodeling was calculated as the difference between the reading at the follow-up examination and the baseline value. Three groups were created in order to avoid bias in marginal bone remodeling: all implants, implants placed into post-extraction sites and implants placed into healed sites.

Periodontal parameters around the implants were assessed at the last follow-up examination. The sulcus bleeding index was assessed using a plastic periodontal probe (Plast-o-Probe, DENTSPLY Maillefer, Ballaigues, Switzerland) at four sites around each implant (mesial, distal, buccal and lingual), according to the Mombelli Index,²⁴ and was reported at the implant level. The plaque score was recorded using a plastic periodontal probe (Plast-o-Probe) and defined as the presence of plaque (yes/no) on the abutment-restoration complex. The gingival index was defined as follows: 0 = normal gingiva; 1 = mild inflammation, slight change in color, slight edema, and no bleeding on probing; 2 = moderate inflammation, redness, edema, glazing, and bleeding on probing; and 3 = severe inflammation, marked redness and edema, ulceration and tendency to spontaneous bleeding.

Implant and prosthetic survival and success rates were evaluated by an independent dentist (EP). Complications were assessed and treated by a nonblinded treating clinician (GP). The marginal bone remodeling was evaluated by an independent radiologist. An independent blinded dental hygienist who was not involved in the study performed all of the periodontal measurements.

Statistical analysis

Statistical analysis was performed using SPSS for Windows (Version 18.0; SPSS, Chicago, Ill., U.S.). Descriptive analysis was performed using mean, standard deviation and frequency distribution. A life table analysis of implant cumulative survival rates (CSRs) was calculated. Kaplan–Meier survival analysis was performed to allow estimation of survival over time, even when patients dropped out or were followed for different lengths of time. The Wilcoxon signed-rank test for paired data was utilized to compare overall bone levels between baseline (implant placement) and follow-ups in both healed and post-extraction sites, and to compare bone remodeling between post-extraction and healed sites at the last follow-up examination. The implant was used as the statistical unit of the analysis. All statistical comparisons were conducted at the 0.05 level of significance.

Results

All 27 selected and analyzed patients met the inclusion criteria. Patients received a total of 160 NobelActive implants (22 narrow diameter, 106 regular diameter and 32 wide diameter) with a moderately rough surface (highly crystalline and phosphate-enriched titanium oxide). One hundred and five implants were placed into healed sites and 55 into post-extraction sockets. Each patient received at least one post-extraction implant. Patients were clinically followed for up to five years.

At the last follow-up, no patients had dropped out and no deviation from the original protocol had occurred. All of the collected data were in-

cluded in the statistical analysis. Only one post-extraction implant failed in one patient, who showed poor oral hygiene, during the second year, and showed clinical signs of mobility and infection, resulting in an overall implant CSR of 99.4%. The life table analysis is summarized in **Table 1**. All prostheses were *in situ* at the last follow-up, accounting for a cumulative prosthetic survival rate of 100% up to five years after insertion.

Two implants (1.25%) showed marginal bone remodeling of greater than 3 mm at the last follow-up. However, none of the implants presented with an exposed implant neck, and no surgical intervention was performed. All of the affected patients underwent nonsurgical therapy consisting of manual debridement using titanium curettes and a glycine-based air–powder abrasive device, and local application of antimicrobial agents (minocycline HCl 1 mg, Arestin, Ora-Pharma, Horsham, Pa., U.S.), followed by oral hygiene instructions and motivation, together with a strict follow-up protocol. At the subsequent follow-ups, the bone recession had stopped and the soft tissue remained stable. No other biological or mechanical complications occurred during the entire follow-up period, resulting in a cumulative implant and prosthetic success rate of 97.9%.

At the last follow-up (mean of 29 months), the marginal bone remodeling was -0.58 ± 0.98 mm. Implants placed into post-extraction sockets (0.42 ± 0.99 mm) showed statistically lower marginal bone remodeling compared with implants placed into healed sites (-0.67 ± 0.97 mm; $P = 0.026$).

At the last follow-up session, bleeding after careful insertion of a periodontal probe 1 mm into the mucosal sulcus parallel to the abutment surface was detected around three implants (1.6%).

Table 1

Period (years)	Surviving implants	Failed implants	Not followed	CSR (%) [†]
0–1	160	0	0	100.0
1–2	160	0	0	100.0
2–3	160	1	11	99.4
3–4	148	0	48	99.4
4–5	100	0	79	99.4
5	21	–	–	99.4

* According to the last recorded patient follow-up.

† Cumulative survival rate.

Table 1

Life table analysis of all surviving implants.*

Twelve patients with 68 implants showed a slight amount of plaque around the implant–abutment interface; thus, the overall plaque score was 36.0% and 44.4% at implant and patient level, respectively. The gingival index was reported as 90.5% normal gingiva, 7.9% with mild inflammation and 1.6% with moderate inflammation.

