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Retrospective clinical study

Tilted implants and sinus floor elevation techniques compared in posterior edentulous maxilla: retrospective clinical study of four years follow-up

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Abstract: The aim of this study was to evaluate implants survival rate, marginal bone loss, surgical and prosthetic complications of implants placed through sinus floor elevation and tilted implants engaged in basal bone in order to bypass maxillary sinus. 60 patients were enrolled for this study. According with residual bone height of posterior maxilla the sample was divided in three groups of 20 patients: Group A (lateral sinus floor elevation), Group B (transrectal sinus floor elevation) and Group C (tilted implants employed to bypass sinus floor). Follow-up visits were performed one week after surgery, at 3, 6 months and then once a year for next 4 years. The outcomes were implants survival rate, marginal bone loss and surgical and prosthetic complications. Although the Group A, B and C have demonstrated an implants survival rate of 83.3%, 86,7% and 98,3% respectively, the statistically analysis showed that there was no statistically significant difference between groups. Statistically significant differences between the groups were also not found concerning marginal bone loss, as recorded by intra-oral X-ray measurements during follow-up. About complications it wasn't possible to perform a statistical analysis. To as to reduce potential surgical risks implants placement in basal bone should be preferred.

Keywords: posterior edentulous maxilla, maxillary sinus, sinus floor elevation, tilted implants.

1. Introduction

Fixed rehabilitation of the atrophic maxilla may represent for clinicians a real challenge. Following tooth loss, the physiological process of bone resorption is combined with sinus pneumatisation, which often impedes traditional implants' placement in posterior sectors [1-3].

To allow patients fixed rehabilitations, several therapeutic alternatives have been proposed.

Although bone grafting and sinus lift techniques have provided good long-term results [4][5], several complications including Schneider's membrane perforation, grafted material's infection or resorption, implants' dislocation in maxillary sinus, acute or chronic sinusitis, alveolo-antral artery injury and benign paroxysmal vertigo, could occur [6][7].

Short [8] and tilted [9] implants might be preferred to engage basal bone, to reduce the risk of intra- and post-operative complications and the clinical time required.

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In case of severe bone atrophy (less than or equal to 5 mm), as around ultra-short (5 mm length) implants, micromovements and peri-implant stresses and strains were recorded [10][11], tilted implants could represent a more viable alternative for rehabilitation of the posterior edentulous maxilla [12-14].

If residual bone height is at minimum of 5 millimetres, the transcrestal sinus lift technique, described by Summer in 1994 [15][16], could be considered adequate [17].

If residual bone height is less than 5 millimetres, sinus augmentation via lateral approach could be a viable solution, reporting good long-term results [18].

However, considering the risk of intra- and post-operative complications [7], inclined implants could be preferred, provided the following conditions are achieved: adequate bone volume in the retrocanine area for implant placement at least 10-mm long and combination with an axial implant [19][20].

In addition, implants' placement in basal bone should always be considered in presence of any conditions that could represent a possible contraindication to sinus augmentation, such as sinusitis, including allergic rhinitis, polyp, cyst or tumour in maxillary sinus and history of sinus surgery [21][22].

The aim of this retrospective clinical study was to evaluate and compare implants survival rate (first outcome), marginal bone loss (second outcome) and surgical and prosthetic complications of implants-prosthetic rehabilitation through implants placed through sinus floor elevation techniques (lateral approach and osteotome mediated technique) and tilted implants engaged in basal bone in order to bypass maxillary sinus.

2. Materials and Methods

2.1. Patient Selection

This retrospective study was performed at the Department of Dentistry, San Raffaele Hospital, Milan, Italy. The ethics committee approval number is 190/INT/2021.

The investigation was conducted according to the principles of the Declaration of Helsinki. STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) guidelines were followed (http://www.strobe-statement.org/).

During the period from January 2015 to April 2019 patients with posterior edentulous maxilla (Appel-gate-Kennedy Class I or II [23]) or severe impairment of residual teeth in posterior maxilla were consecutively enrolled.

