Title page

1. A new technique for minimally invasive sinus floor augmentation: a single center prospective cohort study on 339 patients

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Abstract

Aims The aim of this prospective non comparative cohort study is to describe a one-step minimally invasive sinus floor augmentation (SFA) technique performed in a single centre by a single surgeon, and report on implant loss, implant survival and clinical complications.

Material and method A new minimally invasive one step SFA using inorganic bone matrix with crestal approach, developed by the author, was performed by a single surgeon in all consecutive patients from November 2000 to August 2006 with a protocol including all patients in need of SFA without exclusion criteria. Residual bone heights (RBH) were accurately measured at implant site from post operative X-ray using known implant sizes as reference markers. Implants were to be loaded 6 months after placement. Time of loading, implant loss, clinical complications were recorded in a questionnaire sent to the referring prosthetic specialist during the summer of 2007. Data were computerized and analyzed using StatPlus 2007 Professional. Means and 95% confidence intervals (CI) were used as appropriate. A Cox-proportional-hazards model was used including minimal RBH in the model to assess its association with implant failure. Implant loading exposure was calculated by adding the total number of loading days for each implant and failures reported as rate per 100 implant years. Outcome data were compared to the literature.

Results A total of 419 sinus augmentation were performed in 339 patients. Mean (95% CI) post-operative RBH was 6.05 mm (5.84-6.26mm) and mean (95% CI) time to loading was 245 days (236-254 days).Two patients not loaded at the time of follow up questionnaire were excluded from further analyses. Five implants were lost at 1

year post loading, giving a first-year failure rate of 1.2% on an implant basis and 1.5% on a patient basis. No further failures were recorded afterwards. Mean post-loading implant exposure was 832 days (782-882 days; 95% CI) and overall implant loading exposure amounted to 944 implant years giving a failure rate of 0.5 per 100 implant years. The estimated implant survival rate was 98.8 % at 3-year time point. Patients with very low minimal RBH were at increased risk of failure (p=0.012). The technique was well tolerated by the patients**.**

Conclusions The one-step minimally invasive procedure for sinus floor elevation developed by the author has acceptable low level of failure rates compared to other crestal procedures.

Introduction

A low ridge height in the posterior region of the maxilla makes sinus floor augmentation (SFA) inevitable for many patients before implant placement. Many techniques have been introduced to augment the maxillary alveolar ridge, of which SFA from a lateral window has been the most commonly used. It was first presented by Tatum[1] in 1977 and published in 1980 by Boyne and James[2]. The procedure described how to add particulate bone through a lateral antral wall approach in order to augment the deficient maxillary alveolar ridge. It has been used as a one-stage (immediate implant insertion) or two-stage (delayed insertion 3-12 months after grafting) procedure in combination with auto-, allo- and xenogenic augmentation materials. Mean estimated annual failure rates between 1.47 and 7.41% have been reported for the Tatum technique[3]. The spread of the variation has been shown to be associated with type of augmentation material, roughness of surface implants and membrane placement over the lateral window, the best results being obtained using

rough implants with membrane coverage of the lateral window. This technique, however successful, has the drawback of significant patient morbidity.

SFA from a crestal approach using ostetomes with immediate or delayed implant placement was introduced in 1994 to reduce patient morbidity associated with the lateral technique [4]. After surgically accessing the maxillary sinus from the alveolar crest, the alveolar bone around the osteotome was compressed and the Schneiderian membrane elevated after the sinus bone floor has been crushed[4]. As in the lateral window technique, augmentation material could or not be part of the crestal procedure, the outcomes of which provided estimation of annual implant failure rates of around 2.5% (95% CI:1.4-4.5%)[5] .The osteotome hammering on the sinus floor however carried the risk of unknowingly damaging the membrane and were responsible for patient discomfort.

The author has been using both techniques in combination with inorganic bone matrix until late 90' reserving the lateral approach for patients with an estimated residual bone height (RBH) lower than 5 mm and using the Summer's one for patients having more than 5mm, as assessed by X-ray. Based on his experience, the author developed a one-step softer version of the crestal procedure with the aim to reduce patient's morbidity, to improve control for membrane damage and develop a SFA applicable to the broadest possible type of patients, irrespective of RBH and medical history. A prospective cohort design was established in 2001 to all consecutive patients undergoing the newly developed procedure. The objectives of the present work is to describe the procedure step by step, report on implant loss, implant failure rate and survival, and on clinical complications on a sample of patients approaching a thousand-year implant exposure. The author also critically discusses the respective values of this new method in comparison to others as reported in the literature.