Discussion

This study retrospectively evaluated the success and survival rates of variable-thread tapered-body implants placed into post-extraction or healed sites in the maxilla using computer-assisted template-guided surgery in combination with a specially designed two-piece radiographic stent.²¹

The main limitations of this study are its retrospective nature, which may have limited the data collection, and the analysis of possible variables (soft-tissue thickness, time of placement or loading) that may have influenced the bone resorption. Another limitation is the limited number of participants. However, this investigation may be considered as a pilot study for future multicenter randomized controlled trials with sample size calculation and multivariate analysis.

Implants placed into post-extraction sockets showed lower marginal bone remodeling than implants placed into healed sites did; thus, the null hypothesis that there is no difference between the two protocols in terms of hard-tissue response has to be rejected.

In the present study, one out of 160 implants failed over a period of five years, accounting for an overall implant CSR of 99.4%. The major clinical conclusion of this retrospective study is that immediate post-extraction placement of implants and immediate provisionalization may be considered an effective and reliable treatment option for patients who would prefer to have a shortened overall treatment time and to be rehabilitated immediately with the aid of computer-assisted template-guided surgery.

Proper patient selection and well-trained operators are necessary to minimize the risk of implant failure. Immediate implant placement and provisionalization in both post-extraction sockets and healed sites are technically demanding procedures, and the surgical and prosthetic skills required are superior to those necessary for conventional implant treatment.

To the best of our knowledge at the time of writing this article, there were no other published

studies that evaluated the use of a variable-thread tapered-body implant with internal conical connection, in-built platform shifting and a moderately rough oxidized surface in combination with computer-assisted template-guided surgery to treat failing dentition in the maxilla. For this reason, it is difficult to evaluate how the present results fit with other comparable studies. However, there is a randomized controlled trial that investigated the same implant design that may provide some comparable data.²⁵

The marginal bone remodeling reported in the present study, measured from implant placement until the last follow-up examination, was -0.58 ± 0.98 mm. This value is slightly lower than the data reported in the literature for two-piece implants, for which after the initial bone loss during the first year post-placement, about 0.1–0.2 mm of crestal bone loss was found at the annual follow-up.^{26,27} Pozzi et al. recently published three-year results of a randomized controlled trial, reporting a marginal bone remodeling of 0.83 ± 0.27 mm around NobelActive implants placed into healed sites in the posterior mandible.²⁵ One reason for these differences may be that surgeons operating freehand tend to elevate wider flaps to better visualize the area in which the implants are to be placed. With dedicated template-guided implant placement, wider flaps were in many cases considered unnecessary, since the surgeons were able to rely on the surgical template.¹¹ Another explanation that may account for the differences in the observed MBL changes is that, in some of the aforementioned studies, all of the implants were placed into healed sites.^{11, 25} In the present study, statistical analysis showed a statistically significant difference ($P = 0.026$) in mean marginal bone remodeling at the last follow-up between implants placed into healed sites (-0.67 ± 0.97 mm) and those placed into post-extraction sites (0.42 ± 0.99 mm). These findings are in accordance with a recent systematic review and meta-analysis on the alterations of the bone dimension after immediate implant placement into extraction sockets.²⁸

In the present study, the diagnostic protocol included the calibration procedure of the digital workflow for each patient, according to the manufacturer's instructions. Scanning physical objects like the radiographic guide requires an optimized workflow, because the data are converted into 3-D models, which are used not only for diagnostic purposes but also for physical pro-

duction. Since the data are digitized using X-ray technology and since material properties or densities are visualized through various kinds of gray value shades, the workflow is highly dependent on the gray values assigned to the scanned 3-D data from the DICOM files. More precisely, the workflow is dependent on the actual gray value that defines the radiographic guide's borders. This gray value assignment to the DICOM files is unfortunately not standardized for CBCT scanners (almost every scanner assigns different gray values to different objects and materials), making reliable default values for each scanner model almost impossible. This ultimately has implications regarding the produced dimensions of the surgical template, as these dimensions are defined by the gray value selection representing the borders of the scanned radiographic guide. In order to automatically detect and automatically apply the correct settings needed for the software to define the actual physical borders of the scanned radiographic guide, NobelClinician (Nobel Biocare) is designed to work with the unique and innovative NobelGuide calibration procedure. The calibration object is a high-precision object, milled from a material that behaves the same way when penetrated by X-rays as the resins typically used for the radiographic guide in combination with the scanner. This process ensures that each time the CBCT scanner is used with a known scanner the surgical template produced will have the same fitting dimensions as the originally scanned radiographic guide. As a result, the procedure does not calibrate the scanner, but calibrates the full workflow, from an accurately fitting radiographic guide to an accurately fitting surgical template.

