A Comparison of Manual and Electrical Mallet in Maxillary Bone Condensing for Immediately Loaded Implants: A Randomized Study

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ABSTRACT

Purpose: The aim of this clinical study was to compare electrical versus hand mallet in osteotome-assisted surgery for maxillary bone condensing in immediately loaded implant procedure.

Materials and Methods: Edentulous patients in maxillary premolar and molar regions with type III or IV bone were enrolled in this prospective clinical study. The patients were randomly divided in two groups: in the test group (magnetic mallet group [MMG]), the implant site was prepared with osteotomes pushed by electrical mallet, while in the control group (hand mallet group [HMG]), the implant site was performed with osteotomes pressed by hand mallet. Implants were immediately loaded. Intraoral digital radiographic measurements were reported at 6, 12, and 24 months.

Results: Fifty patients were enrolled in the study. Twenty-five patients were included in MMG and 25 patients in the HMG. One hundred thirty-eight dental implants were placed. In 12 cases, six in MMG and six in HMG, sinus elevation was performed. After 24-month follow-up, a survival rate of 94.93% was reported (MMG and HMG reported a survival rate of 97.10 and 92.75%, respectively, not statistically significant [$P > .05$]). In control group, two patients claimed benign paroxysmal positional vertigo following the use of osteotomes with hand hammer. Marginal bone levels remained stable over time for both groups, and no statistically significant differences were found. After 12 months, the bone height increased in both groups and, at 24 months, was stable. Statistical analysis reported no significant differences between test and control groups.

Conclusions: These results demonstrated a stable marginal bone levels over time and a significant increase in bone height between 6 and 12 months in osteotome technique. The use of electrical mallet provided some essential clinical advantages for the patients during surgical procedure in comparison with hand mallet.

KEY WORDS: bone condensing, immediate loading, osteotome, surgery mallet

INTRODUCTION

In recent years, great evidence exists to support immediate loading of implants with high success rates, shortening the treatment time for the patients. Becker and colleagues[1] found a total success rate of 93.3%, Rosenquist and Grenthe[2] obtained an average survival rate of 93% with immediately placed implants, and Watzek and colleagues[3] achieved a cumulative survival rate of 92.4% for maxillae and 94.7% for mandibles after 3 years of loading.

Primary stability has been identified as an important prerequisite in achieving osseointegration, as it may be a useful predictor for success rate for immediate loading procedure[4]; however, it is not possible to draw definitive conclusions regarding threshold values for implant stability that permit immediate loading and bone quality needed for immediate loading.[5]

Quality of bone represents an important factor for implant stability as dental implants placed in dense bone (types I and II) usually show better initial strength

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than those placed in poorer quality bone (types III and IV).[6]

Bone is a biological tissue that can be modeled and compacted toward the desired location and shape by use of osteotomes,[7] improving primary stability of dental implants in the posterior maxilla, but this procedure requires the practitioner to be extremely aware of bone quality.[8]

Types III and IV bone are best suited for trabecular compaction as in premolar and molar maxilla regions, and this surgical procedure offers several significant advantages over the traditional surgical drills. When adequate quantities of dense bone are available, removing bone by drills is not a problem. However, when the alveolar bone is soft or when the ridge has resorbed enough to compromise implant placement, it becomes mandatory the ability to preserve and improve existing bone. Osteotomes take advantage of the fact that bone is viscoelastic[9]; it can often be compressed and manipulated. Additionally, the osteotome technique generates no heat, which is an advantage because heat is a major detriment to osseointegration, and allows for greater tactile sensitivity, making them more appropriate than drills for probing.[10]

With osteotomies, type IV bone can be changed into type III, and type III bone can generally be compacted to resemble type II.[11,12]

Related clinical studies were carried out by hand mallet method that may induce benign paroxysmal positional vertigo (BPPV),[13–16] which has been described as a consequence of osteotome procedure. During the placement of maxillary dental implants using the osteotome technique, the trauma induced by percussion with the surgical hammer, along with hyperextension of the neck during the operation, can displace otoliths and induce BPPV.[14–16]

Thus, the aim of this prospective study was to compare electrical versus hand mallet in maxillary bone condensing for immediately loaded implants by assessing implant survival, marginal bone loss, alveolar bone height, and clinical incidence of BPPV.

