Placement of tapered implants using osteotome sinus floor elevation technique without bone grafting: 1-year results.

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ABSTRACT

***Purpose**:* Achieving implant primary stability in poor bone density ~~with parallel-walled implants~~ is rather difficult when the available bone height is less than 6 mm. This study assesses the 1-year clinical performance of tapered implants in reduced residual bone height sites in combination with an osteotome sinus floor elevation procedure without bone grafting material.

Materials and Methods: An osteotome sinus floor elevation procedure without grafting material was performed in the atrophic posterior maxilla. Tapered implants were placed in maxillary sites with residual bone height varying from 1 to 6 mm. Implant primary stability was assessed by finger pressure exerted on the implant. Bone gain in the elevated sinus as well as crestal bone loss was evaluated at the 1-year radiographic control.

Results: Fifty-four tapered implants were placed in 32 patients and were loaded after 4.2 ± 1.6 months. The mean maxillary residual bone height was 3.8 ± 1.2 mm. All implants achieved primary stability and all were successfully loaded. At the 1-year radiographic control, the mean bone gain within the sinus was 2.5 ± 1.7 mm and the mean crestal bone loss was 0.2 ± 0.8 mm.

Discussion and Conclusions: In the atrophic posterior maxilla, primary stability can readily be achieved with tapered implants even when ~~initial~~ mean residual bone height is 3.8 mm. Despite limited bone support and lack of grafting material, all loaded implants were clinically stable; the crestal bone loss was limited leading therefore to a net bone gain of 2.3 ± 1.8 mm. Survival and success rate was respectively 100% and 94.4%. Elevation of the sinus membrane by the tapered

implants without addition of bone grafting material led to bone formation beyond the original limit of the sinus floor.

KEY WORDS

Dental implants, TE® Straumann implants, osteotome, sinus lift, grafting material, atrophic posterior maxilla, tapered implants, crestal bone loss.

Introduction

After tooth extraction in the posterior maxilla, the alveolar process undergoes progressive and irreversible resorption. Often, this makes treatment of the partially edentulous patients in the posterior maxilla challenging. The lateral window technique for the maxillary sinus floor elevation is one of the most frequently used bone augmentation procedures.[1,2] The sinus lift procedure introduced by Tatum in 1976 is intended to increase the vertical bone dimension in the posterior maxilla.[1] The bone volume augmentation is expected to achieve primary implant stability, promote osseointegration, prevent over-loading situations and provide long-term implant success. The use of this procedure is recommended to treat the posterior maxilla when the residual bone height (RBH) varies between 1 and 6 mm.[2] The increased predictability of the osteotome sinus floor elevation technique allows treating the posterior maxilla when the RBH is at least 4 mm.[3]

Recently, it has ~~even~~ been demonstrated that consistent bone gain within the sinus can be achieved without any bone grafting material.[3,4,5,6,7,8,9,10] It appeared that elevation of the Schneiderian membrane can be sufficient to induce the neo-formation of bone beyond the original limit of the sinus floor. Bruschi et al. termed their technique the “localized management of the sinus floor (LMSF)”.[4] When the RBH was 5-7 mm, these authors reported a long-term success rate as high as 97.5%. With the same technique, Winter et al.[8] placed 56 tapered implants in the atrophic posterior maxilla (when the RBH was 2.87 mm); the survival rate was 91.6% after 22 months.

