Immediate Fixed Implant Rehabilitation of the Atrophic Edentulous Maxilla after Bilateral Sinus Floor Augmentation: A 12-Month Pilot Study

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ABSTRACT

Purposes: The aims of this study were to evaluate a surgical/prosthetic protocol for the immediate rehabilitation of the augmented edentulous maxilla, and to compare the outcomes of implants placed in grafted (test group) versus native (control group) sites in the same patients.

Materials and Methods: Twenty patients were included in the study. Each patient was treated with a bilateral sinus augmentation procedure using a 50:50 composite graft of autogenous mandibular bone and bovine hydroxyapatite. Four to 5 months later, 155 implants (90 test and 65 control) were placed and restored with screw-retained fixed definitive prostheses supported by titanium frameworks within 1 week. All patients were followed for 1 year. Implant stability quotient (ISQ) measurements and radiographic evaluation of the marginal bone resorption (MBR) were performed.

Results: Two test implants failed in two patients, giving a cumulative 1-year success rate of 98.7%; the prostheses success rate was 100%. Insertion torque and ISQ values for test implants were significantly lower than those for control implants (unpaired *t*-test, $p < .0001$). The mean MBR around control and test implants at the 1-year evaluation were similar (0.47 ± 0.25 mm and 0.43 ± 0.21 mm, respectively).

Conclusions: The combination of implants placed in sinus-grafted and native sites can be immediately loaded with a fixed full-arch prosthesis and yield short-term successful outcomes.

KEY WORDS: dental implants, edentulous atrophic maxilla, immediate loading, marginal bone resorption, maxillary sinus augmentation, resonance frequency analysis

INTRODUCTION

Full-arch fixed implant-supported rehabilitation of the atrophic edentulous maxilla is often complicated by poor bone quality and limited bone quantity in the premolar–molar region.[1] Different therapeutic options have been proposed over the years to overcome this anatomical limitation. The use of tilted implants and distal cantilevers may avoid the placement of implants in the posterior regions, but this technique requires an adequate bone volume in the anterior maxilla for the placement of at least four implants; long cantilevers (>15 mm) are reportedly associated with reduced implant and prosthesis survival rates.[2–4] Short implants may represent an alternative, but their predictability in an atrophic posterior maxilla with an unfavorable intermaxillary relationship is controversial; regardless, a minimum vertical bone height of 7–8 mm should exist.[5,6] The placement of implants in specific anatomical areas, such as the pterygomaxillary and tuberosity regions,[7,8] or the zygoma,[9,10] may represent an alternative, but they require demanding surgical and prosthetic procedures because of the variable anatomy and different degrees of alveolar atrophy of the maxillofacial region. They are also associated with an increased risk of morbidity and soft-tissue complications, such as gingivitis and local infections at the implant sites.

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Bilateral sinus floor augmentation using autogenous bone or bone substitute material is a reliable method to enable implant placement in severely atrophic posterior areas.[11,12] The predictability of such an augmentative technique is documented by a growing body of literature even in the long-term follow-up.[13] However, the multistep process of maxillary implant-supported rehabilitation and the long healing periods for bone graft consolidation (4–8 months) and implant osseointegration (4–9 months) may include patient discomfort and inconvenience.[11–14] Another disadvantage is that patients undergoing such therapy need to wear a removable provisional prosthesis over the surgical site for several months, which may be unstable and have traumatizing effects on peri-implant bone, jeopardizing treatment outcome.[15] Therefore, increasing interest among clinicians has been expressed in reducing the treatment time and the number of clinical steps necessary to complete maxillary rehabilitations after bone-grafting procedures.[16]

An emerging protocol is the immediate loading of implants, which can be defined as prosthetic restoration attachment to the implants no later than 1 week after surgery and achievement of occlusion with the teeth of the opposite jaw.[17–19] Changes in macroscopic implant morphology, surface treatments, and rigid cross-arch stabilization have been shown to successfully allow the immediate loading of titanium implants, even in an augmented maxilla where the probability of a successful outcome is lower compared with native bone.[20–22] However, the limited number of study samples in the reported investigations makes statistical interpretations of the results difficult. In particular, limited data are available concerning the stability levels and hard- and soft-tissue changes around immediately loaded implants placed in sinus-grafted sites. Implants placed in augmented sinuses may be negatively affected by immediate loading because the bone quality is generally lower compared with native sites, increasing the risk of implant failure.

Therefore, the aims of this study were to evaluate treatment outcome and patient satisfaction with an immediately loaded full-arch fixed definitive prosthesis supported by dental implants placed in the atrophic edentulous maxilla after bilateral sinus augmentation, and to compare the clinical and radiographic outcomes of the implants placed in sinus-grafted versus native sites in the same patients for up to 1 year of loading.

MATERIALS AND METHODS

Study Design and Patient Selection

This trial was designed as a prospective, single-cohort, clinical trial. Between January 2006 and August 2007, 20 patients (9 men and 11 women; mean age 54.6 ± 5.3 years; range, 47–69 years), referred by their private dentists to the Unit of Oral and Maxillofacial Surgery at the Department of Dental Sciences of the University of Bologna for a full-arch, implant-supported rehabilitation of the totally edentulous maxilla associated with a bilateral severe atrophy of the posterior alveolar process, were consecutively enrolled in this study. The research protocol was approved by the Institutional Review Board of the Department of Dental Sciences of the University of Bologna, and was conducted according to the principles embodied in the 1975 Declaration of Helsinki for biomedical research involving human subjects, as revised in 2000.[23] Information regarding medical and dental history was recorded following a questionnaire.

The inclusion criteria consisted of the following: physical as well as psychological ability to tolerate conventional surgical and restorative procedures (ASA Class I and II),[24] totally edentulous maxilla or having hopeless remaining teeth requiring extraction, adequate bone volume in the anterior maxilla for the placement of two or three implants with a minimum diameter of 3.5 mm and a minimum length of 9 mm, bilateral severe atrophy in the posterior areas with a residual alveolar ridge height $\leq$3 mm, a request for fixed implant-supported prosthesis, and willingness to comply with all study requirements.

Patients were excluded if they presented with one of the following conditions: liver, blood, or kidney disease; immunosuppression; current corticosteroid use; pregnancy or lactation; inflammatory or autoimmune diseases of the oral cavity; a history of irradiation in the head and neck region or endovenous bisphosphonate therapy; chemotherapy during the previous 12 months; uncontrolled insulin-dependent diabetes mellitus (HbA1c >6%, glycemic level >110 mg/dl);[25] current alcohol or drug abuse; previous destructive sinus surgeries (such as the Caldwell–Luc operation); clinical signs and symptoms of ongoing sinus infections or chronic sinusitis; severe skeletal jaw discrepancies with maxillary retrusion and increased inter-arch distance (Class VI Cawood and Howell[26] classification); smoking; poor oral

hygiene if teeth were present (full-mouth plaque score greater than 25%);[27] or a history of bruxism and clenching.[28]

After being informed in detail about the nature of the study, all patients gave their informed written consent.

