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ARTICLE; MEDICAL BIOTECHNOLOGY

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ABSTRACT

The aim of this multicentre prospective study was to evaluate the efficacy and safety of a surgical approach based on a novel osteotome technique, in order to obtain both alveolar ridge expansion and sinus floor elevation. Partially edentulous patients requiring an implant-prosthetic rehabilitation with a fixed prosthesis in the posterior maxilla were included in this study according to pre-established inclusion and exclusion criteria. All implants were placed after site preparation with the 'Alternating Osteotome Technique', which consists of the use of alternating concave and convex osteotomes. After a 4 to 6-month healing period, all implants were restored with a definitive fixed prosthesis. Clinical and radiographic examinations were scheduled over a 36-month follow-up of functional loading according to a well-established protocol. Statistical analysis was used to detect any significant differences or correlations ($P = 0.05$). Seventy-six patients were consecutively treated with a total of 120 implants in three different centres. The mean ridge expansion and sinus floor elevation were 1.8 ± 0.3 and 2.5 ± 0.7, respectively. After three years of functioning, the implant success rate was 99.1% since one implant had failed and the mean marginal bone loss was 0.6 ± 0.3 mm. No complications occurred during the intraoperative and postoperative periods. All parameters analysed were stable and steady throughout the three-year follow-up. The 'Alternating Osteotome Technique' enables the dental surgeon to achieve an adequate implant osteotomy with limited ridge expansion and sinus floor elevation, increasing modestly the vertical and horizontal dimensions of the alveolar crest but reducing significantly the risk of surgical complications.

Introduction

The loss of one or more teeth has always been a cause of bone resorption, which can be influenced by many factors such as age, gender, osteoporosis, diabetes, smoking, previous lost implants, type of prosthetic rehabilitation, time elapsing before implant rehabilitation and others.[1] The more time passes before implant rehabilitation, the less bone volume will be available for insertion of implants of sufficient length and diameter to ensure a high implant success rate.[2]

On the basis of Atwood's analysis [3] and Cawood and Howell's clinical classification,[2] it appears that resorption vectors differ according to the site. Specifically, maxillae undergo a progressive volumetric reduction and centripetal contraction of the arch: the outcome of this process consists of a class IV atrophic ridge in anterior areas and a class V atrophic ridge in posterior areas.[2,3]

Expansive techniques (split-crest technique, edentulous ridge expansion (ERE) and ridge expansion osteotomy (REO)) can be used in class IV maxillae for expanding the alveolar ridge. These techniques use bone elasticity and plasticity to widen the spongious space between the two cortical plates by means of intracortical osteotomy of the alveolar crest.[4−7]

Dislocative techniques (osteotome sinus floor elevation (OSFE)) can be used in class V maxillae for elevating the sinus floor. Some techniques use osteotomes to dislocate the bone under the sinus floor, while other techniques use burs to reduce bone and dislocate only the sinus membrane in order to increase the bone height available for implant placement.[8−13]

Malchiodi et al. [13,14] proposed the technique based on the use of alternating concave/convex

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osteotomes with variable conicity in an attempt to increase implant success rates in atrophic maxillae. This technique of manual osteotomic preparation of implant sites involves a system based on two kinds of working spikes that cause two vector compression forces apically and surrounding the implant site in order to achieve both alveolar ridge expansion and sinus floor elevation.

The aims of the present study were (1) to measure the clinical horizontal ridge expansion and radiographic vertical sinus elevation, obtained by means of this surgical approach, (2) to assess its safety, reporting intraoperative and postoperative complications and (3) to evaluate its efficacy in terms of implant success rate and marginal bone loss after a three-year follow-up.

Materials and methods

Study design

The patients chosen for treatment with the 'Alternating Osteotome Technique' (AOT) were referred over the period from July 2007 to July 2009 for an implant−prosthetic rehabilitation with a fixed prosthesis in the posterior maxilla in three different centres.