Material and Methods

The surgical procedures were performed between 2001 and 2006. All consecutive patients requiring SFA for implant placement were included. The patients were referred from general dental practitioners or were directly coming to the author's clinic. The only inclusion criteria were the need for SFA to insert implants. There were no exclusion criteria. Preoperative BRH was estimated by conventional panorama X-ray. This information was used to decide which instruments were best suited for transcrestal approach (see step by step description). Age, gender, referring general practitioner and date of intervention were recorded as well as localisation, type of the implant, and requirement for additional lateral augmentation. Adverse events occurring during the procedure were also noted. Mesial and distal radiographs were obtained immediately after implant placement as control, but were also used to calculate minimal and maximal RBH of original sinus floor and implant length in the maxillary sinus, using known implant dimensions as reference. One post-operative control was carried out after 1 to 2 weeks, when sutures were removed. Referring dentists were recommended to load the implant 6 months after placement or patients asked to come back at the author's practice for implant loading, as appropriate.

During the summer of 2007, information on outcome was obtained through a questionnaire sent to, and filled in by the referring dentist or by the author in the case of non-referred patients. The questionnaire was to record implant status (in place, loaded, unloaded, loss) with corresponding dates. Overall outcome (recorded as uneventful or not) were also obtained together with description of the undesirable

event(s). Questionnaires were signed and dated for all patients by the referring dentist or the author, as applicable. All questionnaires were returned, and no patients are missing in the follow up. In November 2007, two implants had not yet been loaded because of patients' wish to delay the loading. These 2 patients were excluded from survival and follow up analysis.

Minimal and maximal values for RBH were calculated with the implant length as reference after implant placement, as shown in figure 1 and are reported in mm. Exposure time for implants was calculated, in days, from date of loading until date of last assessment recorded in the questionnaire or date of implant lost or failure, whichever occurred first. The event rates were calculated by dividing the total number of events by the total implant exposure time in years. Overall implant survival was estimated by Cox-proportional hazards model including age, requirement for additional lateral augmentation and minimal RBH as independent variables. Data were computerized and analyzed using StatPlus 2007 Professional and reported as means, with range and 95% confidence intervals (95%CI), where appropriate. The STROBE recommendations were applied in the preparation of this report.

Description of the procedure step by step: Sinus Augmentation with the Benex Technique

All patients were given a prophylactic dose of 1g amoxicillin (Co-Amoxi-Mepha, Mepha Pharma SA, Aesch/BL, Switzerland) at the beginning of the surgical session, followed by a dose of 1g amoxicillin one hour after the operation. Patients with a history of penicillin allergy were given the same quantity of trimetoprim and sulphamethoxatol (Escoprim forte, G. Streuli & Co. SA, Uznach, Switzerland). The patients were locally anaesthetized with Ubistesin (3M, ESPE, Switzerland AG, Rüschlikon, Switzerland). The alveolar ridge was incised longitudinally. The flap extension was done as appropriate, according to alveolar ridge condition. Lateral mesial and distal incisions were performed in cases where lateral bone augmentation was deemed necessary.

Cases with medium RBH (> 3mm): The alveolar ridge was carefully trepanned with an implant burr onto the cortical bone of the sinus (Fig.2). The cortical bone of the sinus floor of the same patient was then thinned with a round diamond burr before breaking it with the osteotomes. With the thinnest convex osteotome placed at the borders of the canal (Fig.3), 3 or 4 small perforations were made through the cortical bone (Fig.4) in order to prepare for a smooth breaking of the sinus cortical bone with the large osteotome (Fig.5).

Cases with very low RBH (Fig. 6 to 11): For cases with less than 3 millimetres, a round diamond burr was used for sinus access, without using any implant burr in order to prepare the entire canal (Fig.6). The sinus mucosa was carefully loosened in all directions using the two different Benex sinus floor elevators (Helmut Zepf, Medizintechnique GMB, Germany), which give four operative parts (Fig.7, 8).