MATERIALS AND METHODS

The prospective clinical study was composed of a population of patients presenting to the Department of Dentistry, San Raffaele Hospital, Milan, Italy, for evaluation and management of maxillary edentulism between January 2007 and October 2009. Fifty patients had a modified implant placement procedure with an under-preparation of the implant bed using the bone expander and immediate loading of the implant.

The following inclusion criteria were adopted:

- edentulism in maxillary premolar and/or molar regions with type III or IV bone[17];
- good general health;
- nonsmokers.

Exclusion criteria were the following:

- presence of chronic systemic diseases;
- presence of acute or chronic sinus problems;
- alcohol or drug abuse;
- history of vertigo.

The local ethical committee approved the study, and all patients signed an informed consent form. The diagnosis was made clinically and radiographically. The patients were treated by one oral surgeon (R.C.) and one prosthodontist (E.G.) at the Department of Dentistry, San Raffaele Hospital, Milan, Italy.

Surgical Protocol

One hour prior to surgery, the patients received 1 g of amoxicillin and 1 g twice a day for a week after surgical procedure. Surgery was performed under local anesthesia (mepivacaine [Optocaine, Molteni Dental, Scandicci (Fi), Italy] 20 mg/mL with adrenaline 1:80,000).

Patients were randomly divided in two groups by lots in closed envelopes. In 25 patients (magnetic mallet group [MMG]), the implant site was prepared with osteotomes pressed by electrical mallet (Magnetic Mallet, Meta-Ergonomica, Turbigo, Milano, Italy), while in 25 patients, the implant site was prepared with osteotomes pushed by hand mallet (hand mallet group [HMG]).

One hundred thirty-eight Titanium Plasma Spray implants (Outlink, Sweden Martina, Due Carrare, Padova, Italy), with a machined neck for 0.8 mm and a rough surface body with a progressive thread design with external hexagon as implant/abutment junctions, were positioned (Table 1).

The same oral surgeon (R.C.) performed all surgical procedures.

The bone crest that needed implant was exposed with a modified partial thickness flap with the tip of the no. 64 Beaver blade (Becton Dickinson Acute Care, Franklin Lakes, NJ, USA). The edentulous bone crest

TABLE 1 Implant Dimensions and Positions

Implant (Diameter × Length)	5 × 13 (mm)	5 × 10 (mm)	4.2 × 10 (mm)	4.2 × 13 (mm)	Total
Position					
First premolar	0	0	8	50	58
Second premolar	0	0	23	39	62
First molar	9	9	0	0	18
Total	9	9	31	89	138

was covered by the preserved suprabony connective tissue and the underlying periosteum (Figure 1). The proposed implant site was first clearly marked with a 2.0-mm round drill followed by a 2.0-mm twist drill.

The degree of resistance encountered in this initial drilling procedure will enable the operator to confirm the density of the bone at the site, as bone in the posterior maxilla is generally spongy (types III and IV).[17]