All patients had advanced alveolar bone resorption in the posterior areas of the maxilla, which had to be treated by implant placement. They had been advised that they were not candidates for long or wide implants without extensive preparatory implant site development, because of insufficient alveolar ridge height and width.

However, all sites had an alveolar ridge volume of at least 5.0 × 3.5 mm which is considered mandatory for performing AOT in order to have a low risk of buccal dehiscence or sinus perforation.

The decision to use a novel technique was made after discussion with the patients and after obtaining their informed written consent. The following criteria were used to select the patients in whom successful results could be achieved with this type of surgical technique:

- inclusion criteria: partial edentulism, need of an implant-supported fixed prosthesis in the posterior maxilla, residual bone volume of at least 3.5 mm in width and 5.0 mm in height, highly controlled oral hygiene, absence of acute infection in the oral cavity and willingness to participate in an oral hygiene maintenance programme;
- exclusion criteria: insufficient bone volume, bruxism, smoking more than 10 cigarettes/day, abuse of alcohol, radiotherapy in the maxillofacial district, chemotherapy, liver disease, blood disease, kidney

disease, inflammatory and autoimmune disease, immunodepression, corticosteroid therapy, pregnancy and insufficient oral hygiene.

Treatment was performed in three centres − the Department of Morphological and Biomedical Sciences, Section of Dentistry and Maxillofacial Surgery, University of Verona and two private offices. All three centres provided details of all implants placed after site preparation with AOT in partially edentulous patients.

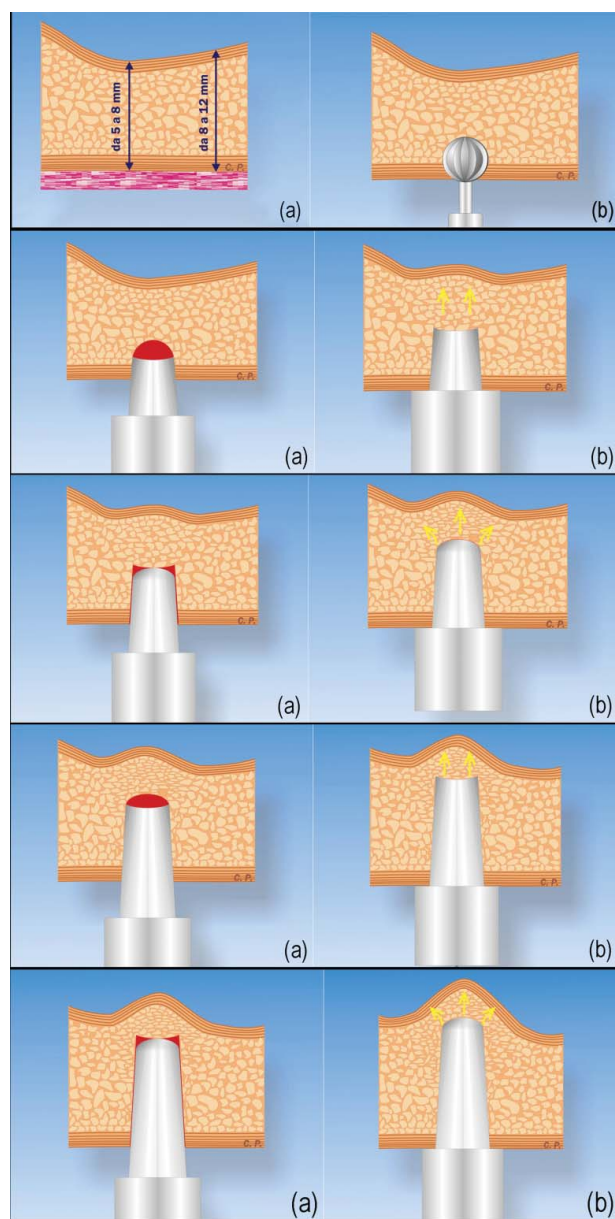### Osteotome surgical kit and surgical technique