Preoperative Evaluation

Prior to treatment, each patient was accurately evaluated through (a) clinical analysis of oral status, residual dentition of the opposite arch, and inter-arch relationship; (b) panoramic radiograph and cone-beam computed tomography (CT) scan (NewTom® 3G; Quantitative Radiology, Verona, Italy) of the maxilla to evaluate the sinus anatomy and pathology and the volume of residual alveolar bone (Figure 1); and (c) dental study casts and diagnostic setup of teeth in wax. Factors considered in the diagnostic setup included aesthetics (support for lips and cheeks), position of the anterior teeth, vertical occlusal dimension, and the space available for the prosthetic rehabilitation.

The opposing dentition was natural teeth or full-arch fixed prostheses on natural teeth in six patients, natural teeth and removable prostheses in two patients, natural teeth and implant-supported fixed partial prostheses in five patients, and full-arch fixed implant-supported prostheses in seven patients.

Surgical Procedures

For both surgical procedures (sinus augmentation and implant placement), the patient received antibiotic therapy with 875/125 mg of amoxicillin/clavulanic acid (Augmentin; GlaxoSmithKline, Research Triangle Park, NC, USA) every 12 hours, starting the day of surgery and continuing for 6 days postsurgery. In case of allergy to amoxicillin, clarithromycin (500 mg twice a day, Klacid; Abbott Laboratories, Abbott Park, IL, USA) was given for 6 days. For pain, 600 mg of ibuprofen (Brufen; Boots Healthcare, Milan, Italy) was given 1 hour before surgery, and then three times a day for 5 days. All patients were sedated with Triazolam 0.25 mg (Triazolam; Roche, Milan, Italy) administered orally 1 hour before surgery. Just before surgery, patients underwent a perioral skin disinfection with 0.5% povidone–iodine and then a 3-minute mouth rinsing with 0.2% chlorhexidine gluconate (Corsodyl; GlaxoSmithKline). A

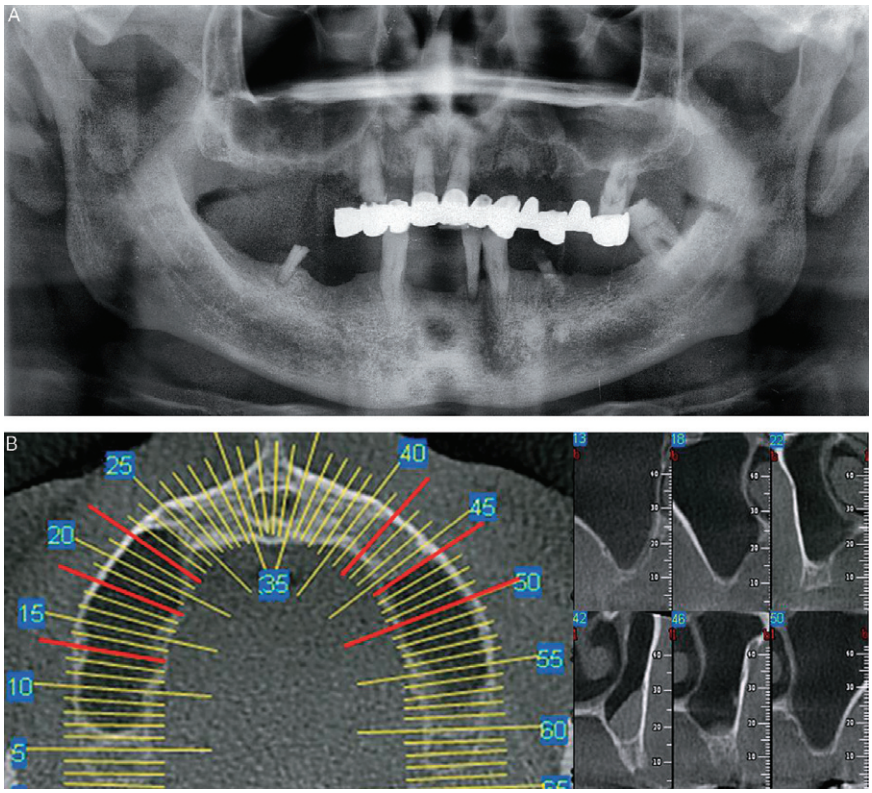

Figure 1 (A) Preoperative panoramic radiograph showing relevant bilateral sinus pneumatization. The patient had periodontally compromised teeth in the maxilla that were used to support a provisional fixed prosthesis during bone graft healing. (B) Preoperative computed tomography scan showing severe bone atrophy of the posterior edentulous maxilla. Red lines indicate six possible implant sites in the premolar–molar areas.

single surgeon (F.P.) performed all surgical procedures under local anesthesia with articaine chlorhydrate and adrenaline 1:100,000 (Ultracain, D-S forte; Aventis Pharma Deutschland, Frankfurt, Germany).

Maxillary Sinus Augmentation Technique. Maxillary sinus augmentation was performed bilaterally during the same surgical session according to the technique described by Boyne and James.[29] A composite graft was used in both sides of the maxilla, and consisted of autogenous bone chips combined approximately 50:50 with deproteinized bovine bone mineral (Bio-Oss; Geistlich Pharma AG, Wolhusen, Switzerland). The autogenous bone chips were harvested from the ascending ramus of the mandible. The block grafts were harvested and particulated with a bone mill (R-Quétin bone-mill; Hu-Friedy, Chicago, IL, USA). A resorbable collagen membrane (Bio-Gide; Geistlich Pharma AG) was used to close up the buccal window. The oral mucosa was then sutured with 4.0 bioresorbable interrupted sutures (Vicryl 4.0 polyglactin 910; Johnson & Johnson International, St. Stevens, Woluwe, Belgium). Postoperative edema was controlled with 4 mg of intramuscular betamethasone (Bentelan; Defiante Farmacêutica, Madeira, Portugal) injected immediately after the surgical procedure and continued orally at a dose of 1 mg for 5 days after surgery. Patients were instructed to avoid blowing their noses and to cough or sneeze with an open mouth to prevent increased pressure in the operated sinuses for the first 2 weeks after surgery. They were also instructed not to wear their provisional removable prosthesis for 1 week after surgery. Subsequently, provisional removable prostheses were relined using soft lining material (Softliner; GC Corporation, Tokyo, Japan), which was changed every month during the entire treatment period. Chlorhexidine mouthwash (0.2%, three times a day) was prescribed for 1 week. Sutures were removed after 2 weeks.