In all patients the membrane was elevated to about 5 millimetres, and the profile drilling was then performed with a modified profile burr, the sinus access enlarged and the implant position defined. This step was followed by elevation of the sinus mucosa to nearly10 millimetres from the crest.

The augmentation material, inorganic bone material (Geistlich Bio-Oss® 0.5 g Geistlich Pharma AG, Switzerland) was spread between the cortical sinus floor and the sinus membrane (Fig 9) with a thin convex osteotome, which was applied with a light vibrating pressure. Excessive augmentation material in the implant canal was removed before implant was inserted (Fig.10). Sutures for transmucosal (70% of the cases), submerged (21%) or semi-submerged (9%) healing were applied (Fig.11). Perforated sinus membranes were covered with a resorbable membrane of highly purified collagen of porcine origin, (Geistlich Bio-Gide® Geistlich Pharma AG, Switzerland). The membrane was applied through the canal to cover the defect. Further lateral access was necessary in only two cases in order to cover the mucosa perforation with the collagen membrane. All implants were inserted using the one-step method. Cylindrical as well as conical implants (Straumann, Basel, Switzerland) with a diameter of 4.1 (28%), and 4.8 mm (72%), and implant length of 8 to 16 mm were used, with 10 mm and 12mm contributing for 95% of implants placed. Conical implants 10 mm of length were used in most cases in molar sites. Paracetamol (Dafalgan® Bristol-Meyers Squibb SA, Baar, Switzerland) or mefenamic acid (Mefenacid® G. Streuli & Co. Uznach, Switzerland) was prescribed for postoperative pain. The patients were advised to rinse with chlorhexidine, three times a day, for 1 to 2 weeks.

Results

The author performed 419 sinus floor augmentations in 339 patients between November 2001 and October 2006 using the minimally invasive one step technique. The average age of the patients at the time of surgery was 59.7 years (age range from 19 to 88). Molar sites (n=269) contributed for 64% of the cases.

Mean minimal RBH values were 4.73 mm (+/- 0.23; 95%CI) and 5.98 mm (+/-0.33; 95%CI) in the molar and premolar areas, respectively. Likewise, the longest implant length in the sinus was 6.2 mm (+/-0.23 mm; 95%CI) and 5.45 mm (+/-0.28 mm; 95%CI) for the molar and premolar area, respectively (Tab.1).

Schneiderian membrane perforation occurred in 64 cases, all of which were immediately and successfully closed, with 2 cases requiring lateral fenestration.

The follow up questionnaires were filled in by the authors for 26 patients out of the 339 included. The mean duration between implant placement and loading was 245 days (236-254 days; 95% CI; range 68 to 763 days).

The post-loading implant exposure ranged between 8 and 2297 days, with a mean of 832 days (782-882 days; 95% CI). Four implants were lost on the first day while placing the abutment because of unsatisfactory osseointegration. The overall implant loss was 5 out of the 417 cases loaded (1.2 %), with the fifth implant loss occurring 87 days after loading. Since all failures occurred during the first year of loading, the first-year failure rate was 1.2%. On a patient basis, the failure rate at one-year was 1.5 %. The post-loading exposure represented a total of 944 implant-loading years, giving an estimated overall failure rate of 0.5 per 100 implant years.

The overall implant survival rate was 98.8 % at 3 year as estimated by Cox-proportional-hazards regression (Fig 12.) Age and additional lateral augmentation were not found to be significantly associated with implant failure ($p>0.05$), but lower minimal RBH was significantly associated with shorter survival time ($p=0.012$), with

a risk ratio of 2.3 (+/-1.2; 95% CI). The minimal RBH in implant failure cases noted on day one were 0.67, 0.96, 2.59, and 7 mm. The implant lost spontaneously 86 days after placement had a minimal RBH of 3.92mm at the time of insertion.

The clinical complications in the follow up questionnaire were absent in 407 (98%) of the 417 evaluable cases. Reasons for undesirable outcome were: lack of osseointegration and implant loss (5 cases, already reported), prosthetic fracture (2 cases), peri-implantitis (2 cases) and undefined malaise with the implant (1 case). There were no reports of sinus complications in any patients, especially in those 64 cases that developed a sinus membrane perforation during the initial procedure.