The AOT is based on the use of 11 alternating osteotomes with variable conicity (Bontempi Medizintechnik GmbH, Tuttlingen, Germany), 8 initial osteotomes with a tapered design and 3 corrective osteotomes, one for 5 mm diameter implants and two for cylindrical implants. The eight initial osteotomes have alternating concave and convex spikes, with the same 2.5 mm apical diameter, but different conicity; they are between 4 and 13 mm in length, with 1.5 mm spacing from one to the next. The spikes and working bases have a constant diameter, while the difference between the devices lies in their lengths. The various lengths cause a progressive conicity of the osteotomes, with each device having greater conicity than the previous one in the sequence. Therefore, this system should be used when tapered and cylindrical 8−13 mm implants are to be placed.

Osteotome characteristics are reported in Table 1.

The operative sequence is as follows: a rose-headed bur (2 mm in diameter) is used up to its working range limit to create a generous pathway for the first osteotome. Since a 2 mm bur needs at least 1 mm of vestibular and palatal bone, the minimum thickness required for the use of this technique is 4 mm. If there is an hourglass-shaped crest with clear vestibular resorption, a progressive axial correction can be performed. The osteotomes should be used sequentially to create an adequate osteotomy according to implant size (Figure 1).

Table 1. Osteotome characteristics.

Device number	Concave spike	Convex spike	Length (mm)	Apical diameter (mm)
No. 1	x		4.0	2.5
No. 2		x	5.5	2.5
No. 3	x		7.0	2.5
No. 4		x	8.5	2.5
No. 5	x		10.0	2.5
No. 6		x	10.0	2.5
No. 7		x	11.5	2.5
No. 8		x	13.0	2.5
5 mm corrector		x	10.0	3.1
Cylindric corrector No. 1	x		13.0	3.0
Cylindric corrector No. 2		x	13.0	3.0

Figure 1. Alternating Osteotome Technique: (a) initial position; (b) final position.

Surgical and prosthetic protocols

Each patient was evaluated clinically and radiographically to choose the correct treatment planning: orthopantomography and peri-apical X-rays were used as a primary radiographic examination to evaluate baseline bone height available for implant surgery, while computed tomography, in the dentascan mode, was performed in all cases of alveolar atrophy in order to accurately evaluate bone height and width. A clinical examination was carried out aimed at evaluating oral hygiene, tissue health, keratinized mucosa, residual tooth stability and many other factors capable of influencing treatment planning.

Local anaesthesia was administered with articaine + adrenalin 1:100.000 in the site of intervention; and articaine + adrenalin 1:200.000 in other sites. A full-thickness mucoperiosteal flap was raised and implant sites were prepared using a 2 mm rotating bur and alternating osteotomes with variable conicity, as described by Malchiodi et al. [14] No graft biomaterial was used during implant site osteotomy.

Implants (Biotec BTK, Povolaro di Dueville (VI), Italy; Biomet 3i, Palm Beach Gardens, FL, USA) were placed using a 'two-stage delayed function' approach, as described by the manufacturer. It is necessary to install the implant in the osteotomy site using low speed (25 rpm) and 30−45 Ncm torque, turning the implant until it is fully inserted; a cover screw is then positioned on the implant using a screwdriver; finally, the mucoperiostal flap is re-positioned and sutured in a tension-free manner to ensure first intention healing and better osseointegration of implants.

During the first 7 days, patients were instructed to observe a fluid diet; while during the next 15 days, patients were instructed to observe a soft diet and good oral hygiene. Chlorhexidine 0.2% three times daily was recommended. Patients used no removable prostheses with mucosal support in the operation site. Occasionally, a provisional tooth-supported fixed prosthesis was used.

The initial healing period ranged from 4 to 6 months depending on the clinical circumstances and the treating clinician's preference. A temporary healing abutment is then positioned on the implant to achieve adequate peri-implant soft tissue healing. After achieving correct soft and hard tissue healing, implant-supported prostheses were created.

All definitive restorations were placed in occlusion, where the occlusal surface was thoroughly modelled so that it was in contact with reduced areas during laterality and protrusion excursions, in order to reduce the dislocating vectorial components; several contacts were maintained in maximum intercuspation.

