Comparison of Initial Implant Stability placed using Bi-cortical Fixation, Indirect Sinus Lift and Uni-cortical Fixation

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Dedication

To mom, dad, manana, baz and miaw.

ABSTRACT

Purpose: This study aim was to determine if self-threading dental implants placed using stopper drills so to bi-cortically engage both the alveolar crest and sinus floor (bi-cortical fixation) achieved comparable primary and/or secondary stabilities to that of short implants only engaging alveolar crest cortical bone (uni-cortical fixation) or implants engaging both crest and sinus floor but via greenstick fracture and grafting (indirect sinus lift).

Material and Methods: Thirty-eight patients exhibiting 7 – 11 mm of bone coronal to the sinus floor as confirmed by pre-operative CBCT were recruited. Forty-five implants were randomly assigned to one of the placement techniques. No patient received more than two implants, which were placed in opposite sides of the maxilla while using different surgical techniques. An Osstell ISQ was employed immediately after implant placement to measure stability 6 times in a buccal/lingual dimension. Secondary stability was measured at 2nd stage surgery after a 3- to 6-month healing period.

Results: The greatest primary implant stability was achieved via indirect sinus lift. However, no statistical significant difference was found among the three surgical techniques (P = 0.13; bi-cortical fixation: 71.4 [SE 2.1], uni-cortical fixation: 69.6 [2.1], indirect sinus lift: 75.9 [2.3]). The three techniques had similar secondary stability (P = 1.0; respectively 79.9 [1.2], 80.0 [1.2], 80.0 [1.3]). Baseline residual ridge height measured on CBCT was similar (P = 0.1; respectively 8.8 mm, 9.9 mm, 9.4 mm) but implant diameter and length placed in the maxilla differed (P = 0.03/P < 0.001; respectively 4.7/11.4 mm, 4.3/8.1 mm, 4.7/11.8 mm). Primary implant stability was significantly correlated to CBCT bone density (r = 0.37).

Conclusion: Primary and secondary implant stabilities of bi-cortical fixation did not differ significantly from those of uni-cortical fixation and indirect sinus lift. However, use of the bi-cortical fixation technique is warranted since it is simpler and more economical than the indirect sinus lift plus allows for longer implants than the uni-cortical fixation while yielding similar secondary implant stability.

Key words: Initial implant stability; bi-cortical fixation

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Chapter I

Introduction

Loss of a maxillary posterior tooth is followed by diminished ridge height in conjunction with ridge resorption and sinus pneumatization.[1] Residual alveolar bone height of ≤ 4mm has been associated with reduced initial implant stability[2-4] and reduced implant survival rate diminished from 96% to 86%.[4] In addition to deficient bone quantity, the posterior maxilla is characterized by a thin bony cortex with poor medullary strength and low trabecular density.[5] These anatomical characteristics make it difficult to achieve initial stability.[6,7] Since primary implant stability is an important predictor for osseointegration,[8-10] surgeons may vary their surgical technique and select a specific implant design that will optimize success.

Various surgical techniques have been developed to overcome these limitations. A lateral window technique has been advocated in severely resorbed ridge height (≤ 6mm) for maxillary sinus augmentation[2,11] in order to gain up to 10-12mm of bone[12] with or without simultaneous implant placement. However, this surgery is complex, invasive and requires a variable healing period (6-9 months).[13] In the presence of a mildly reduced ridge height with 7-11mm remaining but still requiring vertical gain, the

less invasive osteotome technique (indirect sinus lift) can be used, with or without additional bone grafting material at the apex of the implant.[14-16] Although surgeons may be able to elevate the sinus membrane by 6- 8mm, the risk of perforation is greatly diminished when it is limited to 3-4mm.[17] Without additional bone grafting, the osteotome technique has consistently shown a minimum of 2mm intra-sinus radiographic bone gain.[16, 18-21] Complications associated with indirect sinus lifts employing bone grafting or not include an incidence of sinus perforation of 3.7% [21-22], minor post-operative nasal bleeding[18,23], and rare sinus infection at a rate of 0.8%.[22] Alternatively, shorter implants can be used to avoid involving the sinus cavity. The above-mentioned sinus grafting procedures are often performed to place longer implants. Recent findings indicate no significantly greater failure rate among short implants as compared to longer implants,[24- 27] when using textured-surface implants. These implants are characterized by a rough surface with an increased implant surface area, thus providing greater bone-to-implant contact compared to the smooth surface found on machined-surface implants. According to Fugazotto's data collected over 7 years, short implants (6-9mm) and long implants (>10mm) exhibit comparable survival rate (98.1-99.7%)[27] when using textured-surfaced implants and adapted surgical preparation. This is in contrast to the failure rate of machined-surface implants <7mm long, which was double that of longer implants (P = 0.01, respectively, 9.5% and 3.8%).[28]

While these traditional sinus augmentation techniques have well-established guidelines, they vary in complexity, invasiveness, extent of intra- and post-operative complications, and cost of additional non-autogenous grafting materials. The use of short implants potentially sidesteps these difficulties but compared to longer implants,

they may be less stable initially and, with the prevalence of peri-implant bone loss ranging from 11 to 47%[29], may raise a concern about having less leeway in the long run.

