Soft and hard tissue response to an implant with a convergent collar in the esthetic area: preliminary report at 18 months

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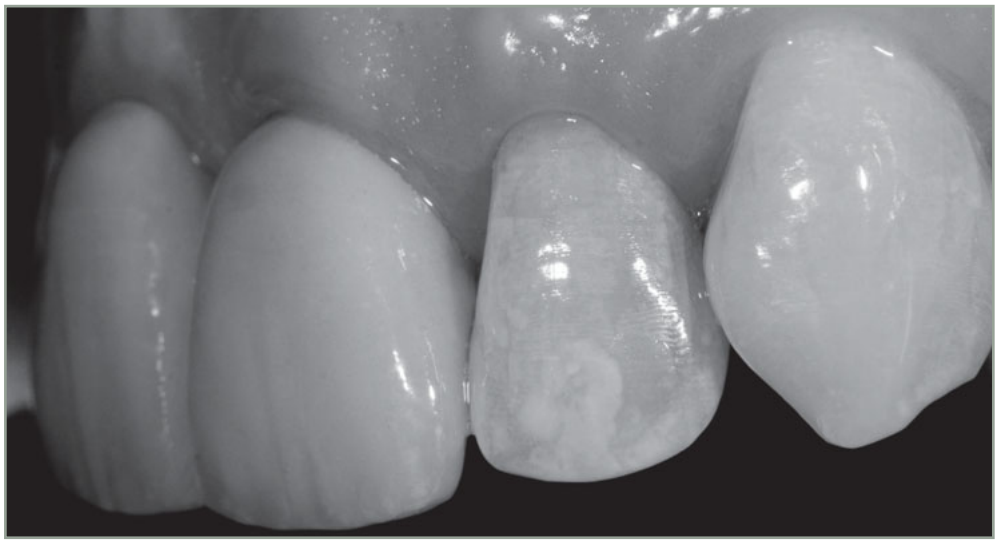

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Abstract

Aim: The purpose of this prospective cohort study was to investigate, over an 18-month period, soft and hard tissue response to a transmucosal implant with a convergent collar inserted in the anterior maxillary esthetic area.

Materials and methods: From June 2013 to January 2014, 14 consecutive patients were enrolled (7 men and 7 women; mean age 63.7 ± 14 years) with 20 implants, needing at least one implant-supported restoration between the canines in the maxillary anterior esthetic area. Six months after hopeless tooth extraction and an alveolar socket graft, a transmucosal-type implant with convergent collar walls was inserted in a midcrestal position with mini-flap surgery. An impression was taken 2 months later, and a definitive abutment with a provisional restoration was positioned. The final restoration was seated 2 weeks later. Clinical parameters, photographs, radiographs, and impressions were taken at this timepoint, and after 6 and 18 months. Using dedicated software, radiographic analysis (to detect marginal bone-level changes) and cast analysis (to detect soft tissue vertical and horizontal changes) were performed.

Results: At the 18-month follow-up, all implants were clinically osseointegrated, stable, and showed no sign of infection. At baseline, interproximal radiographs revealed no bone defect around the implant. After an initial minimal bone loss (0.09 ± 0.144 mm), radiographic analysis showed a stable condition of bone remodeling (mean value 0.09 ± 0.08; range 0.0 to 0.5 mm) at the 18-month follow-up. No statistically significant horizontal dimensional changes of the alveolar ridge were observed between each timepoint. Mean soft tissue levels significantly improved between baseline and 18 months. The mean heights of the mesial papilla (MP) and distal papilla (DP) changes were 0.38 ± 0.22 and 0.47 ± 0.31, respectively. The level of the labial gingival margin (LGM) was 1.01 ± 0.63. Periodontal parameters never exceeded the physiological levels.

Conclusions: Within the limitations of this preliminary study, the analyzed implants produced positive results in these esthetically demanding cases. This outcome should encourage long-term studies in order to assess, through controlled clinical trials, whether this convergent collar design offers advantages over other designs. Furthermore, due to the peculiar crestal module, together with the use of delayed implant insertion and a postextraction ridge preservation technique with biomimetic hydroxyapatite, the analyzed implants seem to help prevent the negative bone remodeling typically associated with two-piece implant systems, but without the well-known drawbacks of traditionally designed transmucosal implants. Therefore, wherever crestal bone preservation is a critical issue for clinical success in the anterior maxillary area can be considered of particular interest.

(Int J Esthet Dent 2017;12:306–323)

Introduction

The last 30 years have shown high success rates over time for implants in edentulous areas.[1] Today, replacing one or more missing teeth with implants is routine treatment for restoring proper function.[2] With predictable functional success widely reported in the literature, attention has increasingly turned to the management of periimplant tissue in the esthetic area. In fact, the maintenance of soft and hard tissue stability over time has become part of the long-term outcome assessment for implant-supported restorations in the esthetic area.[3] However, a variety of systemic and local factors are involved in the achievement of a successful clinical result.[4-6] Bone and soft tissue remodeling can also be influenced by surgical and restorative techniques and materials.[6]

One major aspect of early periimplant bone loss is the formation of a chronic inflammatory infiltration at the implant–abutment interface when a two-piece implant system is used.[7] To reduce the clinical impact of this phenomenon, different strategies have been attempted in order to move the microbiological contamination away from the vital bone; platform switching, the intention of which is to do this on the horizontal plane, has been demonstrated to be effective.[8]

A completely different approach was suggested by the soft tissue level implant concept, intended to relocate the implant–abutment interface and its associated bacterial infiltration above the crestal bone.[9] The implant design presented a smooth polished collar with a divergent profile, intended to interface the soft tissue and thus eliminate, de facto, a subgingival prosthetic interface. In fact, minimal (0.5- to 1-mm) bone level changes were noted, both around implants inserted in fully healed bone, and around postextraction sites.[9,10] The proven efficacy of this concept to preserve crestal bone loss in the esthetic area has been challenged.[11]

Zhao et al[12] have shown that transmucosal implants presented good longitudinal periimplant and esthetic outcomes; however, to prevent esthetic failures in the anterior zone, transmucosal implants were placed in a more apical position to hide the metal collar in the gingival thickness. This could lead to bone resorption around the subcrestal polished portion of the metal collar. Moreover, the divergent design of the collar (initially conceived for a screw-retained restoration) made it more difficult for the prosthodontist to manage the subgingival portion of the restoration.