Implant Placement. Second-stage surgery to place the implants was performed 4–5 months after the sinus augmentation procedure. Panoramic radiographs and CT scans were re-performed for implant placement planning (Figure 2). All implants used in this study were OsseoSpeed™ implants (Astra Tech, Molndal, Sweden) with diameters of 3.5, 4.0, and 4.5 mm and lengths of 9, 11, 13, and 15 mm. Following a midcrestal incision to preserve as much keratinized mucosa as possible, a full-thickness mucoperiosteal flap was carefully raised and all remaining teeth were extracted. In each patient, seven to eight implants were placed with the aid of a surgical template and inserted into native bone in the anterior maxilla (control group) as well as in posterior sinus-grafted sites (test group). The drilling protocol was adapted to the bone quality subjectively assessed by the surgeon to ensure high primary implant stability.[30] The surgical sequence was as follows: a 2-mm diameter pilot drill was used at a speed of 800 rpm to start the preparation of all implant sites and to determine bone quality based on intrasurgical drilling cutting resistance. Bone quality was classified as "dense," "normal," or "soft." In dense bone, a 2.5-mm diameter twist drill was used to place 3.5-mm-diameter implants, followed by a final 3.2-mm-diameter twist drill. To place 4-mm diameter implants, 2.7-, 3.2-, and 3.7-mm diameter drills were used. To place 4.5-mm diameter implants, 2.5- and 3.2-mm diameter twist drills were used, followed by a 4.5-mm diameter conical drill. In normal bone, 3.2-mm- and 3.7-mm-diameter twist drills were used to enlarge the first 2 to 3 mm of the osteotomy site for the 3.5-mm-and 4-mm-diameter implants, respectively. If a 4.5-mm-diameter implant was to be placed, the implant site was prepared along its entire length with a surgical drill 3.2 mm in diameter, and the final 4.5-mm-diameter conical drill was avoided. In soft bone, the 2.5- or 3.2-mm diameter twist drills were used to prepare the crestal 2–3 mm of the osteotomy site for 3.5- or 4.0- and 4.5-mm wide implants, respectively. The implants were then threaded into place at low speed (10 revolutions per minute) using an electronic drilling unit (Uniko, Mariotti & C, Forlì, Italy) with the torque set at 10 Ncm, which progressively increased as the implant stopped. The final peak of the insertion torque (IT) of each implant was measured when the implant was fully seated. To improve primary stability, implant platforms were placed level with the alveolar bone crest. Immediately after implant placement, 20° or 45°Cresco All Parts Included inserts (Astra Tech) with two different heights (0.5 and 2 mm) were screwed to the implants with a torque controller at 10 Ncm. Implant stability quotient (ISQ) readings were also obtained for each implant at placement time using the Osstell Mentor™ device (Integration Diagnostic Ltd, Göteborg, Sweden).

Sterile impression copings were mounted and the flaps tightly sutured around the copings with bioresorbable sutures (Vicryl Rapid 4.0 polyglactin 910; Johnson

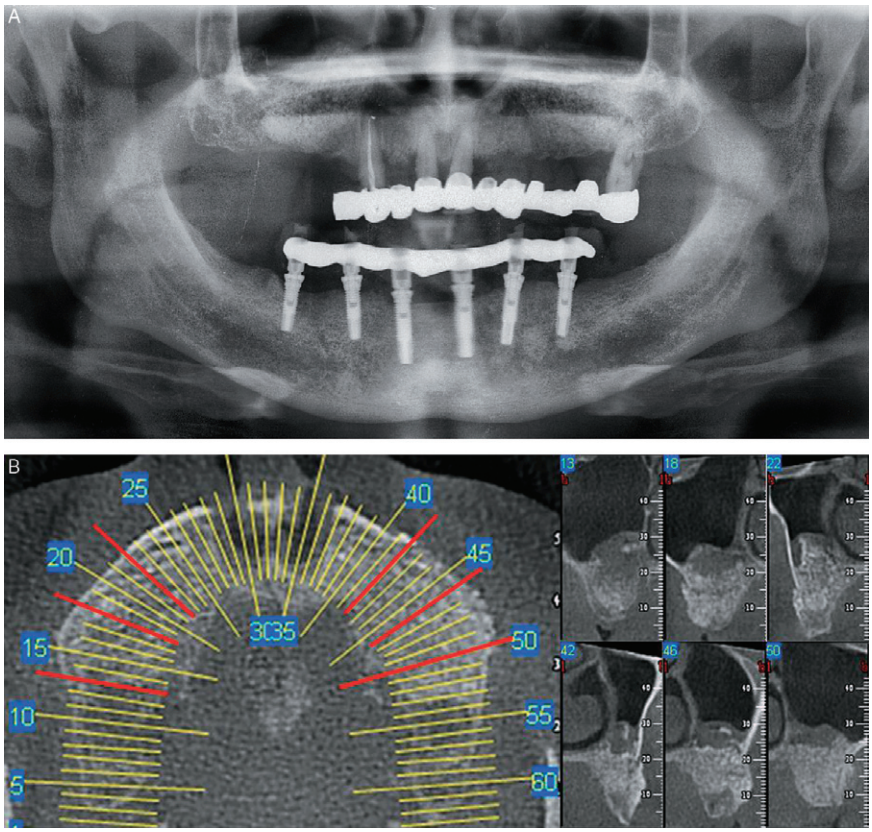

Figure 2 (A) Postoperative panoramic radiograph after bilateral sinus augmentation using a 50:50 composite graft of autogenous mandibular bone and bovine hydroxyapatite. The patient had been previously rehabilitated with an immediate full-arch implant-supported fixed prosthesis in the mandible. (B) Postoperative computed tomography scan showing good bone filling of the highlighted posterior implant sites.

& Johnson International). The copings were joined together with orthodontic wire and light-polymerized composite resin (Tetric EvoFlow; Ivoclar Vivadent, Amherst, NY, USA) placed on the facial surface, and the impressions were taken with an open tray and a polyether material (Permadyne; ESPE, Seefeld, Germany). After removing the copings, healing abutments were inserted and the vertical occlusal dimension and intermaxillary relation were determined. The patients were instructed to avoid brushing the treated area and to rinse with 0.2% chlorhexidine gluconate twice daily for 1 week.