Bi-cortical fixation is a novel approach intended to increase implant stability in the maxillary posterior by engaging two layers of cortical bone at the cervical crest and apically into the sinus floor. The technique involves protruding a modest portion of the implant into the sinus cavity thereby allowing for longer implants to be placed. The use of a stopper drill and self-threading implants contribute to tight engagement with the sinus floor for superior initial implant stability compared to an indirect sinus lift which induces a green stick fracture of the sinus floor. Since the sinus floor has a similar elastic modulus as the alveolar crest cortical bone and is considerably higher than that of the middle trabecular bone,[30] intentional engagement of the sinus floor when placing implants may increase initial implant stability[31-33] and potentially improve long-term survival of maxillary posterior implants. In vitro and animal studies that measured insertion/removal torque or resonance frequency analysis have reported notably favorable results for bi-cortical fixation over uni-cortical fixation[32,34] in terms of greater implant stability, 20-50% greater stress reduction under various loading conditions [34-36] and no difference in marginal bone loss regardless of bi-cortical or uni-cortical implant anchorage.[36]

An implant protruded in a controlled manner has the potential to preserve the integrity of the sinus membrane, creating a tent shape space under the membrane that will be filled by a blood clot. The presence of stem cells in the periosteum of the maxillary sinus floor[37] as well as the innate osteogenic potential within the Schneiderian membrane[38,39] allow for bone formation if the space around the implant is stable.

Approximately 2 millimeters of bone formation has been observed after elevation of the sinus membrane and clot formation around the protruded implant without additional grafting material.[40] This bone formation around the longer implant used provides a biomechanical advantage in limited bone quantity area like the posterior maxilla, compared to a shorter implant placed with a uni-cortical fixation technique, and potentially increases the chance for long-term survival. Since bone graft materials are not used with this technique, it is more economical than conventional indirect sinus lift technique requiring graft materials.

The concept of bi-cortical stabilization using surgical drills with vertical stoppers to precisely control the amount of implant apex protrusion into the sinus, and applying self-threading implants to maintain an intimate contact between implant threads and the dense sinus floor without additional bone graft materials in low-density bone has not been tested for its safety and efficacy compared to other conventional surgical techniques. Therefore, the primary purposes of this preliminary study is to (1) determine if initial implant stability is comparable between dental implant engaging both the alveolar crest cortical bone and sinus floor using stopper drill and self-threading concept (bi-cortical fixation), short implants engaging only alveolar crest cortical bone (uni-cortical fixation) and/or implants engaging both crest and sinus floor but with green stick fracture (indirect sinus lift technique), as well as to determine (2) if different surgical techniques, residual bone height, bone density, and length and width of the implants used affect initial implant stability in the posterior maxilla.

Chapter II

Material and methods

The study protocol was approved by the Institutional Review Board at the University of Minnesota. This pilot study presents the findings of a prospective single-center, randomized controlled clinical trial.

Patients

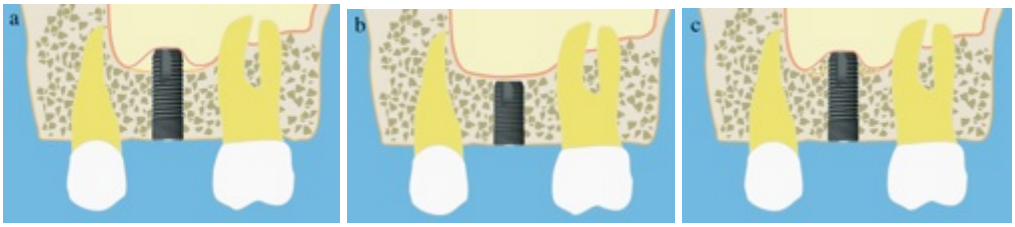
Patients were recruited from the Graduate Periodontics program, Graduate Prosthodontics program as well as the Faculty Dental Practice clinic at the University of Minnesota and treated between March 2010 and July 2013.

