Delayed post-extraction implants placed using a modified Summers technique: Preliminary results of a single cohort study

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The aim of this retrospective case series was to evaluate the clinical and radiographic outcomes of the patients that underwent implant surgery with a modification of the sinus lift summers protocol. Forty healthy patients in need for oral rehabilitation with dental implants were included in this study. Inclusion criterion was the need for extraction of one compromised tooth due to persistent abscess/ periodontitis/cyst in the atrophic posterior maxilla region. The treatment consisted of two stage surgery for all patients. In the first stage, after tooth extraction, the sockets were preserved with allogenic bone graft and equine collagen membrane. After 4-5 months, 40 implants with a sandblasted surface, were inserted with osseodensification technique and a modification of the Summers sinus lift protocol for fracturing the sinus floor. The implant survival rate was the primary outcome. Intra- and postoperative complications were additional criteria for success. The mean follow-up from implant surgery was 28.0±7.3 (standard deviation) months (range 17.8-43.4 months). One implant was lost before the delivery of the prosthesis. The overall implant survival rate was 97.5%. The overall mean peri-implant marginal bone level change after 6 and 12 months of function was, respectively, 0.26±0.24 mm (95% CI: 0.19, 0.34 mm) and 0.71±0.36 mm (95% CI: 0.60, 0.82 mm). Marginal bone loss was statistically significant at both time frames respect to implant placement, and also the difference between 6 and 12 months was significant ($p<0.001$ in both cases). No biological nor mechanical complications were recorded throughout the observation period. As a conclusion, the technique presented in this cohort study can be an effective and safe alternative to standard maxillary sinus floor augmentation procedures and immediate implant insertion protocol, especially in cases of periodontitis and infected sites, which can represent a high risk for implant failure in patients with atrophic posterior maxilla.

Dental implants are commonly used for replacing missing teeth to restore tooth function. In the last years, the need for dental implant therapy is constantly increasing among the population. The global market for dental implants is expected to increase more than US $6.50 billion by 2024 at a Compound Annual Growth Rate (CAGR) of 7.9% (1). The reasons for such increase in the demand can be due to factors like a larger prevalence of tooth loss related to increased life expectancy, aesthetic needs, awareness of the excellent performance and benefits of implant treatment, etc. The success of

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dental implants is estimated to be superior to 90% in the medium-long term for most implant systems, and the implant success can be affected by a variety of patient- implant-, surgery-, prosthesis-related factors like age, gender, implant size, implant shape, material of implant, length and diameter, location of implant, and bone quality (2-3). Some studies have estimated the rate of failure of dental implants (2-9) in evidence-based studies, in different clinical situations and surgical protocols, and found to be 0.8% when assessed for individuals and 0.5% at implant level. Again, these figures can vary when different factors are considered, for example, 1.0% is the rate of implant failure in patients who are >40yrs of age, 1.3% is the rate of failure among smokers, which is much higher than non-smokers 0.3% (10). In the recent years socket preservation (SP) procedures have become popular to reduce physiological bone resorption, at the alveolar site, occurring after tooth extraction, that would compromise implant placement. To prepare the extraction site for implant placement, socket and ridge preservation using bone substitutes is a clinically viable approach to maintain the remaining bone following extraction (11). Currently, SP procedures are performed routinely, for increasing the success rate of dental implants by using various techniques and biomaterials. Guided bone regeneration (GBR) with osteoconductive bone substitutes alone or in combination with growth factors and covering membranes (12-14) are considered as the most predictable. There are different GBR modalities depending on the defect size and location. SP can also be used to to overcome the maxillary sinus lift augmentation, which can represent a risk of oro-antral communication following implant placements (15). Even though systematic reviews and meta-analyses represent the best way to summarize the evidence for success and the ranking of treatments, it is difficult to apply a meta-analysis to SP techniques since the heterogeneity among studies, protocols and outcomes is extremely wide (16).

The aim of the present case series is to demonstrate the predictability of a modified Summers technique for the preservation of alveolar socket using GBR, and its impact on implant outcome after at least one-year follow-up.

MATERIALS AND METHODS

This retrospective case series study was carried out in a single private clinic in France, that had agreement with University of Milano and IRCCS Orthopedic Institute Galeazzi, and consisted of patients in need of oral rehabilitation with dental implants in the posterior maxilla. All the patients were treated between January 2017 and February 2019 with a modification of the Summers technique for maxillary sinus elevation. The study was compliant to the principles laid down in the Declaration of Helsinki on medical protocol and ethics. Institutional Review Board approval of the IRCCS Orthopedic Institute Galeazzi was obtained for retrospective studies on implant therapy and a retrospective review of the Clinics' database of patients undergoing GBR technique for socket preservation and implant placement was undertaken after the approval from the institutional review board.

The inclusion criterion was patients older than 18 years of age, who had tooth extraction planned in the posterior maxillary region due to large cysts, persistent infection and/or periodontitis and when immediate implantation was not applicable. Additionally, absence of general medical contraindications for oral surgery procedures (American Society of Anaesthesiologists ASA-1 or ASA-2) was required. The subjects with active infection in the oral and maxillofacial region and/or suffering from any major systemic illness like immunocompromised patients, oncologic patients, patients with organ failures, as well as pregnant patients were excluded. Smoking habits, controlled diabetes, osteoporosis, and minor systemic conditions were not considered as exclusion criteria.

