Maxillary and Mandibular Split Crest Technique with Immediate Implant Placement: A 5-Year Cone Beam Retrospective Study

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Purpose: This study aimed to test the effectiveness and reliability of the alveolar ridge-splitting technique in atrophic posterior arches, investigating the middle-term volumetric and clinical outcomes. ***Materials and Methods:*** Atrophic alveolar ridges in the maxillary and mandibular posterior areas were treated with the alveolar ridge-splitting/expansion technique (ARST), immediate implant placement, collagen sponges covering the defect, and healing by secondary intention. Areas were rehabilitated by fixed dental prostheses supported by dental implants. Changes in volume and width of the alveolar ridge were retrospectively calculated by comparing the x-ray tomography scans obtained before and 5 years after surgery. Report of failure in the case sheets was taken into account. Cross-sectional images were also used to assess the thickness of the labial alveolar plates at the implant shoulder. Nonparametric analyses of variance with post hoc and pair-comparison tests were performed with a level of significance of .05. ***Results:*** A total of 38 patients were retrospectively selected (23 women and 15 men). Six patients underwent ARST surgeries in both the maxilla and the mandible and were excluded from statistical analysis. Differences between 16 maxillae and 16 mandibles and between 12 single crowns and 20 fixed partial dentures (FPDs) were searched. Episodes of minor swelling occurred within the first 2 days after surgery. Neither mucositis nor flap dehiscence had been registered. The mean values of buccal cortical thickness were 2.46 ± 0.49 mm and 1.15 ± 0.33 mm, respectively, in the maxillary and mandibular areas. After 5 years of survey, maxillary increases in alveolar ridge width and volume were +4.4 ± 0.4 mm and +295 ± 45 mm^3, respectively, whereas the same outcome variables (+3.5 ± 0.7 mm and +217 ± 53 mm^3) measured in the mandible appeared to be significantly smaller than those in the maxilla ($P < .0001$). One maxillary single implant failed. Cumulative survival rates at 5 years were 100% for mandibles and 95.5% (95% CI: 86.8% to 100%) for maxillae. ***Conclusion:*** Posterior areas of the maxilla displayed a higher increase in alveolar width and volume than mandibular areas, and even if it would be premature to draw survival conclusions at this stage without any statistical support, a lower cumulative survival rate was reported for the maxillary single implants. *Int J Oral Maxillofac Implants 2021;36:999–1007. doi: 10.11607/jomi.8572*

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Several bone augmentation techniques, such as grafts with either cortical or particulate bone substitutes (xenogeneic, allogeneic, or synthetic scaffolds), and with or without membranes (resorbable, absorbable, or otherwise) could be used for correcting inadequate bone conditions due to very narrow alveolar ridges.[1–3] Before dental implant placement, the recipient sites of the bone grafts had a variable healing time depending on the type of well-documented procedures that were employed; moreover, the use of bone substitute might enhance the risk for nonintegration and thus increase the rate of implant failure. As said, given the findings of the literature, the clinician could also decide not to use a bone substitute for bone augmentation, especially because in the case of autologous bone, a secondary surgical donor site was a necessary surgical step to increase the risk for postoperative complications and morbidities. In addition, it might be remembered that there was strong evidence that alveolar bone augmentation success rates had been hindered by partial bone loss resulting from negative remodeling phenomena.[4,5]

Guided bone regeneration and distraction osteogenesis were also used to increase the amount of

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bone volume and to improve prosthetic rehabilitation outcomes. However, both of these techniques might present potential disadvantages, such as tissue dehiscence, displacement or collapse of the membrane, inappropriate distraction, unpredictable amount of bone loss, and delay in implant placement.[6]

To find an alternative solution for increasing the bone volume before implant placement in case of an insufficient width of the alveolar ridge, a splitting/expansion technique was used to separate the buccal and the lingual/palatal cortical plates to increase the space from each other created by a greenstick fracture and to induce new bone formation in the inner cavity.

The ridge/expansion technique created a recipient bed without the use of bone grafts, providing successful outcomes with high predictability and low risk of complications compared with those of other techniques that make use of autologous donor sites.[7]

Horizontal alveolar expansion of the narrow edentulous ridges followed by placement of implants or "alveolar ridge-splitting/expansion technique" (ARST) was originally described by Simion and coworkers and later by Scipioni and colleagues.[8,9]

A few authors also mentioned some surgical variants of the standard ridge-split procedure, such as a "sandwich" technique, which attempted to address several of the methodologic difficulties and the major challenges still existing with hard tissue augmentation procedures.[10–13]

An outline and a rough description of the surgical technique was that the surgeon used to expand the narrow edentulous ridge by splitting the cortical plate, further opening the space between the two halves, and moving them away from each other; the space in the middle of them was occupied for the most part by an immediate endosseous dental implant.

The main advantages of ARST were that it was simple and quick, probably because of both the relatively atraumatic flapless procedure and the use of alternatives to bur preparation.[14] Moreover, the way the residual alveolar ridge underwent an expansion in width appeared to also be highly predictable.[15] As said in the literature, studies for assessing middle-term quantitative evaluation of bone volume change after ridge-splitting/expansion were not reported.

The aim of the present study was to test the effectiveness and reliability of ARST for fixed rehabilitation supported by osseointegrated implants in the atrophic posterior arches, investigating the middle-term linear and volumetric outcomes of patients who underwent splitting/expansion surgery, immediate dental implant placement, a simple collagen sponge covering of the wound, and healing by secondary intention.

The secondary aim was to reveal the clinical difference between the maxilla and mandible sites, and between two different rehabilitation strategies (single crown [SC] vs fixed partial denture [FPD]).

MATERIALS AND METHODS

Patient Selection

From a single cohort of consecutive patients treated between June 2012 and July 2014, by one oral surgeon and one prosthetic specialist at Tuscan Stomatological Institute, who underwent implant-supported fixed rehabilitation in the posterior areas, a subgroup was scheduled for the present retrospective study.

To be included in the analysis, patients had to match the following inclusion criteria:

- Split crest procedure with an immediate dental implant in a split alveolar ridge
- Report of long-standing edentulism in posterior sites (loss of tooth at least 2 years before implant placement)
- Clinical report of a thickness of the keratinized gingiva equal to or greater than 3 mm[16,17]
- Restored implant (SC or FPD)
- Implant axis perpendicular to the occlusal plane[17]
- 5-year follow-up from the first surgery

Patients were excluded from the present data analysis when in the medical record, it appeared that:

- They had undergone any surgical treatment different from that described earlier within or in an area close to the selected site (other tissues' augmentation techniques, to be more precise).
- Absence of an antagonist tooth of any sort (natural teeth, composite-restored tooth, tooth-supported fixed prosthesis, or implant-supported fixed prosthesis).

Although this was a retrospective selection of previously treated patients, it was a common practice of the clinician to fulfill the following contraindication guidelines, even if a single-patient rehabilitation strategy was decided on a case-by-case basis.

Absolute contraindications included: chronic systemic disease (report of immunocompromised condition, uncompensated/uncontrolled diabetes, coagulation disorders); intravenous and/or oral bisphosphonate therapy, chemotherapy, or radiotherapy.

Relative contraindications included: heavy smoker habit (> 10 cigarettes per day), alcohol or drug abuse.

Patients had to sign a routine informed consent form regarding surgical treatment and additional informed consent for analysis of their data, as requested by the ethical committee according to principles embodied in the Helsinki Declaration of 1975 and further revisions.

Surgery

One hour before surgery, the patients received 1 g amoxicillin (Zimox, Pfizer Italia) and 1 g twice a day for a week after the surgical procedure (or clindamycin if allergic to penicillin, 600 mg before surgery, then 600 mg 3 times daily for 7 days). Surgery was performed under local anesthesia (optocaine, 20 mg/mL with adrenaline 1:80,000, Molteni Dental, Scandicci).

In the edentulous alveolar ridge, a palatal or lingual incision in the crestal direction was performed, followed by transperiosteal incisions made perpendicular to the initial one on each side, allowing the raising of a partial-thickness flap (Figs 1a to 1c). After the flap reflection, two vertical grooves were made by the penetration of the vestibular cortical bone plate on the mesial aspect and one on the distal aspect of the flap edges of the buccal site by keeping a safe distance of 1 mm from the adjacent teeth. In the absence of teeth, the discharges were performed 3 to 5 mm away from the closest implant planned site. The crestal incision was continued into the bone to perform an intraosseous groove (Fig 1d) with a blade directly attached and pushed by an electromagnetic device (Magnetic Mallet, www.osseotouch.com, Meta-Ergonomica, Turbigo).[18–21] The device was set to apply different forces from 85 to 260 DekaNewton with a duration of 120 microseconds according to the different bone densities. The clinician was cautious and prudent during bone penetration and enlargement to prepare the alveolus for subsequent handling of a proper implant bed preparation: In particular, it was appropriate that the blade might penetrate down into the alveolar ridge no less than 7 mm and no more than 11 mm.

Subsequently, in the maxillary site, specific tool sequences of bone expanders[22] were loaded on the handpiece of an electromagnetic device to create a site to allocate the implant by expanding the bone tissue in both the lateral, against the preexisting bone walls, and the apical directions, by moving it up and compressing the residual bone on the surfaces inside the newly created space. In mandibles, different tools of blades with an increasing thickness were used for ridge splitting so that the buccal plate was slowly dislocated in the lateral direction with care to maintain a zone of spongiosa beneath the cortical plate with a minimum thickness of 1.5 mm. Moreover, the final sequence of burs was used to underprepare the implant host site up to 1.2 mm less than the nominal implant diameter, although the value of the threshold appeared to be reduced depending on the local bone density.

Rough plasma-spray–surface, 2-mm machined-neck, progressive-thread-design external-hexagon osseointegrated dental implants (Out-Link, Sweden & Martina) were placed completely subcrestal within the boundaries of the newly augmented volume (Fig 1e).

The buccal flap was apically repositioned and sutured to the margin of the palatal/lingual flap, and anchored with a loose loop to the periosteum at the level of the alveolar mucosa. The surgical field was covered by collagen (Gingistat, Acteon Pharma) that was inserted under the undermined keratinized mucosa that lined the flap edges. The collagen ensured that the bleeding stopped and intended to stabilize the blood clot.[12]

Prosthetic Procedure

The submerged dental implant was loaded (Fig 1f) after 2 months with a healing abutment and a temporary cement-retained restoration (TempBond, Kerr Italia) with custom-shaped acrylic resin to maintain a relationship with the mucosal margins. The registration of the emergence profile was performed by impression compound with the addition of silicone of two different consistencies (polyvinyl siloxane impression material, Flexitime Heavy + Flow, Heraeus/Kulzer) in an individual acrylic impression tray. An ideally constructed definitive abutment was fabricated, and then, a ceramic-fused-to-metal definitive fixed prosthesis was cemented (TempBond) 4 months after implant placement. Each patient received a single implant crown or an implant-fixed partial denture supported by two or three implants.

Primary Predictors

The primary predictors were: group A—maxillary implants and group B—mandibular implants.

Secondary Predictors

The secondary predictors were: type of prosthesis (single-implant crown vs implant-supported FPD), type of opposing tooth (porcelain vs enamel/restorative material), patient sex (male vs female).

Radiographic Examination and Outcome Variables

Planning and follow-up examinations were assessed radiographically using a CBCT scanner (Gendex GXCB-500, Gendex Dental Systems) with the following setting: 120 kV, 30.89 mAs, isotropic voxel size of 200 mm, and 8.72-cm-diameter field of view (FOV).

Preoperative and postoperative CBCT scans were superimposed according to Crespi and coworkers.[23] Then, superimposed data were saved (in .DICOM [Digital Imaging and COmmunications in Medicine]).

All CBCT scans were then sent to a single, blinded examiner (T.P.), who performed all the measurements.