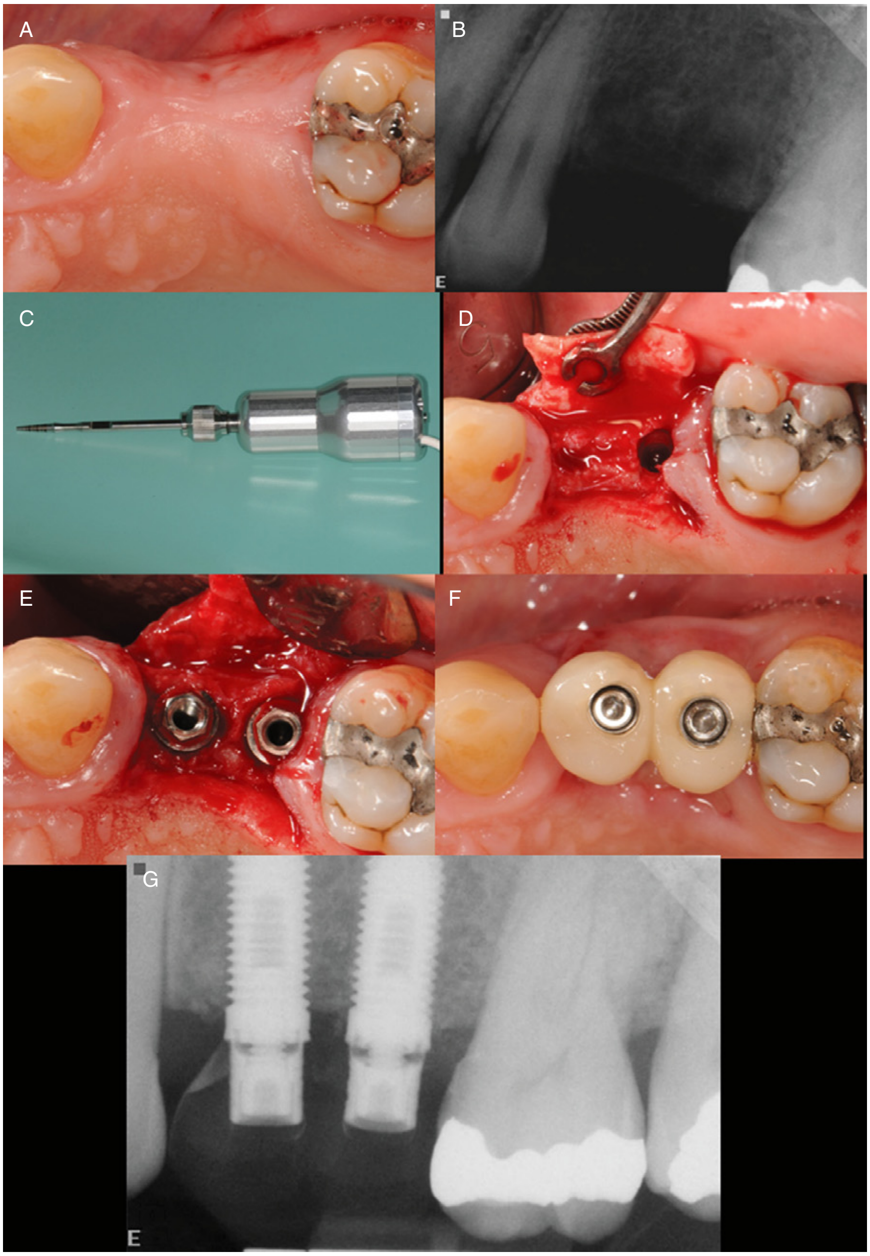

Figure 1 Clinical photograph showing the edentulous ridge of the maxilla before surgery (A); periapical radiograph of alveolar crest (B); and electrical mallet and osteotomes (C); when all the occlusal portion of the edentulous crest was marked, bone expander was used. A progressive in diameter bone expander starting from smallest instruments, which were inserted in the previous osteotomy site created with the small surgical bur; the bone expanders are pushed deep in the bone (D); clinical aspect of implant placement (E); temporary crowns screwed on the implants (F); and periapical radiograph at immediate loading (G).

In HMG, expansion of the osteotomy was carried out with a combination of drills and concave-tipped osteotomes pushed by hand mallet.

The implant site was created expanding the bone tissue both laterally against the preexisting lateral walls and apically moving up and compressing with hand mallet a progressive series of bone expanders[18] (Sweden Martina). An axial force was applied.

The osteotomy was gradually expanded in 0.5-mm increments using osteotomes inserted to the working depth. The final diameter of the osteotomy was 1.2 mm less than the anticipated implant diameter, depending on local bone density.

In MMG expansion, the osteotomy was carried out following the same procedure reported in HMG with similar osteotomes, but they were directly attached and pushed by electrical mallet.

The electrical mallet (Magnetic Mallet) is a magnetodynamical instrument assembled into a handpiece energized by a power control device, delivering forces by timing of application (see Figure 1). The osteotomes are attached to the handpiece that push a shock wave on their tip. The magnetic wave and the subsequent shock wave are calibrated regarding the timing of application of the force and induce axial and radial movements applied on the tip of osteotome, with a fast force of 90 daN/8 μs.