On the first visit, a detailed clinical history and intra- and extra-oral findings were recorded for each patient. The patients were radiologically evaluated with panoramic radiographs and/or cone beam computed tomography (CBCT) scans for assessing the size and shape of the maxillary bone and for assessing any maxillary sinus pathologies. Fig. 1 shows representative pre-operative CBCT of a patient showing right maxillary bone with infected tooth.

One week before surgery, a professional oral hygiene session was given to each patient, and chlorhexidine digluconate 0.2% oral rinses were prescribed. One day before surgery antibiotics were prescribed: Augmentin (amoxicillin and clavulanate potassium) at a dosage of 1 g, or Azithromycin 500 mg as an alternative in case of

allergy to penicillin. In brief, the treatment consisted of two-stage surgery for all patients.

First stage surgery

All surgeries were carried out under local anesthesia (4% articaine with 1:100,000 adrenalin) by the same surgeon (R.B.). Following atraumatic extraction of the tooth, curettage was applied to the tooth socket, followed by saline irrigation. After mechanical curettage, the infected sites were all treated with a diode laser followed by a filling of the alveolus with a continuous irrigation of oxygenated water for an average of two minutes. At this stage, special attention was paid to avoid sinus perforation, to drain the infection, and to remove all cyst epithelial remnants, in case of cyst presence. Then, allogeneic bone graft Phoenix cancellous bone powder, TBF, Mions, France) was carefully packed into the socket and a collagen equine membrane (Proguard collagen membrane, Euroklee, Barcelona, Spain) was positioned to cover the graft. Finally, the membranes were sutured using non-resorbable 4-0 silk sutures (Ethicon, Johnson&Johnson, New Jersey, USA) to achieve primary closure. Fig. 2 shows representative post-extraction CBCT of a patient showing grafted alveolar socket.

Second stage surgery

Four months after tooth extraction and GBR surgery, the patients were re-evaluated with a second

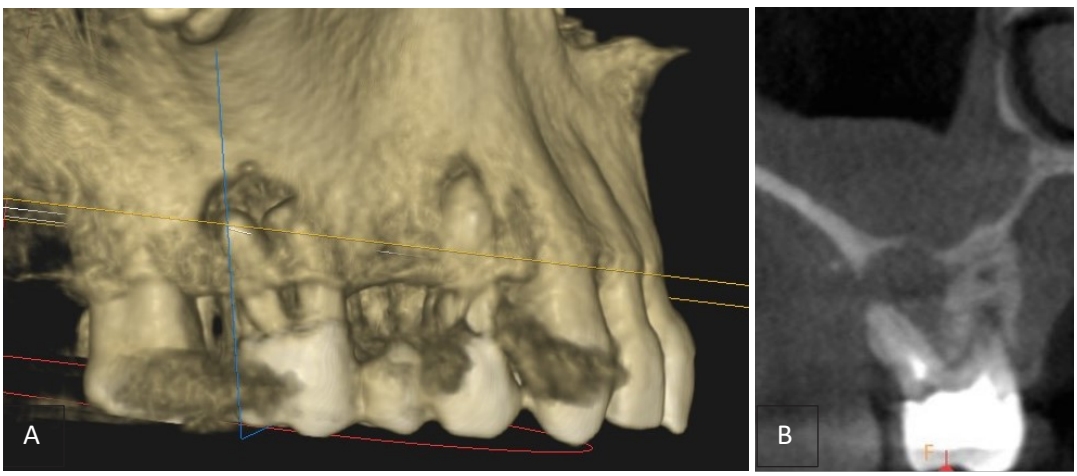

Fig. 1. ***a):*** *Pre-operative tomography of a patient showing right maxillary bone with infected tooth;* ***b):*** *pre-operative CBCT of infected tooth.*