Recently, a transmucosal implant with a convergent collar design was launched onto the market (Prama Implants, Sweden & Martina). In its peculiar design, the transmucosal component (2.8 mm in height) has a conical shape with a parabolic profile. When the corresponding tapered abutment is connected to the implant, the result resembles a tooth prepared with a feather-edge design with no finish line. This is in accordance with the principles of the biologically oriented preparation technique (BOPT),[13] where the margin of the crown is placed within the periimplant sulcus, and its emergence profile supports and shapes the gingival margin (Fig 1). In fact, this technique can be used for metal-ceramic or zirconia restorations, in which provisional cement can be used for defini-

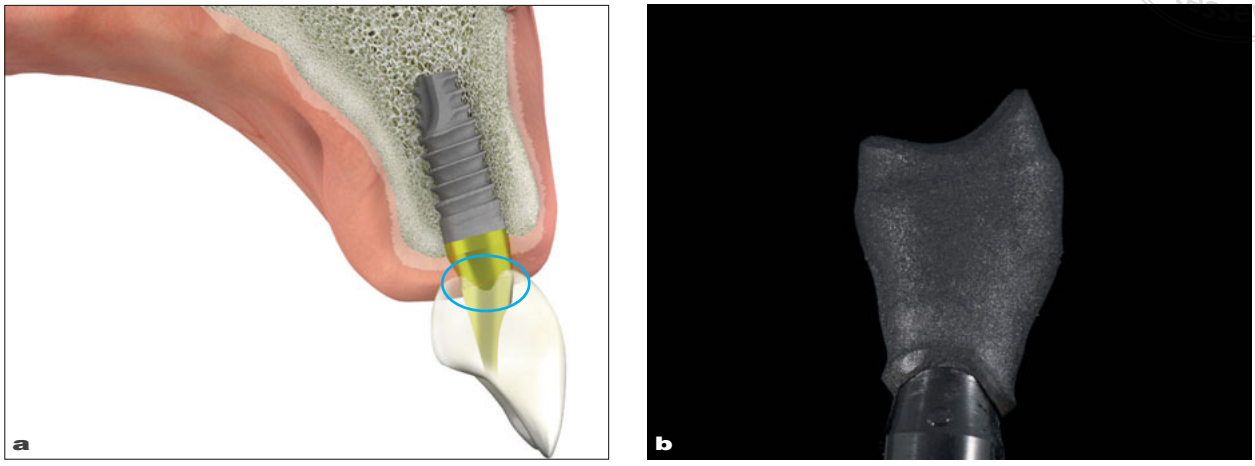


Fig 1 **(a)** Representative diagram of a convergent-necked implant, traditionally restored according to the BOPT approach (blue circle represents the implant–abutment interface), to better explain the different approach used in esthetically highly demanding cases. **(b)** Definitive metallic restoration showing the different vertical height of the finishing line in a case restored using the BOPT approach.

tive cementation. Full ceramic crowns should be cemented using a resin cement (this is controversial). The intrinsic risk of periimplantitis might suggest that a different approach should be taken in cases where full ceramic restoration is the only option.

The purpose of this prospective cohort study was to investigate the soft and hard tissue reaction over an 18-month period to a transmucosal implant inserted in the anterior maxillary esthetic area and restored with a full ceramic restoration. The null hypothesis was that periimplant soft and hard tissue shrinkage would be detected during the follow-up period.

This study is reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for improving the quality of observational studies (http://www.strobe-statement.org).[14]

Materials and methods

From June 2013 to January 2014, patients were selected who had presented at a private practice in Rome, Italy, needing an implant-supported restoration in the maxillary anterior esthetic zone between the canines. Inclusion/exclusion criteria are summarized in Table 1. The investigation was conducted according to the principles embodied in the Helsinki Declaration of 1964 for biomedical research involving human subjects, as amended in 2008. All subjects were informed about the study protocol and signed a consent form.

Clinical procedures

Hopeless teeth were extracted 6 months before implant placement, and postextraction sites were preserved using a magnesium-enriched hydroxyapatite

Table 1 Subject and study site inclusion and exclusion criteria

Subject inclusion criteria
Need for fixed implant-supported prosthesis in the anterior maxilla (from the maxillary left to the maxillary right canine)
Missing teeth extracted at least 6 months before surgery
Healthy periodontal conditions
Age > 18 years
No relevant medical conditions
Non-smoking or smoking up to 10 cigarettes/day (all pipe or cigar smokers were excluded)
Possibility for follow-up for 18 months after prosthetic loading
Specific subject and site exclusion criteria
Sites with acute infections
Pregnant and lactating patients
Sites needing a horizontal regenerative procedure
Patients with a history of bisphosphonate therapy

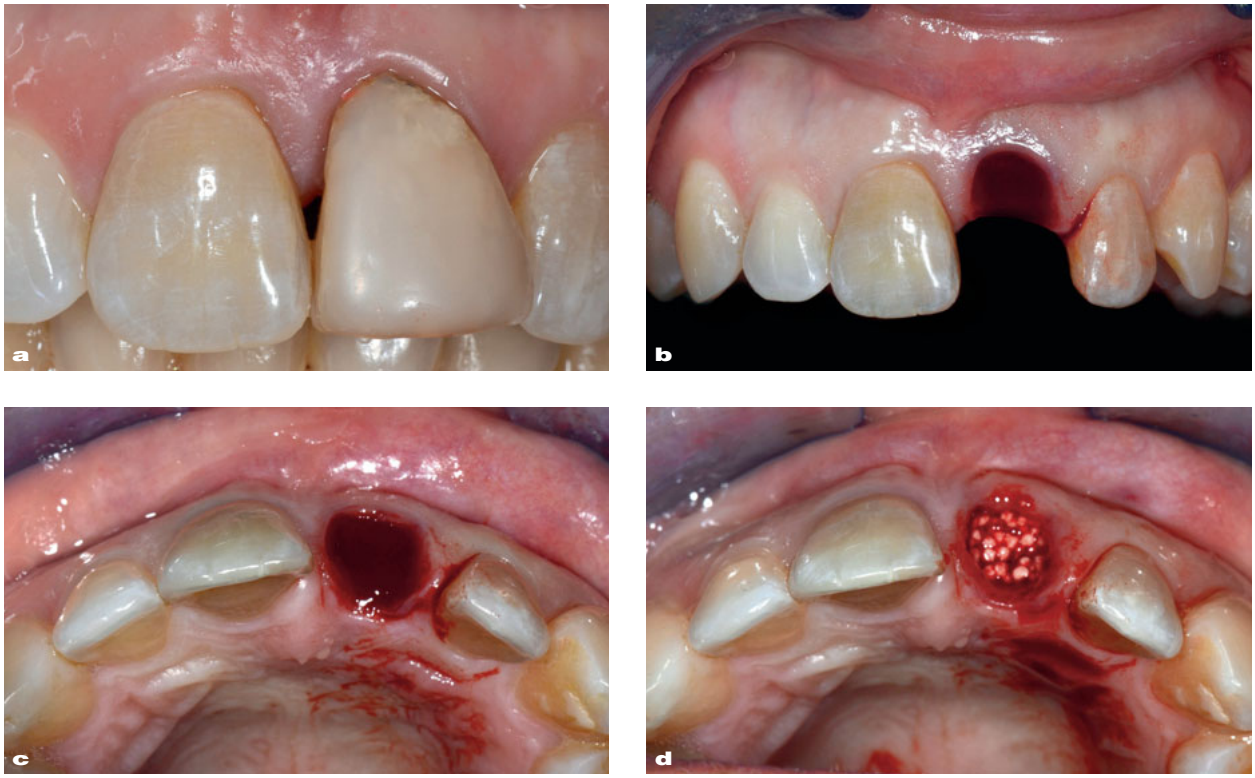


Fig 2 **(a)** Preoperative situation: The tooth was extracted due to a vertical fracture. **(b and c)** Buccal and occlusal views of the postextraction site. **(d)** Magnesium-enriched hydroxyapatite inserted in the postextraction site.

