

Stability evaluation of implants placed in the atrophic maxilla using osteotome sinus floor elevation with and without bone grafting.
A 5-year prospective study.

Abstract:

Aims: Osteotome sinus floor elevation (OSFE) is a technique aimed at simplifying implant placement in the posterior atrophic maxilla. The necessity of bone grafting under the elevated Schneiderian membrane has been widely debated. The aim of the present study was to compare the evolution over 5 years of implant stability in sites grafted or left ungrafted.

Materials & methods: Twelve patients (9 women, 3 men) presenting posterior maxillary sites of Initial Bone Height (IBH) ≤ 4 mm were recruited. Thirty-seven implants (TE® SLActive; length 8 mm; Straumann AG) were placed with OSFE. According to the randomization, the sinuses received either bone graft (n =20, control group (grafted)) or no graft (n =17, test group (non-grafted)). Patients received both treatments when both sinuses fulfilled the inclusion criteria. Controls were performed at 1 week, 10 weeks, 12 weeks, and then 1, 3 and 5 years after implant placement. Peri-apical radiographs were taken and implant stability quotient (ISQ) was measured at different time points.

Results: At implant surgery, the mean ISQ was 58.9 ± 11.2 for the test group and 53.8 ± 10.2 for the control group. It dipped at the 10-week control and rose up thereafter. At 5 years, mean ISQ reached 80.8 ± 4.2 for the test group and 79.8 ± 4.3 for the non-grafted group. The difference between the groups was not significant. IBH significantly affected implant stability at implant insertion and at 5 years but not at the other time points.

Conclusions: Implants in sites with OSFE in ungrafted sites were as stable as implants placed in grafted sites.

Introduction.

Due to atrophy following loss of teeth and the maxillary sinus pneumatization, the posterior maxilla very often displays an insufficient initial residual bone height (IBH) and density (1, 2). A sufficient bone density and an appropriate volume of bone are, however, crucial factors for successful implant treatment (3, 4). A higher failure rate was observed following the placement of implants shorter than 8 mm into bone of poor density (5, 6).

These limitations can lead to the indication of a grafting procedure to allow implant insertion in the posterior maxilla. Sinus floor elevation with a lateral window approach is still considered nowadays as the standard approach. Nevertheless numerous studies described techniques aiming at simplifying the augmentation procedures in this area(7-9). The osteotome sinus floor elevation (OSFE) procedure seeks to ensure the preservation of all the existing bone by minimizing or even eliminating the drilling sequence of the surgical protocol. The bone layer adjacent to the osteotomy site is progressively compacted with various bone osteotomes, which will result in a denser bone to implant contact and improved bone density to help optimize primary implant stability (10). Additionally, OSFE allows the placement of implants in ridges of reduced IBH after the Schneiderian membrane has been elevated and the integrity of the sinus cavity secured.

With the improvement of implant design, surface and surgical technique, the higher predictability of implant therapy has encouraged re-evaluation of the necessity of grafting when using OSFE. Favorable results for OSFE without grafting using 10-mm long standard cylindrical implants, in a mean IBH of 5.4 ± 2.3 mm, have been reported (11-14) Eight-millimeter long tapered cylindroconical implants have been successfully used to achieve primary stability in ungrafted sites of even lower mean IBH (2.4 ± 0.9 mm) (13, 15, 16). Few studies have compared the behavior of implants placed using OSFE with and without

grafting but all reported high success rates, regardless of whether grafting material was present or not(16-18).

Several methods allow the quantification of implant stability(19, 20). Nowadays, resonance frequency analysis (RFA) is extensively used in clinical research to monitor implant stability over the healing period(21) and on the long term, mostly due to its higher reproducibility. With this method, implant stability is measured by determining the resonance frequency of the implant–bone complex. Resonance values are expressed by the implant stability quotient (ISQ) on a scale of 0 to 100.

The purpose of the present clinical study was: (1) to measure and compare stability evolution of implants placed in the atrophic maxilla with or without bone graft using RFA measures over 5 years, and (2) to evaluate the influence of IBH and bone quality on implant stability.

Material and Methods

Ethics Committees and study population

The prospective study was approved by the Ethics Committees for human research of the University Hospitals of Geneva and Lausanne (Switzerland; respective reference number 06-089 and 245/06). Patients were recruited over a 12-month period according to the inclusion criteria presented in Table 1. At the initial screening appointment, the medical and dental history of the subjects were reviewed and inclusion criteria were confirmed. Patients requiring 1-2 implants per side in the atrophic and edentulous posterior maxilla were recruited. IBH was determined via an orthopantomograph X-ray and had to be inferior or equal to 4 mm at the osteotomy site for the patients to be enrolled.