The patient was included in a maintenance programme to achieve optimal hard and soft tissue healing, which comprised of professional oral hygiene every six months and rinsing twice daily with chlorhexidine digluconate 0.2% during the first two weeks.

Clinical evaluation was performed monthly during the first six months after definitive restoration. Further checks were performed every 6 months and consisted of analysis of soft tissue health (modified plaque index (mPI), modified gingival index (mGI) and bleeding on probing (BOP)) and evaluation of the probing pocket depth; radiographic examination with intra-oral radiographs was performed every 12 months after definitive restoration.

Data collection

A clinical examination was carried out aimed at evaluating the presence of chronic or aggressive periodontitis; the presence of parafunctional habits (bruxism or clenching); gingival biotype (thick or thin), via visual assessment and assessment with a periodontal probe, as described by Kan et al. [15]; mPI, as described by Abraham et al. [16]; mGI, as described by Lobene et al. [17] and BOP, as described by Tagge et al. [18] For each implant, the authors recorded implant length; implant diameter and implant site (first premolar, second premolar, first molar and second molar).

During implant surgery, the width of the alveolar ridge was measured clinically prior to the osteotomy and after implant placement in order to evaluate the initial and final width; buccal−palatal ridge expansion was indicated as the difference between final and initial ridge widths. Similarly, the height of the alveolar ridge was measured radiographically prior to the osteotomy and after implant placement in order to evaluate the initial and final heights. Vertical sinus floor elevation was indicated as the difference between final and initial ridge heights. All these measurements were carried out using a Castroviejo caliper with a 1 mm graduated scale and were rounded off to the nearest 0.5 mm; similar measurements were obtained at re-opening surgery to evaluate bone stability.

Crestal bone level was measured at baseline, at the 12-month follow-up, at the 24-month follow-up and at the 36-month follow-up for each implant, considering the first contact point at the bone−implant interface.

All radiographs of implants from each subject's 36-month recall visit were reviewed independently by an oral radiologist at a magnification of $6\times$ for the measurements of marginal bone level. This was assessed mesially and distally by identifying the lowest observed point of crestal bone intimate contact with the implant, and compared to the level at baseline to quantify marginal bone loss. Both measurements were rounded off to the nearest 0.1 mm with the aid of a seven-fold magnifying lens. A peak scale loupe with a seven-fold magnifying factor and a 0.1 mm graduated scale were used, as described by Degidi et al.[19]

Finally, both intraoperative and postoperative complications were recorded: the former included sinus perforation, cortical bone fracture, implant dehiscence, implant fenestration and incomplete osteotomy, and the latter, benign paroxysmal positional vertigo (BPPV), wound dehiscence, persistent pain, sinusitis, rhinorrhoea and nasal obstruction. Other implant−prosthetic complications, such as screw fracture, screw loosening or implant failure, were recorded postoperatively up to the 36-month follow-up examination.

Follow-up and success evaluation

All patients were recalled every six months as a part of their routine oral hygiene programme. A clinical and radiographic examination was scheduled after the implant surgery, after four or six months of healing, at the time of prosthetic rehabilitation and every six months (radiographic examination every 12 months) until the 36-month follow-up visit, according to a well-established protocol generally used to determine implant success. Implant success was defined according to the criteria suggested by Buser et al. [20] and modified by Albrektsson and Zarb,[21] including: (1) absence of persistent pain or dysaesthesia or paraesthesia in the implant area; (2) absence of peri-implant infection with or without suppuration; (3) absence of perceptible mobility of the implant and (4) absence of persistent peri-implant bone resorption of >1.5 mm during the first year of loading and 0.2 mm/year during the following years.

The implants were considered successful in the presence of all of the above-mentioned criteria at the most recent follow-up appointment. Clinical complications such as pain, dysaesthesia or paraesthesia were assessed by interviewing the patients. Peri-implant infection with or without suppuration and implant mobility were assessed by clinical observation and pressure. Radiographic complications such as excessive peri-implant bone resorption or radiolucencies were assessed with peri-apical X-rays.