A CBCT cross-sectional image was extrapolated perpendicular to the implant direction and alveolar crest width (ACW); that is, the distance between the most

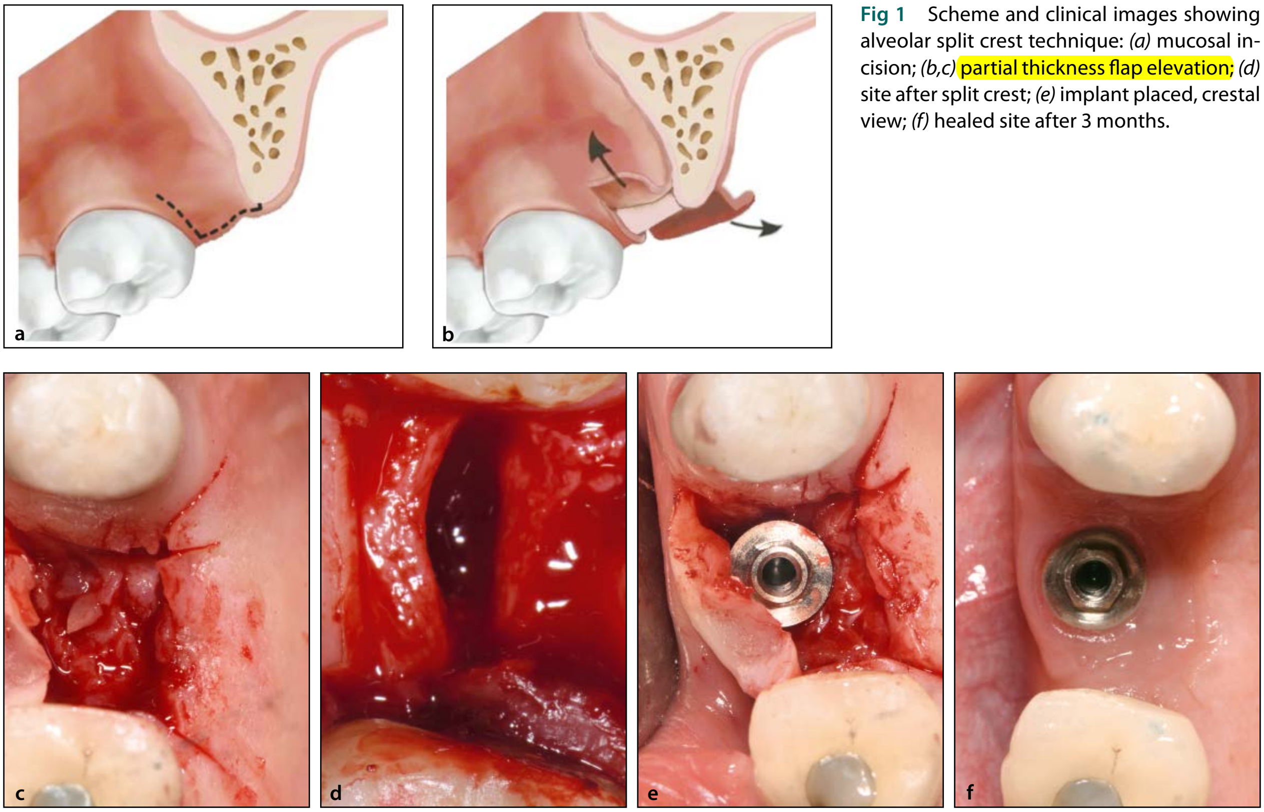

Fig 1 Scheme and clinical images showing alveolar split crest technique: *(a)* mucosal incision; *(b,c)* partial thickness flap elevation; *(d)* site after split crest; *(e)* implant placed, crestal view; *(f)* healed site after 3 months.

prominent points on the palatal and buccal aspect, and the buccal bone wall thickness (CT), were measured at 1 mm apical to the most coronal point (Fig 2).

Change in the width of the alveolar ridge (ΔACW) was the difference between the preoperative (at least 2 years after tooth extraction) and postoperative measurement (5 years after implant placement) following equation 1:

$$\Delta ACW_{baseline \rightarrow postoperative} = ACW_{postoperative} - ACW_{baseline} \quad \text{(equation 1)}$$

At the end of linear analysis, for each patient, volumes were measured as per Crespi and coworkers[21] within a standardized volume of interest (VOI), that is, the volume contained within the following boundaries: 5 mm mesially and 5 mm distally to the center of the implant shoulder, and extending 10 mm apical to the most coronal level of the implant-abutment interface, obtaining an increase at alveolar crest volume (ACV) as per equation 2 (Fig 2):

$$\Delta ACV_{baseline \rightarrow postoperative} = AC_{Vpostoperative} - ACV_{baseline} \quad \text{(equation 2)}$$

in which ACV was the bone volume in the VOI.

Clinical Outcomes

The following clinical parameters had been gathered from patients' case sheets: report of pain, surgical complication, and prosthesis mobility. The following had been considered as dental implant failing criteria: the presence of implant mobility, a radiolucent area close to the implant surface, suppurative mucosa, associated pain, either spontaneous or due to the application of external strength. Survival rates were calculated as per Eckert et al.[24]

Statistical Analysis

All statistical analyses had been performed using a statistical tool package (Statistics Toolbox, MatLab 7.11, The MathWorks). In the case of a patient who underwent a split crest procedure in both the maxilla and the mandible, the subject was excluded from further statistical analysis. Thus, exclusion had ensured that all groups and subgroups were independent, with just one enrolled site per patient. The Brown-Forsythe test of homogeneity was used to test if variance among all the subgroups was or was not the same; normality of data was tested by the Shapiro-Wilk test. The data passed all the following assumptions: data are continuous; data comes from a single group, measured on different occasions; blocks are mutually independent (ie, exclusion of the six patients treated both in the maxilla and mandible); observations are ranked

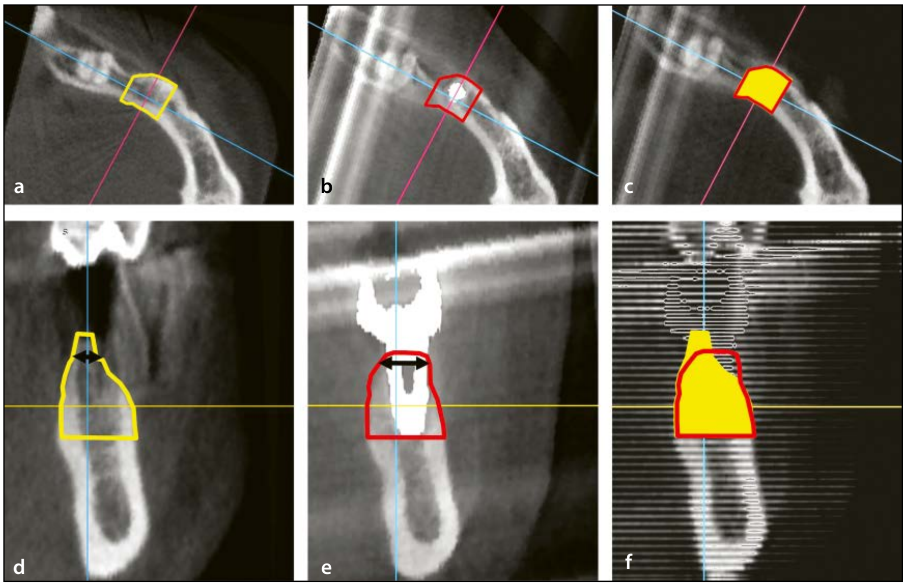

Fig 2 Axial and cross-sectional views of the alveolar crest volume (ACV, colored contours) measured before and after alveolar ridge-split procedure: *(a)* preoperative in yellow; *(b)* postoperative in red; *(c)* fused files with preoperative volume in full. Cross-sectional views with alveolar crestal width (ACW, double arrows in black) measured before and after alveolar ridge-split procedure: *(d)* preoperative; *(e)* postoperative; *(f)* fused files.

Table 1 Demographic Data Description for the Sample

	Selected sample		Enrolled for statistic	
Variable describing sample	**Patient no. (with failure)**	**Percent**	**Patient no.**	**Percent**
Sex				
Male	15 (1)	39.5	11	34.4
Female	23	60.5	21	65.6
All	38		32	
	Site no. (with failure)	**Percent**	**Site no.**	**Percent**
Arch and prosthesis				
Maxilla SC	10 (1)	22.7	4	12.5
Maxilla FPD	12	27.3	12	37.5
Mandible SC	13	29.5	8	25.0
Mandible FPD	9	20.5	8	25.0
All	44 (1)		32	

SC = single-crown; FPD = fixed partial denture.

within blocks with no ties (arches and prostheses are mutually exclusive). The effects on volume and alveolar width were evaluated with a nonparametric two-way repeated-measures test (Friedman). Differences between groups were searched by the unpaired two-sample Wilcoxon rank-sum test for independent groups and by the Wilcoxon signed-rank for matched data. In the text and tables, data were described as mean ± standard deviation (SD) and rounded to the nearest decimal. A *P* value < .05 was the threshold for statistical significance.

RESULTS

Forty-three patients were retrospectively selected for the present study; five were excluded because the patients underwent additional surgeries that might affect the present outcomes. Out of the remaining 38 patients, 6 were excluded to make adequate statistical calculations. The patients, 23 women and 15 men with a mean age of 59.8 ± 5.2 years (ranging from 49.3 to 72.9 years), underwent the placement of 72 dental implants: 33 in mandibles with the diameters ranging from 3.75 to 5 mm and 39 in maxillae with the diameters ranging from 4.2 to 5 mm. Each patient received a single implant crown or an implant-fixed dental prosthesis supported by two or three implants. The distribution of patients according to sex (male vs female), treated site (maxilla vs mandible), and type of prosthesis (SC vs FPD) is shown in Table 1. The descriptions, dispersions, and statistics of all the data are reported in Table 2.

Changes in volume and width of the alveolar ridge were measured by a comparison of cone beam computed tomography scans acquired before and after surgery. Moreover, the cross-sectional images were used

Table 2 Mean and SD of Alveolar Crest Width (AW) and Volume (ACV) in the Volume of Interest, Measured at Preoperative, Preop (or AW_0 and ACV_0), at 5-year survey , 5 y (or AW1 and ACV1), and from Preoperative to 5-year survey, preop-5 y (ΔAW and ΔACV)

		ACV_0 (preop)		ACV_1 (5 y)		ACV_0 « ACV1 (preop vs 5 y)	ΔACV (preop-5 y)	
Volume analysis	**Sample size**	**Variable (cc)**	**Normality test**	**Variable (cc)**	**Normality test**	**Wilcoxon: pair-comparison**	**Variable (cc)**	**Normality test**
Brown-Forsythe (homogeneity of variance): arch		F = 2.3324, df1 = 5, df2 = 90, *P* = .0486§						
Friedman: arch		SS = 582.01, df = 1, χ^2 = 6.61, *P* = .0101+						
Maxilla	16	714 ± 84	.9561^	1,009 ± 98	0.3161^	.0004*	+295 ± 45	.0492^
Mandible	16	687 ± 70	.7236^	904 ± 79	0.3749^	.0004*	+217 ± 53	.8523^
Wilcoxon: (maxilla vs mandible)		.4286°		.0050°			.0005°	
Brown-Forsythe (homogeneity of variance): prosthesis		F = 1.7714, df1 = 5, df2 = 90, *P* = .1267§						
Friedman: prosthesis		SS = 70.08, df = 1, χ^2 = 1.40, *P* = .2363+						
SC	12	742 ± 85	.9643^	988 ± 98	.3794^	.0004*	+246 ± 63	.2420^
FPD	20	676 ± 61	.7654^	938 ± 103	.4650^	< .0001*	+262 ± 62	.3815^
Wilcoxon: (SC vs FPD)		.0307°		.1793°			.5591°	
		AW_0 (preop)		AW_1 (5 y)		AW_0 « AW_1 (preop vs 5 y)	ΔAW (preop-5 y)	
Linear analysis	**Sample size**	**Variable (mm)**	**Normality test**	**Variable (mm)**	**Normality test**	**Wilcoxon: pair-comparison**	**Variable (mm)**	**Normality test**
Brown-Forsythe (homogeneity of variance): arch		F = 1.8187, df1= 5, df2 = 90, *P* = .1171§						
Friedman: arch		SS = 506.25, df = 1, χ^2 = 5.77, P = .0163+						
Maxilla	16	3.7 ± 0.8	.5959^	8.1 ± 0.8	.3409^	.0004*	+4.4 ± 0.4	.7497^
Mandible	16	3.7 ± 1.0	.3458^	7.2 ± 0.7	.1148^	.0004*	+3.5 ± 0.7	.0286^
Wilcoxon: (maxilla vs mandible)		.8209°		.0017°			.0002°	
Brown-Forsythe (homogeneity of variance): prosthesis		F = 1.6278, df1 = 5, df2 = 90, *P* = .1607§						
Friedman: prosthesis		SS = 363, df = 1, χ^2 = 7.28, *P* = .0070+						
SC	12	3.8 ± 1.1	.9128^	7.3 ± 0.7	.6314^	.0004*	+3.5 ± 0.8	.2046^
FPD	20	3.7 ± 0.8	.8950^	7.9 ± 0.9	.1159^	< .0001*	+4.2 ± 0.6	.0113^
Wilcoxon: (SC vs FPD)		1°		.0669°			.0166°	

AW = alveolar crest width; ACV = volume; preop-5 y = preoperative to 5-year survey; SC = single crown; FPD = fixed partial denture. Homogeneity of variance: §Brown-Forsythe test, and + Friedman analysis test (for arch, maxilla/mandible, and prosthesis, SC / FPD); normal distribution test: ^Shapiro-Wilk test; statistical comparisons: *Wilcoxon signed-rank test assessing changes in time from preoperative to 5-year follow-up; °Wilcoxon rank-sum test assessing changes between groups.

to examine the thickness of the labial plates at the level of the implant shoulder.