Twelve patients (9 women and 3 men, mean age 57.6 ± 4.7 years) were recruited. The mean maxillary IBH was 2.4 ± 0.9 mm (range 0.9 - 4.0 mm). A random allocation sequence was generated using an open generator provided online by the university Francois Rabelais (Tours, France; <http://biostat.med.univ-tours.fr>). For each patient, one sinus was randomized to receive either grafting material (control group) or not (test group). If the patient needed implant treatment of both sinuses ($n = 7$), the right side was treated according to the procedure allocated by randomization, whereas the left side was treated with the other procedure(16). The grafted group included 9 sinuses (17 implants) and the non-grafted group 10 sinuses (20 implants)

Bone quality was assessed during the surgery according to the index described by Lekholm & Zarb(22). Four of the 37 implants were placed in type 2 bone, 16 implants in type 3 bone, and 17 implants in type 4 bone.

Surgery and prosthetic procedure

Details of the procedures used were described previously(16). One or two TE® SLActive implants (Straumann AG, Basel, Switzerland; 4.1/4.8mm in diameter, 8 mm in length) were placed per sinus after an OSFE procedure where the floor of the maxillary sinus was pushed up by means of osteotomes percussion. When attributed to the non-grafted group, the elevated sinus was filled with a bovine-derived bone graft substitute (Bio-Oss, Geistlich Pharma AG, Wolhusen, Switzerland) and the implants were placed simultaneously. When attributed to the test group, the implants were placed without insertion of bone grafting material in the cavity created by the bed preparation (Figure 1). The sites were left unloaded during the healing period. After 8 weeks, an impression was taken and the classical prosthetic steps were conducted. Ten weeks after surgery,

prosthetic abutments were tightened at a 15 Ncm torque and the implants were rehabilitated with single crowns. At the 1-year post implant placement control, the abutments were further tightened with a 35 N/cm torque.

Survival criteria

Implants were controlled at 1 week, 8 weeks (impression time), 10 weeks (prosthetic delivery), 12 weeks, and then 1 year, 3 years and 5 years after implant placement. Implant success was evaluated according to the following criteria: 1) no clinically detectable implant mobility, 2) no pain or any subjective sensation, 3) no recurrent peri-implant infection and 4) no continuous radiolucency around the implant(23, 24).

Radiographic measurements

Initial bone height was measured on standardized panoramic radiographs taken immediately after implant surgery (Figure 1). Calibration of the measurements to correct for image deformation was based on the distance between three implants thread (2.4 mm). An illustration of the radiographic follow-up of the study patients over 5 years can be found in Figure 2.

Implant stability measurement

Implant primary stability at insertion (T0) was first assessed clinically by manual percussion exerted on the implant-mount. If the implant was stable, the ISQ value derived from RFA analysis was measured with a commercially available transducer (Osstell, Integration Diagnostics AB, Gothenburg, Sweden). ISQ measurements were repeated at

implant placement (T0), 8 weeks, 12 weeks (before tightening the abutments), 1, 3 and 5 years, in the buccal and proximal directions and repeated 3 times. ISQ data were obtained by averaging the 6 measurements.

Statistical Analysis

Comparisons between treatments and time points were made using a linear mixed model with patient as random factor and treatment and time as crossed fixed factors. Treatments were compared per time and time points were compared with the initial measurements. Šidák corrections for simultaneous hypothesis testing were applied. Each time, the normal distribution of the residual values could be confirmed by a normal quantile plot and their homoscedasticity by a residual dot plot.

The relation between ISQ values and IBH was assessed graphically at each evaluation time by means of an orthogonal regression. After removal of outliers, a locally weighted scatterplot smoothing (LOWESS) showed that the linear relation between ISQ values and initial bone height was applied. Standard errors for the regression coefficients of the orthogonal regression line were obtained by bootstrapping. P-values to test whether the slope was equal to 0 were calculated using these standard errors and assuming a t-distribution. A Pearson correlation coefficient was calculated as well.

The relation between bone densities and postoperative ISQ was assessed on the one hand by a Spearman correlation coefficient and, on the other hand, by a variance analysis (ANOVA) model that compared the ISQ values for the different density scores. Correction for simultaneous hypothesis testing according to Tukey was applied. The threshold value for statistical significance was set at $p < 0.05$.