(Sintlife, Finceramica) according to Sisti et al[15] (Fig 2a to h).

Before the implant insertion procedure, cone beam computed tomography (CBCT) analysis was performed using a customized radiological stent. A full-mouth, professional prophylaxis appointment was scheduled 1 day preoperatively. Patients underwent antibiotic therapy according to the standard protocol.[12]

After a minimal flap elevation using a surgical guide, the implant site was prepared according to the manufacturer's specifications, and Prama implants of 13 mm in length and 3.8 mm in diameter were placed midcrestally (Fig 2i to q). This grade 4 cold-worked titanium implant presents a tapered body with a semi-rough surface, sandblasted with zirconia and acid-etched with titanium (Zir-Ti). Its threads present an asymmetric profile with a pitch of 1.00 mm and a depth of 0.40 mm. The apex, with its three notches for decompression and clot discharge, guarantees a very good penetration in the bone, as well as anti-rotationality and excellent primary stability. The transgingival neck is characterized by a machined (so-called "combed") surface and a straight cylindrical section 0.80-mm high, followed by a section with hyperbolic convergent geometry 2.00-mm high.

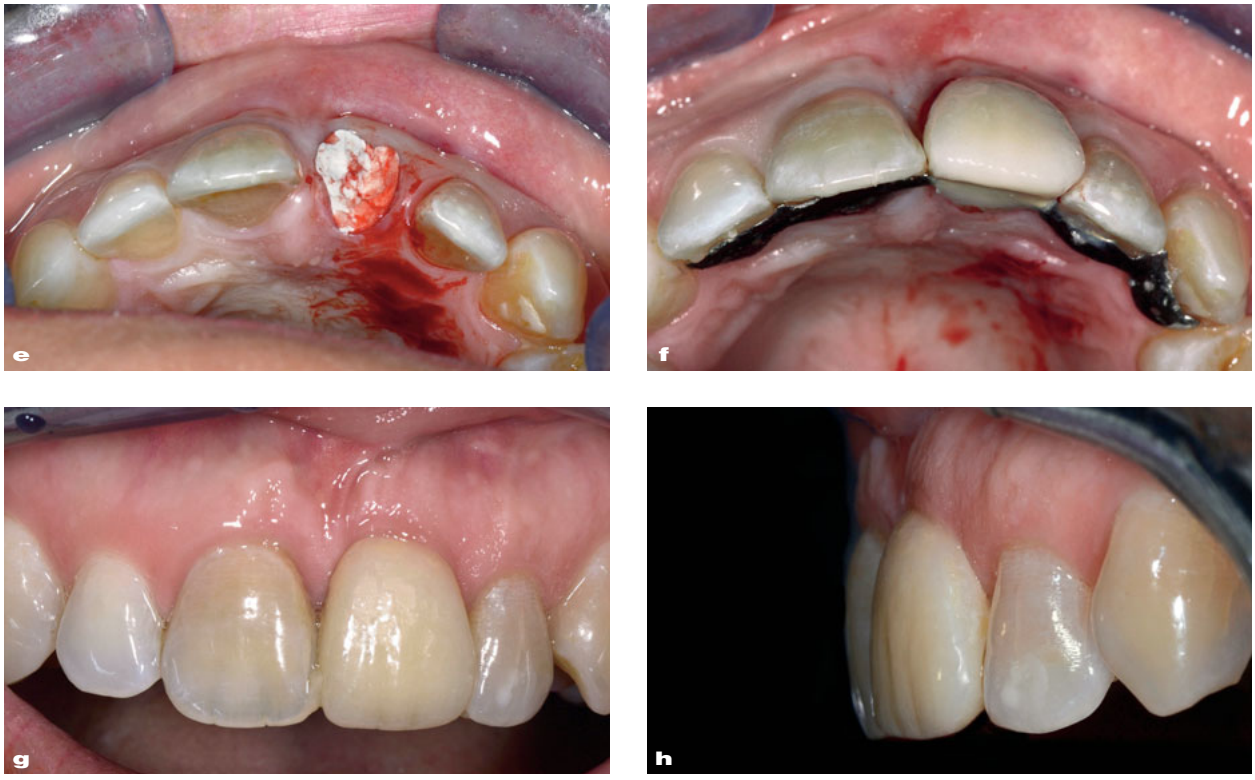
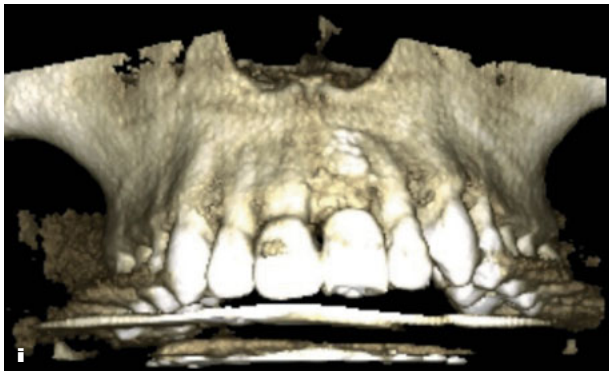
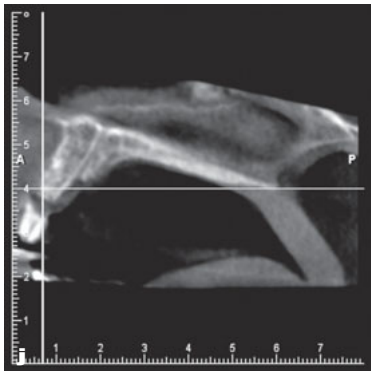
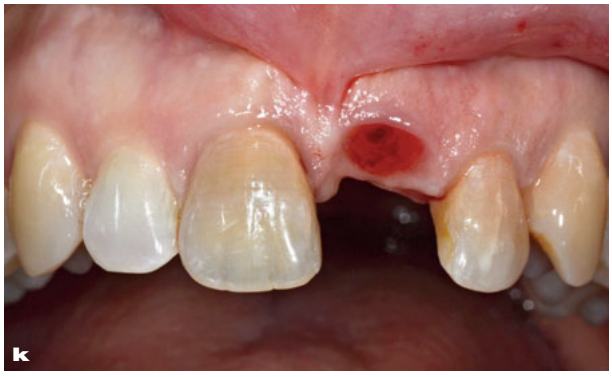
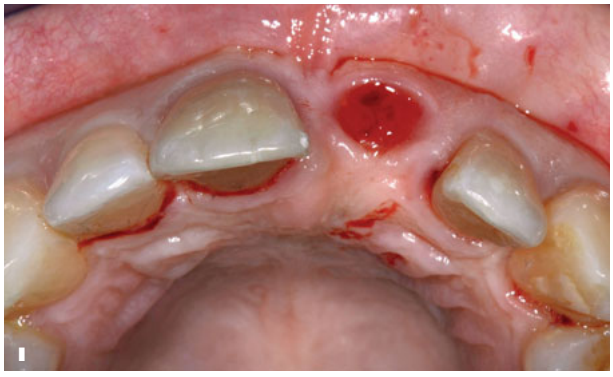