Eligible volunteers had to be partially edentulous in the maxillary posterior region, meet the standard criteria for implant placement and have a residual 7-11 mm of bone height coronal to the sinus floor as confirmed by CBCT scan for diagnosis and treatment planning. Exclusion criteria consisted of smoking, overall health contraindication to implant surgery or sinus augmentation procedures, and/or implants with bone dehiscence and/or fenestration at the time of placement.

Examination

A periapical (PA) radiograph was used to perform an initial screening assessment of ridge height. Once a patient met the inclusion criteria and agreed to participate in the study, a cone beam computer tomography (CBCT) scan of the maxilla was taken prior to surgical placement of the implant. The three surgical implant placement techniques that were compared for the maxillary posterior were: Group 1) bi-cortical fixation (implants intentionally engaging the sinus floor up to 1-2mm into the sinus without graft but using a stopper drill and self-threading concept); Group 2) uni-cortical fixation (short implants placed in proximity of the sinus without sinus floor involvement); and, Group 3) indirect sinus lift technique (Figure 1).

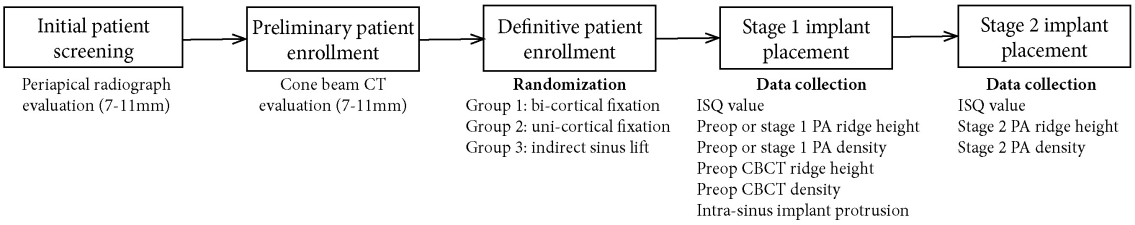
Figure 1. Schematic of implant placed using 3 different surgical techniques: (a) bi-cortical fixation, (b) uni-cortical fixation, and (c) indirect sinus lift.



Each patient was randomly assigned to one of the three surgical techniques, with a maximum of two implants per patient. If a patient had two implants, they were placed using different randomly-assigned surgical techniques and in different quadrants. In the event where a patient was randomized to receive a uni-cortical technique, yet the ridge height required an implant size that was unavailable in the manufacturer's repertoire, the patient was placed in the next randomization group. The subsequent subject enrolled was then assigned to the group that was previously skipped due to limitations of existing

implant sizes. The recruiting investigator was strictly blinded to the allocation of the surgical techniques until the CBCT was reviewed and the patient's enrollment into the study was completed. The schematic study sequence is shown in Figure 2.

Figure 2. Schematic of study design and treatment sequence



Clinical Procedures

Full-thickness flaps were reflected to access the alveolar bone for all treatment groups. The uni-cortical group and the bi-cortical group followed the drilling protocol recommended for soft bone Astra implants whereby the osteotomy was underprepared by one drill size. However, the bi-cortical fixation group differed in the use of stoppers engaged onto each drill. A set of stoppers fabricated to fit each implant drill would rest on the alveolar ridge crest and limit vertical advancement into the sinus (Figure 3 a, b, c).

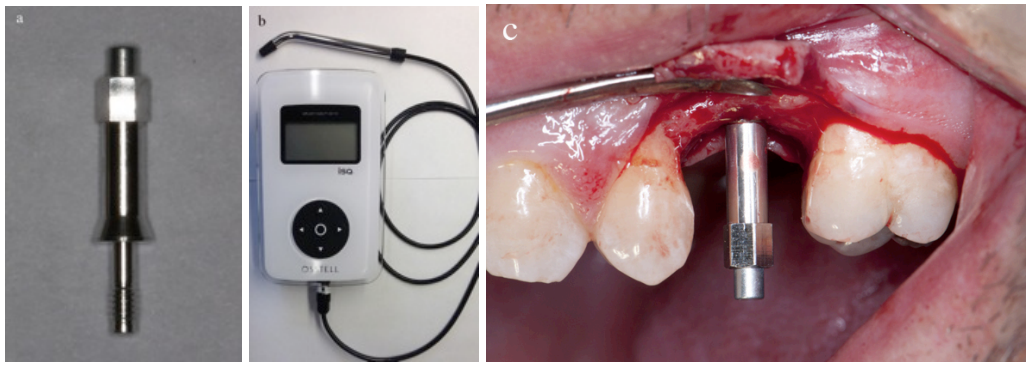
Figure 3. (a) Vertical stopper. A set of stoppers, fabricated to fit each implant drill diameter. (b) A vertical stopper screwed at the desired drilling depth and used in the bi-cortical fixation group. (c) Intraoral picture of the drill with stopper resting on the alveolar crest.