Although the osteotome sinus floor elevation procedure has been fairly predictable,

several authors have reported that the lower the RBH, the higher the implant failure rate. [11,12] Rosen et al.[12] stated that graft material did not appear to influence survival rates; rather, the most important factor influencing implant survival of the osteotome sinus floor elevation procedure was the pre-existing bone height between the sinus floor and the crest. The survival rate was 96% when the RBH was 5 mm or more. It dropped down to 85.7% when the RBH was 4 mm or less. This might be attributed to the fact that primary stability is more difficult to achieve with a decreasing RBH.[12,3]

In a previous study, 25 parallel-walled implants of diameters 4.1 and 4.8 mm were placed in 17 patients in the posterior area under the maxillary sinus while the mean RBH was 5.4 ± 2.3 mm.[3] The implants were placed with the osteotome technique without any grafting material. All implants were stable at the 1-year control and bone gained in the sinus was 2.5 ± 1.2 mm. Due to the limited RBH and the low bone density, primary stability was difficult to achieve; for 18 implants it was obtained by placing the implant deeper in bone so that the bone rested against the flared neck of the implant.

In the maxilla with limited RBH, standard parallel-walled implants with a thread pitch of 1.25 mm are not likely to engage more than a single row of implant threads; therefore primary stability can not be predictable. An implant design providing a better primary stability is desirable. Tapered implant with reduced thread pitch to 0.8 mm has been recently designed to increase primary stability into fresh extraction sockets.[13,14,15,16] Previous in vitro studies suggested that tapered implants can reach a high primary stability even in soft bone.[17,18] In addition, Ferrigno & Laureti[19] performed a split-crest technique in the narrow maxillary ridge (width 3-5 mm) with 42 tapered implants. The reported success rate at the 18-month follow-up suggested that this implant design is able to achieve a satisfactory primary stability.

The present study investigates the clinical performance of tapered implants in the atrophic maxilla while performing an osteotome sinus floor elevation procedure without grafting material. The aim was to evaluate whether:

1) primary stability can be readily achieved in limited RBH with tapered implants;

2) ~~endo-sinus~~ bone within the sinus can be gained without involving any bone grafting material;

3) crestal bone loss with tapered implants can be lower than the one measured for the parallel walled implants ~~lower than the one measured at standard implants,~~ in order to achieve a higher net gain for bone support.

MATERIALS AND METHODS

Patients

Between June 2004 and December 2006, patients were enrolled in the study if they fulfilled the following inclusion criteria:

(1) The patients required implant treatment in the posterior maxilla to support a fixed prosthesis;

(2) A delay of at least three months between tooth extraction and implant placement was respected;

(3) The osteotome sinus floor elevation procedure had to be performed without placing a grafting material;

(4) Tapered implants (TE® Tapered Effect implants, Straumann AG, Basel, Switzerland) of 8 or 10 mm length could be placed;

(5) The RBH measured between the crest and the sinus floor on panoramic radiographs at each implant site varied between 1 to 6 mm.

(6) Patients consented not to wear a removable prosthesis over the implants site during the healing period.

Surgical and Prosthetic Procedures

The patients fulfilling the inclusion criteria were treated by two surgeons (RN and MB); the tapered implants were inserted under clean but not sterile conditions as defined by Scharf & Tarnow.[20] Prophylactic antibiotics (Amoxi-Mepha®, Mepha Pharma SA, Aesch, Switzerland; 750mg, three times per day) was systematically given the day before surgery until six days after surgery.

A mid-crestal incision was performed for flap elevation; vertical or periostal release incisions were avoided. Cortical bone marking, for site positioning, was performed with three round burs of increasing diameters from 1.4 to 3.1 mm. When the crestal and the sinus cortical bone were radiographically distinguishable, the round burs were used to pass thorough the crestal cortical bone, but they were stopped at least 1 mm away from the sinus floor. When the crestal and the sinus cortical bone merged on the radiographs, only the osteotomes were used.

In all cases, the 2.8 mm diameter sinus osteotome was engaged to ~~push~~ elevate the sinus floor. The use of osteotomes instead of drills prevented ovalization of the implant bed. The sinus floor was fractured through the use of light force with a mallet; if this action was too uncomfortable for the patient, the round bur was used once more. The sinus floor was then carefully ~~pushed~~ elevated into the sinus cavity, to a height of no more than 3 mm; further elevation of the Schneiderian membrane was done by implant placement. The osteotomy site was enlarged by the 3.5 mm

diameter sinus osteotome. Integrity of the membrane was controlled with an undersized depth 2.2 diameter gauge.