The eligibility criteria were as follows:

- age > eighteen years
- requiring fixed prosthetic rehabilitation
- unilateral or bilateral partial edentulism of the maxilla with residual bone height equal or less than 6 mm
- severe impairment of residual teeth in the posterior maxilla with residual bone height equal or less than 6 millimetres after the healing period
- need to replace three or four teeth.

Exclusion criteria were:

- immunodeficiency
- smokers patients
- uncontrolled systemic diseases
- bisphosphonates therapy
- head and neck radiotherapy in less than one year
- severe malocclusion
- severe parafunction
- inability to adhere to home and professional hygiene maintenance protocols.

All diagnoses were made clinically and radiographically. The radiographic examination was conducted as first level with panoramic radiography and at second level with cone beam computed tomography (CBCT) to identify residual bone height and whether

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the patient satisfied the inclusion criteria of the study (residual bone height of 6 millimetres or less). According to bone volume, the sample was divided in three groups. **(Table 1)**

Table 1. Sample division according to residual bone height, bone volume in the retrocanine area, possibility or not of combining a tilted implant with an axial one and presence or absence of any contraindication to sinus augmentation.

	Group A (Transcresral Sinus Floor Elevation)	**Group B (Sinus floor augmentation via lateral approach)**	**Group C (One Tilted and One Axial implants)**
Residual Bone Height	Minimum of 5 millimeters [15-17]	less than 5 millimetres, inadequate bone volume in the retrocanine area for tilted implant placement at least 10-mm long, impossibility of combining a tilted implant with an axial one and absence of any contraindication to sinus augmentation [18-22]	less than 5 millimetres, adequate bone volume in the retrocanine area for tilted implant placement at least 10-mm long, possibility of combining a tilted implant with an axial one and contraindication to sinus augmentation [18-22]

A written informed consent for implant-prosthetic rehabilitation was obtained from all patients prior to the beginning of the study and the local ethical committee approved the study; professional oral hygiene was provided before surgery.

2.2. Surgical Procedures

Group A: Sinus floor elevation trough Lateral Window Technique

As for the other surgery, one hour before, patients received 2 gr amoxicillin and clavulanic acid and 1 gr twice a day for a week after surgical procedure (clarithromycin was prescribed as alternative in case of allergy, 2 gr before surgery and gr twice a day for the following week).

Surgery was performed under anesthesia induced by local infiltrations of opticain solution with adrenaline 1:80.000 (AstraZeneca, Milan, Italy). The same protocol was applied for all techniques.

The first Incision was made on the top of the alveolar crest, shifted on palatal side to obtain the same level of keratinized mucosa on both flap's sides. Then, distal and mesial vertical release incisions were performed to expose the underlying bone crest. The Full thickness flap was elevated to preserve anatomical subperiosteal structures.

The flap's detachment was made to expose piriform opening and canine draft, used as landmark, and to identify maxillary sinus, often available in transparency from the lateral bone wall. A bony window was drawn with a sterile pencil on the lateral wall, behind the canine draft, according to size and location of maxillary sinus and implants site insertion. Then, a high-speed handpiece with diamond bur was employed to outline the antrostomy. A bone scraper was used to achieve autologous bone chips from the bony window. To preserve Schneider membrane from injuries, a piezoelectric instrument was employed to bony window detachment.

The elevation' degree was done according with vertical defect's extension, proceeding from the inferior-medial sinus wall to the distal.

The implant sites were prepared with a lance-shaped drill and then drills of increasing diameter; fixtures were placed.

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Autologous bone graft obtained from bony window was placed around implants to promote bone regeneration [24].

Flap adaptation and suturing were performed with 3-0 non-resorbable sutures (Vicryl; Ethicon, Johnson & Johnson, New Brunswick, NJ, USA).