Discussion

The clinical results using this one step minimally invasive SFA procedure compare favourably with data reported in the literature on SFA with respect to primary implant surgery and medium to long term outcome on implant survival rate [3,5] .Indeed the single step procedure was very well tolerated with uneventful follow up also in patients with sinus membrane perforation.

The surgical intervention is minimally invasive because there is a small wound compared to the fenestration technique. The crestal approach using ostetomes as described by the author does not require hard hammering, a source of discomfort to the patient. Visual control of the surgical site is an advantage when lifting the membrane with the elevator compared to the crestal approach according to Summer's. Accidental sinus membrane perforations were easily recognized, and were immediately repaired by covering the perforated site with a collagen membrane. There were only 2 cases out of 64 for which the membrane perforation treatment required additional lateral fenestration to repair the damaged membrane. The 15 %

incidence of membrane perforations is well within the range reported for lateral fenestration (mean of 19.5%)[3] or for transalveolar technique (range of 0 to 21.4 %)[5]. No post operative infections were seen in this study, which is consistent with infection rates below 1% reported in the literature for the transcrestal approach. This infection rate seems to be lower compared to the lateral fenestration technique (2.9%).

The use of inorganic bone matrix to augment bone has a long record of efficacy and safety in SFA [6] . The space for bone augmentation provided by our procedure however is confined to the volume delineated by the implant rough surface, adjoining sinus floor and the covering natural sinus membrane. This limited space volume does not provide much allowance for augmentation volume and it was therefore critical to assess the failure rate in a sufficiently large sample of patient. In addition, it was deliberately decided not to restrain patient inclusion with respect to initial minimal RBH with the objective to test the clinical functionality of our method in a population representative of that likely to be seen in daily practice.. Residual bone heights ranged between 2 and 10 mm in the recent review on crestal studies, and even though method of RBH measurements in other studies may be different from ours, it is believed that our sample, with a mean RBH of 6 mm, is representative of typical patient population for whom SFA have been used while using alternative crestal procedures.

The estimated failure rate of 0.5 per 100 implant loading years is also excellent, since the 95 %CI reported in a recent review on crestal technique was between 1.37 and 4.49 % per 100 implant years[6]. Likewise, the estimated implant survival rate after 3 years (98.8%) in this study falls above the upper 95% confidence interval boundary (96%) reported in the same review.[6] By contrast, it is interesting to note that a recent survey on lateral fenestration showed an estimated failure rate of 6.86 per hundred implant years and a 3-year survival of only 81.4%.[5] Caution is required to make an

over interpretation of relative advantages of one technique over the other in the absence or properly randomized comparative investigations. In particular, the Tatum's technique may have been reserved for cases perceived to be at higher risk because of especially low RBH and studies included in the recent review might conceivably have included a higher proportion of high risk patients. Indeed, a recent survey of such studies indicate RBH values regularly in the range of 3 to 5 mm, with many of them simply quoted as being "less than 5 mm. Consequently, the apparent better outcomes of the technique described here may be an effect of selection bias. Indeed, our own results indicate an increased risk of failure associated with very low minimal RBH. It is interesting to note that the proportion of patients having less than 5 mm was around 15% in our sample. How this compares with other studies seems almost impossible to assess. Therefore the relative advantages or risk benefit ratios of one technique over the other must await proper randomized study in higher risk patients.

It would however seem reasonable to conclude that the one step minimally invasive technique using inorganic bone matrix for SFA offers the undisputable advantages of simplicity and convenience for the vast majority of patients requiring SFA, since alternative techniques may have more morbidity without evidence for additional positive benefit on implant survival. Patients with very low minimal RBH are at increased risk of failure with this technique, but the relative increased risk in comparison to other SFA procedures must await proper randomized comparative investigations including enough high risk patients. Longer term data are required and being gathered to further document the benefits and limits of the new technique described here.