All the linear and volumetric outcomes are shown in Table 2. Values of buccal cortical bone thickness (CT) were 2.46 ± 0.49 mm and 1.15 ± 0.33 mm, respectively, in the maxilla and mandible. After 5 years of survey, the preserved augmentation in length (ΔACW in mm) and volume (ΔACV in mm^3) were +4.4 ± 0.4 mm and +295 ± 45 mm^3 in the maxillary bone, and +3.5 ± 0.7 mm and +217 ± 53 mm^3 in the mandible. The changes in the mandibular bone appeared to be significantly smaller than the maxillary changes with *P* values < .0005.

The results of the Friedman test (Table 2) seemed to suggest a significantly different volumetric behavior between the prosthetic treatments, such as single implant-supported crowns in single edentulous sites vs patients treated with two/three implants supporting an FPD, but just for linear outcomes; in fact, a significant difference was encountered when the change in alveolar width (ΔAW) had been compared between the two prosthetic groups (*P* = .0166).

The results confirmed the statistical validity of the present finding when outcomes of the maxilla and mandible were compared. In the group analysis, the increase in bone width and volume appeared to be significant with $P \leq .0005$ (Table 2). The results of the Friedman tests indicated that both effects of sex and type of opposing tooth (with 10 opposed by porcelain surfaces and 34 naturally/restore opponent teeth) were not significant.

No patient showed either signs or symptoms of benign paroxysmal positional vertigo.

The majority of the episodes of minor swelling had been reported as being encountered in the healing gingival mucosa within the first 2 days after surgical procedures. Through the time that the mucosal healing was achieved, surgical sites showed evidence of neither mucositis nor flap dehiscence. The case sheets did not report an unsuitable wound healing around temporary abutments or crowns.

After a follow-up period of 5 years, one maxillary implant failed in a patient treated with a single implant-supported crown, so cumulative survival rates were 90% (95% CI: 71.4% to 100%) for the maxillary single-crown group and 100% for all the other sites.

DISCUSSION

Comparing the surgical outcomes of both guided bone regeneration and the use of bone grafts vs the ARST, the use of the latter allowed clinicians to perform one-step surgical procedures, to effectively place dental implants, to eliminate the need for bone grafting, to reduce the risk of membrane exposure contributing to minimizing complications and morbidities, and finally to shorten the overall treatment time.[25,26]

The present ARST requiring a minimum bone width of 3 mm and at least 1 mm of cancellous bone sandwiched between the cortical plates could be successfully used for the treatment of horizontal alveolar deficiencies.[27]

Despite the limitations of the present study, the radiographic analysis was able to detect different behaviors between the maxillary and mandibular sites concerning all the variables designed to measure any increase in the horizontal bone width.

Concerning the measurement of the horizontal dimension of the alveolar process, the maxillary expansion of the bone crest appeared significantly higher than in the mandibles (+4.4 mm vs +3.5 mm). In line with this trend, the paper also demonstrated a statistically significant increase in the maxillary volume of the alveolar crest after a ridge split procedure (+0.295 cc) than that in the mandible (+0.217 cc). Perhaps, the authors of the present article could find a possible explanation about differences between the maxillary and mandibular sites through the following speculative consideration. As a result of the alveolar ridge-splitting/expansion procedure, it could be supposed that mandibular areas were associated with the smaller increase in width because mandibles had a mean buccal bone wall thickness (1.15 mm) less than half the maxillary thickness (2.46 mm). Moreover, the different behavior and significant gain in bone volume throughout the healing period obtained when the outcome of maxillary and mandibular areas had been compared for ridge width outcomes might depend on features of the bone, that is, a variable degree of its structure/density and elasticity in the two anatomical sites. In the maxillary area, the buccal bone was well-known to be highly viscoelastic and flexible so that, during the surgical procedure, the bone expander was able to minimize the amount of trauma to the bone and to avoid distress to the patient. The interpretation of the present results in terms of survival rates and increase in width of the alveolar bone suggested that they appeared to be very similar to those reported by few systematic reviews and meta-analyses. Irrespective of the surgical devices used (conventional or ultrasound), studies by Waechter et al and Elnayef et al reported horizontal gains in bone ranging from 2.00 to 5.17 mm, with a weighted mean of 3.6 mm.[6,28]

In the present study, the overall survival rate for implants (considering the patient as the unit of analysis) was 97.4% (95% CI: 92.3% to 100%); other studies advocating the use of a partial-thickness flap obtained a very similar result, with a mean implant survival rate of 96.7% and a range between 91.9% and 97.7%.[28] Moreover, ARSTs, without bone grafts, on average, showed a survival rate ranging from 96% to 97.3%, with a mean follow-up from 2 to 3 years.[15]

An ARST with simultaneous implant placement could be used to treat atrophic arches only in the case where the primary stability could be achieved at least at the apex level of the placed implant. One of the additional advantages of placing immediate implants was that the patients underwent a single surgical procedure; thus, the time of treatment and care (from surgery to prosthesis-wearing) and their physical discomfort were significantly reduced.

In the atrophic regions of the mandible, the thickness of the buccal bone plate appeared to be greatly reduced, but the residual bone was replaced by deposition of more resilient lamellar bone; final implant bed preparation was generally achieved by increasing the size of drills and burs after the split stage of the ridge splitting/expansion procedure. The aforementioned surgical steps seemed to be essential for the success of the rehabilitation but also appeared to produce bony wall damage to such a degree that high bone resorption might occur during the healing phase following surgery.

Some researchers reached the same conclusions of this study, stating that the ridge-splitting technique and simultaneous implantation appeared to be less complex and demanding, and easier than in the mandibles; it probably depended on the malleable nature of the maxillary bone (from type III to IV) and its high degree of vascularization.[27,29]

Bone density appeared to be significantly higher in the mandible than in the maxilla; therefore, different approaches of ridge-splitting/expansion might be required. Moreover, a horizontal ridge augmentation of the atrophic posterior mandible with ridge splitting and expansion showed an increased risk of bone fracture during the mobilization of the vestibular flap; it was technically a more demanding surgery, making an early dental implant positioning quite difficult. This was the reason the ridge-splitting/expansion technique with immediate implant placement in the very narrow alveolar bone should be contraindicated in the mandibular areas in which an inadequate volume of cancellous bone did not guarantee a sufficient degree of flexibility.[29,30]

Based on the results of a clinical trial, clinicians recommended that the mandibles be treated by a two-stage technique and a conventional implant loading, as this could prevent thin buccal bony plates from being accidentally fractured, and reduce complications and barriers to treatment.[31]

If clinicians needed to plan immediate implant placement in the posterior mandibular region using a ridge-splitting procedure, the following general considerations should be taken into account:

- Bone density and two-stage surgery: Maxillary alveolar ridges were usually less dense than the mandibular ridges, and that was more manageable for surgeons to perform a single-stage procedure.
- Blood supply and periosteal vascularization: During the ridge-split procedure, the periosteum should be handled with extreme care to protect its role in the vascularization.[29]
- Healing by secondary intention: In most cases, a primary closure could not be achieved, because the soft tissue architecture was essentially unchanged.

Clinical and radiologic outcomes presented in this study showed that the present technique was reliable and also showed an effective bone gain and conservation around dental implants at a 5-year survey in patients who underwent the alveolar ridge-split procedure with an immediate implant, when the bone defect had been covered with collagen sponges alone and the wound was healed by secondary intention. The results attested that maxillary posterior sites had a higher chance to increase the alveolar ridge in width and volume, as it appeared for a 5-year period, than the mandibular sites.

The cumulative survival rate of a single implant placed in maxillary posterior areas seemed to be lower than the mandible and the group of implant-supported FPDs.

CONCLUSIONS

Posterior areas of the maxilla displayed a higher increase in alveolar width and volume than mandibular areas, and even if it would be premature to draw survival conclusions at this stage without any statistical support, a lower cumulative survival rate was reported for the maxillary single implants.

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materials

Article

Biomolecular, Histological, Clinical, and Radiological Analyses of Dental Implant Bone Sites Prepared Using Magnetic Mallet Technology: A Pilot Study in Animals

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Abstract: Background. A new instrumentation exploiting magneto-dynamic technology (mallet) proposed for implant site preparation was investigated. Methods. In the tibias of three minipigs, two sites were prepared by mallet and two by drill technique. Primary stability (ISQ) was detected after implant positioning (T0) and at 14 days (T14). X-rays and computed tomography were performed. At T14, bone samples were utilized for histological and biomolecular analyses. Results. In mallet sites, histological evaluations evidenced a significant increase in the newly formed bone, osteoblast number, and a smaller quantity of fibrous tissue. These results agree with the significant BMP-4 augmentation and the positive trend in other osteogenic factors (biological and radiological investigations). Major, albeit IL-10-controlled, inflammation was present. For both techniques, at T14 a significant ISQ increase was evidenced, but no significant difference was observed at T0 and T14 between the mallet and drill techniques. In mallet sites, lateral bone condensation was observed on computed tomography. Conclusions. Using biological, histological, clinical, and radiological analyses, this study first shows that the mallet technique is effective for implant site preparation. Based on its ability to cause osseocondensation and improve newly formed bone, mallet technology should be chosen in all clinical cases of poor bone quality.

Keywords: dental implants; mallet technique; drill technique; implant stability quotient; osteogenesis; inflammation

1. Introduction

Current bone surgery techniques aim to be less invasive and to accelerate healing processes.

New instruments have been designed for implant bone site preparation, as an alternative to drills, to reduce surgical trauma and phlogosis, obtain greater control of the cut, increase primary and secondary stability, and reduce healing times and morbidity [1–5].

Healing times and the osseointegration process depend on the cascade of biological events, including inflammation and osteogenesis. Therefore, it is necessary to analyze the biological factors involved, such as pro-and anti-inflammatory cytokines and bone morphogenic proteins (BMPs), molecules responsible for osteoblast/osteoclast differentiation or interactions between cells and the extracellular matrix [6,7]. Studies evaluating the biological mechanisms induced by the different preparation techniques and leading to the osseointegration of dental implants are very few. Recently, a new instrumentation exploiting magneto-dynamic technology has been proposed for bone surgery, including dental implant site preparation [8–17]. The literature on this technique is very limited and includes only observational clinical studies regarding the osseocondensation compared to conventional implant site preparation using drill technique. No reports have investigated the histological or biomolecular aspects.

Based on the above observations, this study aimed to compare implant bone site preparation using magneto-dynamic technology with that using the drill technique to identify the most effective means of improving implant osseointegration.

2. Materials and Methods

2.1. Animals

Three male adult minipigs, weighing 70–85 kg, older than two years, and showing the same characteristics of age, sex, weight, and health status were included in this study. They were drawn numerically from a lot of 15 minipigs by a dedicated veterinarian, not involved in the study, responsible for animal logistics. Animals were housed in single boxes in a dedicated room with controlled temperature and humidity at the Animal Pathology Department of Turin University, Italy. Minipigs received a standard pelleted cereal diet and water ad libitum.