After surgery, antibiotic therapy (amoxicillin and clavulanic acid 1 g or clarithromycin 1 gr in case of allergy, twice daily for 7 days after surgery) and analgesic therapy (non-steroidal anti-inflammatory drugs, as needed) were prescribed for each patient. Mouth rinsing with a chlorhexidine digluconate-containing solution (0.12% or 0.2%), were recommended twice daily for 10 days. One week after surgical procedure, sutures were removed. The same post-surgical protocol was applied for all procedures.

Group B: Sinus floor elevation trough Osteotome Mediated Technique

The first Incision was made on the top of the alveolar crest, shifted on palatal side to obtain the same level of keratinized mucosa on both sides of the flap. Distal and mesial vertical release incisions were performed to create a full thickness flap, exposing the underlying bone crest preserving anatomical epiperiosteal structures. A lance-shaped drill

was employed for 2 mm to drill the cortical bone. A pilot drill of ø 2.00 was applied to create an implant way insertion and define fixture's setting. Then, osteotomes of progressively increasing diameter were gradually pushed up to maxillary sinus floor.

When prepared the implant site, using a last osteotome of the same fixture diameter, the sinus floor and the underlying membrane were lift. An adsorbable hemostatic gelatin (Spongostan, Ethicon, Johnson & Johnson, New Brunswick, NJ, USA) was employed to promote clot formation and to retain membrane elevation. Flap adaptation and suturing were performed with 3-0 non-resorbable sutures (Vicryl; Ethicon, Johnson & Johnson, New Brunswick, NJ, USA).

Group C: Tilted implants

The first Incision was made on the top of the alveolar crest, shifted on palatal side in order to obtain the same level of keratinized mucosa on both sides of the flap. Then distal and mesial vertical release incisions were performed to expose the underlying bone crest.

The obtained full-thickness flap allowed to preserve subperiosteal anatomical structures from injuries and to expose canine draft and maxillary sinus, often available in transparency from the lateral bone wall. Every tilted implant was associated with an axial implant, placed according with traditional system in canine or lateral incisor region. Straight implants placement occurred always later tilted implants insertion according with their position and angulation.

A lanceolate drill was employed to perforate cortical bone. A pilot drill of ø 2.00 was applied to create an implant way insertion and to define fixture's setting. A positioning pin was plugged to verify implant location, emergence and angulation. Progressive diameter drills were employed up to final fixture's diameter. The site was over-prepared vertically and sub-prepared transversely to promote the primary mechanical stability. The insertion torque ranging between 30 and 40 N·cm before final seating of the implant, allowing the immediate loading.

A manual screwer was applied when incomplete seating of the implant occurred. The implant neck was aimed to be positioned at bone level, and bi-cortical anchorage was established whenever possible.

To compensate for the lack of parallelism between implants angulated abutments (Extreme Abutment, EA® Winsix, Biosafin) at 30 degrees were screwed on tilted implants; straight abutments were screwed on axial. The flap was adapted around the structure. Suturing was performed with 3-0 non-resorbable sutures (Vicryl; Ethicon, Johnson & Johnson, New Brunswick, NJ, USA).

2.3. Prosthetic Protocol

In both sinus floor elevation procedures (Group A and Group B), the implants were covered for about 4 months. After about 4 months from the surgical procedure, the

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reopening was performed, and cap screws were replaced with healing screws. The provisional prothesis was delivered to each patient. Screw access holes were covered with provisional resin (Fermit, Ivoclar Vivadent, Naturno, Bolzano, Italy). Performed the appropriate evaluation checks of the device, after another four months, the provisional prothesis was replaced with a metal ceramic or resin implant-supported final prosthesis.

Unlike these procedures, which involved a deferred load, Group C, according with several authors' results, patients were subjected to immediate loading [25][26].

One week before surgery preliminary traditional impressions were taken in order to obtain an all-acrylic resin provisional prothesis composed by three teeth.

In order to enable manufacture of a high-density baked all-acrylic prosthesis with titanium cylinders, pickup impressions (Permadyne, ESPE, Seefeld, Germany) of the implants were made after suturing.