Restorative Phase

Master casts were mounted in articulators using interocclusal records and casts of the opposing arch. Straight or individually angulated (by heat) acrylic tubes were mounted on the implant analogs in the master cast with the help of process screws, followed by a conventional wax-up of the prosthesis. The acrylic tubes were bent in a palatal direction for the anterior tilted implant positions so that the retention screw entrance did not penetrate the facial part of the teeth of the prosthesis. On the following day, the vertical dimension, occlusion, aesthetics, phonetics, and fit of the wax-up were checked intraorally. After the wax-up was verified, a rigid one-piece titanium framework was fabricated according to the Cresco Titanium Precision method (CTiP) (Astra Tech),[31] and the passivity was assessed both radiographically and clinically by means of the Sheffield 1 screw test. With a good fit of the framework, the screw-retained, titanium-composite definitive prosthesis was finalized with 12–14 dental units and inserted within 1 week after surgery. The abutment screws were tightened at 10 Ncm using a torque-control device, and their access holes were filled with flowable composite resin (Tetric EvoFlow; Ivoclar Vivadent). The occlusion was checked and adjusted to provide well-balanced occlusal contacts in centric occlusion and group guidance in lateral movements.[32] Following the procedure, the patient was discharged home and instructed to maintain a soft diet for the next 6 weeks. The sutures were removed after

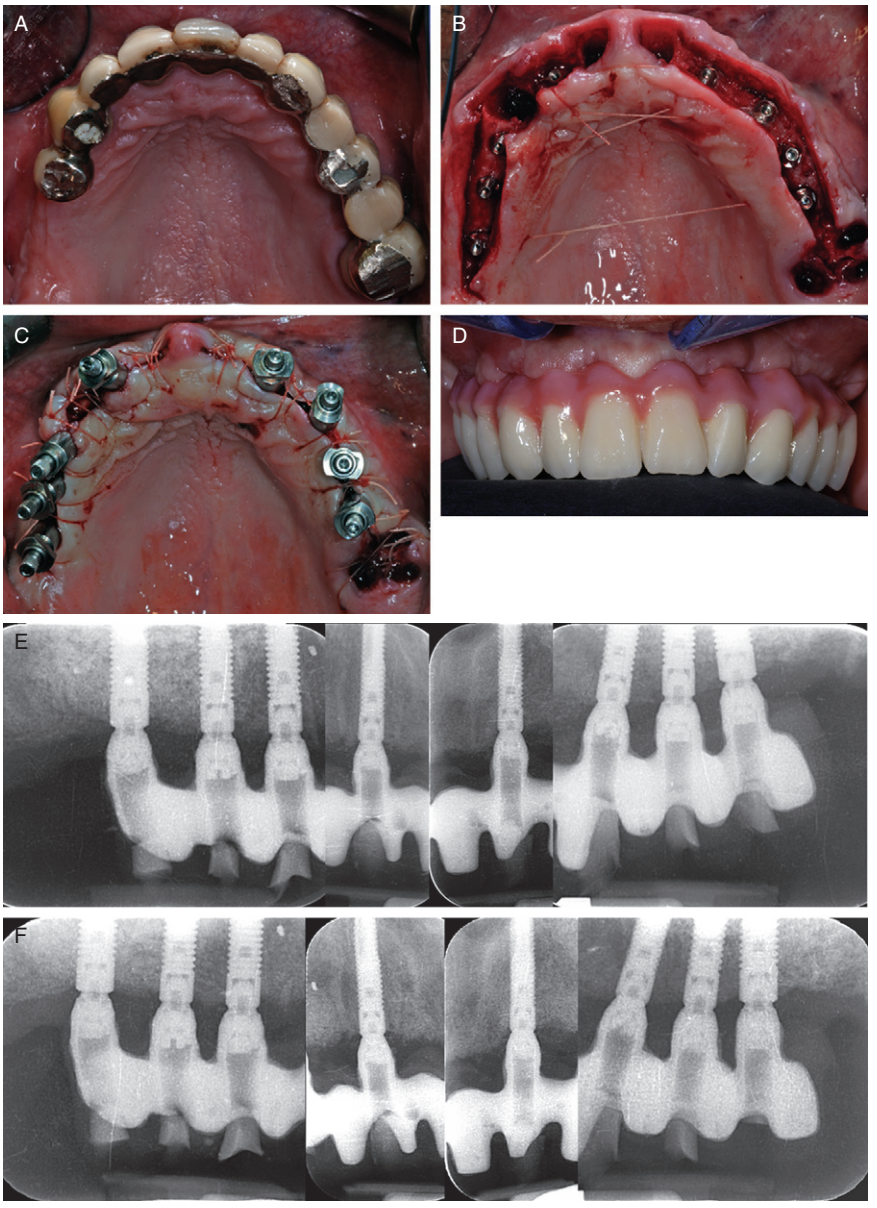

Figure 3 (A) Occlusal view before implant treatment. (B) Intraoperative view immediately after implant placement. (C) Impression copings in position. (D) Frontal view of the screw-retained definitive restoration positioned within 1 week. (E, F) Periapical radiographs taken at the start of prosthetic loading (E) and after 1 year (F); minimal crestal bone remodeling is visible around all implant sites.

1 week, and hygiene instructions, including the use of toothbrushes and flossing techniques, were given.

The patients were recalled at 2 and 4 weeks after implant surgery and at 3, 6, and 12 months to evaluate their oral hygiene maintenance and any possible clinical or biologic complication. At the 3-, 6-, and 12-month follow-up visits, the screw-retained prostheses were removed and the implants and abutments were evaluated individually for tenderness, swelling, and mobility. At each postoperative visit, occlusion and the potential need for any prosthetic maintenance were checked. The number and nature of any unplanned visit or prosthetic/mechanical complications were recorded. After 6 months, all prostheses were relined for compensation of soft tissue shrinkage. One representative case is presented in Figure 3.

Clinical and Radiographic Examinations

The health and stability of the soft tissues around the implants were evaluated using the modified plaque

index (mPI) and the modified bleeding index (mBI) recorded at the mesial, distal, buccal, and palatal aspects of each implant.[33] At the same time and sites, the peri-implant probing depth (PD) was also registered using a calibrated manual periodontal probe (UNC 15; Hu-Friedy) and rounded off to the nearest mm. For each implant, one MPI, MBI, and PD value was calculated based on the mean of the four obtained values. In addition, the width of keratinized mucosa (KM) was assessed on the midfacial aspect. These parameters were assessed at 3 and 12 months after removing the prostheses.

Direct implant stability was measured by resonance frequency analysis (RFA) at implant placement and at 3 and 12 months. The Osstell™ equipment (Integration Diagnostic Ltd) was used for measuring, and transducers (type A5 and A12) were screwed at abutment level. The measurements were given in implant stability quotient (ISQ) units. Data were collected on a PC using dedicated software (Osstell™ Data Manager; Integration Diagnostic Ltd).