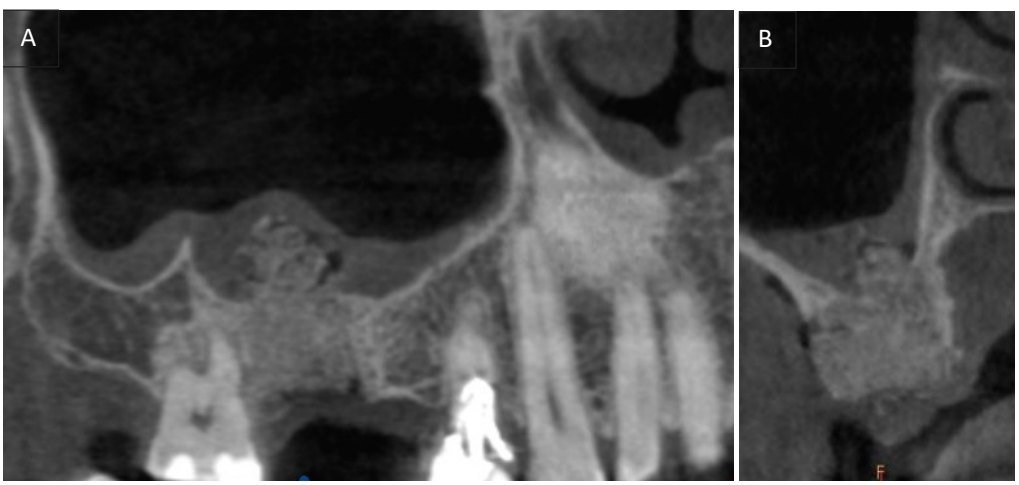

Fig. 2. ***a-b):*** *Post-extraction CBCT of a patient showing grafted alveolar socket.*

cone beam computed tomography (CBCT) scan (Fig. 3), to assess healing and to measure the residual crestal bone height and width at the intended implant site.

Five to six months after first stage surgery, the dental implant (IDI All, Implant Diffusion International, Paris, France) was inserted, using a modification of the sinus lift Summers technique. The implant length was determined as 1-3mm longer than the residual bone height. Drilling for implant site preparation was primarily done following the osseodensification technique, by using special cylindro-tapered drills in reverse rotation (IDIAll drills, Implant Diffusion International, Paris, France), of the same size and shape as the implants (Fig. 4). Due to their specific features and design, only one drill was used for each implant site preparation (17).

Drilling was stopped maintaining 2 mm of safety thickness below the sinus floor. Then, the surgery continued with implant placement utilizing a contra-angle hand piece with a torque of 35N/cm. When the implant reached the cortical bone at the apex of the implant site, the implant was further pushed with the help of the ratchet, until fracture of the sinus floor occurred. As a result, all the implants were inserted in a subcrestal position with the neck 1mm deeper from the bone crest level. Fig. 5 shows CBCT of the patient after implant insertion , and Fig. 6-7 show the final case.

The bone type was recorded according to Misch Classification (18). The prosthetic loading was done after 3 to 5 months of implant placement. All the patients had single metal-ceramic crowns cemented as prosthetic superstructures.

Follow-up

The patients were prescribed with post-operative antibiotics: amoxicillin and clavulanate potassium at a dosage of 1g tablet every 8 hours for a total of 6 days, or azithromycin 500 mg for 3 days as an alternative in case of allergy. Analgesics (Ketoprofen, 30mg twice/day) were also prescribed in cases of need.

Standard follow-up visits, including clinical examinations were scheduled at 1 month, 3 months, 6 months, and 12 months; then, every 6 months for the following years. A control CBCT was taken at the 12-month follow-up for a general assessment of the sinus and skeletal condition at the involved site. Post-operative oral hygiene instructions were explained in detail and a regular maintenance program was recommended to each patient at all stages of the treatment protocol, with 6 months intervals.

Outcomes

Implant survival and success, ridge height changes at the involved site and peri-implant bone level (MBL) changes were considered as the primary outcomes of the study. The intra-surgical and post-surgical complications were assessed as secondary outcomes. Criteria for implant survival were as follows: an implant that is still functional, supporting a prosthetic restoration and surrounded by healthy peri-implant tissues. Implants were considered to be successful according to the following conventional criteria established by Albrektsson (19): clinical absence of mobility; no radiographic evidence of peri-implant radiolucency; annual bone loss of no more than 1.5-2mm in the first year of loading

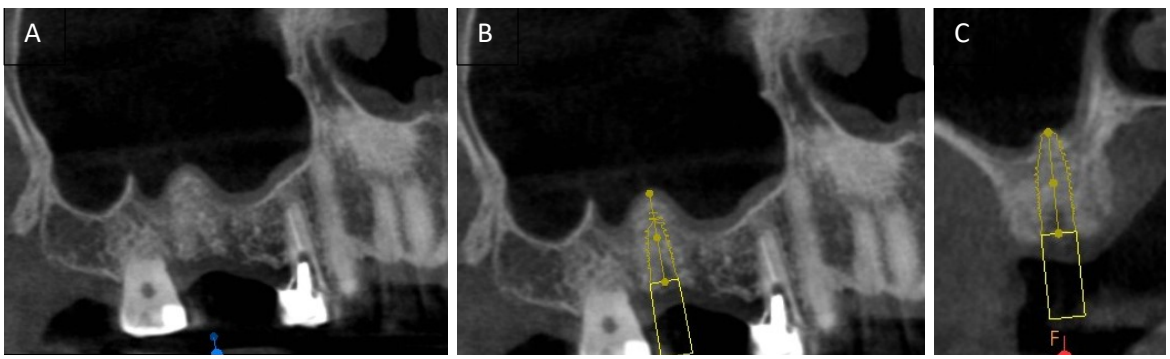

Fig. 3. ***a):*** *Implant site evaluation and* ***b-c):*** *planning with CBCT.*