About 3 hours after the surgery, a screw-retained, metal reinforced, acrylic provisional prosthesis with 3 teeth was delivered. Screw access holes were covered with provisional resin (Fermit, Ivoclar Vivadent, Naturno, Bolzano, Italy). Four months later, a the provisional prothesis was replaced with a metal ceramic or resin implant-supported final prosthesis composed by 3 teeth.

2.4. Follow-up

Follow-up visits were performed one week after surgery, at 3 and 6 months and then once a year for the next 4 years. Each patient was placed in a professional oral hygiene program that would allow for both limiting complications [27][28] and monitoring and interception of any complications.

1. *Implants survival rate.* Implants survival rate was defined as absence of signs of peri-implantitis, implants mobility, radiolucent areas around fixtures, mucosal suppuration or pain during the follow-up period.
2. *Marginal bone loss.* Digital phosphor endoral radiography was performed for each patient using the parallel cone technique at 6, 12, 24, 36 and 48 months. In order to assess marginal bone trends, measurements were performed only after image calibration. The Digora 2.5 software ((Soredex, Tuusula, Finland) was used as the analysis platform, making use of the specific measurement tool contained therein. As a first step, the calibration (pixels/mm) of the instrument was performed, using the implant diameter of the survey site as the known unit. Next, any changes in the height of the peri-implant marginal bone in relation to the most coronal part of the implant fixture and the point of contact between the implant fixture and the marginal ridge were measured. In order to evaluate the trend of the bone, a line passing over the shoulder of the implant was considered as a reference point for measurement from which a straight line was drawn parallel to the long axis of the implant to the most coronal point where the bone met the fixture both mesially and distally. The software automatically provided, in relation to the calibration, the distance between the two points measured in millimeters. To reduce human error, this measurement was performed by three separate operators and the average of the three measurements was considered. Then, to calculate the marginal bone level, a mesial measurement was taken, a distal measurement was taken and then the average of the mesial, distal and the average between the two values of a single implant site (MBL, marginal bone level) was calculated, as reported in the "results" section. The data thus obtained were then statistically evaluated.
3. *Surgical complications.* Surgical complications were divided according to the surgical procedure.
4. *Prosthetic complications.*
   - Fracture of the provisional prothesis.
   - Unscrewing of temporary crowns and/or MUAs in group C;
   - Unscrewing of final crowns and/or MUAs in group C;

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- Chipping.

2.5. Statistical analysis

Statistical analysis was performed for numerical parameters using SPSS for Windows version 18.0 (SPSS Inc., Chicago, IL, USA). Descriptive analysis was performed using mean ± standard deviation.

The different implant survival rate between the surgical procedures, based on the number of implants lost in each group, was compared using the Between-Subjects pair-wise effects test. Analysis of variance was used to investigate changes in bone level over time. All statistical comparisons were conducted at the .05 significance level. The null hypothesis was that there would be no difference in mean marginal bone changes between implants. Regarding complications, due to the few cases observed, a statistical analysis could not be performed.

3. Results

According to the inclusion and exclusion criteria, sixty patients (32 males, 28 females) with an edentulous posterior maxilla (Appel-gate-Kennedy Class I or II) or need for avulsion of residual teeth in posterior were enrolled for this study. The mean age was 64 years (range: 52-76). The sample was divided into three groups of 20 according to the surgical procedure they received.

Every surgery involved the placement of two implants to support screw-retained prostheses of a minimum of three and a maximum of four dental units according with antagonist arch (presence or absence of the lower first molar). Fixtures were placed at sites 14 and 16/24 and 26 or at sites 15 and 17/25 and 27 depending on the antagonist arch. A total of 144 dental implants (Winsix, Biosafin, Ancona, Italy) were placed. Group A received 48 implants, Group B, 46 and Group C, 50 implants. **(Table 2)**

Table 2: *Number, diameter and length of dental implants classified by group.*

		Dental Implants Details			
		length 9 mm	length 11 mm	length 13 mm	lenght 15 mm
Group A n=48	diameter 3.3 mm	6	7	0	0
	diameter 3.8 mm	29	6		0
Group B n=46	diameter 3.3 mm	2	3	1	0
	diameter 3.8 mm	16	21	3	0
Group C n=50	diameter 3.3 mm	0	0	4	4
	diameter 3.8 mm	0	2	29	11

Immediate loading was performed only in Group C; moreover, in both sinus floor elevation techniques, implant loading occurred approximately 4 months after implants placement.