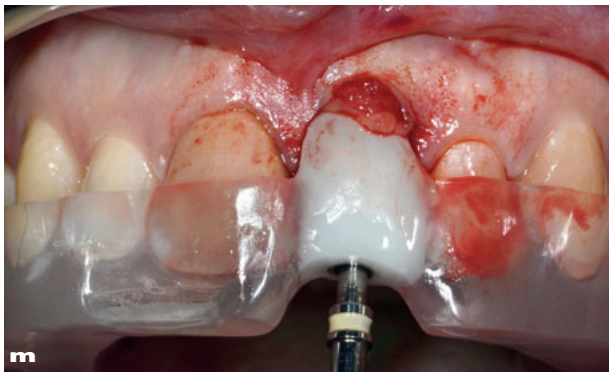
Fig 2 (continued) **(e)** Collagen sponge inserted to fill up the cavity. **(f)** Maryland bridge fixed to stabilize the graft material and prevent discomfort. **(g and h)** Frontal and lateral views showing the soft tissue healing.

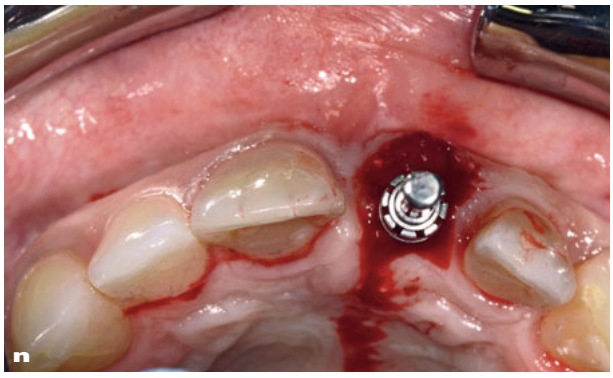












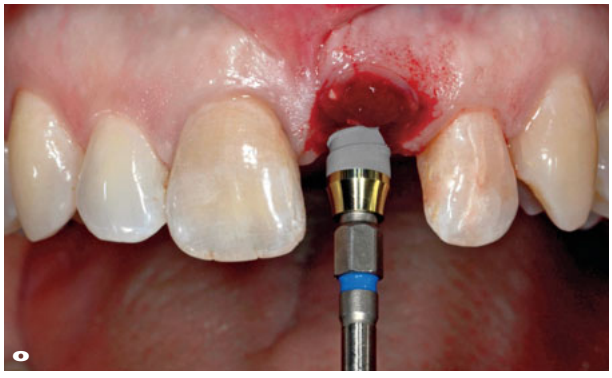
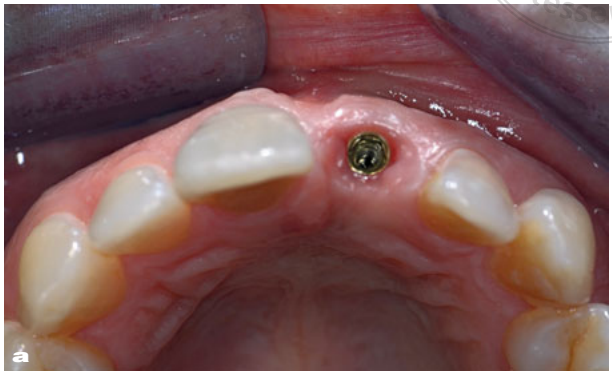
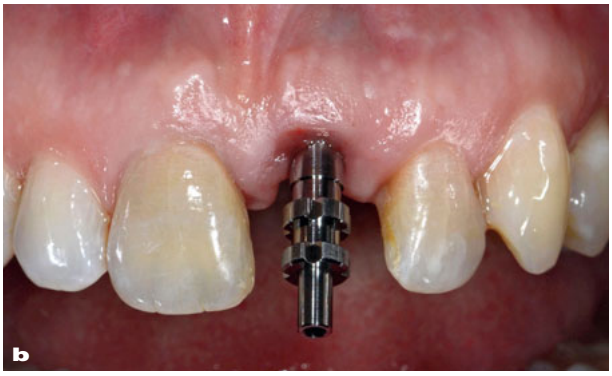


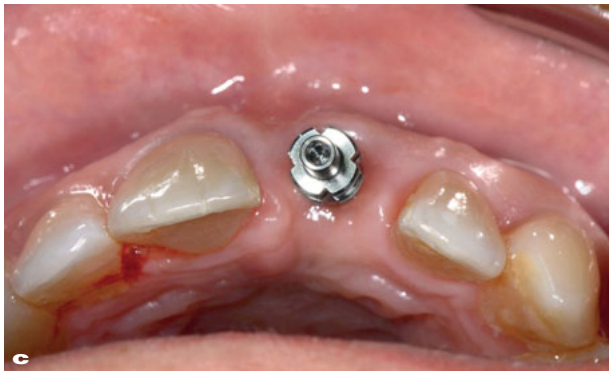
Fig 2 (continued) **(i and j)** Cone beam computed tomography (CBCT) analysis of the site before implant insertion. **(k and l)** Buccal and occlusal views of the site preoperatively. **(m)** Microflap overlapping the surgical guide with the first drilling bur. **(n)** Drilling bur highlighting the midcrestal, buccally inclined positioning. **(o)** Implant insertion. Note the convergent shape of the collar.

From a surgical point of view, the cylindrical section of the implant collar was placed vertically at the bone level, and horizontally only 1 mm away from the margin of the buccal bone wall. Monofilament 6.0 sutures were used, and soft tissue margins were adapted to the implant collar. The sutures were removed 2 weeks later, and an impression was taken (Fig 3) after a healing period of 2 months. Hence, a definitive abutment and a provisional restoration were delivered. The final abutment was duplicated in polyurethane resin following a specific laboratory procedure.[16] A resin coping for the transfer impression for the final restoration was also fabricated.

With the traditional BOPT approach, the crown conforms to the soft tissue contour. In the present study, however, an alternative restorative approach was followed in which the zirconia abutment was individually designed to make selective contact with the combed surface collar, displacing the soft tissue and interfacing with the metal-free restoration at a chamfer margin (Fig 4).[13,17] The purpose of this treatment choice was to demonstrate the prosthetic flexibility of the implant used in this study.







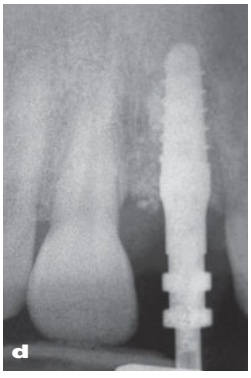


Fig 3 **(a)** Occlusal view of the implant connection at the time of impression taking. Note the midcrestal position. **(b and c)** Buccal and occlusal views of the impression taking with a pick-up transfer. **(d)** Radiograph confirming the fit between the implant connection and the impression transfer.