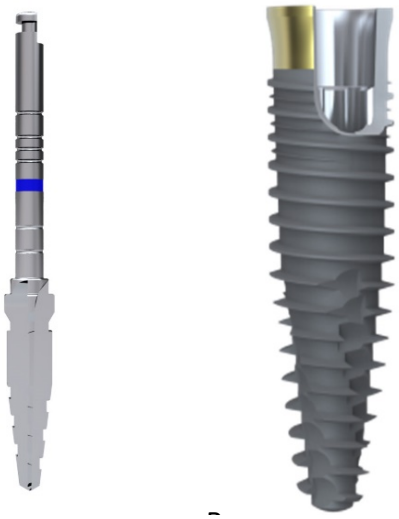

Fig. 4. *The specially designed* ***a):*** *conical drill and* ***b):*** *implant used in this study.*

and 0.2 mm/year thereafter; absence of signs and symptoms such as: pain, inflammation, infection, neuropathy, hyperesthesia.

Ridge bone height (RBH) was assessed using the diagnostic CBCTs (for the residual bone height), and the CBCTs were taken subsequently up to the 1-year follow-up. The vertical distance between the crest at implant level, and the sinus floor was taken. Peri-implant bone level changes were assessed by measuring the distance between the implant shoulder and the most coronal bone-to-implant contact in mesial and distal site. The baseline was represented by the measurements taken on the day of prosthesis delivery. These were compared with those taken 6 and 12 months after loading. The difference between follow-up and baseline measurements was considered as the MBL change. Mesial and distal values were averaged so as to have a single value per implant and per patient. Measurements were performed using ImageJ v. 1.46 (National Institutes of Health, Bethesda, MD, USA). The implant length and diameter served for calibration. An expert radiologist performed all radiographic measurements.

Statistical analysis

Descriptive statistics of the data was done using mean values and standard deviation (SD) for quantitative variables normally distributed. 95% confidence intervals were also estimated. Normality of distributions was evaluated through the d'Agostino and Pearson omnibus test. The effect of each variable (gender, age, smoking habits, bone type) on implant loss or complications was evaluated by using the Fisher's exact test. Marginal bone level change around implants of different length was compared by unpaired Student's t-test). Marginal bone level change between different follow-up intervals was compared by paired Student's t-test. The unit of analysis was the patient. P=0.05 was considered as the significance threshold. Statistical analysis was performed using GraphPad Prism 5.03 (GraphPad Software, Inc., La Jolla, CA, USA).

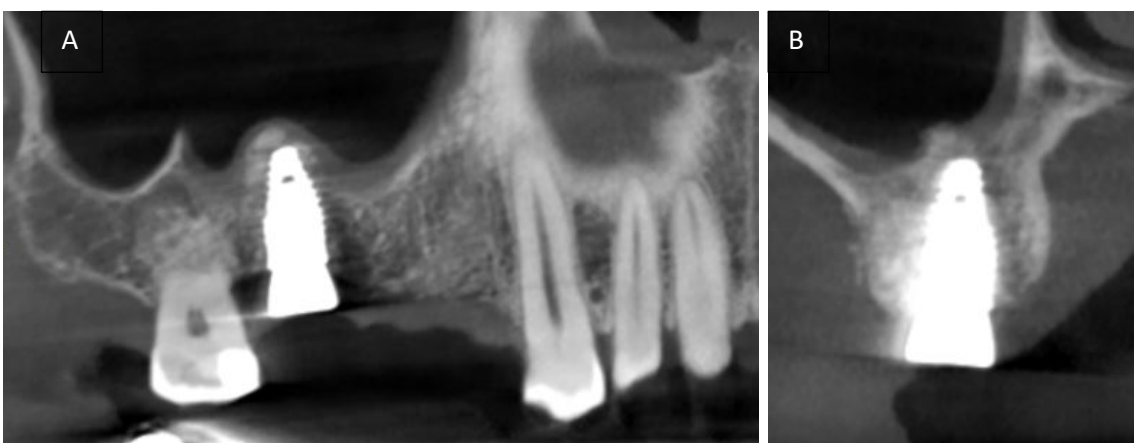

Fig. 5. ***a-b):*** *CBCT of the patient after implant insertion.*

RESULTS

Forty patients (14 males, 26 females) were included and consecutively treated by following the present protocol. The mean age of the study population at the time of surgery was 52.50±12.48 (standard deviation, SD) years, ranging from 24 to 75 years.

There were 13 smokers (32.5%) and 27 non-smokers. Fourteen patients had bone type II, 24 bone type III and only 2 bone type IV at the implant site. All the patients had occlusal antagonist and there was no presence of septa into the sinuses. Two-thirds of the patients (27/40) had no systemic conditions at all. One patient was a previous oncologic patient whose situation was under control. Four patients were under anticoagulants, three had controlled diabetes, two of