The electrical mallet (Magnetic Mallet) imparted to osteotomes a longitudinal movement along central axis, moving up and down toward pilot bone hole, providing a driving mechanism of longitudinal movements.

Such mechanical sequence of osteotomes progressively condensed internal bone wall of initial hole radially outward with respect to central axis to create high-density bone tissue along substantial portion of length of implant site preparation.

In 12 cases, sinus elevation was performed, using the technique reported by Cavicchia and colleagues.[19]

In these cases, the final osteotome punched out the cortical plate of the sinus floor with the adherent membrane. Immediately after fracture, the implant site was tested for perforation of the sinus membrane by the Valsalva maneuver.

A minimum insertion torque of 35 N/cm^2 was considered. All implants were placed with a hand drive unit (Sweden Martina) set at a torque value of 35 N/cm^2. Implants that reached the 35 N/cm^2 value during the insertion of the total implant body into the preparation site were considered having an insertion torque ≥35 N/cm^2.

The buccal flap was apically repositioned and stabilized with sutures tied to the margin of the palatal flap and anchored buccally with a loose loop to the periosteum at the level of the alveolar mucosa. This suture design avoided tissue traction in the repositioned buccal flap. The gap between the superficial margin of the buccally repositioned tissue and lower part of the palatal tissue healed by secondary intention in order to increase the size of keratinized mucosa.

Radiographic Assessments

Intraoral digital radiographic examinations (Schick CDR, Schick Technologies, Long Island City, NY, USA) were made at baseline, 6, 12, and 24 months after implant placement. The periapical radiographs were taken perpendicularly to the long axis of the implant with a long-cone parallel technique using an occlusal template. A blinded radiologist (P.C.) measured the changes in marginal bone height over time.

The marginal bone level was considered from the reference point represented by more coronal portion of the implant in contact with the bone, to the point, where the bone tissue met the implant surface at the mesial and distal sites. The difference of bone level was measured by software included (Schick Technologies).

In 12 cases in which sinus lift procedure was performed, the following parameters were assessed:

- a presurgical distance from the alveolar crest to the floor of the maxillary sinus;
- the amount of new radiopacity between the sinus floor and alveolar crest measured from the mesial and distal surfaces of each dental implant surface.

A mean for initial and gained alveolar bone heights was obtained from these readings by a specific software (Schick Technologies) and evaluated at 12 and 24 months of healing from implant placement.

The intraexaminer error was calculated by comparing the first and second measurements with a paired *t*-test at a significant level of 5%. No statistically significant difference was calculated between values ($P > .05$).

Prosthetic Protocol

Immediately after surgical procedure, pickup impressions (Permadyne, ESPE, Seefeld, Germany) of the implants were made, and temporary resin crowns were

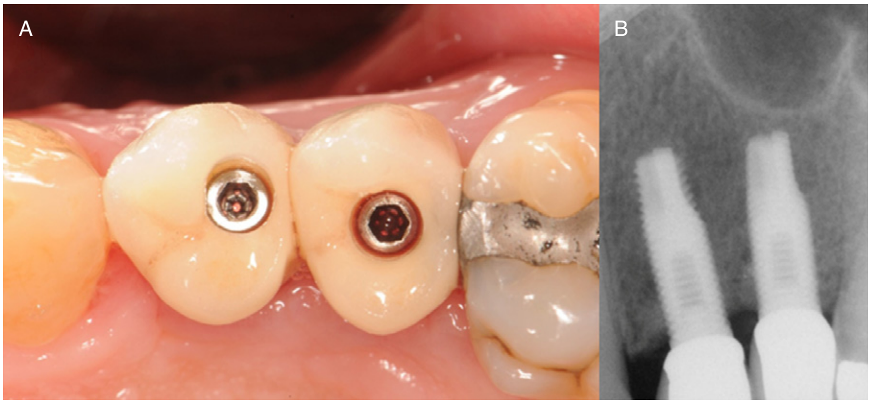

Figure 2 Three months later, final metal ceramic restoration was delivered (A); intraoral radiograph at 2-year follow-up after surgery (B).

performed and screwed directly on implant external hexagon (see Figure 1). All temporary crowns were in full contact in centric occlusion, making the occlusal surfaces flat avoiding horizontal relations. All patients followed a soft diet for 2 months.