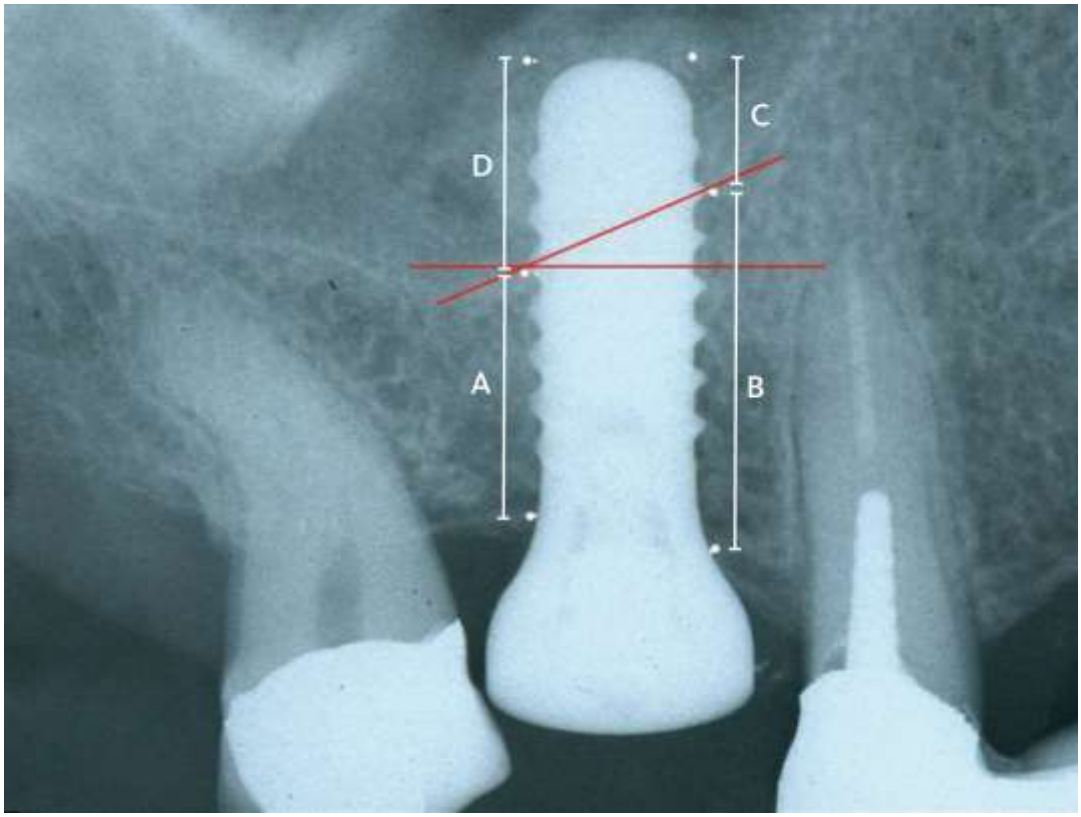
Conclusions

The described minimally invasive one-step SFA technique with inorganic bone matrix has shown a very low implant failure rate, causing little discomfort in patients requiring augmentation before implant placement,. As a next step the author will expand the database and extend the follow up in order to bring clinical, functional and radiological evidences in support of its usage.

References

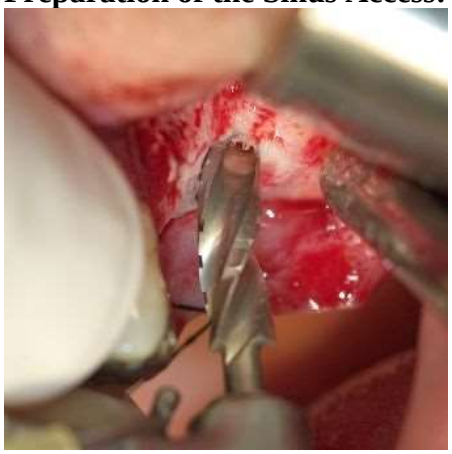
1. Tatum, O.H. Jr. Maxillary and sinus implant reconstructions. 1986: Dent Clin North Am 30(2): 207-29.
2. Boyne, P.J. and R.A. James. Grafting of the maxillary sinus floor with autogenous marrow and bone. 1980: J Oral Surg 38(8): 613-6.
3. Pjetursson, B. E., W. C. Tan, et al. A systematic review of the success of sinus floor elevation and survival of implants inserted in combination with sinus floor elevation. 2008; J Clin Periodontol. 35(8 Suppl): 216-40**.**
4. Summers,R.B. A new concept in maxillary implant surgery: the osteotome technique. 1994; Compendium 15(2): 152, 154-156, 158 passim; quiz 162.
5. Tan, W. C., N. P. Lang, et al. "A systematic review of the success of sinus floor elevation and survival of implants inserted in combination with sinus floor elevation. Part II: transalveolar technique." 2008; J Clin Periodontol 35(8 Suppl): 241-54.
6. Aghaloo,T.L., Moy, P.K. Which hard tissue augmentation techniques are the most successful in furnishing bony support for implant placement? Int J Oral Maxillofac Implants 2007;22 (suppl): 49-70