Many factors are likely to affect the success of immediately loaded implants, including bone quality and quantity, the skill and experience of the clinician, implant design, implant primary stability, micro- and macromovement, as well as occlusion. The quality and quantity of bone at the implant site have been shown to be important in determining the success of dental implants and are critical for ensuring the initial stability of the implant upon insertion.²⁹ Primary implant stability and lack of micromovement are considered to be two of the main factors necessary for achieving predictable high success rates for osseointegrated oral implants.³⁰ Thus, a high insertion torque value appears to be one of the prerequisites for a successful immediate or early loading procedure. The variable-thread tapered implant

design with a moderately rough surface was introduced into the market to facilitate one-stage surgical procedures and to allow for immediate placement and anticipated loading protocols.³¹ According to the results of the present study, in which all of the patients included had failing maxillary dentition and refused interim complete removable dental prostheses, the major indication for such implants is medium- or low-density bone sites in the maxilla. Nevertheless, a slight modification of the original drilling protocol was adopted in that implant sites were underprepared according to the bone density. However, a guided screw tapping for half the depth of the osteotomy site was performed immediately before the implant placement. Great care was taken to ensure optimal accuracy during implant placement because the implant mount had a smaller diameter than that of the sleeve. Nevertheless, this feature allowed the clinician to perceive the implant stability within the bone, without any friction between the implant mount and the sleeve.

Conclusion

Within the limitations of this retrospective study, variable-thread tapered design implants placed using computer-assisted template-guided surgery, in combination with a specially designed two-piece radiographic stent, can be considered a successful treatment option for immediate implant placement and loading in the maxillae of completely edentulous patients, based on the results of up to five years of follow-up. Post-extraction implants showed statistically lower marginal bone remodeling compared with implants placed into healed sites. The results should be interpreted with care and data should be investigated further in randomized controlled clinical trials.

Competing interests

The authors declare that they have no competing interests related to this study. No financial support was received for this study.

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An *in vitro* study on viscosity using an electromagnetically spinning sphere viscometer

Abstract

Objective

The purpose of this study was to investigate the reproducibility of measurements of salivary viscosity using an electromagnetically spinning (EMS) viscometer.

Materials and methods

An EMS viscometer was used to measure viscosity. A viscosity standard fluid and artificial saliva (Saliveht) were used.

Results

Viscosities of 20.14 mPa s (SD $\pm$ 0.04) and 4.26 mPa s (SD $\pm$ 0.08) were recorded for the standard fluid and Saliveht, respectively. These values did not substantially differ when the measurements were repeated five times at different time points and when using different sets of tubes, spheres and viscosity standard fluids, as well as various amounts of the fluids.

Conclusion

The use of a newly developed EMS viscometer demonstrated high reproducibility. This device might make chairside measurement of salivary viscosity simple.

Keywords

Salivary viscosity, electromagnetically spinning sphere viscometer.

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Introduction

Saliva is mainly secreted by the three major salivary glands: the parotid, submandibular and sublingual glands. The saliva secreted from all three glands mixes in the oral cavity and exerts physiological functions. Saliva has important bacteriological, biochemical, and physical effects on the inside of the mouth, and is relevant to studies in many different fields.

In particular, the viscosity of saliva is mainly responsible for the lubricating action that aids in the movement of the tongue and lips. It is also essential for ingestion, swallowing, speech and other functions.¹ Salivary viscosity is correlated with periodontal disease,^{2,3} dental caries^{4,5} and xerostomia,⁶ and plays a role in the maintenance and stability of dentures;⁷⁻⁹ therefore, it is an important research topic. Various rotational viscometers and capillary viscometers have been used to measure salivary viscosity, but they are not easy to use and require large amounts of saliva.¹⁰⁻¹⁷

The electromagnetically spinning (EMS) viscometer, developed by Sakai et al. in 2008,¹⁸ uses a minute metal sphere of approximately 2 mm in diameter submerged in a sealed sample and subjected to electromagnetic induction, which is a remote operation that applies rotational torque. In this new system, the viscoelasticity of a substance is assessed by a camera that records the rotational movement of this sphere. This method uses disposable tubes and spheres, preventing the possibility of infection. The use of this device might make the chairside measurement of salivary viscosity simple.

To the best of our knowledge, no report has examined the reproducibility of this device. The aim of the present study was to evaluate the reproducibility of measurements of salivary viscosity using an EMS viscometer.