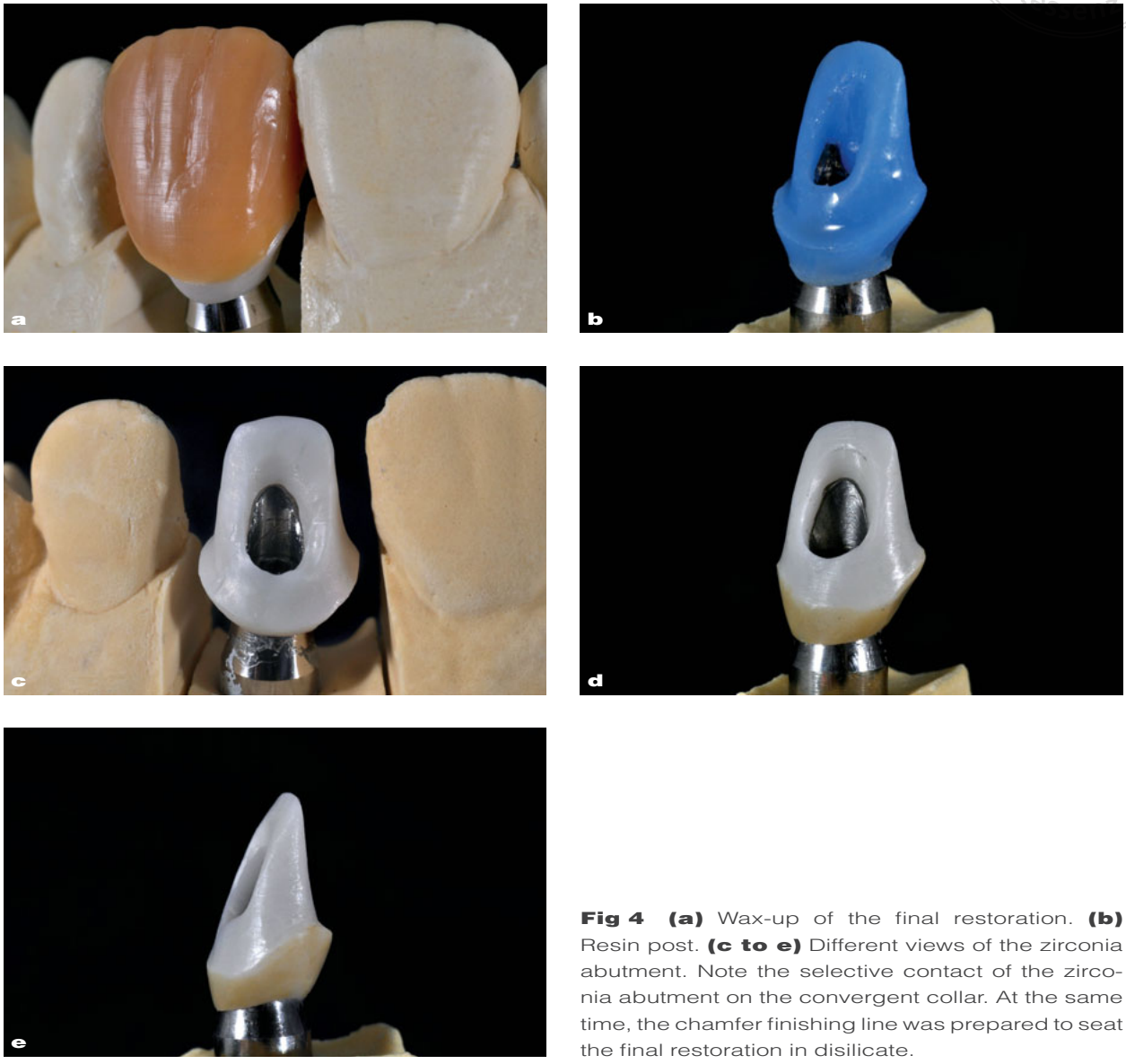
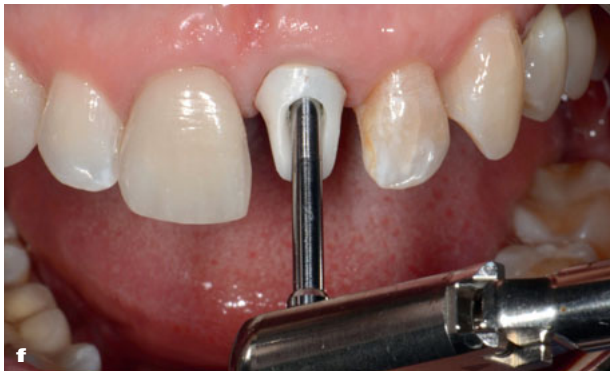
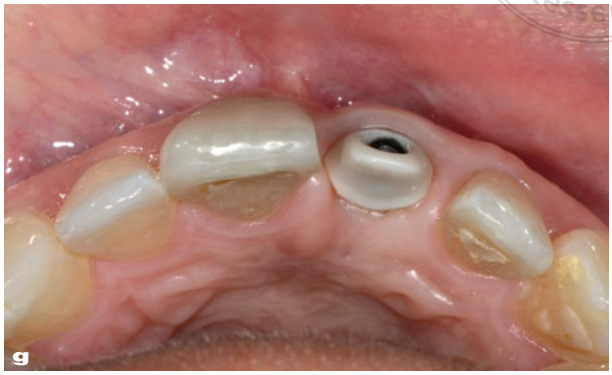


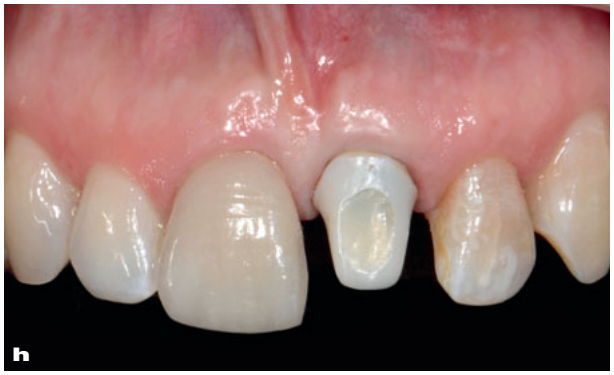
Fig 4 **(a)** Wax-up of the final restoration. **(b)** Resin post. **(c to e)** Different views of the zirconia abutment. Note the selective contact of the zirconia abutment on the convergent collar. At the same time, the chamfer finishing line was prepared to seat the final restoration in disilicate.