These stoppers were secured at the shortest distance from the alveolar crest to the sinus floor, based on ridge height measurements obtained from preoperative CBCT scan. Consequently, sequential drilling with depth determining stoppers created an adequate hole at the sinus floor enabling the self-threading implant to engage the cortical bone and protruded approximately 1-2 mm through the sinus floor.

The initial implant drill for the indirect sinus lift group was set to stop 1mm short of the sinus floor. The osteotome (3i, concave tapered) carrying some bone was then tapped with a mallet to create a greenstick fracture of the sinus floor. The osteotomy was sequentially widened as bone was condensed apically into the sinus. A maximum of 4 mm of implant length was protruded into the sinus. The integrity of the sinus membrane was confirmed for both the bi-cortical fixation and indirect sinus lift groups by using the Vasalva maneuver (nose blowing test) and by light tactile sensation with a blunt instrument rebounding on the membrane prior to placement of the implant.

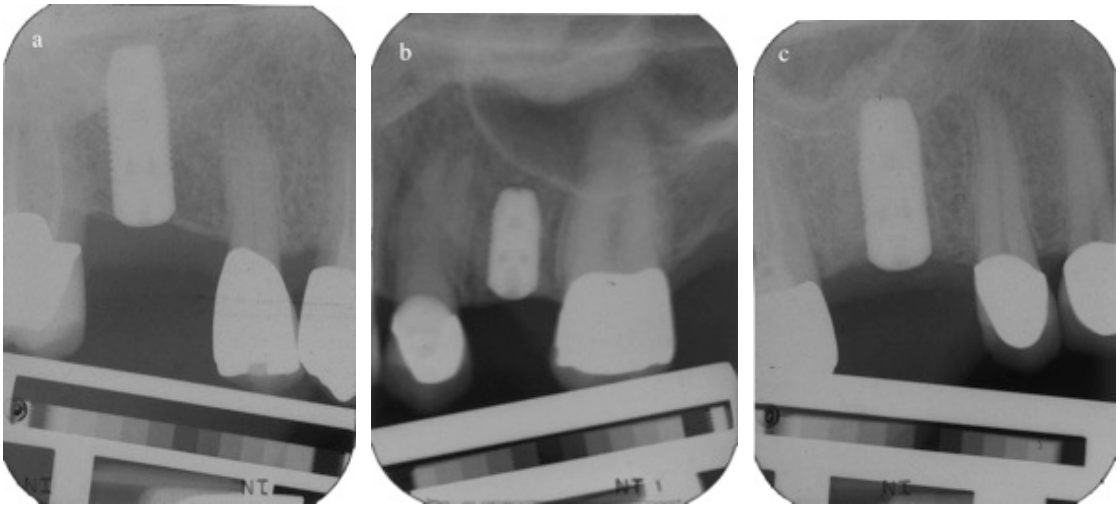
Once the Astra OsseoSpeed TX implant (fluoride-modified nanostructure, parallel walled with tapered apex) was placed, the implant stability was taken as three consecutive measurements in a buccal and lingual direction, using resonance frequency analysis (RFA) with the Osstell device (Integration Diagnostics, Savedalen, Sweden). This value was recorded as the implant stability quotient (ISQ) (Figure 4 a, b, c).

Figure 4. (a) Transducer. (b) Resonance frequency analysis Osstell measurement device. (c) Transducer screwed on implant for RFA measurement.



An aluminum (Al) step-wedge PA radiograph was taken immediately before and after the implant placement using a dental XCP (Extension Cone Paralleling) technique (Figure 5 a, b, c). All stage-1 radiographs were taken using F-speed films (Kodak Insight, Rochester, New York), processed through the same developing machine, and digitized using the same machine under the same settings at 1200 dpi. Stage-2 radiographs were taken initially with conventional radiographs, and later on with a digital sensor.

Figure 5. Radiograph of stage-1 implant placement. (a) The bi-cortical fixation group shows the implant apex protruding into the sinus. (b) The uni-cortical fixation group shows the implant apex not involving the sinus floor. (c) The indirect sinus lift shows a radiopaque dome created by the mineralized bone graft, surrounding the apex of the implant.



Pre and post-operative management

A cover screw was placed and primary closure was obtained over the implant. All patients were given a pre-operative loading dose of antibiotic and continued for 7-10 days following surgery. Post-operative analgesic was prescribed prn as needed and 0.125% chlorhexidine mouth rinse was utilized twice daily. Post-operative complications and patient's subjective symptoms were recorded throughout the follow up periods.