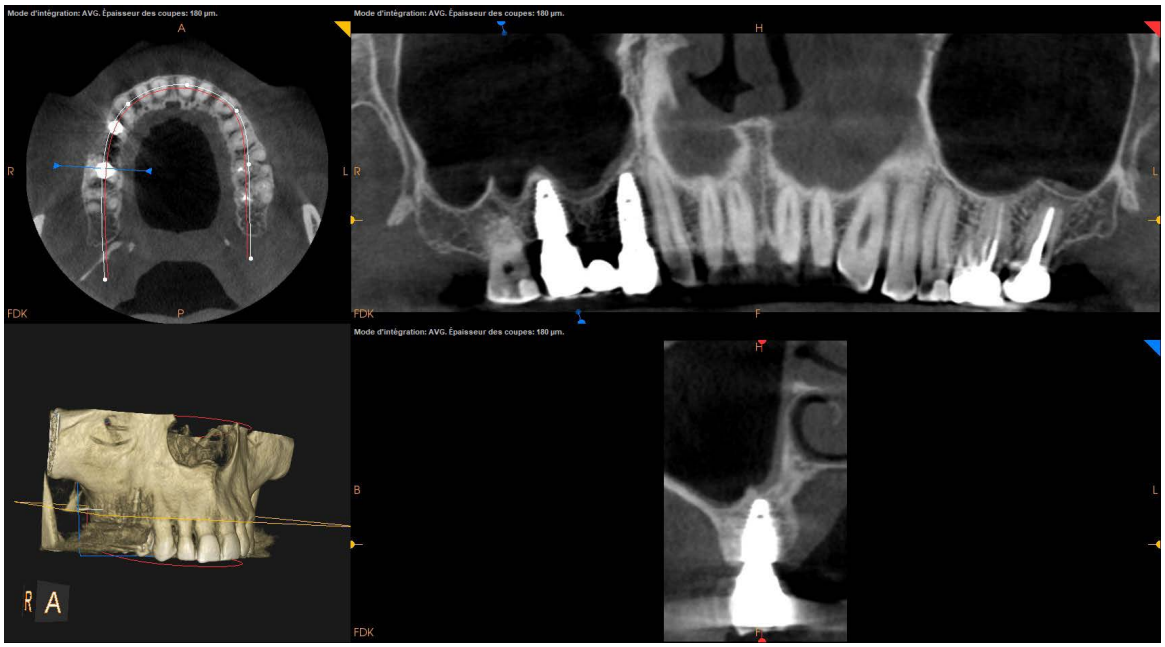

Fig. 6. *CBCT images showing the patient with the final restoration.*

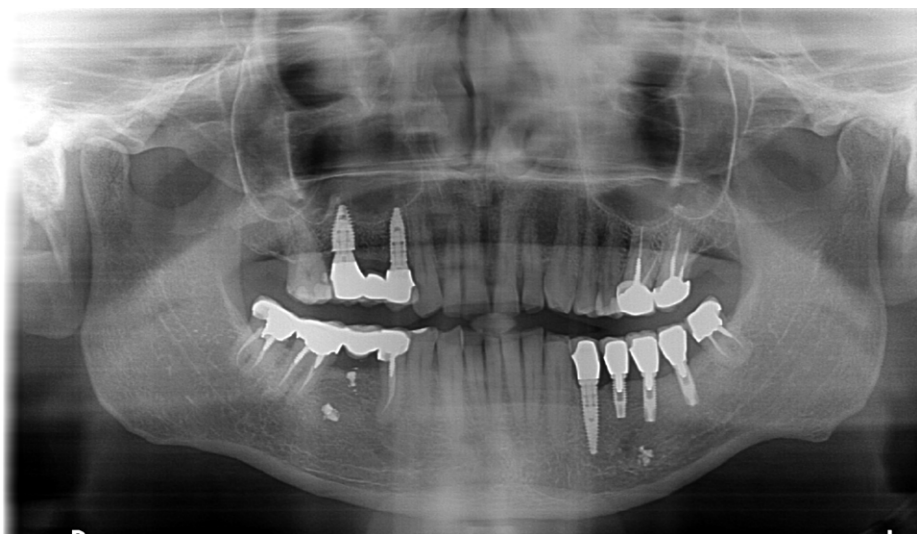

Fig. 7. *Panoramic radiograph of the patient with the final restoration.*

the patients had high cholesterol level. One patient each had one of the following medical conditions of asthma, osteoporosis, and a hemodialysis.

The mean time elapsing between implant placement and prosthesis delivery was 4.03±0.74 (range 2.7-5.7) months. The mean follow-up time after prosthetic loading was 24.0±7.0 months (range 14.1-38.9 months). The total mean follow-up from implant placement was 28.0±7.3 months (range 17.8-43.4 months)

The mean residual crestal bone height and width at the intended implant site were, respectively, 8.34±0.96 mm (95% CI: 8.03, 8.64 mm) and 7.96±1.11 mm (95% CI: 7.52, 8.21 mm). The overall mean bone height (mm) of residual ridge after sinus floor elevation with implant placement was 10.03±1.21mm (95% CI: 9.56, 10.33 mm). The average height increase was 1.69±0.80 mm, which was highly significant ($p<0.0001$). After one year of functional loading, the total ridge height averaged 10.32±1.05 mm (95% CI: 9.99, 10.64 mm). Such further increase, possibly due to bone remodeling, was significant too ($p<0.001$). Data, in Table I, show the effect of different variables like gender, smoking habits (yes or no, independent of the amount of smoking), bone quality (type II, III, or IV), implant location (premolar or molar) and the side (right or left) on the ridge height changes up to 1-year loading. There was no difference in ridge height at baseline and at subsequent follow-ups, as related to gender, smoking habits and side. Conversely, there was a significant difference in RBH between premolar and molar sites, and between bone type II and bone type III/IV. The difference persisted up to 1-year follow-up.