RESULTS

Failures & complications:

During surgery, no perforation of the sinus membrane was detected. Six patients complained about typical post-operative events (moderate pain, swelling, etc...) without further consequences. At 8 weeks, before impression, two control implants placed in merged corticals were clinically mobile and were considered as early failures. At the 10-week milestone, while applying the 15-Ncm screw abutment tightening of the final crown, in a single patient, two additional implants rotated (spinners). After three additional months of healing, these implants resisted tightening and were successfully rehabilitated. At the 1-year control, 35 implants were clinically stable with their final prosthesis in function. At 2.7 years, one osseointegrated test implant was removed because of peri-implantitis.

Influence of bone grafting on implant stability (Table 2)

Mean ISQ at implant surgery (T0) was 58.9 ± 11.2 for the non-grafted group and 53.8 ± 10.2 for the grafted group. The difference between both groups was not statistically significant ($p = 0.53$). For the two cases of early failure, mean ISQ at surgery was low (38.5 and 34.0) but not for the two spinner cases (64.5 and 54.0). Only 10 implants were analyzed at week 1 because of doubts regarding the rotational stability of those implants and apprehensions towards affecting their osseointegration process by tightening the transducer. These 10 implants showed a decrease in mean stability level at this 1-week time point. For both grafted and non-grafted implant groups, stability increased up to an overall mean ISQ of 76.9 ± 4.8 at 1 year and 80.2 ± 4.2 at 5 years (Figure 3, Table 2).

There were no significant differences ($p > 0.05$) at any time point between grafted and non-grafted sites.

Influence of initial bone height on implant stability

Implant stability was plotted against the IBH at each time point (Figure 4). At implant placement, a low but statistically significant correlation was found between the two variables ($r = 0.33$, $p < 0.05$). The relationship lost significance at the later stages. However, a stronger and statistically significant correlation was found at the 5 years follow up appointment ($r = 0.51$, $p < 0.01$) (Figure 4).

Influence of bone quality on primary implant stability

At implant placement, the average ISQ value was 62.8 ± 7.0 for implants placed in type 2 bone ($n = 4$), 57.0 ± 14.3 in type 3 bone ($n = 16$) and 52.5 ± 7.2 in type 4 bone ($n = 17$), but this difference was not statistically significant (Figure 5).

DISCUSSION

Nowadays, implant therapy has reached very high survival rates nearing the 100% (25, 26). However, there's a constant strive towards offering a better treatment to the patients. Implant survival has become irrelevant as it is considered as practically guaranteed. What is sought now are treatments aiming at reducing the treatment time (27, 28). Long treatment protocols with long healing times are now frowned upon and fewer patients are willing to wait long for complete peri-implant healing to be achieved. Aesthetically, implants are now expected to perfectly mimic the natural tooth and meet the rising expectations of patients. Moreover, new treatment concepts aim towards simplifying

implant treatments while keeping the results at a very high standard.

In recent years several authors suggested the use of short implants in sites with limited bone height in order to avoid bone grafting or other invasive procedures (29-31). In this study, only implant sites with an initial bone height under the maxillary sinus of 4mm or less were included (IBH = 2.4 ± 0.9 mm). Therefore, even if shorter implants were used, a sinus floor elevation would have still been required. In the present study all implants used were 8mm long. According to the latest ITI guidelines (32), the definition of “short” implants has been set as implants below or equal to 6mm in length. According to the consensus conclusions, 6mm implants seems to be a valid solution when available bone height is limited while accounting for special considerations when using such implants (such as splinting or using wider diameter implants (≥ 4 mm), etc...) This study investigated different bone characteristics and their influence on the stability of implants placed in reduced bone height. No difference in stability was found between grafted and non-grafted sites at any time point over 5 years and a dip in implant stability was noticed around 1 week' post implant placement where mechanical stability has been partially lost due to the start of the remodelling process and biological stability has not yet replaced it (Figure 3).

These results were expectable at implant surgery when implant stability is purely mechanical as it relies on the density and micro-architecture of the bone and is not influenced by the grafting material. The lack of significance between grafted and non-grafted sites remained at the next time points when mechanical stability is gradually replaced by biological stability as a result of the process of osseointegration, bone regeneration and graft integration.

This observation tends to suggest that a bone graft does not accelerate nor

decelerate the overall speed of new-bone formation in the augmented sinus. Additionally, a study by Merheb et al.(33) showed very low changes in implant stability as long as cortical anchorage and marginal bone integrity were ensured. Those factors might then overhaul the influence of the bone graft and spongy bone anchorage on implant stability.