Digital intraoral radiographs (Digora PSP plate system; Soredex/Orion Corp., Helsinki, Finland) were taken using a long-cone paralleling technique with an individualized film holder (Rinn film holder; Dentsply RINN, Elgin, IL, USA) immediately after prosthesis placement and at 6 and 12 months. The radiographs were taken so that the platform and threads were clearly visible both mesially and distally. An image analysis software (Digora for Windows 2.1; Soredex/Orion Corp.) was used to measure the distance between the implant–abutment junction and the most coronal level of the bone deemed to be in contact with the implant surface by an on-screen cursor after magnifying the digital radiograph 3×.[34] This cursor was calibrated on the known diameter of the implant head, and measurements of the marginal bone resorption (MBR) were made at the mesial and distal sites of each implant to the nearest 0.1 mm. For each implant and each examined time period, one MBR value was calculated as the average of the obtained mesial and distal values. The error of the radiographic assessment was determined through double recordings at one randomly selected implant from each patient representing the 1-year follow-up examination. The mean difference between the two readings was 0.02 mm (SD, 0.21).

All clinical and radiographic measurements were made by one independent investigator (G.C.).

Success and Failure Criteria

The success criteria for the implants were chosen according to Albrektsson and colleagues[35] and included the following: the absence of persistent subjective complaints such as pain, a foreign body sensation, and/or dysesthesia; absence of peri-implant infection with suppuration; absence of mobility; absence of a continuous radiolucency around the implant; and MBR less than 1.5 mm in the 1 year of function. Implants that did not fulfill the success criteria were considered failures.

A prosthesis was considered successful if it was functional, had no fractures, and provided patients with adequate masticatory, aesthetic, and phonetic function, even if one or more implants were lost. The prosthesis was considered a failure if the number of implant failures was large enough to require the removal of the entire prosthesis, therefore leading to the lack of function of the prosthesis.[36]

Postoperative Pain and Swelling

The level of postoperative pain and edema was assessed at the first control visit 1 week after the reconstructive procedure and implant placement. The patients rated pain intensity based on the following 4-point category rating scale: 1 = no pain, 2 = mild pain (almost unnoticeable pain), 3 = moderate pain (noticeable pain, but patient can still engage in routine daily activities), and 4 = intense pain (very noticeable pain that disturbs the patient's daily routine). Swelling was rated as follows: 1 = none (no visible swelling), 2 = mild (intraoral swelling in the surgical zone), 3 = moderate (extraoral swelling in the surgical zone), and 4 = severe (extraoral swelling extending beyond the surgical zone and visible hematoma and ecchymosis).[37]

Patient Satisfaction

At the 1-month follow-up visit after prosthesis placement, patients completed a self-administered questionnaire for assessment of satisfaction with function, chewing comfort, aesthetics, ability to speak, and ease of cleaning. Each item was rated on a verbal scale as excellent, good, sufficient, or poor. The same questionnaire was completed at the 12-month evaluation.[38]

Statistical Analysis

All data were analyzed with Statistical Package for the Social Sciences (SPSS) version 15.0 statistical package

(SPSS Inc., Chicago, IL, USA), utilizing the implant as the unit of measure. Clinical and radiographic data are presented as the mean value ± standard deviation (SD). Differences between groups with respect to clinical and radiographic parameters at the different time periods were tested using the unpaired *t*-test for normally distributed values. When normal distribution and homogeneity of variance were not verified by the Levene test, the nonparametric Mann–Whitney *U*-test was used. For comparison of changes in all clinical and radiographic parameters over time within each group, the one-way repeated measures analysis of variance was applied. Differences between the two groups in the proportion of failures at 12 months were compared by means of Fisher's exact test. The paired *t*-test was used to compare the pain and swelling scores reported by the patients between reconstructive and implant surgeries. All tests were two-tailed and conducted at the 5% significance level.

RESULTS

All patients could be rehabilitated with their final prosthetic restorations as planned within 1 week of implant placement, and attended the scheduled follow-up visits for 1 year. No clinical dropouts occurred.

The preoperative residual bone level at sinus augmentation sites, as measured by CT, ranged from 1 to 4 mm (mean value, 2.37 ± 0.91 mm). During sinus augmentation surgery, the sinus membrane was perforated in six cases (15% of all 40 operated sinuses). The perforations of the Schneiderian membrane were treated intraoperatively with the aid of a resorbable collagen membrane (Bio-Gide; Geistlich Pharma AG) that was trimmed and placed at the site of the perforation before inserting the graft material. Healing was uneventful in all patients, and no clinical or radiographic signs of maxillary sinus infection were observed. Minor nosebleeds occurred in two of these patients the day after the surgery.

Of 155 implants placed and immediately loaded after 4–5 months, 65 (41.9%) were positioned in the control sites and 90 (58.1%) in the test sites. Eighty-three implants (53.5%) were placed in soft bone, 42 (27.1%) were placed in normal bone, and 30 (19.4%) were placed in dense bone. In seven control sites, implants showed limited peri-implant dehiscences, which were treated by packing autologous bone chips collected during drilling and covered by a collagen membrane (Bio-Gide; Geistlich Pharma AG). The lengths and diameters of the placed implants are presented in Table 1.

During the observation period, two implant failures in two patients were recorded in the test group, giving a cumulative success rate of 97.7% (2/90); however, no implants were lost in the control group, giving a cumulative success rate of 100% (0/65). The difference in cumulative success rates between the control and test groups was not significant ($p = .2989$). All failed implants were placed in the first or second molar position and in a soft bone quality. The patients felt some pain when the prostheses were unscrewed for stability evaluation at 3 months after surgery. The implants were found to be mobile and were immediately removed. In the two patients in whom implants failed, the fixed screw-retained prostheses were supported by the remaining implants. At the 12-month follow-up, the overall implant success rate was 98.7%. The cumulative success rate for the prostheses was 100%.

Four biologic complications occurred in four patients. One patient reported intermittent soft-tissue soreness around an implant in the left canine region. The implant was stable and displayed no signs of soft-tissue inflammation. It was left in situ, untreated.

TABLE 1 Implant Size Distribution

Implant Length (mm)	Implant Diameter (mm) 3, 5	4	4, 5	Total (%)
9	2	3		5 (1)
11	8	12	8	28 (18)
13	31	16	19	66 (42.6)
15	29	16	11	56 (38.4)
Total (%)	70 (45.2)	47 (30.3)	38 (24.5)	155

TABLE 2 Distribution of Implants According to Surgical Site and Peak of IT

	Peak of IT (Ncm)				
	15	25	35	45	55
Surgical site					
Augmented sinuses	8	52	22	8	
Native bone		16	24	17	8
Total (%)	8 (4.9)	68 (44.1)	46 (29.7)	25 (16.1)	8 (5.2)

IT = insertion torque.