Results and discussion

In total, records were analysed for 120 implants in 76 subjects (aged 31−68 years; 41 females and 35 males), who needed to restore a partial edentulism in the posterior maxilla. The University Center contributed 60 implants in 38 subjects (33 in molar sites and 27 in premolar sites). Private office 1 (Mantova, Italy) contributed 32 implants in 20 subjects (20 in molar sites and 12 in premolar sites), performed by an oral surgeon; and private office 2 (Brescia, Italy) contributed 28 implants in 18 subjects (16 in molar sites and 12 in premolar sites), performed by an oral surgeon. Two patients (3 implants) dropped out during the follow-up period.

According to length, 8.5, 10, 11.5 and 13 mm long implants were used in 28.3% ($n = 34$), 30.9% ($n = 37$), 22.5% ($n = 27$) and 18.3% ($n = 22$) of cases, respectively; according to the diameter, 4 and 5 mm implants were used in 65.0% ($n = 78$) and 35.0% ($n = 42$) of cases, respectively.

One implant had failed because of excessive crestal bone loss, during the three-year follow-up: 116 out of 117 maxillary implants fulfilled the previously established

success criteria, giving a 99.1% implant success rate. As a result, the prosthesis survival rate was 100% because the failed implant was still in function.

The mean dimensions of the alveolar ridge before surgery were 4.6 ± 0.8 mm in width and 8.5 ± 1.9 mm in height; after AOT, the mean width and height of the alveolar ridge were 6.4 ± 0.9 and 11.0 ± 1.8 mm, respectively. The mean horizontal ridge expansion and vertical sinus elevation were 1.8 ± 0.3 and 2.5 ± 0.7 mm, respectively, which correspond to 39.1% and 29.4% augmentation compared to the initial dimensions. The differences between alveolar ridge dimensions before and after AOT were statistically significant ($P < 0.05$).

The mean crestal bone level at baseline was 0.5 ± 0.4 mm, while the mean crestal bone level value at the three-year follow-up was 1.1 ± 0.5 mm. Analysis of crestal bone levels revealed a mean marginal bone loss during functional loading of 0.6 ± 0.3 mm. Four implants (3.4%) presented no bone resorption; most implants ($n = 75$) (64.1%) showed bone resorption ranging from 0.1 to 0.5 mm; twenty-seven implants (23.1%) presented bone losses ranging from 0.6 to 1.0 mm; seven implants (6.0%) between 1.1 and 1.5 mm and only three implants (2.6%) showed bone loss up to 1.6 mm. None of the osseointegrated implants showed a marginal bone loss of more than 2.1 mm, with the exception of the failed implant.

The baseline clinical values for mPI, mGI and BOP were 0.4 ± 0.2, 0.5 ± 0.2 and 0.4 ± 0.2 mm, respectively. At the 36-month follow-up evaluation, statistically significant reductions in mGI and BOP were recorded compared to baseline ($P < 0.05$). The 36-month follow-up clinical values for mPI, mGI and BOP were 0.4 ± 0.2, 0.4 ± 0.2 and 0.2 ± 0.1 mm, respectively.

Three cases of intraoperative complications were recorded: the first was a sinus perforation (0.9%) in a patient with a residual bone height of 5.5 mm and the other two were cortical bone fractures (1.7%) after implant placement in patients with a residual bone width of 3.5 mm. No postoperative complications, such as BPPV, wound dehiscence, acute or chronic sinusitis, were reported. Finally, only one case of screw fracture (0.9%) and two cases of screw loosening (1.7%) were observed during the 36-month follow-up.