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1. Implants survival rate. In lateral sinus floor elevation technique (Group A) 4 implants were lost in the first six months after surgery and 2 in the following period. In transcrestal approach (Group B), 2 implants were lost in the first six months after surgery and only one later. Only one tilted implant (Group C) was early lost; two were lost one year after surgical procedure.

Group A, Group B and Group C have demonstrated an implants survival rate of 83.3%, 86,7% and 98,3% respectively. ***(Table 3)***

Table 3. *Implants failure before 6 months, after osseintegration period (after 6 months) and implants survival rate according with surgical procedure.*

	Implants placed	Early failure	Late failure	Implants survival rate
Group A	48	4	2	89%
Group B	46	2	1	94%
Group C	50	1	2	96%

However, a one-way analysis of variance (ANOVA) revealed no differences among groups in proportion of lost implants, F (2, 60) = .54, p = .59, n.s. Though seemingly different from one another, the estimated mean values did not differ statistically. ***(Table 4)***

Table 4: *differences among groups in proportion of lost implants.*

Table 3: Tests of Between-Subjects Effects

Dependent Variable: prop_lost dental implants

Source	Type III Sum of Squares	df	Mean Square	F	Sig.
Corrected Model	.036[a]	2	.018	.539	.586
Intercept	.363	1	.363	10.775	.002
Group	.036	2	.018	.539	.586
Error	1.920	57	.034		
Total	2.319	60			
Corrected Total	1.956	59			

a. R Squared = .019 (Adjusted R Squared = -.016)

2. Marginal Bone Loss. Statistical analysis was also performed for marginal bone loss, evaluated 6 months after the surgical procedure, 12 months and once a year in the subsequent period for each implant. ***(Table 5)***

Table 4: *average marginal bone loss (millimeters) observed during follow-up.*

Descriptive Statistics

	GROUP	Mean	Std. Deviation	N
I1_MBL 6 months (mm)	A	.970	.1455	20
	B	.915	.1387	20

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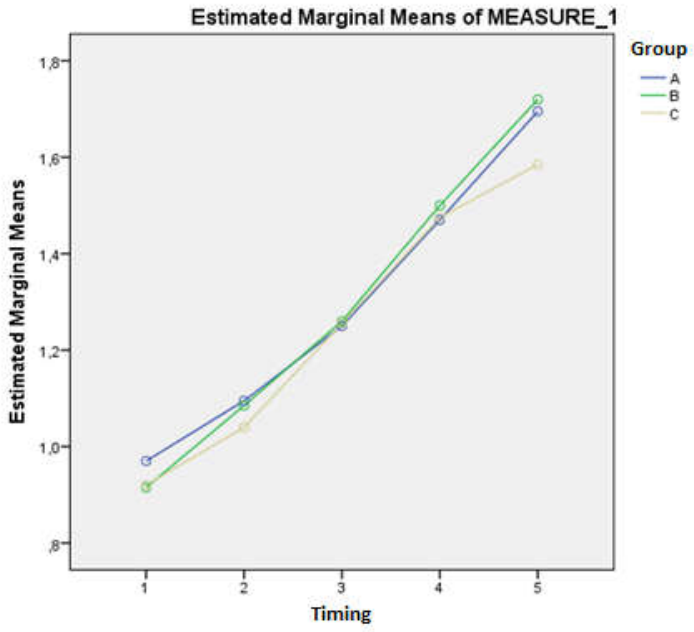
	C	.920	.1508	20
	Total	.935	.1448	60
I1_MBL 12 months (mm)	A	1.095	.1356	20
	B	1.085	.1663	20
	C	1.040	.1847	20
	Total	1.073	.1625	60
I1_MBL 24 months (mm)	A	1.250	.1235	20
	B	1.260	.1729	20
	C	1.255	.1572	20
	Total	1.255	.1501	60
I1_MBL 36 months (mm)	A	1.470	.0801	20
	B	1.500	.1338	20
	C	1.475	.0786	20
	Total	1.482	.1000	60
I1_MBL 48 months (mm)	A	1.695	.1986	20
	B	1.720	.2238	20
	C	1.585	.0933	20
	Total	1.667	.1875	60