An earlier article based on the same pool of patients and focused on marginal bone loss and implant survival, found that, after 5 years of function, implants in the grafted group lost an average of 0.7 ± 1.4 mm of marginal bone, while there was an average of 0.6 ± 0.9 mm of marginal bone loss in the non-grafted group. It was also found that three implants failed over a period of 5 years. At the 8 weeks post-operative control, it was noticed that two implants did not achieve. Both implants belonged to the control group (grafted group). The third implant was lost to peri-implantitis after 2.7 years of function. This implant belonged to the test (non-grafted group) (34). Because of this sole failure after osseointegration, it is difficult to draw any statistical conclusion as to the effect of bone grafting on implant survival.

In the present study, the relationship of implant stability and IBH was also investigated. A significant correlation was found at implant surgery, in accordance with previous studies (35),(36, 37). This correlation was lost at the subsequent controls which follow osseointegration. Surprisingly, a strong correlation was found again at the 5-year follow-up. This discrepancy could be explained by the resorption of Bio-Oss® in the grafted sites. Bio-Oss® is known to undergo a slow resorption along time but histological studies have shown that Bio-Oss® particles are still significantly present in the grafted sites even more than 10 years after grafting(38, 39). However, after a few years, a complete bone integration of Bio-Oss® in a lamellar structure, in absence of bone

remodelling, has been observed(40). Hence, it could be hypothesized that a positive correlation between IBH and implant stability was found once bone maturing had finished taking place.

Implant primary stability seemed to be higher in denser bone. This trend has already been well established in previous reports(41, 42). However, in the present study, this superiority did not reach statistical significance. This lack of significance could be attributed to the rather limited sample sizes specially in the dense bone group (group 2, n = 4). Additionally, the osteotome technique which aims at condensing bone particularly in areas of lower bone density may have played a role in attenuating the differences in the density of the different bony beds(43). Finally, the particular tapered design of the implants used in this study is engineered to take maximal advantage of the available bone and secure good anchorage in areas with deficient bone quality or quantity(44, 45). The use of this implant type might have helped in providing good stability even in the softer types of bone.

Several cut-off values of ISQ have been suggested as thresholds for the prediction of implant survival (46-48). Those values have differed from one author to another and from one system to another. Nevertheless, they provide broad guides to the surgeon about the safety of deviating from the traditional two-stage protocol towards one-stage protocol and further on towards immediate loading of the implants. In addition to absolute values, special attention should be devoted to monitoring the trend of evolution of the ISQ values. A positive trend is the sign of an uneventful healing while a negative trend could be announcing a possible bone-implant complex degradation with ensuing failure. The decreasing ISQ values of the two spinner implants at the 10-week milestone were possibly predicating of implant failure if the implants had effectively been loaded on the

day of the measurements.

In conclusion, this study demonstrated that the stability of implants placed with OSFE in non-grafted sites was as high as that of implants placed in grafted sites up to 5 years after implant placement. Further research should be conducted to confirm and explain the correlation between implant stability and IBH after 5 years.

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Figure 1: Illustration of surgical techniques and radiographic measurements of Initial bone Height (A)