Three months after implant placement, final metal ceramic screw-retained restorations were positioned (Figure 2). The occlusion was checked using 8-μm foil (Shimstock, Hanel, Germany) to resist withdrawal only under maximal clenching.

Follow-Up Evaluation

The following clinical parameters were checked: pain, occlusion, and prosthetic mobility. Criteria for implant survival were accepted as presence of implant stability, absence of radiolucent zone around the implants, no soft tissue suppuration, and no pain. Follow-up examinations were performed at baseline, 6, 12, and 24 months. Probing depths (PDs) were determined on the mesial, distal, buccal, and palatal surfaces of the implants with a periodontal probe (Hu-Friedy PGF-GFS, Hu-Friedy, Chicago, IL, USA).

Assessments and Statistical Analysis

In the present study, the predictor variable was the surgical technique (different devices) for bone condensing, while outcome variables were marginal bone loss (primary outcome), alveolar bone height, implant survival, and occurrence of BPPV (secondary outcomes). A specific software was used for all statistical calculations (SPSS 11.5.0, SPSS Inc., Chicago, IL, USA). Data were presented as mean ± standard deviation. Comparisons between mean values of bone height and marginal bone loss at different time points (baseline, 12, and 24 months) and comparisons between test and control groups were performed by a two-tailed Student's *t*-test ($P < .05$ was considered the threshold for statistical significance). Statistical power calculations showed that the minimal sample size was 13, with an alpha value of 0.05% and 80% power (primary outcome variable was used to estimate the sample size). The multivariate analysis of variance was used in adjusting multiple comparisons over time. The significance level was set at $\alpha = 0.05$.

RESULTS

Fifty patients were enrolled in this clinical study; they were randomly divided in two groups ($n = 25$ per group). The mean patient age (31 women and 19 men) was 56.4 years (range 45–70 years). One hundred thirty-eight Titanium Plasma Spray implants were positioned (69 in MMG and 69 in HMG). In 12 cases, six in MMG group and six in HMG group, sinus elevation was performed (Table 2).

Surgical and Prosthetic Procedure

After 24-month follow-up, a survival rate of 94.93% was reported. Seven implant failures occurred within 1 month from implant placement (two implants in MMG and five in HMG, not in sinus lift procedures – MMG and HMG reported a survival rate of 97.10 and 92.75%, respectively, not statistically significant [$P > .05$]). The implants were replaced 2 months later.

Among 12 cases of sinus elevation, no sinus membrane perforation was performed. No pain or final prosthesis mobility was recorded. There was a suitable

TABLE 2 Predictor Variable versus Study Variables

Technique	No. of Patients	Sex	Mean Age (Years) (± SD)	No. of Patients Needing Sinus Lift	Baseline Bone Levels (mm)
MMG	25	18 F; 7 M	59.5 ± 18.9	6	6.63 ± 1.41
HMG	25	13 F;12 M	53.3 ± 19.9	6	6.81 ± 1.35
P value	—	—	NS	—	NS

F = female; HMG = hand mallet group; M = male; MMG = magnetic mallet group; NS = not significant.

wound healing around temporary crowns. Minor swelling of gingival mucosa was present in the first days after surgical procedures; no mucositis, implant mobility, or flap dehiscence with suppuration was found.

In HMG, two patients developed BPPV following the use of osteotomes and percussion with a hand hammer (incidence of BPPV in HMG = 8.00%).

On sitting up after surgery, one patient experienced intense vertigo, accompanied by distress, nausea, and vomiting. The vertigo remitted spontaneously after 1 day. The second patient presented a similar clinical course. Other 10 patients complain brief mild rotary vertigo, accompanied by neurovegetative symptoms.

The patients in MMG presented no symptoms of BPPV or other related symptoms. The surgical procedure was more precise with electrical mallet.