The AOT was introduced in 2003 after analysis of implant positioning risk factors in atrophic maxillae, which are often deficient in bone width and height.[13]

All osteotomes present a wide stop at the basis of the working spike as well as progressive working spike conicity. These structural characteristics facilitate osteotome insertion in sequence: each osteotome is inserted passively via a path corresponding to the osteotomy created by the previous device and continues the osteotomic action for only 1.5 mm, i.e. the difference in length between one osteotome and the next. It is sufficient to manually rotate the device clockwise with a slight push to allow the latter to go deeper until reaching the mechanical stop, thus, reducing the risk of maxillary sinus perforation. Additionally, the osteotome design is extremely useful for achieving the apical and buccal dislocation of alveolar bone, gradually increasing the depth and diameter of the implant site.[14]

In the present study, the use of AOT made it possible to achieve both alveolar ridge expansion and sinus floor elevation, with over a 25%−30% increase compared to original bone volume. The increase in width is rather small in comparison to ERE techniques or similar split-crest techniques, which yield a horizontal expansion of about 25%−80%.[22,23] Similarly, the increase in height is low in comparison to other OSFE techniques, which permit a vertical augmentation of about 30%−90%. [8,11,24,25]

As regards the sinus floor elevation effect of AOT, it is clear that the amount of vertical bone gain was smaller than that reported in other studies, where transcrestal sinus floor elevation was achieved by means of osteotomes and burs plus autogenous bone and graft biomaterial (6.75 mm),[26] osteotomes plus deproteinized bovine bone mineral (DBBM) (6.9 mm) [27] or osteotomes and burs plus synthetic hydroxyapatite or DBBM (7.70 and 6.50 mm, respectively).[28]

However, the majority of studies where sinus elevation was performed by means of the use of osteotomes alone or combinations of osteotomes and burs, with or without graft material, reported a mean vertical bone gain lower than 5 mm.[29−37]

AOT makes it possible to minimize the risk of intraoperative and postoperative complications, creating an adequate implant site for the placement of a conventional-sized implant. The conical conformation of the spikes, the alternation of apical concavity and convexity, the wide stop and the comfortably sized handle eliminate the need to use a hammer percussively, thus, reducing the risk of BPPV and sinus perforation.

OSFE is considered a predictable technique that makes it possible to achieve an increase in bone height and successful results similar to those of conventional implants.[25] However, sinus perforation is the most common complication of maxillary sinus surgery.[38,39] The force applied should be sufficient to fracture the sinus cortical floor but restrained enough to prevent the osteotome tip from traumatizing the Schneiderian membrane, although tapping the remaining bone of the sinus floor carries a risk of perforation of the sinus membrane. [39]

Garbacea et al. [40] conducted an *ex vivo* investigation of the occurrence of sinus membrane perforation

during surgery utilizing three different transcrestal sinus floor elevation techniques; they reported high rates of sinus perforation. Although an endoscopic study has revealed that the sinus floor may be elevated by anything up to 5 mm without perforating the sinus membrane, [41] other studies have demonstrated the risk of membrane perforation while performing transalveolar sinus floor elevation of more than 4 mm.[42,43] Lai et al. [44] have published a randomized clinical trial comparing OSFE with and without graft materials, reporting membrane perforation rates of 7.8% and 2.6%, with mean residual bone heights of 4.7 and 5.6 mm, respectively.

BPPV is another common complication of OSFE. It consists of a high-prevalence, vestibular end organ disorder due to the detachment of the utricular otoconia floating in the posterior or lateral semicircular canal. Di Girolamo et al. [45] reported a BPPV rate of 2.7% as a complication of OSFE: the authors hypothesize that the surgical trauma, and specifically the pressure exerted by the osteotomes and mallet, cause the detachment of the otoliths from the utricular macula, while the patient's head position, hyper-extended and tilted to the side opposite to the one where the surgeon is working, which favours the entry of these free-floating particles into the posterior semicircular canal of the implanted side. Pennarocha et al. [46−48] reported high rates of patients affected by BPPV after the use of osteotomes and mallet for sinus floor elevation and recommended that particular care be taken when using these devices in order to avoid BPPV, although this complication is a benign, self-limiting peripheral disorder that is promptly solved by means of the Epley re-positioning manoeuvre. Sammartino et al. [49] in a randomized controlled trial demonstrated that the use of osteotome and mallet for closed sinus floor elevation and implant site preparation is associated with a higher risk of BPPV compared to the use of manual or screwable osteotomes; the authors observed a BPPV rate of 3.1% for the mallet osteotome group and a BPPV rate of 0% for the screwable group. In the present study, one case of sinus perforation (0.9%) and no cases of BPPV (0%) were reported, indicating the safety of the AOT. Further randomized controlled studies are needed, however, to demonstrate its safety definitively.