Illustrations (including legends)



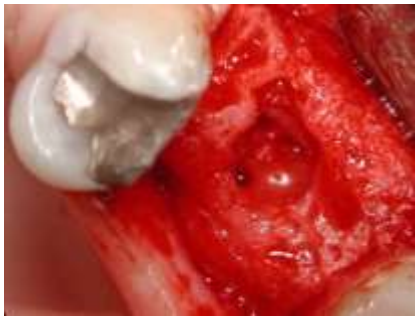
1. Measurements of bone - elevation height after minimally invasive one step sinus floor augmentation technique, calculation of angle of sinus floor:
A) Minimal RBH
B) Maximal RBH
C) Shortest implant length in maxillary sinus
D) Longest implant length in maxillary sinus

Preparation of the Sinus Access: Fig.2 to 5 represent a case with RBH >3mm



2. Trepanation of the alveolar ridge with an implant burr

3. Light hammering with the finest osteotome at the border of the canal



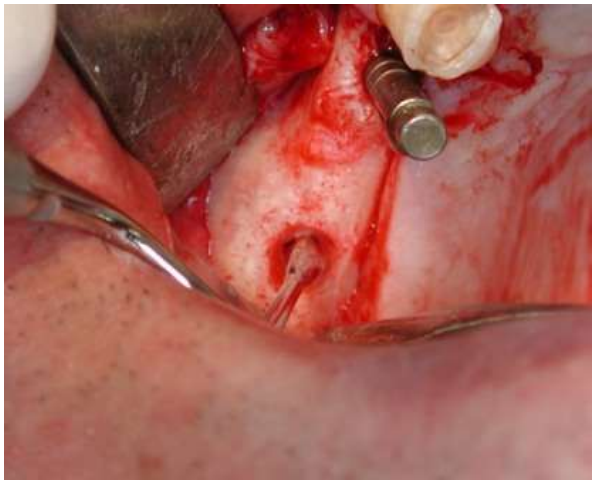
4. Small cortical perforations at the border of the canal

5. Breaking of the cortical bone with the large osteotome

Preparation of the Sinus Access: Fig. 6 to 11 represent a case with RBH <3mm

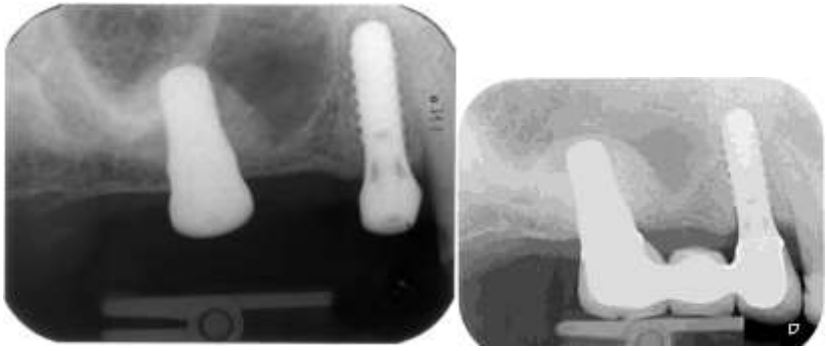
6. A round diamond burr used for the entire sinus access