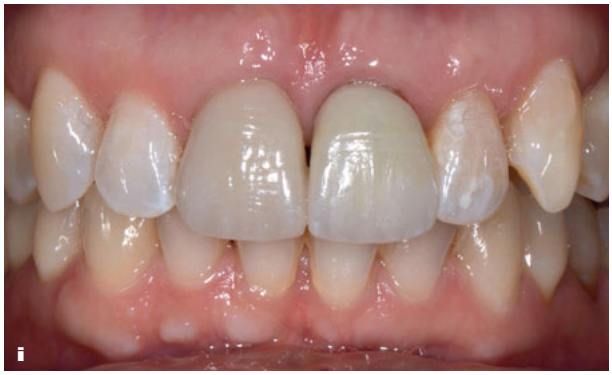
Standardized digital periapical radiographs using the paralleling technique and a picture with a millimetric reference were taken. These radiographs were used as a reference point (baseline: T_0) for the following radiographic evaluations.

A soft tissue impression was recorded 2 weeks later using the resin coping, and the final master cast was produced using the polyurethane duplicated abutment. The final crown was connected 1 week later, and the occlusal centric and eccentric contacts were finalized (Fig 5).









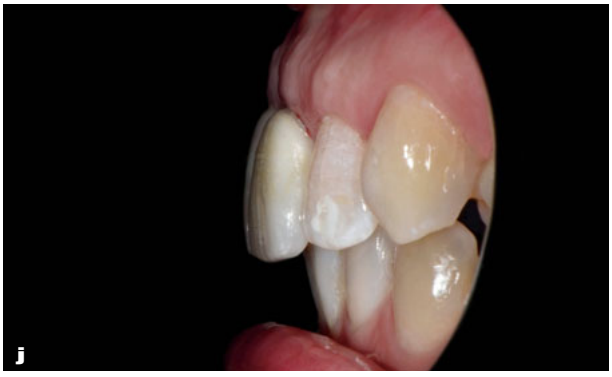
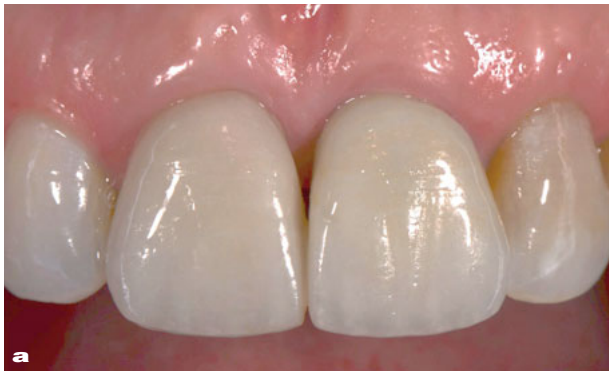


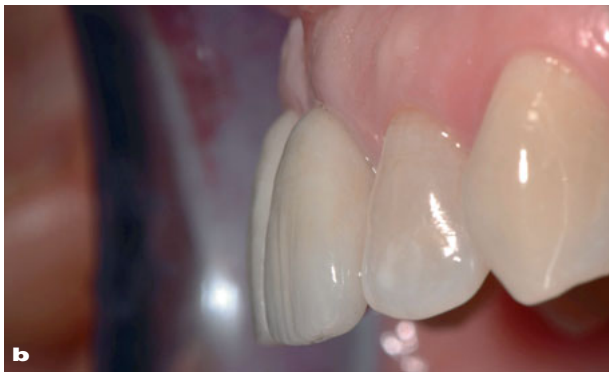
Fig 4 (continued) **(f)** Screwing of the final abutment at 32 N. **(g)** Occlusal view. **(h)** Frontal view with the screw hole filled with a composite inlay. **(i and j)** Frontal and lateral views of the provisional restoration.

Clinical follow-up

Clinical assessments were made (bleeding on probing: BOP; probing pocket depth: PPD). A frontal photograph, silicone impression, and periapical radiographs were taken before implant placement (T_0), at 6 months (T_1), 12 months (T_2), and 18 months (T_3) (Fig 6).

Radiographic analysis was carried out using dedicated image analysis software (Autocad 2006, version Z 54.10, Autodesk), which is able to compensate for radiographic distortions and calcu-





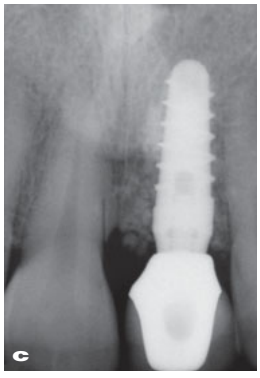
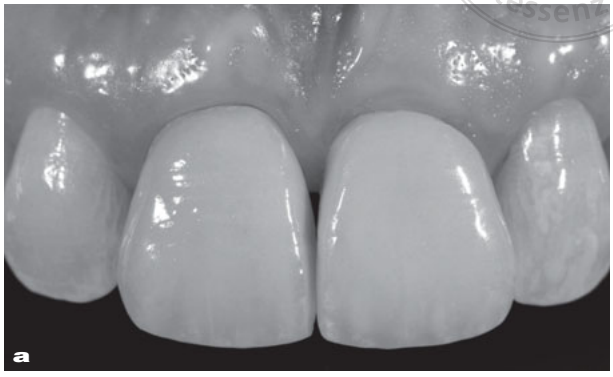
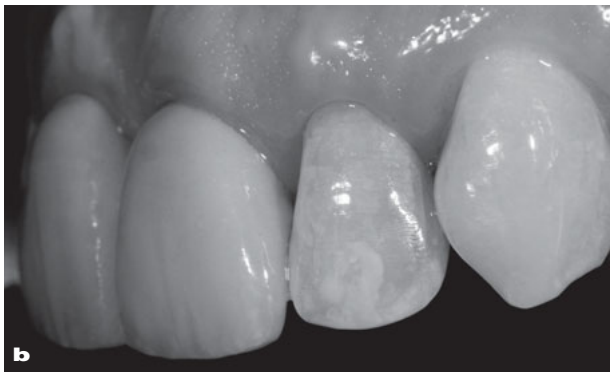


Fig 5 **(a and b)** Clinical, and **(c)** radiographic follow-up at T_1.





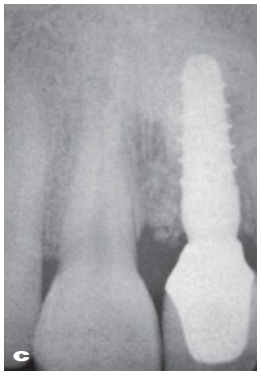


Fig 6 **(a and b)** Clinical, and **(c)** radiographic follow-up at T_3.

late periimplant bone remodeling at the mesial and distal aspects.[18] Bone resorption was measured using the smooth collar as reference: at T_0, T_1, and T_2.