The research was performed as a blinded study and in accordance with the Declaration of Helsinki. The study was approved by the Italian Ministry of Health (General Management for Animal Health and Veterinary Drugs. Office 6, Authorization number 304/2020-PR on 14 April 2020) and was conducted in compliance with the ARRIVE guidelines [18].

2.2. Focal Point

About the PICO (patient, intervention, comparison, and outcome), this study aimed to answer to the question "Does the magneto-dynamic mallet technique for implant site preparation, compared to conventional drilling technique, improve implant osseointegration?".

- Population: three minipig animals (we performed biomolecular and histological analyses on 3 implants for each technique).
- Intervention: magneto-dynamic mallet technique for implant site preparation.
- Comparison: conventional drilling for implant site preparation.
- Outcomes: improving implant osseointegration.

2.3. Implant Insertion and Explantation

Before surgery, food and water were withheld for 12 h. Animals were given intramuscular meloxicam (5 mg/kg) (Inflacam 20 mg/mL, Laboratoires Virbac, Carros, France) 12 h before surgery. After induction with intramuscular xylazine (2.2 mg/kg) (Rompun 20 mg/mL, Bayer S.p.a., Milan, Italy) and tiletamine/zolazepam (6.6 mg/kg) (Zoletil 200 mg/mL, Laboratoires Virbac, Carros, France), an oro-tracheal tube was positioned and anesthesia was maintained with oxygen/isoflurane. Heart and respiratory rate, end-tidal CO_2 ($EtCO_2$), and oxygen saturation (SpO_2) were monitored. In addition to preemptive meloxicam administration, minipigs received butorphanol (0.03 mg/kg IV) (Dolorex 1 mg/mL, Intervet, Aprilia, Italy) prior to surgery.

A conventional X-ray of the tibia of the left hind leg was carried out before surgery to examine the tibial anatomy. Each tibia was set up in a sterile way and exposed by ungluing the periosteum. Twelve titanium implants (ProActive Tapered 9 mm $\times$ 4 mm, implant neck 4.3 mm. Neoss®, Implants, Milano, Italy) were surgically inserted into the tibias. For each animal, the implant sites were prepared using the magnetic-dynamic mallet technique (Meta Ergonomica, Turbigo, Milano, Italy) (two implants) or the drill technique (two implants) according to the Neoss® protocol (Neoss®, Implants, Milano, Italy).

All implant sites were prepared, at the cortical level, at 4 mm in diameter, applying the specific protocols for each type of instrumentation, allowing the same conditions for each single site.

For the mallet technique, the following inserts were used: PF 10–160 F–200 F–230 F, program Power 2 to 4. For the drill technique: lanceolate drill–2.2 mm Ø–3 mm Ø–3.2 mm Ø–3.4 mm Ø–3.6 mm Ø–countersink 4 mm Ø. Drills were used at 1300 rpm and countersink at 350 rpm.

For the first animal, the first two implant bone sites were randomly selected; in the other animals, the sites were chosen so that each type of preparation was situated in each tibia position (proximal, central, caudal) to avoid giving an advantage to one or the other technique.

Intraoperatively, the cortex bone thickness, using an appropriate instrument, and the bone quality were evaluated. All the implants were placed with a torque ranging from 35 to 70 (N·m); when necessary, the wrench was used to position the implant neck at the bone cortical level.

A distance of 5–6 mm was maintained between the two sites prepared with the same technique; the distance between the different preparations was greater than 9 mm. This distance was chosen to avoid overlap of biological phenomena between the two techniques.

The primary stability at four points (proximal, medial, lateral, and caudal) using the Penguin RFA instrument (Neoss®, Penguin, Milano, Italy) was detected for a total of 12 measurements for each implant. A bone sample for evaluating the biomolecular basal conditions was taken. The cover screws were placed, and a layered closure of the tissues was performed (T0). A second X-ray was taken to verify that the implants did not engage to the opposite cortex.

After surgery, the animals were treated for three days with meloxicam (5 mg/kg) (Inflacam 20 mg/mL, Laboratoires Virbac, Carros, France) as painkiller, and for five days with ceftiofur (3 mg/kg) (Norbrook® Laboratories, Newry, Northern Ireland) as antibiotic therapy. At 14 days (T14), after anesthesia with intramuscular xylazine (2.2 mg/kg) (2.2 mg/kg) (Rompun 20 mg/mL, Bayer S.p.a., Milan, Italy) and tiletamine/zolazepam (6.6 mg/kg) (Zoletil 200 mg/mL, Laboratoires Virbac, Carros, France), the tibia of each animal was subjected to a computerized tomographic (CT) scan (Siemens Somatom Emotion Computerized Tomograph 16, Siemens Healthineers, Milano, Italy) with the following parameters: 160 mA, 130 KV, and 1 mm thickness. CT scans, in helical acquisition mode, were acquired with the subject in lateral decubitus with the limb under examination placed dorsally and in the center of the gantry, to repeat the same position for each animal. Each CT image was reconstructed in 3D and evaluated by two blinded operators in the advanced imaging diagnostics, not aware of either the implant sites or the surgical procedures.

All investigations were repeated three times at multiple different points.

Subsequently, the tibias were exposed as previously described; on each implant, the primary stability using the Penguin RFA (Neoss®, Penguin, Milano, Italy) instrument was detected.

For the two procedures in each animal, two bone slices (one mallet and one drill) were utilized for histology and the other two for biomolecular analyses. The final euthanasia was performed by an intracardiac injection of embutramide, mebezonium iodide, and tetracaine hydrochloride (70 mg/kg) (Tanax, Intervent International GmbH, Unterschleißheim, Germany) (Figure 1).

2.4. Histological Analyses

After implant removal, bone specimens were immediately fixed in 10% neutral buffered formalin and maintained at room temperature. Then, they were decalcified for at least 72 h in a mixture of formic and hydrochloric acids (BIODEC R, Bio Optica Milano, Italy), sectioned along the longitudinal implant axis and embedded in paraffin. From each bone portion, sections (5 μm) were obtained and stained with hematoxylin-eosin (H&E) for optical microscopy. The following parameters were analyzed in peri-implant tissue corresponding to 2 mm around each implant site: (1) maximum length of the newly formed bone (mm) measured from the implant profile; (2) bone tissue percentage; (3) number of osteoblasts. All data represent the mean of 10 fields.

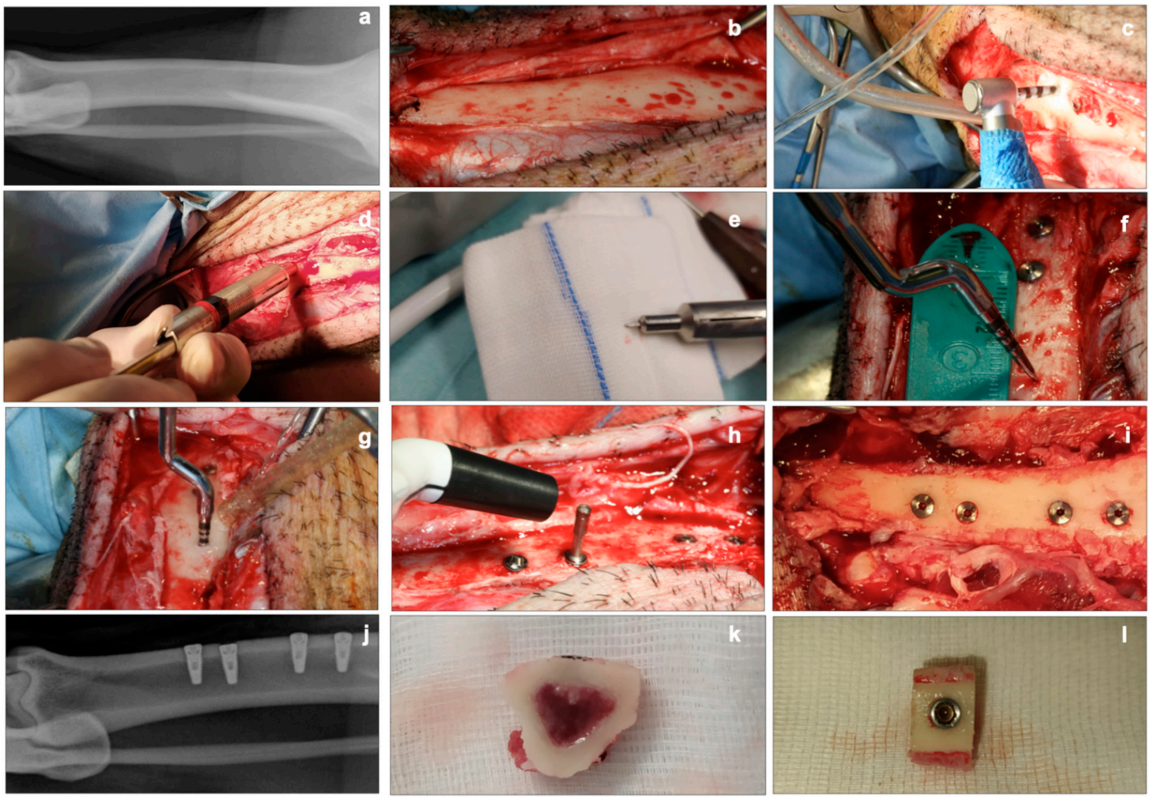

Figure 1. Clinical aspects. (**a**): conventional X-ray of the tibia before surgery. (**b**): exposure of the tibial bone after ungluing of the periosteum. (**c**): implant site preparation using a drill. (**d**,**e**): device used for intraoperative measurement of cortical thickness. (**f**,**g**): distance measurement for implant site preparation, using the mallet technique. (**h**): detection of the implant stability quotient (ISQ) with the Penguin RFA instrument at T0. (**i**): clinical view of the four implants inserted (two sites with the mallet technique, two sites with drill technique). (**j**): conventional X-ray of the tibia after implants placement. (**k**,**l**): bone slices for histological and biomolecular analyses.

Furthermore, sections stained with H&E were digitized using the Hamamatsu's Nanozoomer 2 scanner (Aperio ImageScope, Buccinasco, Milano, Italy). Areas of new bone deposition and fibrous tissue were marked using an imaging computer software (Aperio ImageScope, Buccinasco, Milano, Italy), analyzed according to a protocol proposed by Han, J.-M. et al. [19], and expressed as total surface area.

2.5. Biomolecular Analyses

To protect mRNA, the specimens were placed in RNALater (Thermo Fisher Scientific, Monza, Italy) immediately after removal from the animals and stored at −80 °C until use. To perform the biomolecular analyses on the bone closest to the implant and actual site of osseointegration, specimens were cut so that the volume used for mRNA extraction was similar and corresponded to 2 mm around each implant site.

To obtain bone powder, samples were ground under a liquid nitrogen stream using a surgical stainless steel mortar and pestle. Total RNA was extracted from the powder (150 to 200 mg) using TRI Reagent (Merck Life Science, Milano, Italy).

For each sample, 1 µg of total RNA was reverse transcribed to cDNA using the FIREScript RT cDNA synthesis Kit (Solis Biodyne, Tartu, Estonia). Real-time PCR was performed on cDNA using 5 x HOT FIREPol® Evagreen® qPCR Supermix (Solis Biodyne, Tartu, Estonia). The forward (FW) and reverse (RV) primers, designed using the Primer3 tool available at https://bioinfo.ut.ee/primer3, accessed on 26 January 2021, are reported in Table S1 from Supplementary Material.

The expression of the following genes was evaluated at the bone-implant interface:

1. Osteogenesis: BMP-4; BMP-7; transforming growth factor-beta2 (TGF-β2); RUNX2, alkaline phosphatase (ALP); osteocalcin (OCN); collagen type I α1 (COLL1A1); Wnt3a; Wnt5a; Wnt10b; Wnt16.
2. Inflammation: interleukins (IL-1β; IL-6; IL-8; IL-10), tumor necrosis factor alpha (TNF-α).

Each sample was tested in triplicate and the quantitation cycle (Cq) values averaged. GAPDH was used as the housekeeping gene. The relative changes in the expression of different targets were defined as relative expression compared to that present in the corresponding bone sample T0, calculated as $2^{-\Delta\Delta Cq}$, where $\Delta Cq = Cq_{sample} - Cq_{housekeeping}$ and $\Delta\Delta Cq = \Delta Cq_{sample\ T14} - \Delta Cq_{sample\ T0}$.