Regarding implant 1, as shown in Figure 1, a 3 (groups) x 5 (time) MANOVA revealed a main effect of time, $F(1, 57) = 786.11$, $p < .001$, while other effects did not reach the conventional threshold of statistical significance. In other words, the MBL for implant 1 tended to increase over the five time periods, regardless of the surgical approach (i.e. group). ***(Figure 1)***

Figure 1: *MBL for implant 1, which tended to increase over the five time periods, irrespective of surgical approach.*



Regarding implant 2, as shown in Figure 2, a 3 (groups) x 5 (time) MANOVA revealed a main effect of time, $F(1, 44) = 680.31$, $p < .001$, while other effects did not reach the

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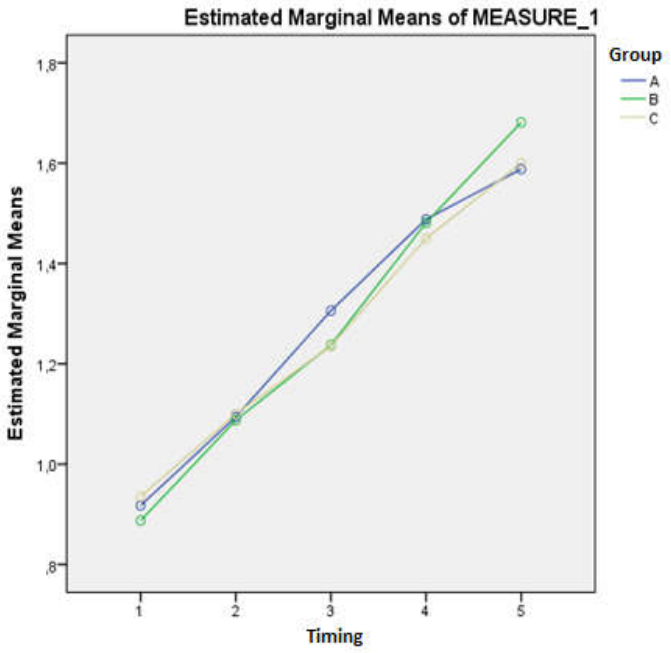
conventional threshold of statistical significance. In other words, the MBL for implant 2 tended to increase over the five time periods, regardless of the surgical approach (i.e. group). ***(Figure 2)***

Figure 2: *MBL for implant 2, which tended to increase over the five time periods, irrespective of surgical approach.*



About implant 3, due to a relatively high rate of implant loss, it was not possible to perform reliable statistical analyses on this implant.

3. Surgical Complications. All recorded complications were related to the lateral sinus floor elevation technique (Group A) or transcrestal sinus floor elevation (Group B). In Group C there were no intra-operative complications. Three membrane perforations were reported in Group A. The complication was resolved intra-operatively by further detaching the Schneider membrane from the inferior-medial region to reposition the hole under the bone wall. This avoided leakage of the graft material and possible subsequent infection. In the same group, no other complications were reported. In group B, the only problem encountered was paroxysmal benign positional vertigo (PPBV), associated with the percussive action induced by the surgical mallet. After about one month, the complication resolved itself in all four cases where it was found.