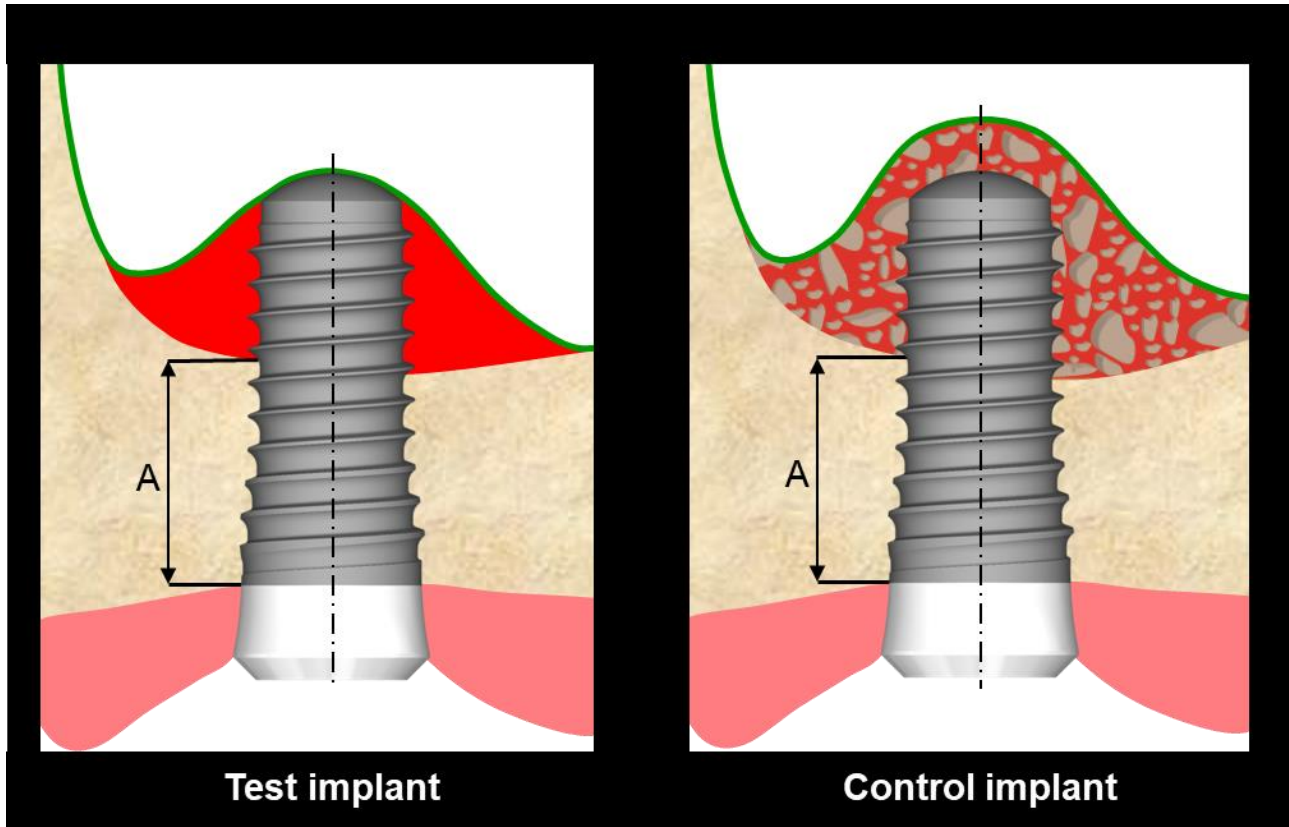
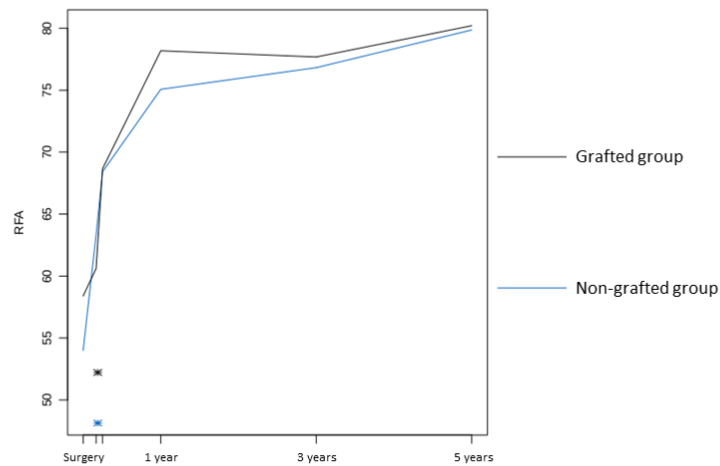


Figure 2: Radiographic follow up of both control and test groups over 5 years. An example.



Figure 3: Mean ISQ measured immediately after surgery, at 1 week, 8 weeks, 12 weeks, 1, 3 & 5 years.



PS: The Asterisk (*) refers to the 1 week post-operative dat which was not included in the curve because it only was measured on n=10 implants.

Figure 4: Relationship of IBH and implant stability.