2.6. Statistical Analysis

All data are expressed as mean ± SEM. Differences between group means were assessed using the Instat package, Version 3.10 (GraphPad Software, San Diego, CA, USA). Data were analyzed by unpaired two-tailed Student's *t*-test or one-way ANOVA analysis followed by the Bonferroni post hoc test. A p-value < 0.05 was considered statistically significant. Pearson's correlation coefficient (r) was computed to investigate the linear dependence of the ISQ and the cortical bone thickness.

3. Results

3.1. Biomolecular Data

The mRNA content of the factors involved in the induction of bone synthesis is reported in Figure 2.

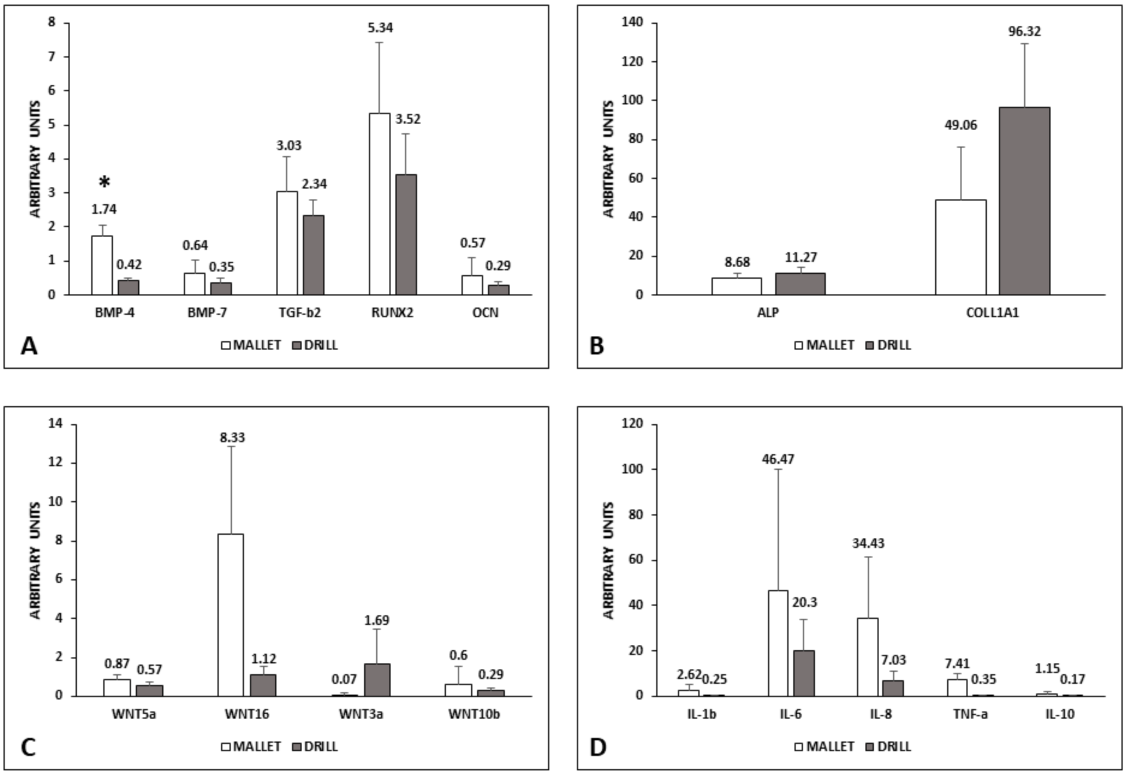

Figure 2. mRNA level of osteogenic and inflammatory factors in peri-implant bone tissues. Panels (**A**,**B**): osteogenic factors; panel (**C**): WNT pathways; panel (**D**): inflammatory factors. Data represent the mean ± SEM of the evaluations carried out on bone samples obtained at T14. For each animal, the mRNA amounts detected at this time were normalized with respect to the values found in the corresponding bone at T0. Student's *t* Test: BMP-4 * $p = 0.017$. BMP-4, bone morphogenetic protein-4; BMP-7, bone morphogenetic protein-7; TGF-β2, transforming growth factor-β2; RUNX2, RUNX family transcription factor 2; OCN, osteocalcin; ALP, alkaline phosphatase; COLL1A1, collagen 1A1; WNT, wingless-related MMTV integration site; IL-1β, interleukin-1β; IL-6, interleukin-6; IL-8, interleukin-8; TNF-α, tumor necrosis factor-α; IL-10, interleukin-10.

In tissues surrounding implants using the mallet technique, the expression of BMP-4, BMP-7, TGF-β2, RUNX2, and OCN was higher than those with drill ones. Only the difference in BMP-4 was statistically significant (Panel A). Conversely, ALP and COLL1A1 were lower in mallet sites (Panel B).

The canonical Wnt3a was less expressed in the case of mallet instrumentation, whereas all the other members examined (Wnt5a, Wnt10b, and Wnt16) were higher than in drill sites (Panel C). Moreover, regarding Wnt expression, the differences were not statistically significant.

Pro-inflammatory cytokines IL-1β, IL-6, Il-8, and TNFα showed no significant increase in mallet sites; in these sites, a similar trend was observed in anti-inflammatory IL-10 (Panel D).

3.2. Histological Data

Figure 3 shows that in mallet sites, a significant increase of newly formed bone area, bone percentage, and osteoblast number was present. The greater amount of bone tissue was coupled with a smaller, nonsignificant amount of fibrous tissue. No significant increase in the maximum length of the newly formed bone was observed.

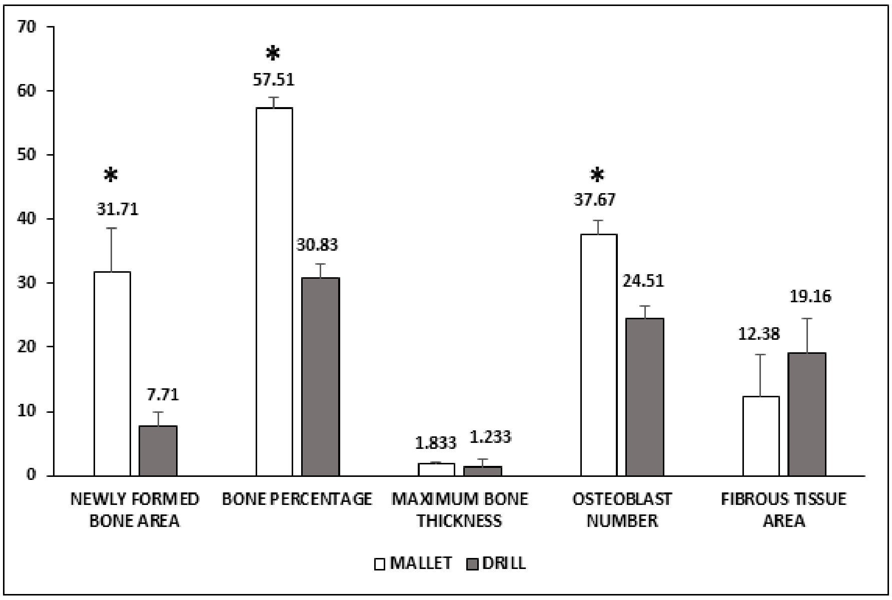

Figure 3. Histological evaluation of peri-implant bone tissues. Areas of newly formed bone and fibrous tissues are expressed as mm^2 and have been evaluated using an imaging computer software. Maximum bone thickness is expressed as mm and was evaluated, as the osteoblast number, by optical microscopy. Data represent the mean ± SEM of the evaluations carried out on bone samples obtained at T14. Student's *t*-test: Newly Formed Bone Area * $p = 0.031$; Bone Percentage * $p = 0.001$; Osteoblast number * $p = 0.009$.

Figure 4A,B reports histological pictures representative of newly formed bone (yellow line) and fibrous tissue (green line). In Panel C, representative images of the total peri-implant surfaces, measured by using computer imaging software, are illustrated. Panel D describes the scheme of the calculation of the tissue areas surrounding implant.

3.3. Clinical and Radiological Data

At all sites, the cortex showed type 1 quality, while the cancellous bone showed type 4 [20]. In mallet sites, the mean cortical thickness (mm) was 3.95 ± 0.30; in drill sites, 3.72 ± 0.316 ($p = 0.51$). The insertion torque was high in the sites prepared with the mallet technique: in one case, it was 50 (N·m), in all others 70, and in one of the latter cases, a wrench was needed. At the drill sites, the insertion torque ranged from 35 to 59 (N·m); in two cases, it reached 70. For both techniques, a significant increase in ISQ was evidenced at T14 compared with the corresponding T0; conversely, no significant difference was observed at

T0 and T14 between the mallet and drill ISQ values. No correlation was evidenced between cortical thickness and ISQ values (Table 1).

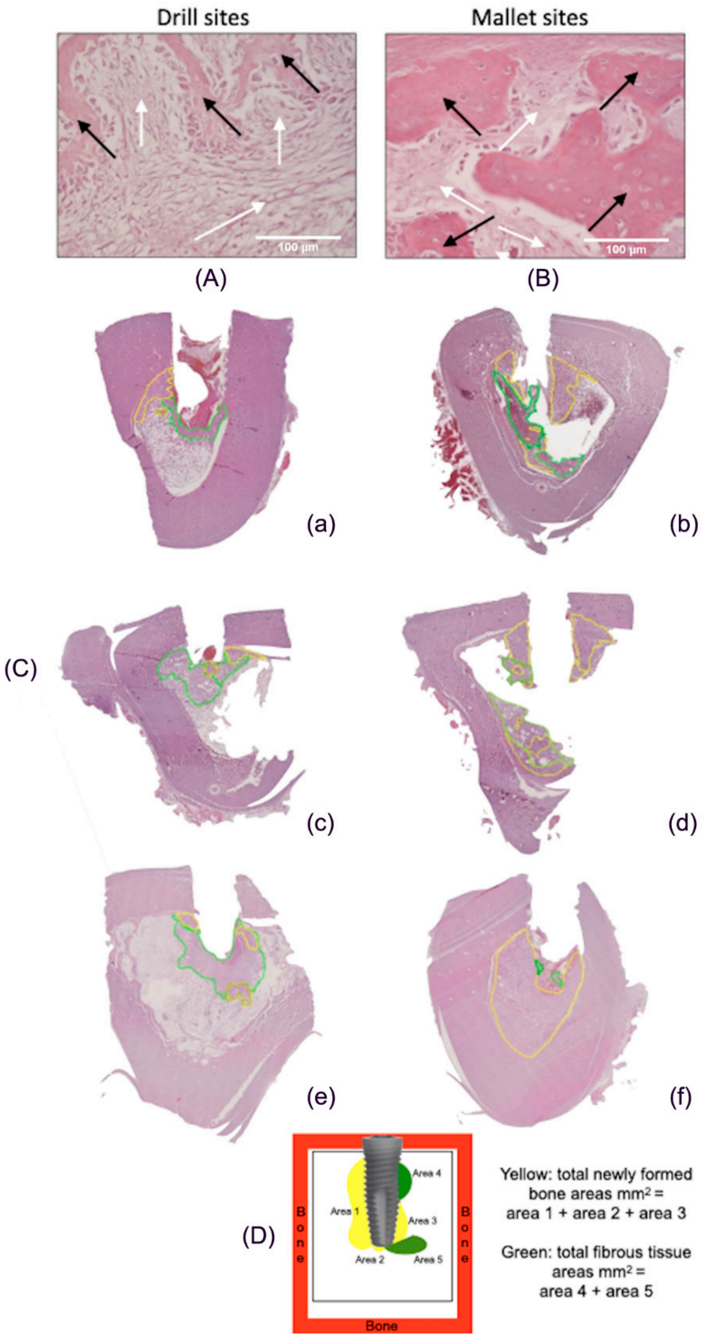

Figure 4. Histological images of peri-implant tissues and scheme of area calculation. (**A**) The fibrous tissue (white arrows) was greater than newly formed bone tissue (black arrows) in drill-prepared sites (Hematoxylin and Eosin, 400×). (**B**) In the mallet site, the amount of newly formed bone tissue (black arrows) is greater than that of fibrous tissue (white arrows) (Hematoxylin and Eosin, 400×). (**C**) Areas of new bone and fibrous tissue deposition, expressed as total surface (mm^2), using an imaging computer software, according to the Han, J.-M. et al. [19] protocol. In every picture, in yellow, areas of new bone deposition and in green, areas of fibrous tissue. (**a**,**c**,**e**): tissues from sites prepared with drill technique, in the three different animals; (**b**,**d**,**f**): tissues from sites prepared with mallet technique in the three different animals. The bone samples obtained from mallet sites show a greater area of newly formed bone and a lower area of fibrous tissue compared to drill ones. (**D**) Example of scheme for calculating the newly formed bone and fibrous tissue around the implants.