Materials and methods

An EMS viscometer (Kyoto Electronics Manufacturing, Kyoto, Japan) was used to measure viscosity (**Fig. 1**). An amount of 300 μ L of a viscosity standard fluid (Showa Essential Oils, Tokyo, Japan) was poured into the test tube, the sphere submerged, and the test tube covered with a sealed cap and inserted into the device. The thermostatic bath in the device was set to 36 °C and a rotational speed of 1,000 rpm. Once the

temperature of the viscosity standard fluid had stabilized, measurements were taken. All measurements were repeated five times at 30 min intervals within the same day using the same set of tubes, spheres and viscosity standard fluid.

We prepared five different sets of test tubes, spheres and viscosity reference solutions. A 300 μ L aliquot of viscosity reference solution was added to the device, and five measurements were taken after the temperature of the solution had stabilized. This procedure was then repeated using various amounts of viscosity standard fluid (300 μ L, 500 μ L, 750 μ L and 1,000 μ L) placed into different test tubes with different spheres, and these spheres were then inserted into the device. Measurements were repeated five times within the same day.

Reproducibility with a low-viscosity solution, Saliveht

A solution of 100% Saliveht (Teijin, Osaka, Japan) was used as test. The thermostatic bath inside the device was set at 36 °C and the rotational speed was set at 1,000 rpm.

The Saliveht (300 μ L) was placed into a test tube and the sphere was immersed in the solution. The tube was then capped with a sealing cap and inserted into the device. Once the temperature inside the device had stabilized, the measurements were repeated five times every 30 min using the same sample, the same test tube and the same sphere on the same day.

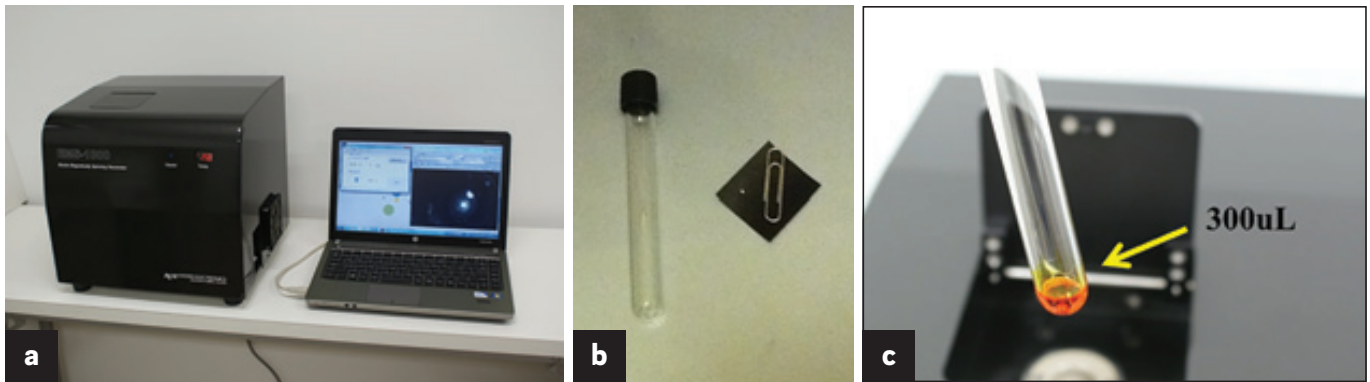
The procedure was then repeated using different five sets of tubes, spheres and Saliveht (300 μ L), and the measurements were repeated five times within the same day. This procedure was then repeated using various amounts of Saliveht (300 μ L, 500 μ L, 750 μ L and 1,000 μ L) placed into different test tubes with different spheres, and these spheres were then inserted into the device.

Statistical analysis

The mean and standard deviation were calculated for the data obtained.

Results

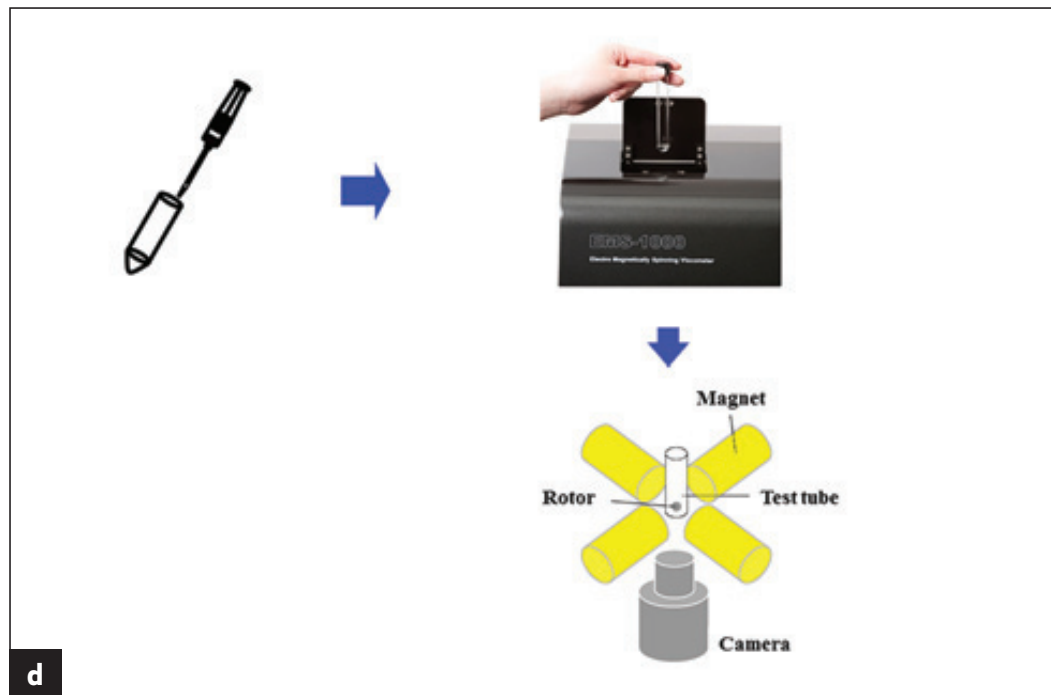
Using the same viscosity standard fluid, test tube and sphere, the results of the five repeated measurements within the same day showed mean and