Second stage

The implant was uncovered between 3 to 6 months after initial implant placement. A healing abutment was placed and an Al step-wedge PA radiograph was taken. Secondary implant stability was again measured in triplicate with the Osstell device.

Radiographic examination and evaluation

The preoperative CBCT scan was used to determine ridge height in millimeter (mm) being the average of the buccal and lingual ridge height of the most mesial and most distal slices of the hypothetical implant position. Bone density was calculated from the CBCT in Hounsfield units (HU) using the HU density-measuring tool provided by iCAT. Density was gauged from a 1.0 mm thick slice selected immediately mesial and distal to the planned implant diameter. The selected area excluded crestal cortical bone, the sinus floor and adjacent tooth structure while representing the implant position within the bone. The bone density was calculated as an average of the mesial and distal selected slices.

The PA radiograph ridge height was measured at the shortest distance (in mm) from the sinus floor to the alveolar crest using Adobe Illustrator CS5. The PA bone density measurement was calculated by taking the best available Al step-wedge (preoperative radiograph or the stage-1 implant). Using Adobe Photoshop CS5, a rectangular area was selected mesial and distal to the implant (or the anticipated implant position if a preoperative radiograph was used). The selected area excluded the implant structure, the adjacent root structure, the sinus floor and the crestal cortical bone. All data are inputted into a table to obtain a graph from which an Al step wedge equivalent radiodensity (Al eRD) is calculated. The best available Al step-wedge PA radiograph (either stage-1 or stage-2 surgery) was selected for the intra-sinus implant protrusion measurement. The average of the mesial and distal protrusion was measured using Adobe Illustrator CS5.

Only one researcher measured the CBCT ridge height (mm) and bone density (HU) and PA ridge height (mm) and bone density (Al eRD in mm) and was blinded to the surgical technique used for the images being measured.

Statistical analyses

Descriptive statistics are expressed as frequencies, percents or mean and standard error (SE), where appropriate. The p-value for comparing baseline characteristics among three surgical techniques is calculated from the generalized linear mixed model to account for within-subject correlation. This method was also used to compare primary and secondary stability between surgical techniques as well as different implant diameters and lengths. The correlation between stability and baseline characteristics is assessed by Pearson's correlation coefficient (r) using the bootstrap method to account for within-subject correlation. Bootstrap median and 95 percentile interval are presented. Adjusted analysis was done to compare primary and secondary stability controlling for ridge height or bone density effect by the linear mixed model. All analyses were carried out using the SAS system (v. 9.3; SAS Institute, Cary, NC, USA). All P-values were two-sided and 0.05 was considered statistically significant.

Chapter III

Results

A total of 45 dental implants were placed among 38 patients. The data of two patients was not included at 2nd stage surgery. One patient wished to withdraw at 2nd stage surgery and did not proceed because of a newly diagnosed severe illness. One patient proceeded with 2nd stage but the data was removed from analyses because of significant inconsistency in the reported ISQ (initial stability ranged 25-44 for a clinically stable implant placed using an indirect sinus lift technique) and the clinical findings. The only post operative complication reported was one patient experiencing vertigo symptoms but no involuntary eye movements (common with benign paroxysmal positional vertigo) subsequent to the indirect sinus lift but symptoms resolved on their own after a couple of months.

Table 1. Baseline patient demographic information and outcome parameters (Average and SE) for the three treatment groups.

	Estimate (SE)			
Variables	**Bi-cortical fixation (N=15)**	**Uni-cortical fixation (N=15)**	**Indirect Sinus Lift (N=15)**	**P-value**
Age (Year)**	60.40(7.90)	60.00(13.00)	52.87(12.52)	0.14
Sex (n%)**				0.63
Male	9(60.00)	6(40.00)	7(46.67)	
Female	6(40.00)	9(60.00)	8(53.33)	
PA ridge height (mm)	8.62(0.41)	9.40(0.40)	9.16(0.44)	0.41
PA bone density (AI eRD; mm)	6.73(0.40)	6.52(0.41)	7.52(0.38)	0.09
CBCT ridge height (mm)	8.81(0.33)	9.89(0.33)	9.39(0.33)	0.09
CBCT bone density (HU)	349.08(43.59)	444.44(43.40)	371.03(44.45)	0.29
Implant location (n%)				<0.01*
1st premolar: #5,12	0	4(26.67)	1(6.67)	
2nd premolar: #4,13	3(20.00)	8(53.33)	3(20.00)	
1st molar: #3,14	9(60.00)	2(13.33)	10(66.67)	
2nd molar: #2,15	3(20.00)	1(6.67)	1(6.67)	
Implant diameter (mm)	4.69(0.13)	4.25(0.13)	4.72(0.13)	0.03*
Implant diameter (n%)§				0.04*
4.0 mm	3 (21.43)	9 (75.00)	4 (26.67)	
5.0 mm	11 (78.57)	3 (25.00)	11 (73.33)	
Implant length (mm)	11.39(0.38)	8.11(0.37)	11.81(0.38)	<0.01*
Intra sinus implant protrusion	3.48(0.29)	-1.50(0.29)	3.42(0.30)	<0.01*