7. Elevation of the sinus floor mucosa with a Benex sinus floor elevator (Helmut Zepf, Medizintechnique GMB, Germany)

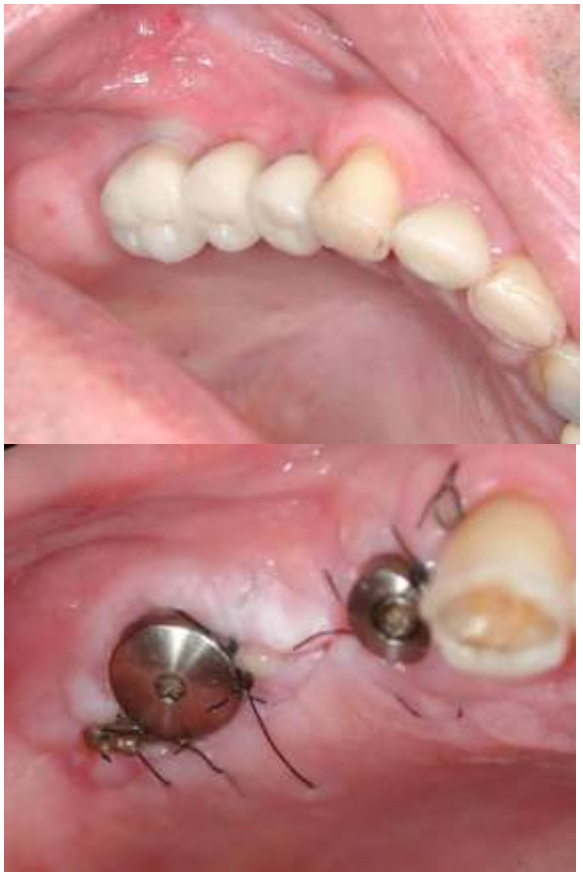


8. Elevation of the sinus floor mucosa

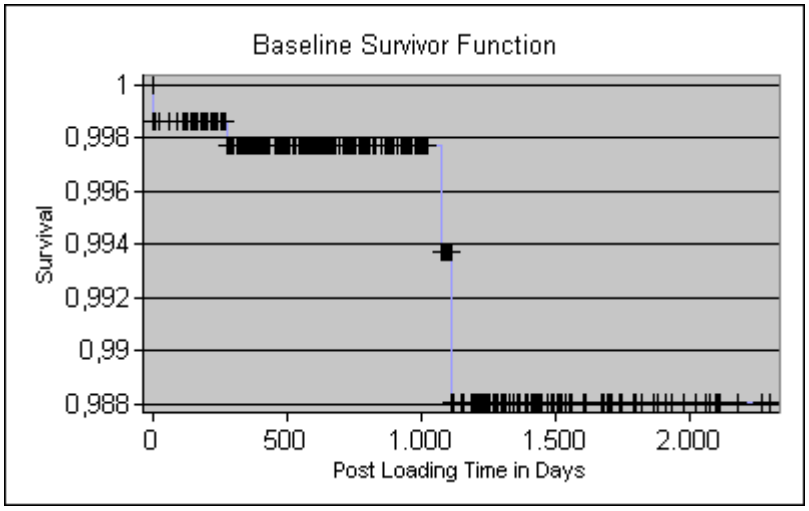
9. Insertion of the augmentation material followed by spreading of the augmentation material through vibration



10 X-ray after implant insertion and 26 months after implantation



11. Sutures for transmucosal healing of implant
Situation 26 months postoperative



12. Overall implant survival rate by Cox-proportional-hazards regression

Tables

Table 1.

Circumference n, mean m, standard deviation s und 95% confidence interval for RBH and implant length of the implant groups according to localization of the teeth.

Variable	Sub-group	Statistic			
		n	m	s	±95%CI
Minimal residual bone height [mm]	Molar	269	4.73	1.93	0.23
	Premolar	150	5.98	2.02	0.33
	Total	419	5.18	2.05	0.20
Maximal residual bone height [mm]	Molar	269	6.15	2.36	0.28
	Premolar	150	8.31	2.26	0.37
	Total	419	6.92	2.55	0.24
Medium residual bone height [mm]	Molar	269	5.44	2.07	0.25
	Premolar	150	7.14	2.00	0.32
	Total	419	6.05	2.20	0.21
Shortest implant length in maxillary sinus floor [mm]	Molar	269	5.04	2.06	0.25
	Premolar	150	3.54	1.66	0.27
	Total	419	4.50	2.05	0.20
Longest implant length in maxillary sinus floor [mm]	Molar	269	6.20	1.91	0.23
	Premolar	150	5.45	1.73	0.28
	Total	419	5.93	1.88	0.18
Medium implant length in maxillary sinus floor [mm]	Molar	269	5.62	1.93	0.23
	Premolar	150	4.50	1.55	0.25
	Total	419	5.22	1.88	0.18
Angle of maxillary sinus floor [Angular degree]	Molar	269	13.3	10.0	1.20
	Premolar	150	22.1	13.4	2.16
	Total	419	16.5	12.1	1.16