Casts (CAM-base, Dentona) poured from vinyl polysiloxane impressions (Aquasil Putty DECA, and Aquasil Ultra LV/XLV Regular Set, both Dentsply) were taken at each timepoint. All the impressions were taken with anatomically customized light-curing acrylic impression trays (Elite LC Tray, Zhermack) fabricated onto a preliminary cast derived from an irreversible hydrocolloid impression taken with a stock metal impression tray. A conventional single-pouring tech-

nique was used, and the stone was vibrated into the impression (CAM base). The stone casts were allowed to set for 2 h before separation from the impressions. The casts were scanned using a CBCT scan (CRANEX 3D, Soredex) with a 1 mm copper filter. To perform all the measurements, the Digital Imaging and Communications in Medicine (DICOM) data were exported into the OnDemand3D software, (version 1.0.9.3223, Cybermed). Two superimpositions of the DICOM data were performed between T_0 and T_1, as well as between T_1 and T_3. The DICOM data were matched based on the adjacent teeth, and manually checked for a complete match using the Fusion adjunctive module (Cybermed). Horizontal dimensional changes were calculated on a two-dimensional (2D) section taken along the long axis of the implants, as the differences between the two superimposed casts. The horizontal ridge width was measured at three levels, localized 1, 3, and 5 mm below the most coronal aspect of the soft tissue, and named levels A, B, and C, respectively (Fig 7).

Comparison of the mean height of the mesial papilla (MP), the distal papilla (DP), and the level of the labial gingival margin (LGM) before tooth extractions (T_0) and after 18 months of function (T_3) were measured on the superimposed scanned casts after conversion to STL (STereoLithography) files (MeshLab 1.3.3 on MacOSX 10.9; http://meshlab.sourceforge.net). The incisal edges of the adjacent teeth were used as references. The changes in the MP, DP, and LGM of the implant restoration were evaluated by measuring its distance from the reference line; the direction of the meas-

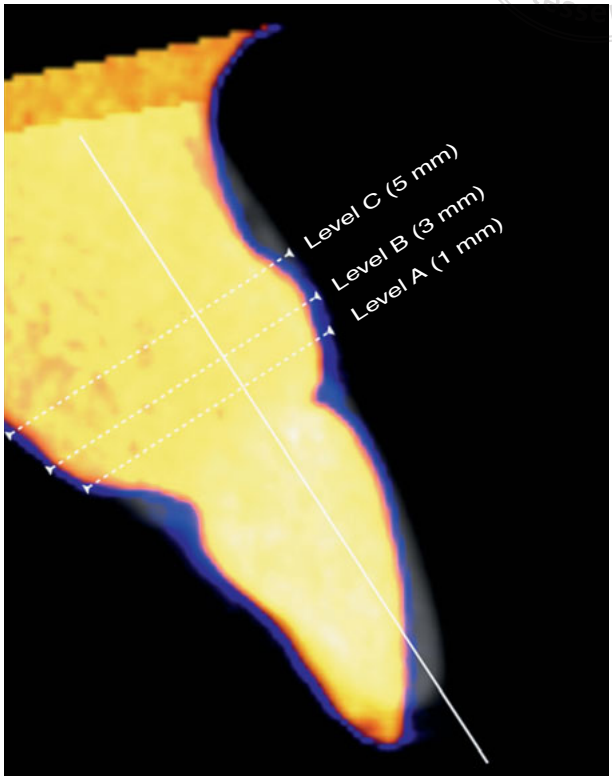


Fig 7 Horizontal measurements of bone volume changes calculated on three levels by the superimposition of the preoperative (pink – see Fig 8) and postoperative (gray – see Fig 8) casts, performed using unchanged anatomical areas (adjacent teeth).

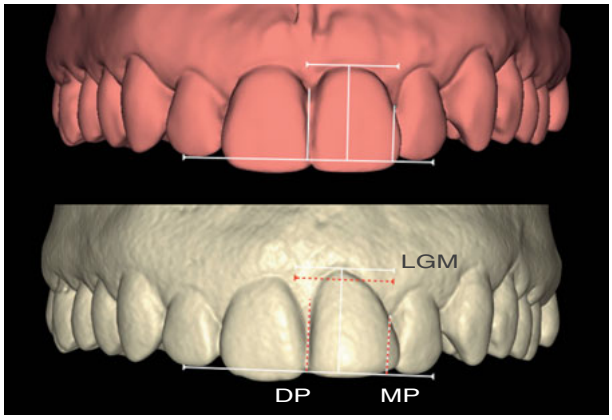


Fig 8 Comparison of mean height of the mesial papilla (MP), distal papilla (DP), and level of the labial gingival margin (LGM) between T_3 (above) and T_0 (below).

urement was parallel to the long axis of the reconstructed tooth (Fig 8).[19-21]

At each timepoint, the following periodontal parameters were recorded using a periodontal probe (PCP UNC-15, Hu-Friedy) on six surfaces per tooth (mesiobuccal, midbuccal, distobuccal, mesiolingual/palatal, midlingual/palatal, and distolingual/palatal):

- PPD, measured as the distance between the gingival margin and the deepest aspect of the pocket.
- BOP, recorded as the presence or absence of bleeding after the measurement of PPD.

All the measurements were evaluated by a blinded assessor who had not been previously involved in the study. A descriptive analysis was performed for continuous data using mean ± standard deviation (SD), median, and 95% confidence interval (CI) (SPSS for Mac OS X, version 22.0, SPSS). Comparisons between each timepoint were made for each group using the paired *t* test. All statistical comparisons were two-tailed, and conducted at the 0.05 level of significance. The patient was used as the statistical unit of analysis.

Results

At T_3, all the 14 consecutive patients (7 men and 7 women) with 20 implants completed the study. At the time of implant insertion, the patients ranged in age from 32 to 78 years (mean age: 63.7 ± 14 years). Only two patients included in the study were light smokers.

During the study follow-ups, all implants were clinically osseointegrated and stable, and showed no sign of infection.

Radiographic outcomes

At T_0, interproximal radiographs revealed no bone defect around the implants. At T_1, the postoperative interproximal radiographs revealed an average bone loss of 0.09 mm (range: 0.0 to 0.3 mm; SD = 0.144 mm). At T_3, the periapical radiograph showed a stable condition of bone remodeling (mean value: 0.09; range: 0.0 to 0.5 mm; SD = 0.08 mm; $P = 0.891$).

Esthetic outcomes

Between T_0 and T_1, differences in horizontal dimensional changes were 0.21 ± 0.23 (95% CI: 0.08 to 0.32 mm; $P = 0.56$) at level A; 0.23 ± 0.16 mm (95% CI: 0.03 to 0.33 mm; $P = 0.61$) at level B; and 0.05 ± 0.06 mm (95% CI: -0.02 to 0.14 mm; $P = 0.67$) at level C. Between T_1 and T_3, differences in horizontal dimensional changes were 0.06 ± 0.26 (95% CI: 0.02 to 0.28 mm; $P = 0.59$) at level A; 0.11 ± 0.14 mm (95% CI: -0.01 to 0.21 mm; $P = 0.68$) at level B; and 0.04 ± 0.08 mm (95% CI: -0.03 to 0.13 mm; $P = 0.72$) at level C. No statistically significant difference was observed between each timepoint ($P > 0.05$).

Mean soft tissue levels improved between T_0 and T_3. The mean heights of the MP and DP changes were 0.38 ± 0.22 and 0.47 ± 0.31, respectively. The levels of the LGMs were 1.01 ± 0.63. Statistically significant differences were observed between T_0 and T_3, with increased values at the last follow-up ($P < 0.05$).