Table 1. Clinical data representing the values of the Implant Stability Quotient (ISQ), the cortex thickness, and their correlation.

ISQ Values			
Mallet		**Drill**	
T0	**T14**	**T0**	**T14**
77.531 ± 0.542 a	80.979 ± 0.441 b	76.250 ± 0.479 a	81.062 ± 0.455 b
ISQ Percent Increase			
Mallet		**Drill**	
4.592 ± 0.325		6.467 ± 0.525 *	
Cortex Thickness (mm)			
Mallet		**Drill**	
3.625 ± 0.311		3.475 ± 0.204	
Correlation between Cortex Thickness and ISQ (r)			
Mallet		**Drill**	
T0	T14	T0	T14
0.51	0.36	0.65	0.55

Data are expressed as mean ± S.E.M. Differences between group means were assessed using one-way ANOVA analysis followed by Bonferroni post hoc test or unpaired two-tailed Student's *t*-test. Means with different letters are statistically different. A *p*-value < 0.05 was considered statistically significant. Student's *t*-test: * $p = 0.0028$. Person's correlation coefficient (*r*). ISQ, Implant Stability Quotient.

The CT scan showed a moderate trabecular densification organized at the cortico-cancellous junction adjacent to all implants in the sites prepared with the mallet technique. By contrast, drill sites did not show trabecular bone densification adjacent to the implants, except in one site where a slight, nonorganized trabecular densification with the presence of radiodense millimeter spots was observed (Figure 5). The mean weight of explanted bone samples was 3.15 ± 0.20 g in mallet sites and 2.63 ± 0.37 g in the drill ones ($p = 0.065$).

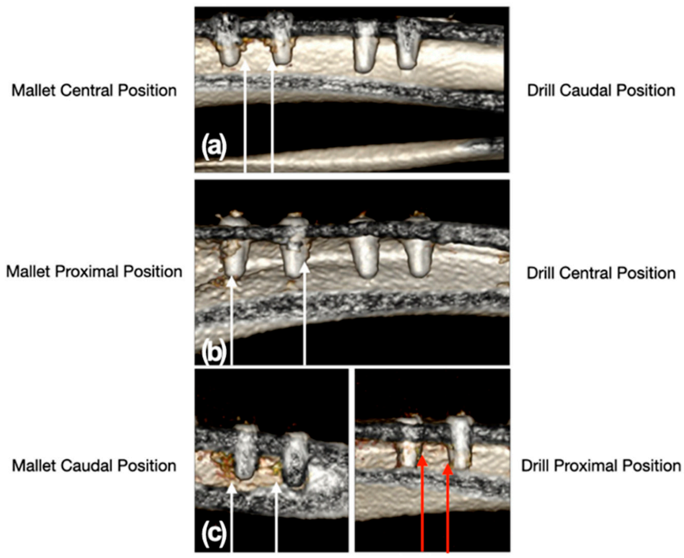

Figure 5. CT scan images of the position of the implant sites relative to the tibial bone. Panel (**a**): mallet in central and drill in caudal position; panel (**b**): mallet in proximal and drill in central position; panel (**c**): mallet in caudal and drill in proximal position. The white arrows indicate the two sites, with the relative implants, prepared with the mallet technique. In these sites, a moderate trabecular densification organized at the cortico-cancellous junction adjacent to all implants could be noted. The sites prepared with drill showed no trabecular bone densification adjacent to the implants, except in one site where a slight, nonorganized trabecular densification with the presence of radiodense millimeter spots was present (red arrows).

4. Discussion

The magnetic-dynamic technique has recently been introduced in oral bone surgery, such as dental extraction, split crest, sinus lift, and implant site preparation. Only few observational clinical studies, almost all conducted by the same group, investigated the efficacy of this new instrumentation [8–17]. To the best of our knowledge, this is the first study exploring, by means of clinical, radiological, histological, and biological analyses, the effects of mallet instrumentation on bone implant site preparation, compared with the drill technique. The minipig model was chosen because it is frequently used in dental implant research [2,7]. The implants were positioned in the tibia due to the difficulty inserting them in the oral cavity [21]. The analyses were performed at 14 days based on literature showing that significant changes in primary implant stability and osseointegration process are already present at this time [2,22].

4.1. Biological Factors

4.1.1. Osteogenic Process

The expression of genes involved in early and late stages of osteogenesis was evaluated.

BMPs are cytokines belonging to the TGF-β superfamily which regulate several physiological processes. BMP-4 and BMP-7 possess strong osteogenic properties. BMP-4 is mainly responsible for recruitment of mesenchymal stem cells (MSC) and their commitment to the osteoblast lineage, inducing the transcription of osteoblast characterizing genes, such as *ALP, Osterix*, and *RUNX2* [23,24]. In rat calvaria osteoblasts, BMP-2-induced BMP-4 expression has been demonstrated to increase ALP, type I collagen, and OCN [25].

With a partially overlapping mechanism, BMP-7 induces the expression of ALP and OCN and favors bone mineralization [26–29]. Among the BMP-induced osteogenic factors, OCN plays a crucial role in the last phase of bone deposition, contributing to matrix mineralization [30]. The TGF-β pathway is involved in osteogenesis by stimulating the proliferation of osteoblast precursors and in the early phase of differentiation [31]. In our model, the expression of BMP-4, BMP-7, and TGF-β2 is increased in mallet sites compared with drill ones, even though the difference was only statistically significant for BMP-4. The increased expression of BMP-4 and 7 is associated with that of RUNX2 and OCN, genes known to be under transcriptional control of these BMPs.

To explain why ALP and COLL1A1 expression is lower in mallet sites, it could be suggested that in these sites the induction of osteogenesis occurs earlier, and the major expression of these factors could have occurred before 14 days. Regarding the lower COLL1A1 level, the hypothesis agrees with histological data showing a major bone tissue and a minor fibrous tissue. In sites prepared with the mallet technique, the increased expression of all osteogenic factors investigated (BMP-4, BMP-7, TGF-β2, OCN, and RUNX2) might be at the origin of the significant increase in newly formed bone area and number of osteoblasts, and of the nonsignificant increase in bone thickness, highlighted by the histological analysis.

4.1.2. Inflammatory Process

The occurrence and the entity of the osteogenesis process are strictly correlated with the inflammatory response consequent to surgery injury. It is well known that some inflammatory mediators also favor tissue regeneration/repair. The determination of pro-inflammatory molecules revealed that in mallet sites, the mRNA levels of IL-1β, IL-6, IL-8, and TNF-α were higher than in drill ones, although in this case the differences were also not significant.

However, in mallet sites, the inflammation seemed to be under control; in fact, the bone deposition and the number of osteoblasts were greater in these sites than in those prepared with a drill. In mallet sites, the action of pro-inflammatory cytokines was probably reduced by the increased expression of IL-10 and TGF-β2, which negatively modulate phlogosis [32].

4.1.3. Wnt

Wnt pathway is involved in regulation of signal transduction from outside to inside the cell, cell proliferation, differentiation, polarity, and inflammation [33–37]. It can be divided into: 1. canonical, which causes the stabilization of β-catenin; 2. noncanonical, which works independently of β-catenin.

Both pathways concur in the osseointegration of dental implants and are upregulated on porous titanium implant surfaces [38]. It has been reported that a high level of Wnt signaling at the moment of implant positioning prevents excessive deposition of fibrous tissue and favors osseointegration [39]. It has been shown that Wnt/β-catenin promotes the expression of Runx2, ALP, BMP-7 [40], and noncanonical pathway up-regulates BMP-2 and BMP-4 [41]. Olivares-Navarrete et al. evidenced that, during osseointegration on microstructured and hydrophilic surface of grade 2 unalloyed Ti, the canonical pathway is activated in early-stage of differentiation of osteoblast-like MG63 cells, and noncanonical in late-stage of differentiation, improving osseointegration [42].

In our study, we investigated the expression of some canonical (Wnt3a, 10b) and noncanonical (Wnt5a, 16) proteins. In the sites prepared using the mallet technique, Wnt3a was less expressed than in drill sites; by contrast, Wnt5a was increased. These results agree with previous reports showing that the transient exposure to Wnt3a causes a quick and early bone formation and that Wnt5a inhibits Wnt3a [43].

The major amount of bone in the mallet sites could reflect a more advanced phase of osteogenesis due to the Wnt5a increase at 14 days. The low levels of Wnt3a in the mallet sites, at 14 days, may explain the low levels of ALP and COLL1A1 since these genes are under the transcriptional control of Wnt3a and normally increase early in bone healing. The major quantity of bone observed in histological analysis in tissues surrounding mallet sites could also be due to the increased expression of Wnt16 and Wnt10b. The former blocks osteoclast differentiation [44]; the latter triggers transcription of genes that drive MSC osteogenetic differentiation [45].

The osteogenic property of Wnt10b has been indirectly confirmed by the observations that mice that do not express it, show a reduction of bone mass and that, in mouse embryonal development, the expression of Wnt10b induces fibroblast differentiation to osteoblasts [46]. The increased Wnt5a can also explain the increment of the inflammatory indices, since it has been reported that IL-1β, IL-6, IL-8, and TNF-α increase consequent to Wnt5a enhancement [47,48].

4.2. Histological Analyses

Histological analyses were used, together with the biomolecular analyses, to outline a complete view of osseointegration process. The results obtained with the optical microscope and computerized analysis showed a significant increase in the deposition of newly formed bone and in the number of osteoblasts, associated with a lower quantity of fibrous tissue, in the sites prepared using the mallet technique. It is to be noted that newly formed bone probably also includes the "scar" fibrous tissue and bone spicules formed by the osseocondensation induced by the surgical mallet technique. These observations agree with the increase in osteogenic factors and the decrease of collagen found with biomolecular analyses, even though the differences are not statistically significant. The discrepancy in terms of statistical significance between the two types of investigations could be because the histological evaluations present a picture that is the result of previous changes while biological parameters are the basis for changes that will occur in the following healing times.

4.3. Clinical and Radiological Observations

Positioning of the implants in different portions of the tibia did not affect the results obtained from either surgical technique. The mean cortical thickness and mean weight of bone samples did not statistically differ between the two experimental groups. However, the mean cortical thickness of tibias influenced the preparation of bone implant sites using the mallet device. In fact, before its use, it was necessary to make small holes for almost the entire thickness of the cortex with a lanceolate drill.

In this way, the cortical portion was weakened to favor the progression of the subsequent magneto-dynamic inserts suitable for site preparation. After this action, the progression of the inserts occurred without problems. However, the fact that it was necessary to make small holes in the case of a very thick and dense cortex could suggest that the mallet technique shows a minor penetration capacity, probably due to the reduced instrument power or to the not very aggressive design of the first insert.

Furthermore, it can be suggested that the inserts be used starting from power 2 of the slider; only when the penetration capacity of the insert is reduced can the power be progressively increased reaching the maximum power of 4.

Starting the preparation using maximum power could cause rupture of cancellous bone trabeculae instead of pushing and compacting them sideways in the cancellous spaces. Moreover, even if mallet technology does not require irrigation, it is advisable to sometimes irrigate the site with sterile saline solution to preserve bone elasticity and reduce its rigidity, thus decreasing the occurrence of microfractures. Nevertheless, in our experimental conditions, the mallet device did not cause fractures; this is probably due not only to the intermittent irrigation, but also to its very rapid action in terms of impulse release [11]. These latter clinical-observational hypotheses require further investigations.

In our study, in the sites prepared with mallet technique, lateral bone condensation was observed in the presence of type 1 cortex and type 4 cancellous bone. This was confirmed by the blinded CT scan analysis. These observations agree with previous studies evidencing bone condensation in implant sites prepared with a magnetic mallet, using conventional X-rays [10,11,14] or CT [16,17]. Nevertheless, the increased stability detected from T0 to T14 with both techniques argues in favor of the effectiveness of the magneto-dynamic device, since the preparation with drills is morphologically dedicated to the implant used, while that with mallet instrumentation is not.