* indicates statistically significant differences.
** The table presents person-level characteristics; because 7 patients had 2 implants and different surgical techniques were used for each implant, these patients are counted twice, once for each pertinent technique.
§ 3.5 and 4.5mm are omitted due to small sample size

The baseline patient demographic information and outcome parameters for the three treatment groups are depicted in Table 1. The treatment groups did not differ significantly in age or sex. A total of 7 patients received 2 implants. There was no significant difference in age and sex among the groups. There was a significant difference ($P < 0.01$) in the implant position depending on the treatment group. A greater number of implants in molar sites were used with either bi-cortical fixation (11 implants) or indirect sinus lift (11 implants), while premolar sites more frequently received uni-cortical fixation of implants (12 implants). Implant diameter and length were

significantly greater in indirect sinus lift (4.7/11.8 mm) and bi-cortical fixation (4.7/11.4 mm) compared to uni-cortical fixation (4.3/8.1 mm). Even though CBCT-based ridge height and bone density (HU) for the bi-cortical group were 1 mm shorter and 100 HU less dense than ones for the uni-cortical group, there was no statistical significant difference in baseline ridge heights and bone density between the three treatment groups. The mean intra-sinus implant protrusion was 3.5mm[SE 0.3] in the bi-cortical fixation group and 3.4mm[0.3] in the indirect sinus lift group, while the implant apex was usually 1.5mm[0.3] coronal to the sinus floor in the uni-cortical fixation group. PA bone density (P=0.09) and the CBCT bone density (P=0.29) were similar among treatment groups.

Table 2. Primary and secondary implant stability based on treatment group, as measured with resonance frequency analysis.

	Estimate (SE)			
Variables	**Bi-cortical fixation (N=15)**	**Uni-cortical fixation (N=15)**	**Indirect Sinus Lift (N=14)**	**P-value**
Primary Stability (ISQ)	71.37(2.14)	69.55(2.14)	75.91(2.27)	0.13
Secondary Stability (ISQ)	79.89(1.20)	80.02(1.16)	79.96(1.27)	1.00

While primary stability was highest with the indirect sinus lift (ISQ=75.9 [2.3]), this did not differ significant from the other two groups (P=0.13) (Table 2). Secondary stability measured after healing demonstrated all 3 surgical techniques achieved high and almost identical implant stability, around 80 (P=1.00).

Table 3. Correlation (r) between primary and secondary implant stability and other variables for implants in all three study groups.

	Primary Stability		Secondary Stability	
Variables	**Estimate**	**95% CI**	**Estimate**	**95% CI**
PA ridge height (mm)	0.03	(-0.27, 0.30)	-0.12	(-0.36, 0.17)
PA bone density (AI eRD)	0.05	(-0.22, 0.35)	0.19	(-0.17, 0.43)
CBCT ridge height (mm)	-0.01	(-0.34, 0.31)	0.02	(-0.32, 0.31)
CBCT bone density (HU)	0.37*	(0.08, 0.58)	0.25	(-0.05, 0.49)
Implant length (mm)	0.18	(-0.13, 0.45)	0.01	(-0.24, 0.32)

*indicates a correlation significantly different from zero.

Correlation between primary and secondary implant stability and other variables is shown in Table 3. There was a statistically significant positive correlation (r=0.37) between primary stability and CBCT bone density (HU), but not ridge height (PA and CBCT), PA bone density, or implant length and diameter. Secondary stability was not impacted by the surgical technique used, the implant site, ridge height or density, the implant diameter or length.