Tapered implants (8 mm long, 4.8 mm in diameter at the collar and 4.1 mm in diameter at the apex) were placed in the prepared osteotomy site. When larger implants were required at molar sites, 10 mm long tapered implants, 6.5 mm in diameter at the collar and 4.8 mm in diameter at the apex, were inserted. In the latter, the osteotome sequence ended with the 4.2 mm diameter sinus osteotome. Thus, the implant bed for Ø 4.8 mm diameter implants was 3.5 mm in diameter, while for the 6.5 mm diameter implants, implant bed was 4.2 mm in diameter.

Implant insertion was performed without tapping; torque tightening until final seating was less than 35 Ncm with forward and backward rotation. The flap was sutured around the implant neck, healing was left non-submerged. During surgery, bone quality at implant sites was categorized according to Trisi & Rao.[21]

After the healing period, implant primary clinical stability was then assessed by finger pressure exerted on the implant. Traditional prosthetic procedures were performed to fabricate metal ceramic restorations that were inserted two or three weeks after impressions were made.

The survival criteria were the following: (1) absence of clinically detectable implant mobility; (2) absence of pain or any subjective sensation; (3) absence of recurrent peri-implant infection; (4) absence of continuous radiolucency around the implant.[22,23] The success criteria included in addition that vertical bone loss should not be more than 1 mm after the first year in function and thereafter less than 0.2 mm annually.[24]

Radiographic analysis

Before surgery, the RBH at each implant site was measured on a panoramic radiograph. Measurements were performed by an investigator not involved in the surgical procedure (NN). Internal calibration was performed on each radiograph based on either the width of the implant shoulder or, when available, by three inter-thread distances (2.4 mm).

As described elsewhere[3], the crestal bone height was determined post-operatively and at the 1-year control on the mesial and distal implant sides by measuring the distance, parallel to the implant axis, between the most apical implant thread and the most coronal bone-implant contact (A in Fig. 1). The bone height within the sinus was measured immediately after implant placement and at the 1-year control. It was defined as the distance between the most apical visible bone-implant contact and a fixed visible coronal implant thread (B in Fig. 1). The initial bone anchorage height was determined at the mesial and distal implant sides on the radiographs by measuring the vertical distance between the most apical visible bone-implant contact and the alveolar crest level on each side (C in Fig. 1).The vertical distance between the implant dome and the first most visible apical bone-implant contact indicated the implant length protruding into the sinus (D in Fig. 1).

Crestal bone loss was calculated by subtracting the A-values measured at the 1-year control and immediately after implant placement. The difference between the B-value, measured at the 1-year control and immediately after implant placement indicated the gain in bone height within the sinus. The net bone gain is expressed by the difference between the gain in bone height within the sinus and the crestal bone loss. The difference between the D-values, measured at the 1-year control and immediately after implant placement described the difference in the level of implant

protrusion into the sinus. Mean values and standard deviations were calculated for each parameter.

RESULTS

Forty-four 8 mm long tapered implants and ten 10 mm long tapered implants were placed in 32 patients with an osteotome sinus floor elevation procedure, without the addition of bone grafting material. The mean age of the patients was 62.6 ± 10.1 years, varying from 39 to 82 years. Implants were inserted in 37 molar and 17 premolar sites with a RBH of 3.8 ± 1.2 mm. The initial bone anchorage height was 4.2 ± 1.5 mm at the mesial side and 3.9 ± 1.4 mm at the distal side. During surgery, normal bone was found at 17 sites and soft bone at 37 sites. The sinus membrane was perforated at 5 sites; none led to nasal bleeding. All implants reached primary stability. No infection occurred, but one patient experienced mild post-operative swelling. After a healing period of 4.2 ± 2.6 months, all implants were clinically stable. Abutment screwing with a torque of 20 Ncm was uneventful; it did not lead to implant rotation. All final prostheses were in function at the 1-year control. The survival rate was therefore 100%.