These results suggest that the increased stability in the case of the mallet technique is probably due to the cancellous osseocondensation caused by this instrument. This hypothesis seems to be confirmed by the increased implant insertion torque, the significantly higher amount of bone evidenced by histological analyses, and the clear trend to a greater expression of all osteogenic factors in mallet-compared to with drill-prepared sites.

4.4. Limitations of the Study

Although overall the results of this pilot study show, for the first time, that the mallet technique is effective for the preparation of the implant site, further studies are required to analyze the implant osseointegrative process at longer experimental times, with a larger sample size. Moreover, human trials are needed.

4.5. Value of the Study

This is the first study that investigates, by biomolecular, histological, radiological, and clinical analyses, implant site preparation using a magneto-dynamic technique.

4.6. Future Directions

Understanding the clinical impact of surgical instruments, in terms of use and performance, through biological studies should offer great benefits not only in dental implantology and oral or maxillofacial surgery but also in all fields relying on bone surgery.

5. Conclusions

The present study demonstrated that, in relation to the bone quality and the experimental time (14 days), the magnetic-dynamic mallet technique can significantly increase the amount of newly formed bone tissue and the quantity of osteoblasts compared with the drill technique, as shown by histological analyses. The intrinsic ability of the mallet to osteocondensate the bone tissue can positively affect the primary stability. In addition, an increase in osteogenetic biological parameters has been observed in these sites, apart from Wnt 3a, suggesting a positive trend regarding secondary implant stability. However, the mallet device was found to be less performing in terms of perforation in conditions of dense and thick bone quality, as cortical areas are. From these considerations, it can be affirmed that the magneto-dynamic turns out to be a technique of choice in the preparation of the maxillary implant site, in the case of poor bone quality or in all clinical conditions in which the cortex is thin or shows low quality.

Supplementary Materials: The following are available online at https://www.mdpi.com/article/10.3390/ma14226945/s1, Table S1. Primer Sequences for PCR Analysis.

Author Contributions: Conceptualization, G.S. and G.M.; methodology, G.S. and D.B.; formal analysis, G.S., D.B., R.N., A.B., R.A., and G.M.; investigation, G.S., D.B., B.P., M.M.v.D., R.N., A.B., J.C., R.A., and G.M.; data curation, G.S., D.B., R.N., A.B., J.C., R.A., and G.M.; writing—original draft preparation, G.S., B.P., M.M.v.D., R.A., and G.M.; writing—review and editing, G.S., D.B., R.N., A.B., J.C., R.A., and G.M.; funding acquisition, G.S. and G.M. All authors have read and agreed to the published version of the manuscript.

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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 Italian Ministry of Health (General Management for Animal Health and Veterinary Drugs. Office 6, Authorization number 304/2020-PR), and was conducted in compliance with the ARRIVE guidelines.

Data Availability Statement: Data sharing not applicable.

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osseotouch
TOTAL CONTROL

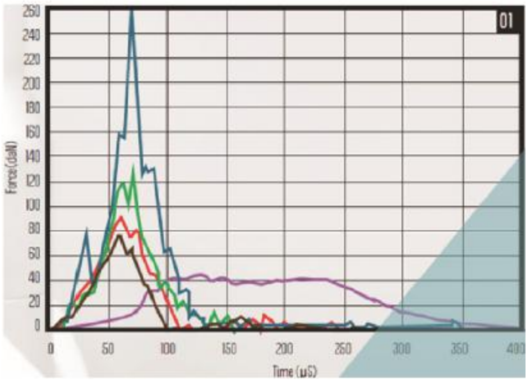
magnetic MALLET

WHAT IS THE
MAGNETIC DYNAMIC TECHNOLOGY?

1. 5.000G's of acceleration.
2. Magnetic-dynamic thrust.
3. Advanced electronic controller that allows the doctor to easily control the forces with the simple turn of a dial.

All this means that much more force is delivered just where the doctor needs it in a fraction of time as compared to using manual tools.

The graph shows the difference between the use of a hand mallet (purple line) and the Magnetic Mallet (blue line with standard handpiece at Force 4). It is 40 decaNewtons (Magnetic Mallet) applied in micro-seconds. It is force that allows the doctor to implement the procedures in a rapid, conservative and minimally invasive way.
It doesn't cut or drill, it conserves the bone and does not increase bone temperature.



01: comparison of applied forces (daN/µs) : Magnetic Mallet Level 1, 2, 3, 4 VS ManualSurgical Hammer Tests conducted at CNR – Centro Nazionale di Ricerca – University of Milan – MIUR

01
CONSERVATIVE

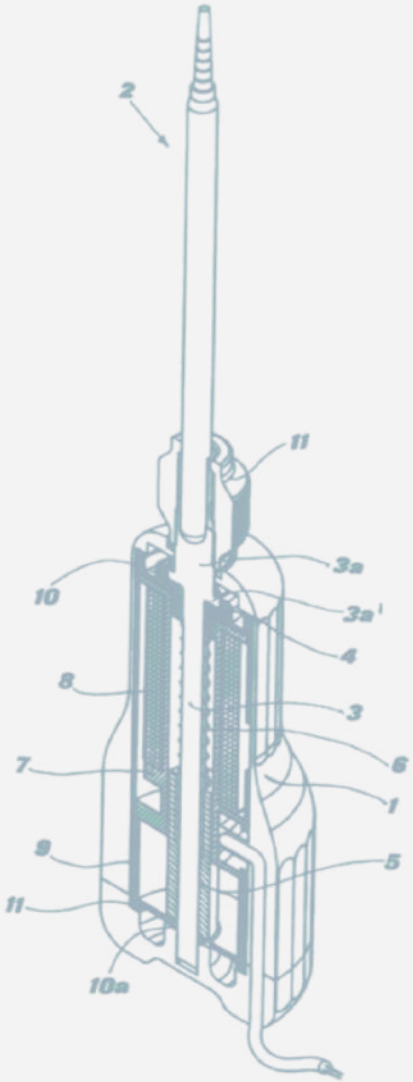
It moves, replaces, re-shapes and condenses the bone.
It never removes the bone, leaving soft tissues untouched.

02
SPEED

The Magnetic-dynamic impulse delivers much more force than manual tools. This means increased effectiveness during a procedure.

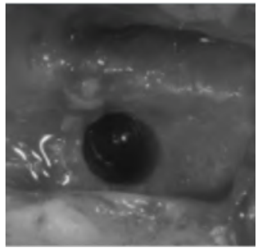
03
PRECISION

The kinetic energy forces are delivered precisely to the treatment area limiting dispersion to the craniofacial mass. This level of precision provides more comfort for the patient during the procedure.

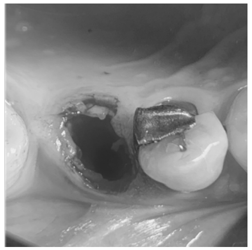


WHAT YOU CAN DO WITH THE magnetic MALLET

CROWN REMOVAL

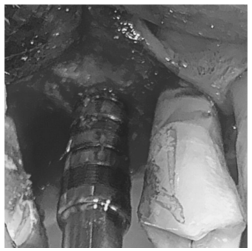


SINUS LIFT

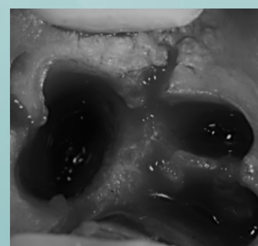


IMPLANT PLACEMENT

RIDGE SPLIT



OSSEODENSIFICATION



EXTRACTION

EXTRACTION

RIDGE
SPLIT

IMPLANT
PLACEMENT

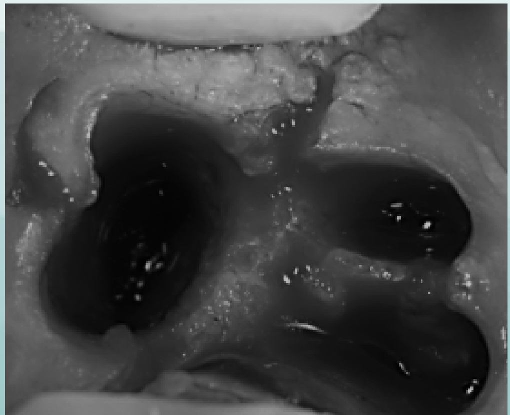
EASY-IN KIT

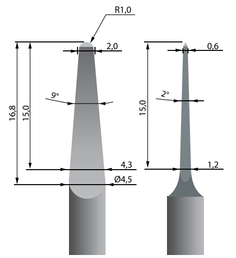
ACCESSORIES

HANDPIECE
PLUS

EXTRACTION KIT

CLINICAL CASES

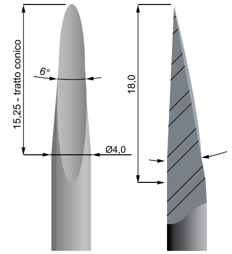




EXTR1

SHARP AND RESISTANT

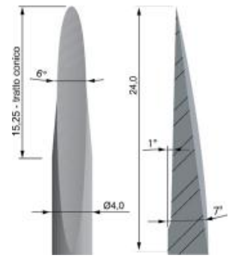
RANGE OF INSTRUMENTS



EXTR2

CONCAVE PROFILE

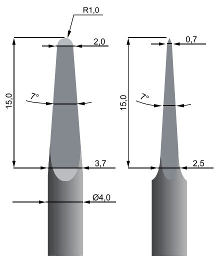
REDUCED HEIGHT



EXTR3

CONCAVE PROFILE

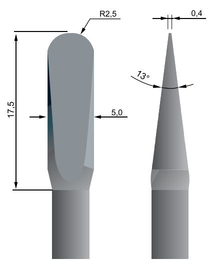
TOTAL HEIGHT



EXTR4

THIN LEVER

3rd MOLARS LUXATION



EXTR5

THICK LEVER

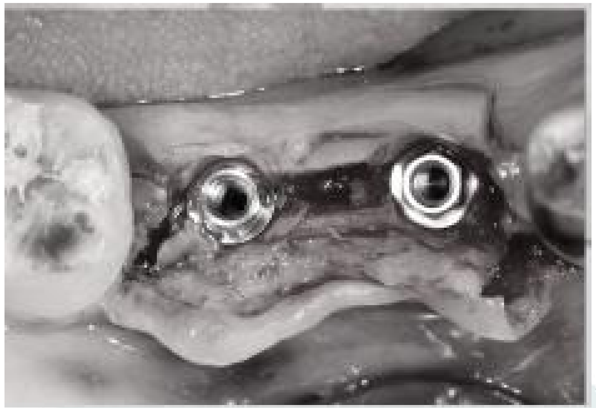
3rd MOLARS LUXATION

All extractors are supplied in the curved version within the kit.