Data in Table II show the effect of different variables like gender, smoking habits, bone quality, implant location, implant length and diameter, and the side on the marginal bone level changes up to 1-year loading. The overall mean peri-implant MBL change after 6 and 12 months of function was, respectively, 0.26±0.24 mm (95% CI: 0.19, 0.34 mm) and 0.71±0.36 mm (95% CI: 0.60, 0.82 mm). Marginal bone loss was statistically significant at both time frames respect to implant placement, and also the MBL change between 6 and 12 months was significant ($p<0.001$ in both cases). From Table

Table I. *Effect of different variables on ridge height modifications.*

			Pre-surgery (RBH)		Post-surgery		1 year loading		Pre-surgery vs post-surgery	Post-surgery vs 1-y loading
variables		**n**	**mean±SD**	**95% CI**	**mean±SD**	**95% CI**	**mean±SD**	**95% CI**	**P-value***	**P-value***
	overall	39	8.34±0.96	8.03-8.64	10.03±1.21	9.64-10.41	10.32±1.05	9.98-10.65	<0.0001	0.0007
Gender	female	25	8.27±1.06	7.94-8.60	10.04±1.29	9.64-10.44	10.26±1.18	9.89-10.62	<0.0001	0.02
	male	14	8.46±0.75	8.23-8.70	10.00±1.11	9.66-10.34	10.43±0.81	10.18-10.68	<0.0001	0.02
	P-value		0.55		0.93		0.63			
Smoking	no	27	8.30±1.01	7.98-8.61	9.98±1.06	9.65-10.31	10.25±0.94	9.96-10.54	<0.0001	0.006
	yes	12	8.42±0.86	8.16-8.69	10.12±1.53	9.64-10.59	10.46±1.28	10.06-10.86	<0.0001	0.056
	P-value		0.70		0.75		0.56			
Bone type	II	14	9.00±0.71	8.78-9.22	10.86±0.99	10.55-11.16	11.07±0.81	10.82-11.32	<0.0001	0.08
	III+IV	25	7.98±0.89	7.71-8.26	9.58±1.09	9.24-9.92	9.91±0.95	9.62-10.21	<0.0001	0.004
	P-value		0.0007		0.0008		0.0004			
Implant location	premolar	16	8.94±0.79	8.69-9.18	10.63±1.12	10.28-10.97	10.84±0.96	10.55-11.14	<0.0001	0.048
	molar	23	7.94±0.85	7.67-8.20	9.63±1.13	9.28-9.97	9.97±0.98	9.66-10.27	<0.0001	0.006
	P-value		0.0006		0.009		0.008			
side	right	20	8.40±1.13	8.05-8.75	10.03±1.46	9.57-10.48	10.41±1.14	10.06-10.76	<0.0001	0.008
	left	19	8.28±0.77	8.04-8.51	10.03±0.95	9.73-10.32	10.23±0.98	9.92-10.53	<0.0001	0.04
	P-value		0.69		1.00		0.59			

**Paired Student's t-test; RBH: residual bone height, measured pre-surgically; SD; standard deviation; CI: confidence intervals.*

II. it appears that MBL changes are essentially independent of all variables evaluated. Indeed, only in the case of smoking patients and sites with bone type II, the difference between 6 and 12 months did not achieve significance (p=0.056 and 0.08, respectively).

Only one implant was lost in a 70y old female smoker with type IV bone, two weeks after placement, due to lack of primary stabilization. The site was grafted for the second time, in order to further increase the bone density, and after 4 months, a new implant was placed. This implant achieved