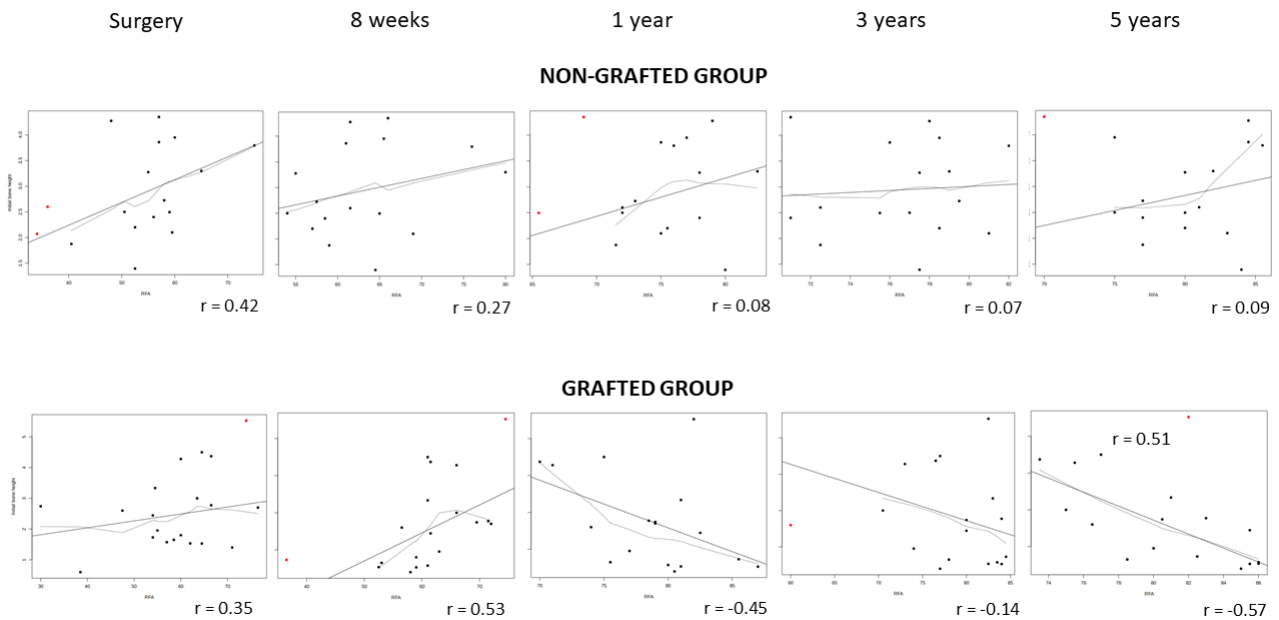


Figure 5: Relationship between primary implant stability and bone quality according to the Lekholm & Zarb index

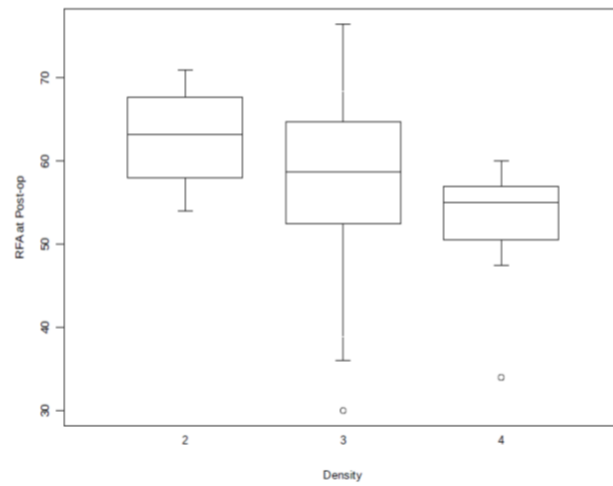


Table 1 : Patient Inclusion criteria

- a- Patient requires implant treatment in the posterior maxilla.
- b- Tooth extractions at the implant sites were performed at least 4 months before surgery.
- c- Residual bone height between the alveolar bone crest and the sinus floor (measured on panoramic radiographs) is ≤ 4 mm.
- d- Patients agree to avoid wearing a removable prosthesis at the implant sites during a healing period.
- e- Absence of medical history of acute or chronic sinusitis, sinus disease or previous sinus surgery.
- f- Absence of active periodontal disease, diabetes or metabolic bone disease.

Table 2: Evolution of Implant stability (ISQ)

Time point	Group	Average ISQ	Standard deviation
Post-Op	Grafted	58.9	11.2
	Non-grafted	53.9	10.2
1 week	Grafted	52.3	9.8
	Non-grafted	50.5	11.3
8 weeks	Grafted	61.2	8.5
	Non-grafted	63.2	7.2
3 months	Grafted	69.3	8.3
	Non-grafted	68.3	5.3
1 year	Grafted	78.7	4.6
	Non-grafted	74.9	4.3
3 years	Grafted	78.2	6.3
	Non-grafted	76.7	3.4
5 years	Grafted	80.8	4.2
	Non-grafted	79.7	4.3