The parameters measured on the radiographs taken immediately after implant placement and at the 1-year control are shown in Table 1. The mean mesial and distal changes of the evaluated parameters after 1 year are reported in Table 2. Figure 2 shows radiographs of one case taken before and immediately after implant placement, at the 1- and 3.5-year controls. Newly formed mineralized tissue on each implant side is clearly visible after 1 and 3.5 years.

The mean crestal bone loss for the 54 studied implants was 0.2 ± 0.8 mm (0.2 ± 0.7 mm on the mesial side and 0.2 ± 0.9 mm on the distal). Only three implants exhibited a mean value higher than 1 mm. Therefore the success rate was 94.4%.

Most implants gained bone height within the sinus on both implant sides. Twenty-two implants sides (20.4%) gained less than 1 mm. The mean gain was 2.5 ± 1.7 mm ranging from 0 to 6.5 mm; the mean mesial bone gain within the sinus was 2.6 ± 1.7 mm whereas the distal bone gain was 2.4 ± 1.6 mm.

Considering the amount of bone gain at the implant apex and the amount of bone loss at the crest, the mean net bone gain was 2.3 ± 1.8 mm. Implant protrusion into the sinus decreased for all implants to reach a mean length into the sinus after 1 year of 1.8 ± 1.7 mm. The mean decrease was 2.3 ± 1.8 mm (2.4± 1.8 mm mesial and 2.1 ± 1.7 mm distal) with a maximal one of 6.6 mm.

DISCUSSION

The present study aimed to extend the application of the osteotome sinus floor elevation procedure without bone grafting material to atrophic sites. All implants were stable at the 1-year follow-up; the survival and success rate was respectively 100% and 94% for the 54 studied tapered implants. Most implants gained more than 1 mm of bone within the sinus with a limited crestal bone loss. This confirms the radiographic evidence showed by Lundgren et al.[7] for bone formation in maxillary sinuses without bone grafting. In limited bone height as low as 1 mm, the reduced pitch of the implant in combination with its tapered shape have permitted to reach a primary stability and to maintain the bone crest level with the machined-threaded junction.

During implant placement, excessive bone compression might prevent bone apposition at the crestal level. Nonetheless, the tapered design does not seem to cause deleterious bone reactions,[25] especially since implants were deliberately placed with an insertion torque < 35 Ncm. In the posterior maxilla, type 4 bone is frequently found, with loose bone trabecules covered with a thin cortical layer. It is generally qualified as "poor quality"; however, it copes better with compressive stresses than dense bone. Furthermore, the conditions for a faster healing at the implant-bone interface are met due to a high regeneration potential.[26]

The five perforations of the Schneiderian membrane did not influence the implant outcome. Minor injuries of the membrane were reported not to impede the ciliary movement and secretion removal function.[27] The mean healing time allowed to the 54 implants in the current study was comparable to the healing time of the previous study using parallel-walled implants in an osteotome sinus floor elevation procedure without bone grafting material with a higher bony support.[3]

Rosen et al.[12] recommended the osteotome sinus floor elevation procedure with simultaneous bone grafting for sites of at least 5 mm of bone height; however, the study presented here confirms that it is possible to achieve the procedure with less of 5 mm of bone. The mean bone gain within the sinus of the 54 implants was equivalent to that previously reported for parallel-walled implants.[3]