Table II. *Effect of different variables on marginal bone level changes.*

			6 months loading		1 year loading		P-value*
variables		**n**	**mean±SD**	**95% CI**	**mean±SD**	**95% CI**	
	overall	39	0.26±0.24	0.19-0.34	0.71±0.36	0.60-0.82	<0.0001
Gender	female	25	0.31±0.24	0.24-0.39	0.75±0.35	0.64-0.86	<0.0001
	male	14	0.17±0.22	0.10-0.24	0.64±0.38	0.53-0.76	<0.0001
	P-value		0.08		0.39		
Smoking	no	27	0.25±0.23	0.18-0.32	0.68±0.37	0.57-0.80	<0.0001
	yes	12	0.29±0.27	0.21-0.38	0.77±0.34	0.66-0.87	<0.0001
	P-value		0.59		0.48		
Bone type	II	14	0.20±0.22	0.13-0.27	0.59±0.37	0.48-0.71	<0.0001
	III+IV	25	0.30±0.25	0.22-0.37	0.77±0.34	0.67-0.88	<0.0001
	P-value		0.23		0.13		
Implant location	premolar	16	0.21±0.21	0.15-0.28	0.63±0.36	0.51-0.74	<0.0001
	molar	23	0.30±0.25	0.22-0.37	0.77±0.35	0.66-0.88	<0.0001
	P-value		0.29		0.23		
Implant length	10mm	27	0.23±0.24	0.16-0.30	0.70±0.34	0.59-0.81	<0.0001
	12mm	12	0.33±0.24	0.26-0.40	0.73±0.41	0.60-0.86	<0.0001
	P-value		0.21		0.80		
Implant diameter	4.2mm	17	0.21±0.21	0.15-0.28	0.64±0.36	0.53-0.75	<0.0001
	5.2mm	22	0.30±0.26	0.22-0.38	0.77±0.36	0.65-0.88	<0.0001
	P-value		0.25		0.26		
side	right	20	0.27±0.23	0.20-0.33	0.71±0.36	0.60-0.82	<0.0001
	left	19	0.26±0.26	0.18-0.34	0.71±0.37	0.60-0.82	<0.0001
	P-value		0.95		1.00		

**paired Student's t-test; SD: standard deviation; CI: confidence intervals.*

successful osseointegration and was regularly loaded and followed up without showing complications. However, the new implant was not considered for statistical analysis. The overall implant success and survival rate was 97.5%. No biological and mechanical complications were recorded throughout the follow-up period.

DISCUSSION

In the present study, optimum clinical and radiographic results were achieved with a protocol consisting of delayed implant placement in posterior maxillary infected extraction sockets preserved with allograft and collagen membranes. The high implant success and survival rate, the absence of complications and the substantial maintenance of bone levels up to one year of functional loading represent the most remarkable outcomes of this study. An extensive analysis on the data regarding ridge height and marginal bone level changes from baseline to 1-year loading was undertaken, to assess if the present technique was effective in preserving the available bone, and maintaining the augmentation achieved using the modified Summers technique.

The placement of implants in infected sites is known to be a feasible procedure, but it is not without risk. The choice of placing implants immediately in extraction sockets or in a delayed fashion may depend on several factors. The major drawback related to immediate implant placement when compared with delayed implants, seems to be the reduction of keratinized soft tissue around implants, which might jeopardize the sealing effect and the safety of the peri-implant tissues in the medium-long term (20-21). Specially, in cases of extraction of an infected tooth in posterior maxillary site, with a reduced residual ridge height and width, it can be prudent, to perform the implant placement at a second stage surgery. After careful debridement, extraction socket is preserved with GBR, and the implant is inserted in a subsequent surgical step. In this way, the implant will be surrounded by an adequate amount of bone, and a concomitant trans-crestal sinus floor elevation could be safely performed, in order to provide further protection to the implant.

The findings of this study showed that the increase in alveolar ridge height after GBR procedure and sinus floor elevation is maintained up to one year, and marginal bone changes are independent of all variables considered. In the analysis of the present work, data relative to sites in bone types III and IV were aggregated, as there were only two cases of the IV type. The latter type was kept as a single subgroup, since it would not have had any statistical relevance, due to such a low number. Ridge height resulted to be significantly greater at baseline in bone type II, and in premolar sites, when compared to bone type III-IV and molar sites, respectively. There was, however, a minor overlapping between bone quality and implant location: 22 out of 26 sites with bone type III/IV were molar sites (84.6%), and 12 out of 14 sites with bone type II were premolars (85.7%). Such difference was maintained during the follow-up, meaning that the ridge data variation was independent of bone type and implant location.

Marginal bone level changes also were not affected by any of the variables considered (Table II). The mean marginal bone loss was well below 1 mm at 6 and 12 months, being greater than 1mm (with the highest value at 1.3mm) only in about 20% (8/39) of the implants at 12 months. Despite a significant difference in peri-implant bone loss between 6 to 12 months follow-up, from preliminary observations the marginal bone level seemed to stabilize thereafter. At the time of this reporting, 18 patients achieved the 2-year loading follow-up, and from the preliminary evaluation of their MBL, no significant changes respect to 1-year values were observed, such changes ranging between 0.0 and 0.1 mm.

The results of the present study on residual bone height are in accordance with previous pre-clinical and clinical studies (22-24). A systematic review by Araujo et al. (24) aimed at determining the socket preservation effect on implant survival. The control subjects demonstrated significant bone resorption on the labial aspect and the sockets with biomaterial prevented resorption on buccal and palatal bone walls. The bone socket undergoes significant resorption more on buccal by 56% (2.2±0.2 mm, i.e., about 45μm/day) than on lingual side by 36% of the socket and these bone changes occur mostly

in the first 2-3 months' phase of bone healing as a part of bone hemostasis and bone remodeling (22). The mean horizontal reduction in ridge width were reported to be~3.8mm and vertical reduction in ridge height was found to be~1.24mm (25). The SP approach can prevent this remodeling of bone in absence of tooth. These changes are well demonstrated in literature clinically and radiologically (23). Bone is a dependent hard tissue on tooth that contributes to maintaining the bone volume by transferring the occlusal forces through Sharpey fibers to the bundle bone (23). The bundle bone slowly disappears and is replaced by woven and lamellar bone during initial phase of wound healing. This is the possible reason why there is a significant change in bone height and width after extraction of the tooth and undergoes significant resorption (22).