Table 4. Primary and secondary implant stability comparisons of the three surgical techniques, adjusted for ridge height and bone density

		Estimate (SE)			
Outcome	**Adjusted Variables**	**Bi-cortical fixation**	**Uni-cortical fixation**	**Indirect Sinus Lift**	**P-value**
Primary Stability (ISQ)	PA ridge height (mm)	71.41(2.22)	69.53(2.19)	75.91(2.30)	0.14
	PA bone density (AI eRD)	71.38(2.20)	69.61(2.20)	75.88(2.40)	0.17
	CBCT ridge height (mm)	71.34(2.27)	69.60(2.25)	75.93(2.30)	0.14
	CBCT bone density (HU)	72.14(1.89)	67.76(1.94)	77.23(2.00)	<0.01*
Secondary Stability (ISQ)	PA ridge height (mm)	79.67(1.24)	80.09(1.17)	80.12(1.28)	0.96
	PA bone density (AI eRD)	79.63(1.22)	80.23(1.18)	79.75(1.34)	0.93
	CBCT ridge height (mm)	79.92(1.29)	80.01(1.20)	79.95(1.29)	1.00
	CBCT bone density (HU)	80.07(1.19)	79.65(1.17)	80.10(1.25)	0.96

*indicates statistically significant differences.

Results for primary and secondary implant stability adjusted for ridge height and bone density for the three surgical techniques is shown in Table 4. Only CBCT bone density showed a significant difference in primary stability among different surgical

techniques, with the indirect sinus lift demonstrating a higher primary stability ($P < 0.01$). However, secondary stability was similar for all three surgical techniques regardless of adjustment on ridge height or bone density (Table 4).

Chapter IV

Discussion

The primary conclusion in this investigation demonstrated that implants placed through bi-cortical fixation achieved comparable primary and secondary implant stability to those placed using the indirect sinus lift or uni-cortical fixation techniques.

The majority of bi-cortical implant stability studies compared their findings primarily to uni-cortical fixation.[32,34] Although not statistically significant, the indirect sinus lift group had the highest mean ISQ value (75.9) in our study. Our ISQ value was similar to the mean ISQ of 69.1 obtained in Lai's study[41] in which Strauman SLA implants were placed using the indirect sinus lift without bone grafting. On the other hand, without the added effect of the osteotome lateral condensation and simply creating a greenstick fracture of the sinus floor, Markovic found a lower initial implant stability.[42] The latter study sequentially drilled up to the sinus floor without underpreparing the osteotomy, without grafting, and without laterally condensing bone, and reported a mean ISQ value of 59.6 $\pm$ 7.1, with a minimum value of 47.0 and maximum value of 75.0.

In the current study, several factors may have contributed to the lower ISQ value (71.4) of the bi-cortical fixation group compared to the indirect sinus lift. The design of

Osseospeed TX Astra implant has an apical portion that tapers over a length of 2.5 mm. Both 4.0S and 5.0S diameter implants have their implant body diameter tapered to 2.4 mm and 3.2mm at the end of the implant apex, respectively. This is narrower than the diameter of the final twist drill (3.2 mm and 4.2mm, respectively) used to prepare the osteotomy of those implants. With the intended 1-2 mm implant intra-sinus protrusion, it may be possible that the sinus floor puncture was wider than the apex of the implant. As a result, the implant walls may not have engaged the sinus floor using the self-threading concept. It is also possible that when the implant was counter sunk, the shoulder of the implant no longer engaged the alveolar crest cortex, and therefore questions whether bi-cortical fixation was truly achieved. Although a post-operative PA radiograph was taken to confirm implant position relative to the sinus floor, the only way to ascertain this would have been to take a CBCT post-operatively. In the future, these surgical variables should be addressed with particular attention to apical implant design as well as control over the last drill bit used to improve engagement of the sinus floor in order to achieve true bi-cortical fixation.

The majority of implants was allowed to heal for 3 to 4 months before stage-2. However, depending on patients' personal reasons and/or scheduling difficulties, some implants were uncovered as late as 10 months after stage-1. Secondary stability as measured at stage-2 was similar among all 3 surgical techniques with an ISQ of 80.

The mean intra-sinus implant protrusion for bi-cortically fixated implants was 3.5mm. This is higher than the intended 1-2mm. When initially selecting the implant length, it was based on the CBCT buccal and lingual bone height, at the position where the implant sides would engage the bone. However, the post-operative intra-sinus

protrusion measurement was taken from the periapical radiograph. Using this 2-dimensional image, the intra-sinus protrusion can only be calculated mesial and distal of the implant and corresponds to the dip in the sinus floor where the shortest distance ridge height would be located. Therefore, it is most likely that the implant does protrude 1-2mm beyond the buccal and lingual bone, but protrudes more in the mesial and distal aspects. Even though our implant protrusion was greater than the intended 1-2mm in the bi-cortical fixation group, risk of sinus membrane perforation was low since stoppers in the bi-cortical fixation group allowed for depth control during the osteotomy preparation.