RIDGE SPLIT KIT

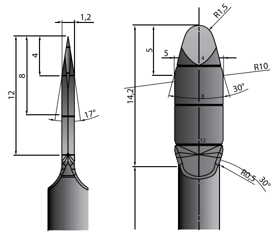
CLINICAL CASES

RANGE OF INSTRUMENTS



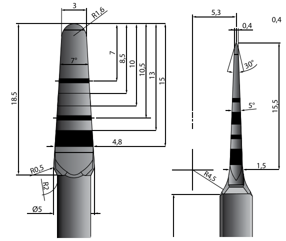
Available in straight and curved versions

EXCEPT GENOA



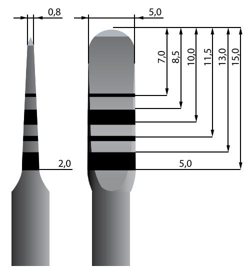
SPLIT

FIRST INVITATION
IN THE CREST



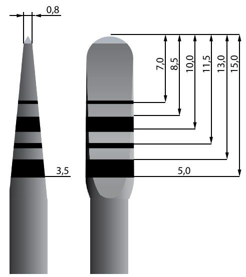
CUT

INITIAL
EXPANDER



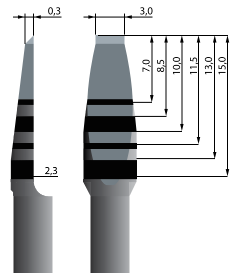
EXP1

EXPANDER 1



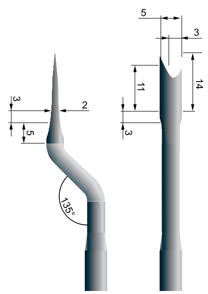
EXP2

EXPANDER 2



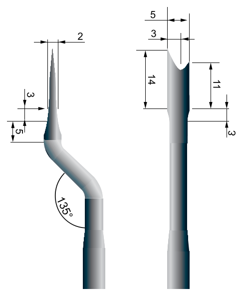
EXP3

EXPANDER 3 WITH DISPLACER
SIDE AND THE PASSIVE SIDE



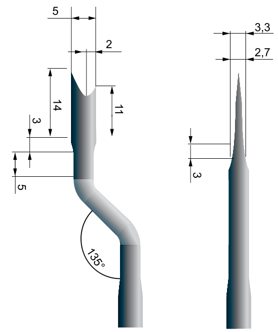
GENOA 1

UPPER RIGHT



GENOA 2

UPPER LEFT



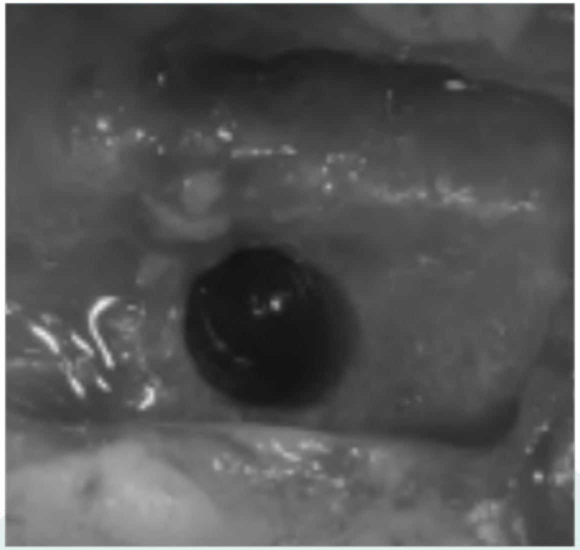
GENOA 3

FOR MANDIBLE

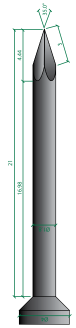
OSTEOTOME KIT

CLINICAL CASES

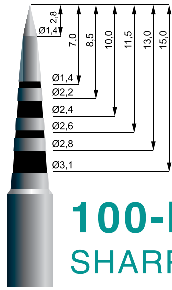
RANGE OF INSTRUMENTS



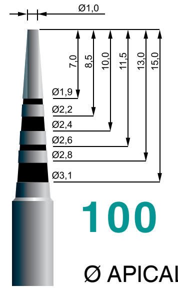
Available in straight and curved versions



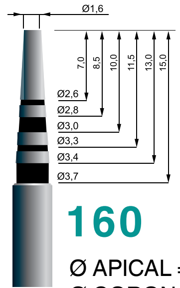
FIRST
Engraver



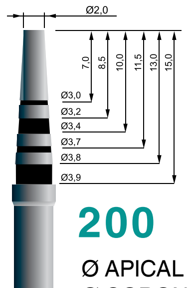
100-P
SHARP TIP
Ø APICAL = 1,0
Ø CORONAL = 3,1



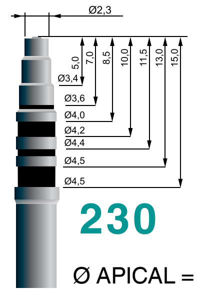
100
Ø APICAL = 1,0
Ø CORONAL = 3,1



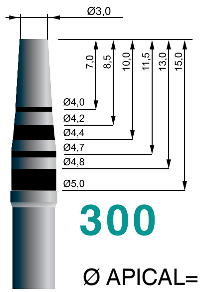
160
Ø APICAL = 1,6
Ø CORONAL = 3,7



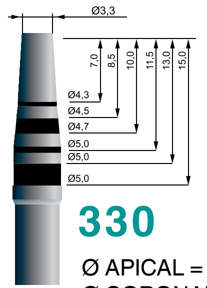
200
Ø APICAL = 2,0
Ø CORONAL = 3,9



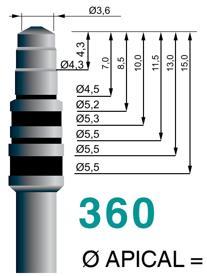
230
Ø APICAL = 2,3
Ø CORONAL = 4,5



300
Ø APICAL= 3,0
Ø CORONAL = 5,0

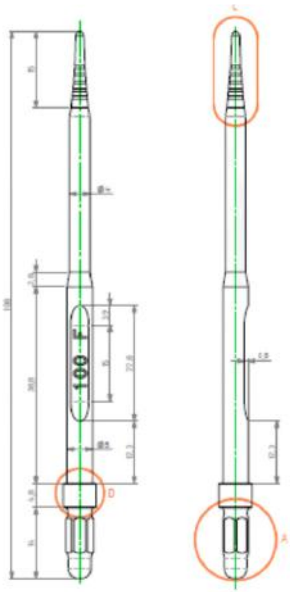


330
Ø APICAL = 3,3
Ø CORONAL = 5,0



360
Ø APICAL = 3,6
Ø CORONAL = 5,5

DEDICATED OSTEOTOMES FOR YOUR IMPLANT PARTNER

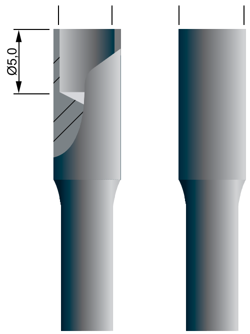


CLINICAL CASES

RANGE OF INSTRUMENTS

CHECK THE AVAILABLE IMPLANT LINES

*** Not all implant options are currently available, constantly adding more.*



Founders

Claudio De Giglio

Manuel Scali

EASY-IN

NEW

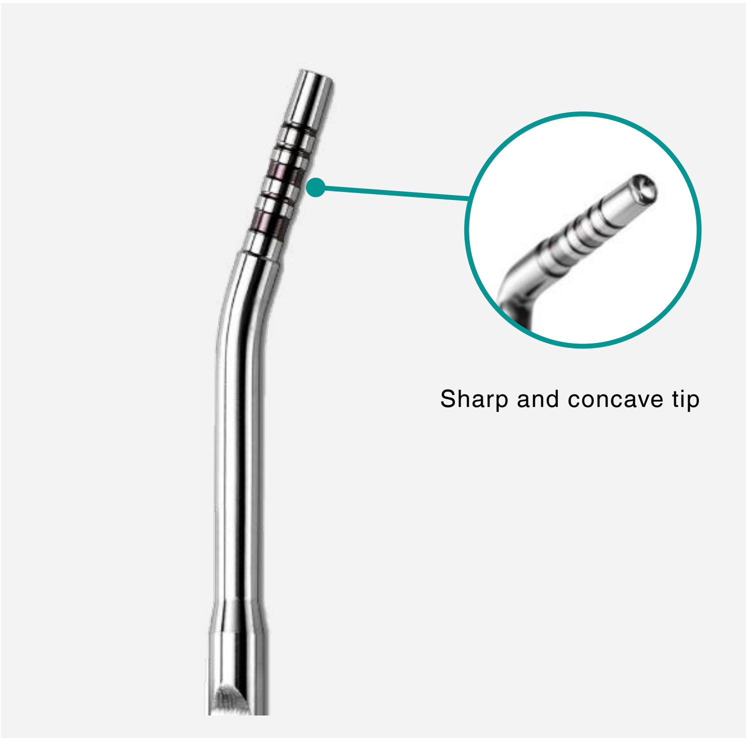
CLINICAL CASES

MANDIBLE

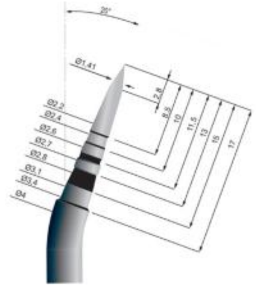
RANGE OF INSTRUMENTS

Designed by **Dr Luca Arduini** & **Drs Daiana Zuccaro**

For atraumatic insertition

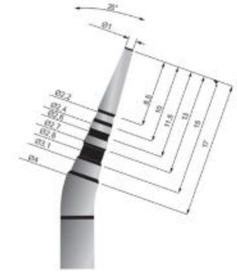


Sharp and concave tip



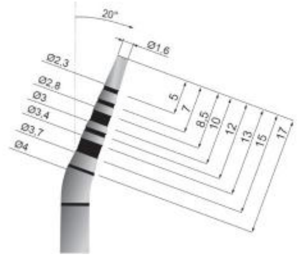
AZ 100P - 20°

Ø APICAL = 1,0
Ø CORONAL = 3,1



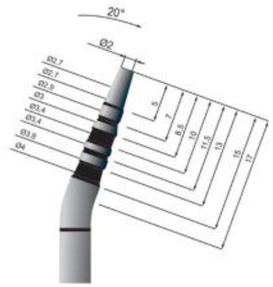
AZ 100 - 20°

Ø APICAL = 1,0
Ø CORONAL = 3,1



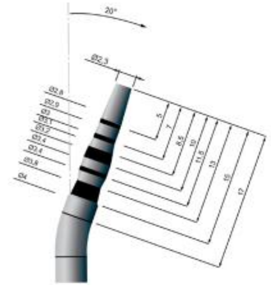
AZ 160 - 20°

Ø APICAL = 1,6
Ø CORONAL = 3,7



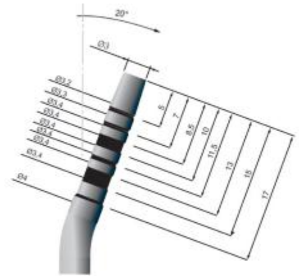
AZ 200 - 20°

Ø APICAL = 2,0
Ø CORONAL = 3,9



AZ 230 - 20°

Ø APICAL = 2,3
Ø CORONAL = 4,5



AZ 300 - 20°

Ø APICAL = 3,0
Ø CORONAL = 5,0

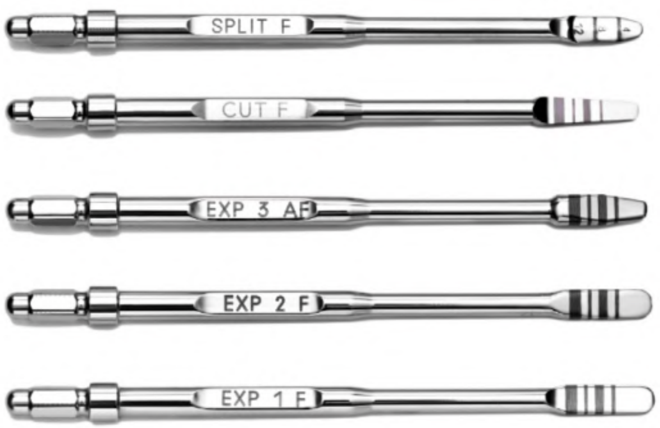
ANTERIOR MAXILLA KIT - STRAIGHT OSTEOTOMES

POSTERIOR MAXILLA KIT - CURVED OSTEOTOMES

PRE-CONFIGURED KITS

OSTEOTOMES KIT
5 STRAIGHT AND 5 CURVED INSTRUMENTS

RIDGE SPLITTING KIT
5 STRAIGHT AND 5 CURVED INSTRUMENTS



EXTRACTION KIT
5 CURVED INSTRUMENTS

THE CROWN REMOVER

The **Crown Remover** is an accessory of the Magnetic Mallet that develops longitudinal traction.

Also in this case the forces are applied with such an acceleration that prevents them from dispersing, causing inertias that are dangerous for the integrity of the elements to be removed.

HANDPIECE PLUS

The Handpiece Plus allows the delivery of a calibrated pulse which results in force levels 30% greater as compared to the regular handpiece

osseotouch
TOTAL CONTROL

Meta Ergonomica, located in Turbigo (MI), Italy, has developed and patented the use of magnetic-dynamic forces in oral surgery. Its mission is to design and manufacture medical devices that allow implementation of procedures in controlled, precise and conservative manner.

Meta Ergonomica is ISO13485.2016 certified by Tuv Rheinland S.r.l. (1936) and by FDA.

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