Araújo et al. explained the beneficial effect of alveolar ridge preservation compared to spontaneous healing through volumetric analysis (24). The premolar and incisor teeth sites were used to demonstrate the effect and concluded the resorption varies from smaller sites and larger extraction sockets. Therefore, placing a biomaterial in the extraction socket can prevent crestal bone resorption both in anterior and posterior teeth (24,26). The use of different augmentation grafting materials like allogenic bone graft, xenograft, autograft, bio-glass, platelet rich concentrates and other dental based materials have proven effects in preserving the extraction socket. A study by Jung et al. in 2018 demonstrated the importance of preservation of extraction sockets using different techniques (24). However, there is still scarce evidence on its impact on implant success, and consequently it can be concluded that more randomised control clinical trials are still required in literature (22,27). The successful healing and implant survival/success after combination of SP along with GBR was found to be 96.1% at 5 years' post-implantation with significant difference in survival rates between maxilla (76%) and in mandible (83.8%) (28).

The augmented socket tissue content was evaluated by Lindhe et.al (2013) in a clinical study (29). As a result, it was reported that the replaced socket with Bio-oss collagen after six months of healing consisted of graft particles surrounded by the vascularized matrix and the woven bone. This indicates that the biomaterial acts as a support after the loss of bundle bone. Autogenous grafts are considered as the gold standard, however, there are various reasons for a critical need of alternative grafts, such as donor site morbidity and limited availability of the native tissue. Allografts and xenografts are first choice alternatives with osteoconductive and osteoinductive properties. The extra-cellular matrix the allograft serves as a scaffold for osteoblasts in the bone defect site for facilitating new bone regeneration. According to the method of processing of the allograft material, it can additionally represent osteoinductive biological properties since they can recruit mesenchymal stem cells into the bone defect/extraction site and can stimulate differentiation into osteoprogenitor cells (11).

The GBR acts as a barrier in the defect by preventing soft tissue migrating into the defect and thereby facilitating the filling of defect with osteogenic cells and form bone. GBR also helps in stabilizing blood clot that enables migration of cells, vascularization and osteogenesis (30-31). GBR through the use of bio-absorbable barrier collagen membranes, such as equine collagen membranes for guided bone regeneration were shown to have positive effects with several advantages, such as single stage surgery and improved soft tissue healing (31-32).

The osseodensification drilling technique was used in this study, which is a surgical procedure for inducing the condensation and deposition of crusts of bone (33). Osteocondensation technique, which is also reported in literature, is a diverse technique, which is mainly based on a plastic deformation of the bony walls around the implant at the defect site (34). However, in both techniques the aim is to increase the density of alveolar bone surrounding dental implants, to improve its stability. Osseodensification technique involves the use of specially designed drills that are run in a counterclockwise direction, in order to create a layer of compacted bone along the surface of the osteotomy site (33).

This study was performed in a general practice setting, using standard materials; therefore, the results

do not reflect those obtainable in the ideal conditions such as a randomized clinical study performed by a top-level research team in a university or hospital setting, but rather could more closely resemble those obtained by general practitioners in the everyday practice. Nevertheless, the authors acknowledge that there were several limitations that might impair the validity of the outcomes. First, the non-comparative study design, that did not allow to estimate the actual performance of the technique respect to other more conventional techniques, limiting the relevance of the findings. Additionally, the absence of data soft tissue parameters which were not recorded, can be considered as a limitation, however the hard tissue changes were assessed using radiographs. Furthermore, despite the promising results herein observed, the relatively short follow-up did not allow to evaluate the technique in the medium-long term, for which all patients should be assessed for at least five years. The low sample size did not allow generalization.

The strong points of the study are that this technique requires a modest learning curve, and the results are very reproducible; the absence of prosthesis and implant failures under function, as well as the absence of complications so far, and the substantial maintenance of bone levels, testify the validity of the technique in the short term. Of course, studies with a longer follow-up period and a wider sample size are needed to confirm the encouraging results observed.

As a conclusion, the novel modification of "Summers's protocol" introduced in this cohort study can be an effective and safe alternative to maxillary sinus floor augmentation procedures and immediate implant insertion protocol, especially in cases of periodontitis and infectious sites which can represent a high risk for implant failure in patients with atrophic posterior maxilla.

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Authors' contributions

R.B., F.G., G.B., S.T., and M.D.F. conceived and designed the analysis. Databases were searched and data was collected by R.B., F.G., S.K., and M.D.F. The surgical interventions implant insertions were performed by R.B. All the authors contributed on analysis and interpretation of data for the work. M.D.F., S.K., and F.G. drafted the work and wrote the manuscript with input from all authors. All authors revised the work critically for intellectual content. Integrity of the work was appropriately investigated and resolved by all authors. All authors contributed, read and approved equally to the final manuscript.

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