After about 6 months, the soreness disappeared. Three patients had one implant each affected by peri-implant mucositis 5–6 months after implant placement. After repeated professionally delivered oral hygiene and diode laser treatments, use of local antibiotics, and re-motivation in oral hygiene maintenance, the situation improved.

During the follow-up period, some minor prosthetic complications occurred. The most commonly occurring problems were composite teeth fractures ($n = 3$), followed by abutment screw loosening ($n = 2$), and the need for prostheses modification because of excessive pressure on the patient's mucosa ($n = 2$). All prosthetic complications were easily solved on the same day the patients came to the practice, and the prostheses served well after revision. Note that all teeth fracture and loose abutment screw complications were recorded on the same two patients, in whom the presence of occlusal wear facets was seen during the follow-up controls at 3–6 months. In both cases, the repeat of such complications was prevented by the fabrication of an occlusal night guard as protection against parafunctional habits.

Implant Stability Evaluation

The mean peak IT for control implants was 37.88 ± 8.72 Ncm. For test implants, the mean IT was 29.18 ± 6.4 Ncm. A significant difference was observed for IT between control and test implants ($p < .0001$). IT distribution according to the surgical site is detailed in Table 2.

Resonance frequency measurements were performed on all implants. The mean ISQ values for test implants were 60.98 ± 2.47 at implant placement, 62.65 ± 2.1 after 6 months, and 64.38 ± 2.41 after 12 months. The increase over time was significant ($p < .001$). A different pattern was observed for control implants. They demonstrated high initial stability at implant placement (66.14 ± 3.72 ISQ), which was maintained over time (66.36 ± 3.48 ISQ at 6 months and 67.08 ± 2.38 ISQ at 12 months). The difference in the mean ISQ values between the two groups was highly significant at all time points ($p < .0001$).

Clinical Parameters

Clinical parameter values at different time points are presented in Table 3. The mean mPI and mBI values indicated significant differences when comparing control and test implants at the 3-month evaluation ($p = .0369$ and $p = .0007$, respectively), but not at the 12-month evaluation ($p = .3653$ and $p = .4762$, respectively). For both groups, a significant decrease was observed when comparing the mean mPI and mBI values at the 3-month evaluation with that after 12 months of loading ($p < .05$) (Table 3).

The mean PD in the control group was 3.42 ± 0.82 mm and 3.17 ± 0.64 mm after 3 and 12 months, respectively; in the test group, the mean

TABLE 3 Gingival Parameters of the Control and Test Implants Evaluated at 3 and 12 Months (Mean ± Standard Deviation)

Parameter	Group	3 Months	12 Months	*p*
mPI	Control	0.79 ± 0.54	0.48 ± 0.68	.0033
	Test	0.6 ± 0.53	0.4 ± 0.42	.0131
mBI	Control	0.58 ± 0.53	0.33 ± 0.39	.0016
	Test	0.88 ± 0.57	0.38 ± 0.43	<.0001
PD (mm)	Control	3.42 ± 0.82	3.17 ± 0.64	.0385
	Test	3.66 ± 0.81	3.38 ± 0.87	.0361
KM (mm)	Control	2.8 ± 0.63	2.92 ± 0.67	.093
	Test	2.62 ± 0.74	2.76 ± 0.78	.0601

KM = width of keratinized mucosa at the facial aspect; mBI = modified bleeding index; mPI = modified plaque index; PD = probing depth. Analysis of variance; $p < .05$.

values were 3.66 ± 0.81 mm and 3.38 ± 0.87 mm, respectively. A significant decrease occurred in the PD values over time in both groups (Table 3), but no significant difference was found between control and test values at both the 3- and 12-month evaluations ($p = .0725$ and $p = .0912$, respectively).

The mean KM in the control group was 2.8 ± 0.63 mm and 2.92 ± 0.67 mm after 3 and 12 months, respectively (Table 3). The corresponding values in the test group were 2.62 ± 0.74 mm and 2.76 ± 0.78 mm, respectively. No significant differences ($p > .05$) were found within or between groups.

At the 12-month evaluation, about 70% of all implants had PD ≤3 mm and KM ≥3 mm, indicating the maintenance and health of the peri-implant soft tissues through the entire duration of the study.

Radiographic Evaluation

The mean MBR values in the control group were 0.07 ± 0.1 mm at prosthesis placement, 0.3 ± 0.17 mm after 6 months, and 0.47 ± 0.25 mm after 12 months of function. The corresponding values for the test group were 0.08 ± 0.11 mm, 0.27 ± 0.18 mm, and 0.43 ± 0.21 mm, respectively. A significant increase in MBR was observed within the groups with time ($p < .0001$), but no significant differences were detected at any time period between the two groups ($p > .05$). One hundred twelve implants (73.2%) had MBR ≤0.5 mm after 12 months of functional loading. In 36 cases (23.5%), the MBR ranged between 0.5 and 1 mm; in five cases (3.3%), it was ≥1 mm. These findings confirmed the good maintenance of marginal bone levels over time.

Pain and Swelling Assessment

Two patients had slight edema after sinus augmentation surgery, 15 had moderate edema, and 3 had severe edema. After implant surgery, three patients had no visible edema. The remaining 17 patients showed slight edema. The mean scores for swelling after sinus augmentation and implant surgery were 3.05 ± 0.51 and 1.85 ± 0.35, respectively. The difference was highly significant ($p < .0001$) (Figure 4).

Sixteen patients reported moderate postoperative pain after sinus augmentation surgery; four subjects stated that they felt severe pain. After implant surgery, three patients reported no postoperative pain, 15 reported slight pain, and two reported moderate postoperative pain. The mean scores for pain after sinus augmentation and implant surgery were 3.2 ± 0.4 and 1.95 ± 0.49, respectively. The difference was highly significant ($p < .0001$) (Figure 4).

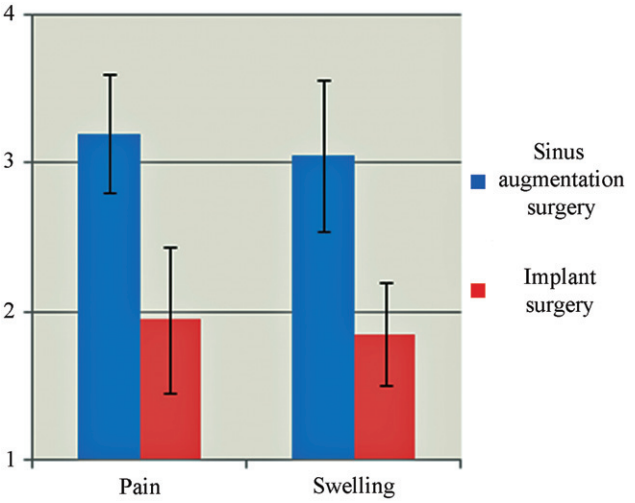

Figure 4 Graphic presentation of rating values (on a 4-point verbal scale, 4 = maximal severity) of perceived postoperative pain and swelling by all patients after sinus augmentation and implant surgery. Mean value ± standard deviation. *$p < .0001$.