Table 2 Differences in horizontal dimensional changes

	T_0 to T_1 (mm) (SD)	T_1 to T_3 (mm) (SD)	*P* value
Level A	0.21 (0.23)	0.06 (0.26)	0.59
Level B	0.23 (0.16)	0.11 (0.14)	0.68
Level C	0.05 (0.06)	0.04 (0.08)	0.72

Table 3 Vertical dimensional changes

	T_0 to T_3 (mm) (SD)	*P* value
Mesial papilla (MP)	-0.38 (0.22)	0.021
Distal papilla (MP)	-0.47 (0.31)	0.007
Labial gingival margin (LCM)	-1.01 (0.63)	< 0.000

The main results are summarized in Tables 2 and 3.

Periodontal parameters

For the duration of the study, BOP was not detected at any implant, and PPDs did not exceed 3 mm. Due to the aforementioned data, the null hypothesis was rejected.

Discussion

The aim of this prospective cohort study was to investigate the clinical and radiological performance of a new implant over an 18-month period for a convergent collar presenting in the esthetic area.

In the present study, following a correct implant insertion technique, soft and hard tissues remained tridimensionally stable even without any additive surgical procedure (soft or hard tissue graft).

The major clinical conclusion of this study is that this implant system might be used with good results in the esthetic zone following a surgical and prosthetic minimally invasive procedure.

To the best of our knowledge, at the time of writing this article, there were no other published studies comparing the esthetic outcomes using the same novel implant design. This makes it difficult to evaluate how the present results relate to other comparable studies.

In the present study, spontaneous soft tissue growth was observed 18 months after implant placement.

The main limitations of the present study were the small sample size and the short follow-up period. According to Kan et al,[20] favorable implant success rates and periimplant tissue responses can be achieved placing implants in the esthetic area; however, continuing recession of the facial gingival tissue may be observed over time.

In the esthetic area, the key to successful long-term treatment outcomes using dental implants is to preserve the facial bone wall dimensions and minimize crestal bone resorption over time.[5,22,23] Nevertheless, the reasons for crestal bone loss over time are multifactorial and remain highly controversial.[24-26] Several factors may contribute to buccal bone crest resorption, such as postextraction physiological changes,[27,28] biologic width establishment,[29,30] incorrect three-dimensional (3D) implant positioning,[5] implant neck designs,[31,32] and implant–abutment connection.[33]

However, the design of the crestal module plays a critical role in the overall success of an implant, particularly in the esthetic area.[31,32,34] The crestal module is that portion of a two-piece metal dental implant designed to hold the prosthetic components in place, and to create a transition zone to the load-bearing implant body, including the implant–abutment connection, the collar, and the more coronal portion of the abutment. Clearly, to better understand data from the present study, the impact of this alternative crestal module should be investigated.[35]

The studied implant system has been developed to transfer the concepts of the BOPT from the prosthesis on natural teeth to the cementable prosthesis on implants.[13] The esthetic advantages of the BOPT concepts on implants has been suggested when a feather-edge abutment design is used in traditional two-piece implant systems, while the control of periimplant residual excess cement (REC) has been analyzed in a randomized controlled clinical study.[17] A modified abutment design which limits the feather-edge portion to only the buccal side of the abutment has also been suggested as a method to further reduce the REC risk.

In the studied implant system, the transgingival neck is characterized by a straight cylindrical section 0.80-mm high, followed by a section with hyperbolic geometry 2.00-mm high, specifically designed to provide continuity with the abutment. The machined "combed" surface of the transgingival implant neck aims to facilitate the regrowth of the soft tissue around it. Furthermore, the complete absence of sharp edges may allow the mucosa to flow on the titanium without obstacles, and reach the adaptation profile established by the abutment–crown complex.

According to previously published randomized controlled trials, crestal bone remodeling can be reduced through the use of an implant with a back-tapered collar instead of straight or reverse conical ones, by reducing the outward pressure on the marginal soft tissue after implant placement.[32,36,37] The back-tapered implant neck design may also have minimized the surgical injury on the crestal bone, allowing for maximum bone volume around the implant neck and reduction of bone strain at the same time.[32]

Clinical studies assessing these aspects in the esthetic area are scarce.[38,39] Hence, there is a need to analyze the effects of these new developments with the aim of preserving crestal bone levels in esthetic areas. The reduction of such bone resorption could be an important factor in achieving good esthetic results in the maxillary anterior region, and in optimizing bone support.[31,40]

The correct positioning of an implant is one of the key factors in both long-term esthetics and function.[5,22,23] To achieve a well-designed restoration with optimal emergence profiles, it is optimal to position the implant in the ideal midcrestal position of the tooth to be replaced. However, according to previously published studies, a minimum buccal bone thickness of 2 mm (preferably 4 mm) is required to avoid losing bone height (Spray et al, 2000). For the latter, positioning the implant 1.5 to 2.0 mm more palatally than the expected buccal emergence profile at the gingival margin of the crown may help to reduce the risk of soft tissue recession.[20] Nevertheless, in order to achieve this amount of bone on the buccal side of the implant, soft tissue and/or bone augmentation may be needed, even if actual evidence remains inconclusive due to the lack of well-designed controlled clinical studies.[41-43]

From a surgical point of view, the Prama implant (with a convergent collar) allows for a midcrestal position of the implant, which is particularly helpful in the esthetic area. In fact, it was demonstrated that traditionally shaped implants with cylindrical or divergent collars need to be inserted slightly palatally to avoid hard and soft tissue recession and therefore esthetic failures. On the other hand, this approach very often produces a prosthetic restoration with an extended buccal offset. Despite no long-term problems being pointed out in the literature, this could make for more difficult plaque elimination. Together with the use of delayed implant insertion and the postextraction ridge preservation technique with biomimetic hydroxyapatite, the specific collar design of the implant used in the present study allowed for more buccal implant placement, avoiding hard and soft tissue compression.

In the authors' opinion, the most relevant factor involved in the virtual absence of periimplant crestal bone loss is the lack of an abutment–implant junction at bone level. With this implant design, the implant–abutment interface is located 2.8 mm above the bone level, and the bacterial infiltration traditionally associated with two-piece implant systems is completely absent.

Conclusions

Within the limitation of this preliminary study, the analyzed implants showed positive results in highly esthetically demanding cases following a minimally invasive surgical and prosthetic approach. These preliminary results encourage long-term studies to assess, in controlled clinical trials, whether this collar offers advantages over other designs. It can be speculated, in fact, that the absence of an implant–abutment interface at bone level eliminates the infiltration of chronic inflammation, with its associated crestal bone loss. At the same time, due to its convergent collar shape, as well as the use of delayed implant insertion and the postextraction ridge preservation technique with biomimetic hydroxyapatite, it might prevent esthetic failures due to incorrect implant positioning. In fact, in the anterior esthetic area, the peculiar shape allows for the insertion of the implant in a more correct midcrestal position.

Acknowledgments

The authors highly appreciate the skills and commitment of Dr Audrenn Gautier in the supervision of this study.

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