As regards the ridge expansion effect of AOT, the amount of horizontal bone gain was smaller than that reported in other studies, where ERE was achieved by means of original ERE (3.5 mm),[50] the split-crest technique with ultrasonic bone surgery (2.8 mm),[22] the split-crest technique plus autogenous bone and graft biomaterial (4.8 mm),[51] the extension-crest device (3.9 mm) [52] or the two-stage split-crest technique (7.1 mm).[23,53]

However, AOT reduces the risk of intraoperative complications, such as cortical plate fractures, and makes it easier to prepare an adequate implant site without the use of split-thickness flaps, sagittal osteotomy and graft biomaterials.

Strietzel et al. [54] showed that REO was associated with 22% rate of cases with a buccal cortical plate fracture and that the risk of fracture was significantly higher in class II bone. Guided bone regeneration (GBR) with a non-resorbable membrane was used to achieve bone augmentation and implant osseointegration.

Ferrigno and Laureti [51] proposed a novel implant design in order to reduce the risk of fracture of the labial cortical plate during the last two steps of the split-crest technique: (1) implant site preparation and (2) implant insertion. Nevertheless, the authors observed that buccal plate fracture occurred in 5% of cases, in which removal of the cortical plate was required in order to perform a GBR technique with minced autogenous bone plus graft biomaterials. This complication could compromise the osseointegration of the implants, as highlighted by the same authors. In cases with total fracture of the buccal bone segment, other authors believe that careful fixation of the buccal cortex to the underlying palatal bone cortex with two bicortical micro screws may be enough to stabilize the bone segment, while allowing the preservation of a gap that should be filled with an autogenous or heterogenous bone graft.[55]

Basa et al. [56] described an alternative expansion technique for edentulous ridges, in which the buccal cortical plates were split, intentionally fractured, held *in situ* by a cortical screw and grafted with biomaterials. This procedure enables the dental surgeon to avoid the risk of unintentional fractures that may occur during ERE. In the present study, two cases of cortical bone fractures (1.7%) occurred after implant placement, but no treatment was required because of the limited extent of the fracture line, which is always less than 2 mm.

Finally, it is important to consider that also Calvo-Guirado et al. [26] evaluated the efficacy of AOT for the posterior alveolar expansion and elevation of the upper maxillary alveolar ridge, reporting a 100% implant success rate after a nine-month follow-up. Although the authors reported a mean increase in bone height of 6.8 $\pm$ 1.3 mm and a mean ridge expansion of 3.2 $\pm$ 0.2 mm, they provided no information regarding complication rates, such as sinus perforation or cortical bone fractures.

Considering maxillary bone and sinus membrane elasticity, the authors of the present study presume that one cannot reasonably expect to achieve 103% and 83% horizontal and vertical ridge augmentation starting from initial ridge dimensions of 3.3 and 8.2 mm, respectively,

as reported by Calvo-Guirado et al. [26] Consequently, the use of autologous bone or biomaterial was necessary to keep the bone corticals apart and to serve as scaffolding for the bone neoformation, in the cases of bone deficiencies.[26]

Conclusion

Bone augmentation techniques are routinely required for implant placement. The AOT is capable of increasing the height and width of the ridge of atrophic maxillae by over 25%−30%, reducing the risk of complications and making implant site preparation easier. The implant success rate and crestal bone levels after AOT were comparable to those of implants placed in native bone, showing that AOT is a viable technique for preparing an increased implant site compared to the initial dimensions of the edentulous ridge.

Acknowledgments

Disclosure statement

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