Patient Satisfaction

All patients completed questionnaires for satisfaction evaluation at the 1- and 12-month recall visits (Table 4). At the final evaluation, aesthetics (teeth and smile) were judged as excellent or good by 90% of patients. Only 1 of the 20 patients was not satisfied with the aesthetics of the fixed restoration, rating its appearance as poor and requesting the remaking of the restoration after 6 months. Masticatory function was considered excellent by 75% of patients and good by 25%. Ability to speak was judged excellent in 35% of cases and good in 65%. In particular, two patients with an imperfect pronunciation of the dental phonemes at the first follow-up examination reported that these problems disappeared after 6–7 months of loading, with a great increase in the speech score. Ease of cleaning was considered good in 55% of cases and sufficient in 45%.

DISCUSSION

The preliminary clinical and radiographic data obtained from this study suggest that the described surgical/prosthetic protocol can be used for immediate implant-supported rehabilitation of the augmented maxilla. The application of an immediately loaded implant procedure in an atrophic edentulous maxilla after a

TABLE 4 Results of the Patient Satisfaction Questionnaires at 1- and 12-Month Follow-Up Evaluations

	1 Month (%)	12 Months (%)
Aesthetics		
Excellent	4 (20)	5 (25)
Good	13 (65)	14 (70)
Sufficient	2 (10)	1 (5)
Poor	1 (5)	0
Function		
Excellent	3 (15)	5 (25)
Good	14 (70)	15 (75)
Sufficient	3 (15)	0
Poor	0	0
Ability to speak		
Excellent	5 (25)	7 (35)
Good	13 (65)	13 (65)
Sufficient	2 (10)	0
Poor	0	0
Ease of cleaning		
Excellent	0	0
Good	6 (30)	11 (55)
Sufficient	11 (55)	9 (45)
Poor	3 (15)	0

bilateral sinus augmentation drastically reduced the total conventional healing time of 12–14 months (surgical and prosthetic healing times combined) before any type of restorations were placed onto the implants.[14,39] In fact, in this study, only a shortened graft-healing period of 4–5 months had been required from augmentative procedure to implant placement and loading.

Immediate loading protocols in grafted edentulous maxillae have seldom been investigated. An implant survival rate of 97.7% was reported after 1 year with the immediate application of a fixed implant-supported prostheses in 35 cases of atrophic maxillae previously augmented with bilateral bone-grafting procedures.[22] The similar implant and prosthesis success rates (98.7 and 100%, respectively) observed at 1 year in the present study confirmed the predictability of this procedure. These results suggest that the immediate loading protocol can be compared with the high implant success rates that had been previously reported in the dental literature for the augmented maxilla with the delayed loading approach.[11–14,39] A recent study in which a composite graft of mandibular autogenous bone and bovine hydroxyapatite was used for sinus augmentation in the same proportion as in this study reported a 99% implant success rate after 24 months of function.[40] The use of autogenous bone may have a significantly positive effect on the quality of newly formed bone inside the sinuses, which may in turn allow for a more efficient implant osseointegration.[41] This may be due to its osseoinductive and osseoconductive properties, resulting in a more rapid bone formation (4–6 months) compared with the use of bovine hydroxyapatite alone.[42] The authors are aware that the use of autogenous bone increases postoperative morbidity because of the necessity of bone harvesting from the mandibular ramus. This assumption was confirmed by the fact that patients experienced pain and swelling at a higher intensity (almost double) after sinus augmentation surgery compared with implant surgery.

The clinical and radiographic outcomes in the present study did not appear to be influenced by the nature of the implant sites (sinus-grafted vs non-grafted). Approximately half of the implant sites were assessed as having soft bone quality; among them, 81% belonged to the grafted group. No contraindication appeared to exist for applying an immediate loading protocol under these low bone quality conditions, which according to earlier reports could be a challenging circumstance because of the difficulty of obtaining an adequate primary stability. In fact, although the peak IT of the grafted group was on average 10 Ncm lower than that of the non-grafted group, and the ISQ values of the grafted group were significantly lower than those of the non-grafted group, the cumulative success rates of the two groups (97.7% for the test vs 100% for the control group) were surprisingly similar. Only two implants that were placed in augmented sinuses failed during the study period, whereas 88 of 90 implants were clinically successful and met the success criteria. Any attempted explanation is obviously speculative, but the following factors applied in the present clinical protocol are worth mentioning: the use of roughened implant surfaces (OsseoSpeed; Astra Tech), the enhanced primary implant stability obtained by using a modified site preparation technique, and, above all, the passive and rigid splinting of the implants. The latter implies that all implants in each case were immediately splinted through a titanium framework fabricated using the CTiP method, which allowed for an easy achievement of a perfect passive fit and marginal precision between the implants and superstructures.[31,43] Furthermore,

titanium frameworks are significantly stronger than all-acrylic resin frameworks.[44] This design feature may have provided increased rigidity to the immediate prostheses, reducing the risk of framework fracture, which can lead to micromotions between the implant and the surrounding bone with consequent implant failure; however, the literature is not conclusive in this matter. In a clinical study, Grunder[45] treated 10 patients with edentulous arches and found that five of the seven implant failures were present in patients with nonmetal-reinforced immediate provisional restorations. Another study by Calandriello and Tomatis[34] on immediate/early function in the atrophic maxilla reported that both implant failures occurred in the same patient as a result of crack propagation and fracture of the provisional acrylic full-arch prosthesis. Other authors[4,22] who have used all acrylic resin immediate prostheses without metal frameworks have reported high survival rates, stating that once multiple implants are splinted together with a rigid and passive connection, the individual implant will become part of an integrated system that supersedes the value of individual implant stability in contrasting micromotions at the early critical phase of the osseointegration process. Consequently, primary stability of the individual implant is important, but not as critical as in a single implant situation. On a related side note, a study has suggested that immediate occlusal loading of implants in the augmented maxilla might provide a positive stimulatory effect on bone/graft maturation and enhance osseointegration outcomes.[46] The significant increase in ISQ values with time in the test sites seems to corroborate this hypothesis and probably reflected the enhanced bone apposition at the implant interface.