4. Prosthetic Complications. No prosthetic complications were reported during the follow-up period.

Discussion

Sinus lift techniques have been extensively discussed and several authors have reported good short- and long-term results on implant survival rate.

Bruschi et Al. in their retrospective clinical study at 10.43 ± 5.01 years (ranged from 5 to 16 years) follow-up reported a survival rate of 95.45% in implants placed with a transcrestal approach. [29]

Similar results were obtained by Qian et Al., in their randomised controlled trial at 10-year follow-up, in which they reported an implant survival of 90.7% in case of

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osteotome sinus floor elevation with deproteinized bovine bone mineral and 95.0% without bone grafting. [30]

Canullo et Al. in their multicenter prospective study at 2 years of follow-up reported an implant survival of 97% in patients with residual bone height between 1 and 4 millimeters who were treated with a lateral sinus lift using a nano-crystalline hydroxyapatite sole bone filler, simultaneous implant placement and deferred loading protocol [31].

Similar results were obtained by Schmitt et Al. in their retrospective clinical study at 10-year follow-up, in which they reported an implant survival rate of 95.45% in patients undergoing sinus lift with a lateral approach using autologous bone graft, implant placement after a four-month healing period and deferred loading protocol [32].

Beretta et Al [33] in their retrospective clinical study at 15-year follow-up compared implant survival in patients subjected to sinus lift with lateral approach, depending on implant placement protocol and biomaterial used. Implants placed at the same time as the sinus lift (residual bone height above 4 mm) provided similar results to implants placed after the healing period; autologous bone, according to other studies [34] provided better results than heterologous bone graft Although autologous bone is currently considered the gold standard in bone regeneration [35], good medium- and long-term results have been obtained in both sinus lift techniques even without bone grafting [36].

Although even concerning marginal bone loss, implants placed with sinus lift techniques have shown values similar to implants placed with traditional methods [37], several surgical complications such as perforation of Schneider's membrane, graft infection, implants or graft dislocation in maxillary sinus, acute or chronic sinusitis, injury of the alveolus-antral artery, benign paroxysmal vertigo, could occur [38][39].

To reduce surgical invasiveness and clinical time, when possible, tilted implants have been proposed as possible alternative.

Aparicio et Al., in their retrospective clinical study at 5-year follow-up reported an implant survival rate of 95.2% in immediate loading rehabilitations of posterior edentulous maxilla with placement of on axial and one tilted implant, concluding that tilted implants, longer than traditional, could increase implant-to-bone contact area, promoting primary stability, allow to reduce the prosthetic cantilever and engage basal bone [40].

Similar results were obtained by Fortin et Al. [41] and Pozzi et Al. [42], who reported an implant survival rate of 100%, at 5-year follow-up, and 96.3% at 3 years, respectively, in the absence of intra- or post-operative surgical complications.

To engage basal bone, as reported by several authors, tilted implants could represent a possible solution also in rehabilitation of totally edentulous maxilla with severe atrophy of the posterior sectors, avoiding more invasive techniques and allowing immediate loading [43-45].

5. Conclusions

Within the limitations of the present study, the obtained results suggest that tilted implants could be a possible alternative to sinus floor elevation procedures.

Although there were no statistically significant differences in im-plant survival and marginal bone loss between the groups, tilted implants placed in the available bone will present fewer complications compared to sinus elevation with lateral window approach or osteotome mediated technique. It is possible to perform immediate partial rehabilitation over maxillary tilted implants with minimal complications.

6. Patents

Author Contributions: Conceptualization, E.F.G. and B.D.; methodology, P.C.; software, X.X.; validation, R.V., P.C. and B.D.; formal analysis, M.N.; investigation, R.V..; resources, M.N.; data curation, B.D.; writing—original draft preparation, B.D.; writing—review and editing, M.N.; visualization, P.C.; supervision, E.F.G.; project administration, E.G.

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Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki and approved by the Institutional Review Board (or Ethics Committee) of Vita-Salute University, Milan, Italy.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on reasonable request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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