Figs. 1a–d

Figs. 1a–d

- (a) Electromagnetically spinning sphere viscometer.
- (b) A glass tube.
- (c) An aluminum sphere.
- (d) A schematic of the measurement method.



standard deviation values of 20.04 mPa s (SD $\pm$ 0.04) (**Fig. 2**). When different disposable test tubes and spheres were used, the calculated mean and standard deviation values were 20.14 mPa s (SD $\pm$ 0.04) (**Fig. 3**). These values were similar to the previous ones. The measurements of the viscosity using different amounts of fluid showed no differences between the five samples. The calculated mean and standard deviation values were 20.12 mPa s (SD $\pm$ 0.06) (**Fig. 4**).

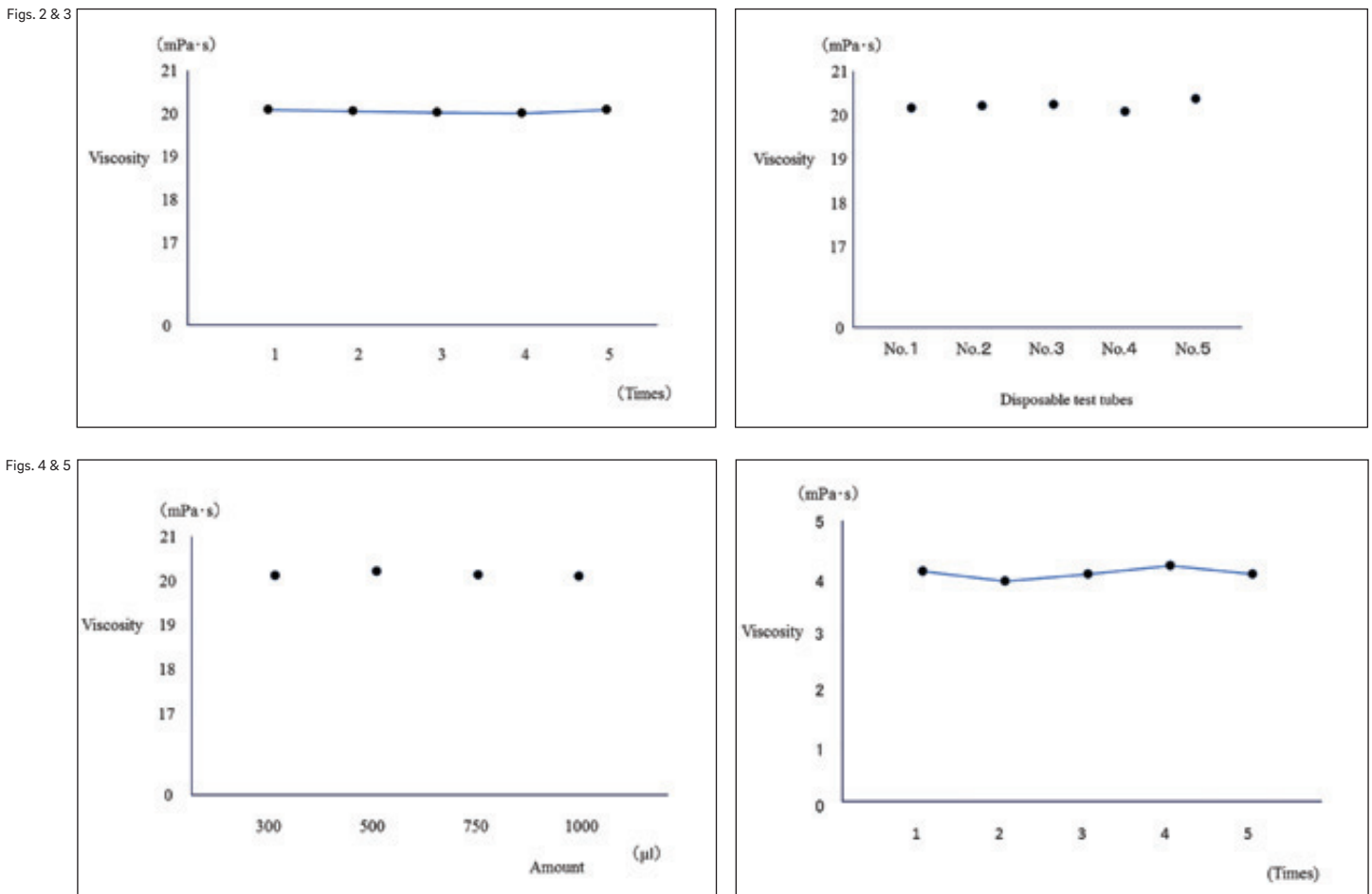
Reproducibility with Saliveht

The five measurements taken on the same day with the same tube and sphere using Saliveht separated by a 30 min interval were quite similar and yielded mean and standard deviation values of 4.02 mPa s (SD $\pm$ 0.06) (**Fig. 5**). Using different test tubes, spheres and Saliveht to obtain five

measurements on the same day resulted in mean and standard deviation values of 4.26 mPa s (SD $\pm$ 0.08), with no differences between the five measurements (**Fig. 6**). Using different amounts of the test solution resulted in mean and standard deviation values of 4.04 mPa s (SD $\pm$ 0.08), and no differences were noted with different amounts of solution (**Fig. 7**).

Discussion

Saliva aids in maintaining healthy dentition throughout one's life and is important for oral health. Saliva contributes to numerous functions in the oral cavity, such as speech and swallowing of foods, maintenance of oral health, protection of the mucosa from bacterial attack and fungal growth, prevention of demineralization of the



Figs. 2 & 3

Figs. 4 & 5