Crestal bone loss reported for standard parallel-walled Straumann implants after 1 year has been consistently in the 0.8-1.0 mm range. Behneke et al.[28,29] and Brägger et al.[30] measured a 0.80 mm bone loss after 1 year; for Weber et al.[31], it was 0.75-1 mm after 1 to 2 years and Bischof et al.[32] reported 0.65 mm for wide neck implants

after 2 years. In a previous study with similar implant type[3], the crestal bone loss reached 1.2 ± 0.7 mm; this more pronounced loss was attributed to the implants that were placed deeper so that the flared machined neck of the implant set on the crest. In the present study, the crestal bone loss (0.2 ± 0.8 mm) was substantially lower; termination of the threads at the machined-rough surface interface might have helped to reduce the crestal bone loss, in the same way that it has been recorded for micro-threaded implant necks[33,34,35,36]. This hypothesis might be confirmed by Shin et al.[36] who compared a cylindrical rough and a micro-threaded neck design. After 1 year of loading, the mean crestal bone loss was 0.76 ± 1.1 mm and 0.18 ± 1.6 mm, respectively. This numbers are in line with the crestal bone loss measured for the tapered implants used in this study and with that of the parallel-walled implants.
Since the crestal bone loss was lower for the tapered implants, the net marginal bone gain was higher (2.3 ± 1.8 mm). It appears therefore that the use of tapered implants might be relevant for two reasons: 1) to achieve predictable primary stability even when the maxillary RBH is < 6 mm; and, 2) to reduce crestal bone loss after loading.

The mean available bone height beneath the sinus was 3.8 ± 1.2 mm. Despite this limited bone height anchorage, no implant was lost in the demanding occlusal conditions of the posterior maxilla. In addition, the absence of specific crestal bone loss after loading showed that such a limited amount of supporting bone is capable to withstand the exerted posterior occlusal stresses. In an in vivo study in primates, Palma et al.[37] compared the level of bone apposition at the bone-implant interface when the sinus membrane was elevated with and without bone grafting material. The authors underlined that no difference was found between the two groups; bone surrounded similarly the overall implant surface. Thus, in the present study, bone

might have surrounded the entire implant length and established a bony shell all along the implant surface. Therefore, although not visible on a radiograph, there would be more bone to support a 8 or 10 mm long implant than a 6 mm long implant.

The implant apex was post-operatively protuberant in the sinus and this protrusion was reduced twelve months later. The presence of grafting material might increase the tenting effect of the implant apex in the sinus, by elevating the Schneiderian membrane, and furthermore it might embed the implant apex in a solid structure. However, it is not needed to add bone as demonstrated in this study.

This study showed that the osteotome sinus floor elevation procedure can be predictably applied in maxillary RBH of less than 6 mm with tapered implants. Any effort to simplify implant treatment should be encouraged, particularly in private practice.

Patients welcome the osteotome sinus floor elevation procedure as a less invasive and more expedite treatment than the direct sinus lifting procedure with the lateral approach. Nevertheless, the osteotome sinus floor elevation procedure, although tending to simplify the treatment, depends heavily on the skills and experience of the surgeon. Furthermore, the practitioner needs still to master the sinus lift technique in case of complications or insufficient implant stability.

CONCLUSION

The present study showed that tapered implants with threads up to the top of the rough surface and a reduced thread pitch can achieve primary stability even when the initial RBH of the posterior maxilla is less than 6 mm. Despite limited bone support and the absence of grafting material, all loaded implants were clinically stable. Elevation of the sinus membrane without addition of bone grafting material led

to bone formation beyond the original limits of the sinus floor. The promising results obtained after one year included 100% implant survival rate and 94.4% implant success rate. Bone gain within the sinus was 2.5 ± 1.7 mm; the crestal bone loss was limited (0.2 ± 0.8 mm). The net for bone support can be thus evaluated to 2.3 ± 1.8 mm.

The suggested indications for tapered implants can therefore be safely extended to placement in the atrophic posterior maxilla. The use of the osteotome sinus floor elevation technique without grafting material combined with the placement of tapered implants can reduce the necessity of direct sinus lift procedures.

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Fig 1: Radiographic analysis.