In both the bi-cortical fixation and indirect sinus lift techniques, the sinus membrane was elevated on average by 3.5 mm and 3.4 mm, respectively. Nkenke[17] showed that the sinus membrane could be safely elevated by 3 ± 0.8 mm without increased perforation risk. In our study, the surgeons reported no sinus membrane perforation during the procedure. However, since direct visualization of the sinus membrane was not possible, one cannot be completely certain that the integrity of the sinus membrane was maintained. Except for a mild self-resolving post-operative vertigo in one patient treated with the indirect sinus lift, there were no sinus infections, nosebleeds, or post-operative infections. This is in comparison to the systematic review on the osteotome technique by Tan[22] which reported membrane perforation (3.8%, range 0-21.4%) as the most common complication, low risk of post-operative infection (0.8%, range 0-2.5%), and other potential complications like post-operative bleeding, epistaxis, nasal blockage, hematomas, and suppuration due to loosened cover screws.

Other studies have used the osteotome approach to fracture the sinus floor. Without grafting and protruding the implants 3 to 5mm, intra-sinus bone gain has been observed ranging from 2mm to 4mm.[16,18-21] However, predictability of bone regeneration using this technique varied. This intra-sinus bone formation in the bi-cortical fixation and the indirect sinus lift groups will be reported in our next one-year post-restoration follow up study. It would be very interesting to see how much of intra-sinus bone formation has been achieved in each group when both bi-cortical fixation without graft and indirect sinus lift with graft groups had similar sinus protrusion (3.48 mm vs. 3.42 mm) at baseline implant placement surgery.

Resonance Frequency Analysis (RFA) has been used to objectively and noninvasively determine initial implant stability at the time of surgical placement. The device assigns an implant stability quotient (ISQ) value that is dependent on the stiffness of the bone-implant surface[43,44] and therefore is influenced more by cortical bone thickness than by implant length.[45,46] In fact, implant macro-geometry such as length and diameter do not appear to affect primary stability as measured by RFA[47,48] as much as local bone quality.[49] As Lai[41] has observed, RFA is most affected by bone type classified using Lekholm and Zarb.[50] Our results agree with these reports.

Our findings support the predictive value of CBCT bone density in determining primary implant stability, with a significant positive correlation of 0.37. According to Bergkvist[51], bone mineral density measured from preoperative CT examination (and confirmed on post-operative CT) was significantly correlated ($p=0.03$) with RFA stability values and bone quality. These density results taken from medical CT can be repeated with accuracy using a CBCT[51], which emits less radiation and is more routinely

used in the dental field. Similar correlation findings from Schnitman[52] and Turkyilmaz[53] suggest that preoperative CBCT bone density may be a useful objective pretreatment tool to predict initial implant stability and the potential of early loading, particularly in sites with bone density >600 HU. Our CBCT bone density was not as high with a mean range of 349 HUs to 444 HUs between the three treatment groups. In our protocol, the implant site selected in the preoperative scan is a hypothetical placement site. Due to the initial scanning setting, the thinnest slice was 1.0mm. In order to avoid including root structures of adjacent teeth, an additional slice devoid of tooth structure was preserved before selecting the slice immediately adjacent to the implant for bone density measurement. However, this technique has limitations. At times, the evaluated slice may be part of the bone that would be drilled out when the implant is placed.

Compared to the indirect sinus lift, bi-cortical fixation still allows for longer implants to be placed without the need for additional cost of non-autogenous grafting material. The risk of benign paroxysmal positional vertigo, which has an incidence of <3%[54], can be eliminated since no malleting of osteotome is needed. One contraindication of indirect sinus lift is the presence of an oblique sinus floor leading to difficulty in infracture of the sinus floor. The use of controlled sequential drilling using stoppers and self-threading implants to achieve bi-cortical fixation offers an alternative to a direct sinus lift that would need to be performed in this clinical situation. The use of short implants is still a viable option but the expected physiologic bone loss around a restored implant, not to mention peri-implantitis, and the lack of long-term research of over 10 years, make the use of short implants less attractive, especially in the weak

bone like the posterior maxilla. Moreover, limited repertoire of the short implants in the combination of length and diameter presents additional challenges to surgeons. With the potential of intra-sinus bone growth with bi-cortical fixation, it may be possible to opt for a longer implant.

Chapter V

Conclusion

Within the limits of this study, our results show that bi-cortical fixation technique achieved comparable primary and secondary implant stabilities to that of uni-cortical fixation and indirect sinus lift techniques. Thus our results support the use of bi-cortical fixation technique, which offers a more economical and safe alternative to placement of longer implants, with low post-operative complications. Nevertheless, while primary implant stability is a strong predictor of implant success, further long-term studies are needed to truly evaluate success of bi-cortically placed implant.

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