teeth and lubrication of the oral cavity. Salivary viscosity is associated with the amount of mucin; both these factors are also associated with the degree of periodontal disease and clinical symptoms.² The physical properties of saliva, including flow, pH, buffering capacity, and viscosity, have been found to be associated with caries activity in children and to act as markers of caries.⁵ Xerostomia patients are known to have low salivary flow and high viscosity compared with healthy individuals.⁶ For the maintenance of a complete denture, the physical properties of saliva between the base of the denture and the mucosa under the base are considered important, and thus there are many studies on the viscosity of saliva and maintenance of dentures.⁷ Determining the amount and condition of saliva at the chairside with ease is important for improvement of oral function and the intra-oral environment, eating and swallowing support, and increased quality of life.

Viscosity has previously been measured using capillary flow methods or rotational viscometry.¹⁷ Capillary flow methods are simple to operate,

require a short measurement time and are accurate. However, when the viscosity of a non-Newtonian fluid is measured, only the mean value is obtained, because the shear rate varies, depending on the location within the viscometer.^{10–12} Generally, in rotational viscometry, a constant, that is the shear rate, allows for a constant, uniform flow in all locations in the viscometer. This can be used to measure the viscosity of non-Newtonian fluids; however, the equipment is complicated and measurement requires 20–30 min. Furthermore, it has inferior precision compared with capillary methods, and it is not suitable for low-viscosity fluids.^{16, 17} A large amount of saliva is needed, and intake saliva needs to be filtered, eliminating large polymers and making it difficult to reflect the exact properties of saliva. Procedures such as equipment cleaning are complex and time-consuming, and the equipment is costly. In addition, with a conventional viscometer, a low torque is generated, making it difficult to measure a low-viscosity sample.

A cone-plate viscometer can analyze small samples (2–3 mL). However, it is not suitable for

Fig. 2

Viscometer reproducibility using a viscosity standard fluid.