A: distance between the most apical implant thread and the most coronal bone-implant contact; it indicates crestal bone height. **B**: distance from a fixed visible coronal implant thread to the most apical visible implant-bone contact; it indicates bone height within the sinus. **C**: bone anchorage under the sinus. **D**: implant length protruding in the sinus.

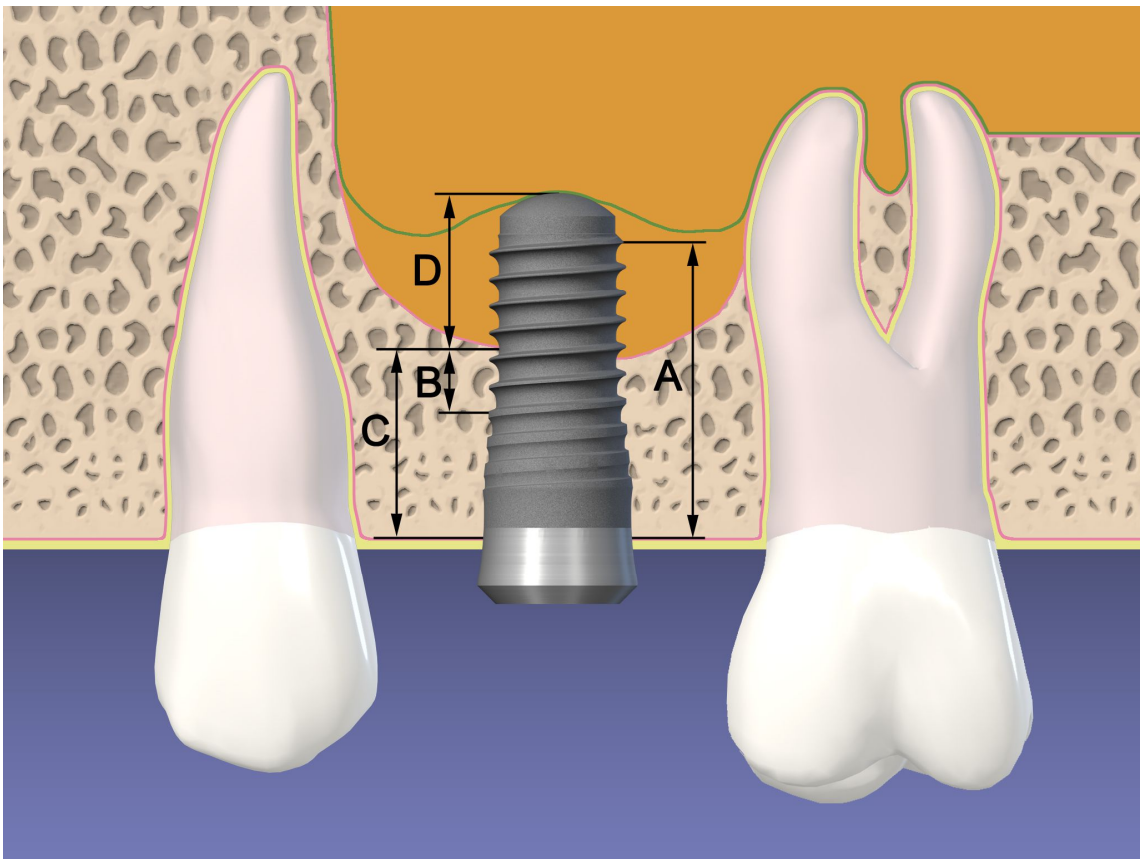


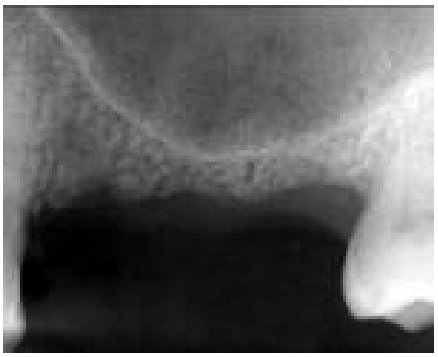
Fig 2: Radiographic controls.