The large number of implants inserted in each patient (seven or eight, for a total of 155) may have been more than necessary. High survival rates have been frequently reported in the literature for immediate function of fixed maxillary complete-arch prostheses supported by four or six implants placed in native bone.[3,4] However, in the present study sample, more implants were deemed essential to lessen the likelihood of prosthetic failure in these more challenging grafted situations. The surgical procedures the patients underwent to obtain fixed teeth, the risks of the grafting technique, and the fact that immediate loading of implants placed in augmented sinuses still lacks a sound scientific background, suggests that caution be exercised. When the behavior of the regenerated bone around immediately loaded implants is known in detail, it will probably be feasible to reduce the number of implants in the premaxilla. Furthermore, the elimination of cantilevers derived by placing implants in the posterior augmented areas may have positive long-term effects on the distribution of the load on the anterior implants.

The main drawbacks of this protocol for the rehabilitation of the atrophic maxilla are its greater surgical invasiveness (two surgical procedures performed and the need for bone grafting) compared with the use of angled or zygomatic implants.[3,4,9,10] However, the creation of adequate bone volume conditions in the posterior maxillary areas through bilateral sinus grafting allows an ideal implant placement with the widest possible anteroposterior distribution. In this way, on each side of the maxilla, at least two implant heads emerge in the molar region, where the highest mastication forces are present. Such an implant configuration aims at optimizing the distribution of the occlusal loads and at the same time allows the fabrication of a 12- to 14-element definitive prosthesis without a distal cantilever. The authors believe that the optimal biomechanical support obtained through this implant distribution should have played a fundamental role not only in the high short-term implant success rate, but also in the limited number of prosthetic complications. In this study, no major complications (such as framework fracture) occurred and the prosthetic interventions required were minor, easy to solve, and attributable to bruxism habits. Bruxism is not easily diagnosed in patients with one edentulous arch. In our study sample, the patients were classified as bruxers based on the presence of occlusal wear facets and on self-reports. The literature has shown that this is an acceptable method to classify the patients, but can lead to underscoring the prevalence of bruxism,[47] as happened in our study, where all composite teeth fractures and abutment screw loosenings occurred in two undiagnosed bruxer patients. In the event of small fractures of the composite resin superstructure, the screw-retained, titanium-composite prosthesis can easily be removed and repaired. This represents a major advantage in terms of cost-effectiveness compared with the cement-retained, porcelain-fused-to-metal prosthesis.

From the patients' self-administered questionnaires, a progressive increase in satisfaction with aesthetics, function, and speech ability was noted passing from the 1-month to the 1-year evaluations (Table 4). Patients

reported a final high level of satisfaction with their full-arch fixed prostheses. The immediate placement of the definitive prosthesis, as in our protocol, implies only one aesthetic trial evaluation before the completion of the prosthesis. This avoids the fabrication of a provisional prosthesis and drastically reduces the duration of the restorative treatment, but the potential chairside time and financial requirements to address aesthetic concerns and accommodate buccal or interprossimal recession of soft tissues at the post-loading stage should not be undervalued. In fact, all the prostheses had to be relined for compensation of soft-tissue shrinkage after 6 months. Although in patients with thin maxillary ridges, anterior implants have inclined positions and are located palatal to the facial incisal portion of the maxillary incisors, the present patients were satisfied with their own aesthetics and speaking ability. Rosén and Gynther[3] evaluated patient opinions and treatment outcomes of 19 patients with severe maxillary atrophy rehabilitated with fixed prostheses over tilted implants. In their study, eight patients reported speaking differently after the application of the new prosthesis; seven patients reported aesthetic problems with the prosthesis, some stating that they were unrecognizable with their new teeth. In our sample, only one patient was not totally satisfied with the aesthetics and required the remaking of the prostheses after 6 months. Two other patients presented an initial minor defect with the pronunciation of dental phonemes that improved during the first year of function. These positive results may be attributable to the possibility, through the CTiP method, to correct screw access holes compensating for angled implant placement as in anterior atrophic sites. This prosthetic procedure also allows for the elimination of the risk of buccal access holes, which compromise the final aesthetic result.

Less satisfaction with cleaning comfort was reported by half of the patients at 1 year. This is a well-known side effect of a fixed implant-supported prosthesis, particularly in atrophic maxillae, where the artificial gingiva must be included in the restorations to fill the horizontal and vertical ridge deficiencies.[48] When patients seek fixed implant-supported prostheses, the importance of hygiene procedures and the need for regular checkup appointments for the long-term success of such restorations must be preoperatively explained and discussed with the patients. Moreover, considering that in some cases, the morphology of these implant-supported restorations rendered hygienic maintenance difficult, the contribution of dental hygienists during the entire course of the study was fundamental because of the professional cleaning they provided and their active role in patient motivation. This may explain the progressive decrease in MPI, MBI, and PD over 1 year.

The mean MBR observed in this study was low: 0.47 ± 0.22 mm for control implants and 0.43 ± 0.21 mm for test implants after 12 months; it compared favorably with the values presented in the literature using a delayed procedure.[14,16] The amount of bone resorption observed in our study was lower when compared with other studies that used a flapless surgery procedure and an immediate final restoration supported by computer-aided design/computer-aided manufacturing (CAD/CAM) frameworks in the edentulous maxilla. Using this actual technique, Johansson and colleagues[49] reported a 1.3 ± 1.28-mm mean MBR after 12 months, and about 19% of observations showed more than 2 mm of bone resorption. One could hypothesize that the high precise and passive fit of the titanium framework associated with the CTiP procedure without the need for any correction or further components, such as those often necessary for CAD/CAM titanium frameworks prepared prior to implant surgery, could reduce possible damage to the peri-implant tissue, thus probably diminishing the risks of bone resorption. Additionally, a platform switching concept[50,51] was adopted in the present study, which may have played a role in the maintenance of the crestal bone around immediately functionally loaded implants. The stabilization of the interproximal bone level after 1 year of clinical function was in accordance with the stabilization of the interproximal bone level observed in patients with edentulous maxillae treated with platform-switched implants placed in native sites.[52,53] However, bone tissue stability around immediately loaded implants using this approach should be investigated in future longer-term clinical studies with increased sample sizes.

CONCLUSIONS

The present preliminary data suggest that patients with atrophic edentulous maxillae can be successfully treated with immediate fixed definitive restorations supported by a combination of dental implants placed in native premaxillary sites and in grafted sinuses. The present surgical/prosthetic protocol may reduce the total treatment time and costs without compromising the

implant and prosthesis success rate when compared with delayed loading protocols. During the first year, implants placed in sinus-grafted and native sites demonstrated similar clinical and radiographic outcomes. Security factors identified for the success of this protocol include the use of an osseoconductive implant surface, under-preparation of osteotomy sites, and stabilization of the implants with a passive and rigid connection. However, given the small number of patients treated ($n = 20$) and the short follow-up time, clinical studies that validate performance over a 5-year period are necessary before this immediate loading protocol can be performed in daily practice.

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