Fig. 3

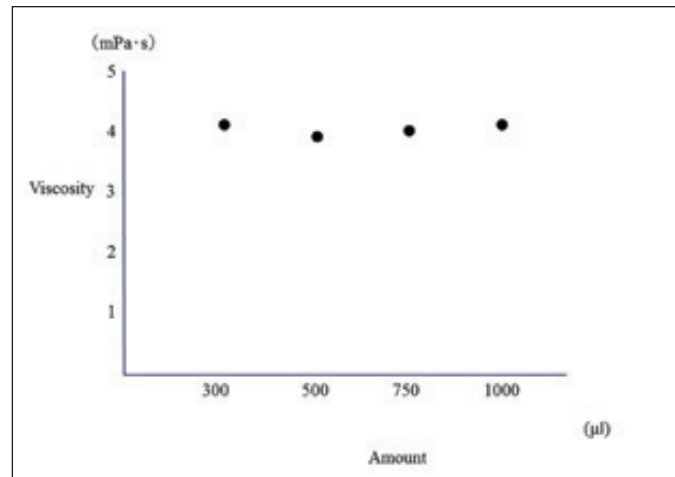
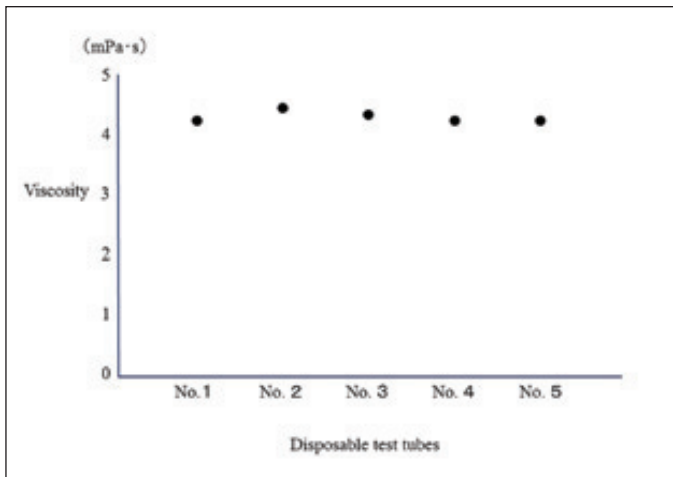
The measurements using different disposable test tubes and spheres with the viscosity standard fluid.

Fig. 4

The measurements using different amounts of viscosity standard fluid.

Fig. 5

Viscometer reproducibility using Salivett.



Figs. 6 & 7

Fig. 6

The measurements using different disposable test tubes, spheres and Saliveht.

Fig. 7

The measurements using different amounts of Saliveht.

measuring samples with low viscosity, such as saliva. When analyzing low viscosity samples, such as water, the torque generated is too small, making stable detection difficult.

Salivary viscosity is not uniform between the measurement methods and devices. In addition, even with the same measurement device, the viscosity is strongly influenced by the measurement conditions, such as temperature and shear rate. Researchers have shown ingenuity and creativity in measuring viscosity. The device that we used is contactless, sealed and rapid, requires samples of low volume and uses disposable components; these features are absent in a conventional viscometer. The equipment is not contaminated by the sample, and all of the containers are disposable. The disposability of the cell unit, which is difficult with conventional methods, is a major advantage of this method. Therefore, it is no longer necessary to expend effort in cleaning after measurement, which is normally a tedious task. This method is superior for measuring salivary viscosity because torque is applied to the rotor without any contact, which has the potential to spread infection and is a major concern with conventional methods. The EMS viscometer enables continuous measurement over a wide range, from 1 to 50,000 mPa s, enabling stable measurement, even in low-viscosity samples such as water. Another feature of this device is the ability to measure both Newtonian fluids and non-Newtonian fluids. Since viscosity is dependent on temperature, a temperature-sensing system was built into the device used, enabling automatic measurement of the temperature dependence of viscosity.^{18–20} Once the test tube has been inserted into the device, the sample is measured in 10 s, and therefore the method has been

simplified. Although the reproducibility of EMS viscometers has been described, the reproducibility has not been studied in terms of whether they are suitable for bio-instrumentation. Therefore, first, we used a viscosity standard fluid, which was a Newtonian fluid, to study the reproducibility of the equipment. Low-concentration solutions are reportedly difficult to measure using a viscometer. Saliva is a low-viscosity polymer solution and a non-Newtonian fluid, making viscosity measurement difficult.

A standard viscosity fluid is intended to calibrate the viscometer and exhibit constant viscosity. Because the aim of this study was to measure saliva, the machine settings were adjusted so that the temperature of the thermostatic bath would be 36 °C, which is close to body temperature. The rotational speed was set to 1,000 rpm because the measurements involved low viscosity. When the standard viscosity solution was used, the viscometer showed high accuracy and very high repeat accuracy. Very high reproducibility too was observed when investigating whether reproducibility is affected by different disposable tubes and spheres. In addition, results from the investigation in which the test material was changed showed very high reproducibility.

Furthermore, the study of saliva at low viscosities is important.¹⁵ Saliva is affected by both time and temperature, and the effect is not consistent. Therefore, commercially available artificial saliva, which has stable properties and known components and additives, was used. The artificial saliva is packaged in an aerosol spray and is easy to use. Its efficacy and stability have been established and it is clinically useful. The main component is the same inorganic electrolyte solution as saliva, to which a thickening agent is

added. Its pH, specific gravity and other properties are also similar to those of saliva, and the salivary viscosity was adjusted to 4–6 mm²/s at 25 °C.