(a) Pre-operative radiograph.

(b) Post-operative radiograph. Note the elevation of the sinus membrane and the presence of fractured bone fragments.

(c) 1-year radiograph. Note the radio-opacity around the implant indicating bone gain within the sinus.

(d) 3.5-year radiograph. Note the stability of the bone levels.



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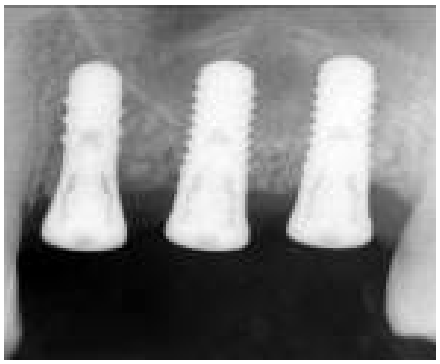

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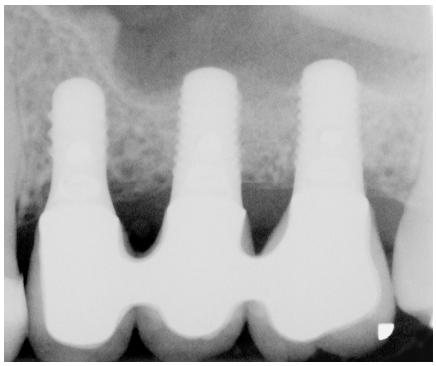

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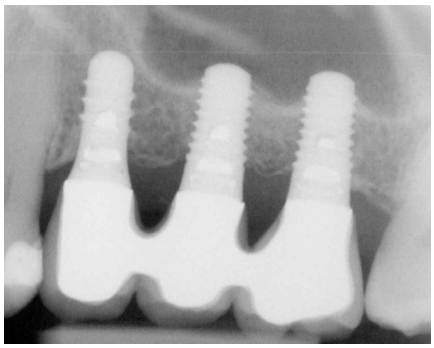

(d)

Table 1: Parameters measured on the radiographs.

A, B, C and D distances are indicated in Fig. 1.

	Crestal bone height **A (mm)**		Bone height within the sinus **B (mm)**		Bone anchorage height **C (mm)**		Implant protruding length **D (mm)**	
	Mesial	Distal	Mesial	Distal	Mesial	Distal	Mesial	Distal
Immediately after implant placement	6.6 ± 1.0	6.2 ± 1.2	2.8 ± 1.5	2.9 ± 1.4	4.2 ± 1.5	3.9 ± 1.4	4.1 ± 1.8	4.0 ± 1.6
Mean value ± standard deviation	6.4 ± 1.1		2.9 ± 1.5		4.0 ± 1.5		4.0 ± 1.7	
At the 1-year control	6.4 ± 0.9	6.0 ± 1.1	5.4 ± 1.6	5.3 ± 1.4	-	-	1.7 ± 1.8	1.9 ± 1.6
Mean value ± standard deviation	6.2 ± 1.0		5.3 ± 1.5		-		1.8 ± 1.7	

Table 2: Variation of measured parameters one-year after implant placement.

	Crestal bone loss **(mm)**		Bone gain within the sinus **(mm)**		Net bone gain **(mm)**		Implant protruding decrease **(mm)**	
	Mesial	Distal	Mesial	Distal	Mesial	Distal	Mesial	Distal
Mean value ± standard deviation	0.2 ± 0.7	0.2 ± 0.9	2.6 ± 1.7	2.4 ± 1.6	2.4 ± 1.9	2.2 ± 1.8	2.4 ± 1.8	2.1 ± 1.7
	0.2 ± 0.8		2.6 ± 1.7		2.3 ± 1.8		2.3 ± 1.8	