Investigation of the low-viscosity solution also showed that the viscometer had high accuracy and very high repeat accuracy. Very high reproducibility too was evident when investigating whether disposable tubes and spheres affect reproducibility. In addition, the investigation in which the test material was changed also showed very high reproducibility. These findings suggest that a measurement method using an EMS viscometer, has the potential to easily assess changes in the properties of saliva, primarily viscosity, in small samples.

Conclusion

This study aimed to assess the measurement of viscosity using the newly developed EMS viscometer, which demonstrated high reproducibility, thereby indicating that simple methods for assessing saliva can be developed.

Competing interests

The authors declare that they have no competing interests.

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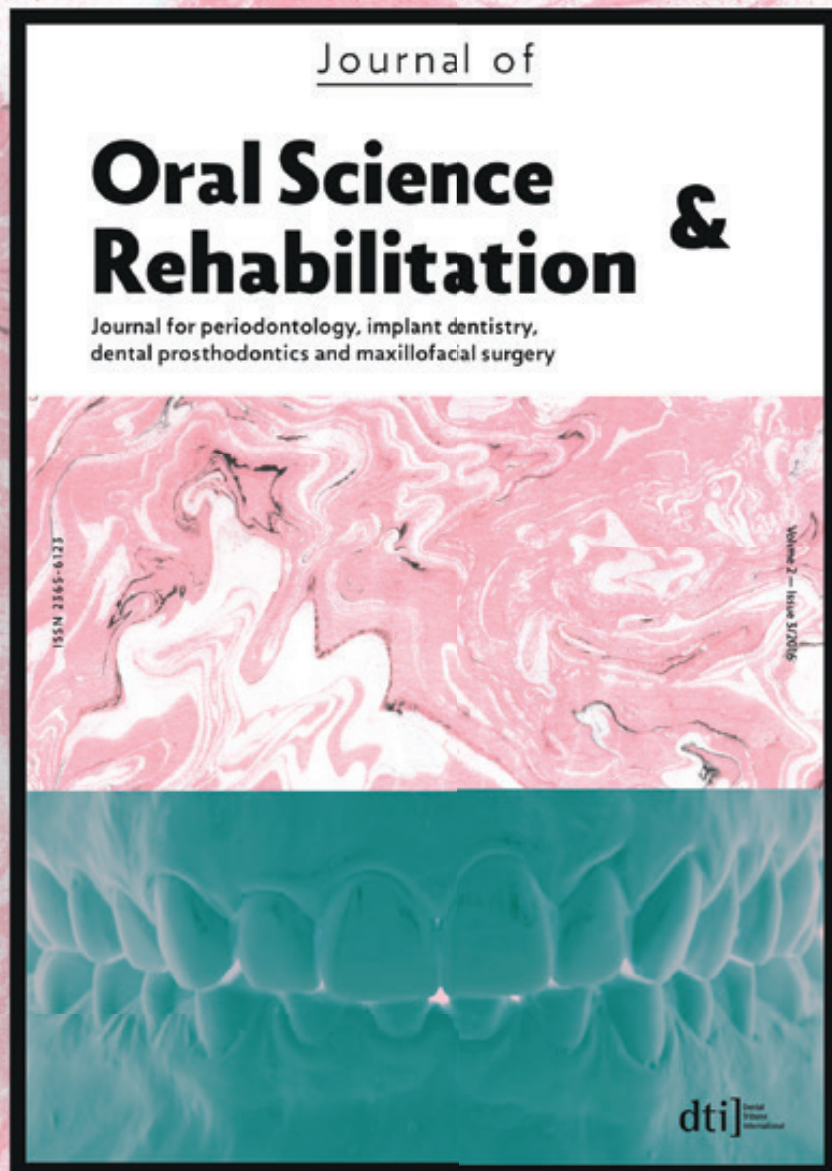
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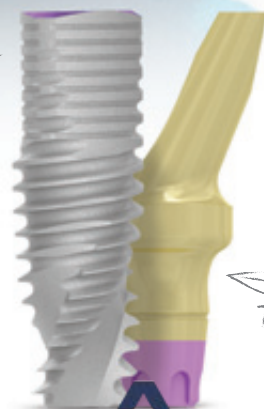
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04

اولین ایمپلنت آسیا و برنده مطمئن و نام آشنای جهانی در بازارهای بزرگ آمریکا، اروپا و استرالیا

05

تنوع بسیار بالای انواع فیکسچر و قطعات پروتزی برای طرح گزیننه های پروتزی

06

ایجاد یکی از بزرگترین مراکز آموزش ایمپلنت دنیا AIC به منظور تربیت ایمپلنتولوژیستهای شایسته و حرفه ای

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