Clinical Parameters

The mean PD was obtained from averaging PD measurements on the mesial, distal, buccal, and palatal surfaces of the implants; the mean values were 1.61 ± 0.51 and 2.11 ± 0.62 mm at baseline and 24 months, respectively.

Radiographic Evaluation

Radiographic results were reported at 6, 12, and 24 months from implant placement (Table 3).

No statistically significant differences were found between the two groups for values obtained at 6, 12, and 24 months from implant placement ($P > .05$, see Table 3).

Multiple comparisons over time reported no statistically significant differences ($P > .05$).

In 12 cases in which sinus lift procedure was performed, baseline bone levels (initial alveolar bone height) were 6.63 ± 1.41 mm for MMG and 6.81 ± 1.35 mm for HMG (see Table 2).

The alveolar bone gain following 6 months of healing, which is evaluated as the presence of radiopacity around exposed mesial and distal implant surfaces within the created space at the floor of the maxillary sinus, resulted in a mean value of 2.64 ± 1.39 mm for MMG and 2.77 ± 1.41 mm for HMG.

Successively, after 12 months, the radiopacity around exposed mesial and distal implant surfaces incremented in a similar trend for both groups (Table 4).

At 24 months from implant placement, the mean bone height measurements were stable (4.12 ± 1.33 mm MMG and 4.17 ± 1.60 mm HMG) (see Table 4).

Statistical analysis reported no statistically significant differences between test and control groups. However, in intragroup time point comparisons, a statistically significant difference ($P < .05$) between 6- and 12-month values was reported, whereas no statistically significant differences between 12- and 24-month values were found.

These results demonstrated a significant increase in bone height between 6 and 12 months, then stable bone levels with a 2-year follow-up.

DISCUSSION

The present study reported that seven of one hundred thirty-eight (94.93%) implants placed with the osteotome technique and immediately loaded were lost, two in MMG and five in HMG.

Donati and colleagues[20] evaluated immediately loaded implants placed with the osteotome technique, conventional site preparation, and implants placed with a conventional site preparation and a submerged healing. They reported that immediately loaded implants placed with the osteotome technique had higher failure rates compared with implants placed with a conventional drill (5.5% vs 2%). Koutouzis and colleagues,[21] using the osteotome technique and immediate loading of the implant, reported that four of 20 implants had insertion torque value >35 N/cm^2. The authors concluded that implants placed with the osteotome

TABLE 3 Predictor Variable versus Primary Outcome Variable (Marginal Bone Levels)

	6-Month Follow-Up			12-Month Follow-Up			24-Month Follow-Up		
	Mesial Bone Loss (mm)	Distal Bone Loss (mm)	Mean Bone Loss (mm)	Mesial Bone Loss (mm)	Distal Bone Loss (mm)	Mean Bone Loss (mm)	Mesial Bone Loss (mm)	Distal Bone Loss (mm)	Mean Bone Loss (mm)
MMG	0.89 ± 0.32	1.00 ± 0.31	0.94 ± 0.31	0.88 ± 0.42	0.91 ± 0.55	0.89 ± 0.48	0.82 ± 0.36	0.89 ± 0.49	0.85 ± 0.42
HMG	0.93 ± 0.29	1.02 ± 0.41	0.97 ± 0.35	0.91 ± 0.47	0.94 ± 0.50	0.92 ± 0.48	0.96 ± 0.54	0.93 ± 0.37	0.94 ± 0.45
P value	NS	NS	NS	NS	NS	NS	NS	NS	NS

HMG = hand mallet group; MMG = magnetic mallet group; NS = not significant.

TABLE 4 Predictor Variable versus Gained Alveolar Bone Height

	Mean Gained Alveolar Bone Height (mm)		
Technique	6-Month Follow-Up	12-Month Follow-Up	24-Month Follow-Up
MMG	2.64 ± 1.39	4.09 ± 1.41	4.12 ± 1.33
HMG	2.77 ± 1.41	4.13 ± 1.45	4.17 ± 1.60
P value	NS	NS	NS

HMG = hand mallet group; MMG = magnetic mallet group; NS = not significant.

technique and immediately loaded did not demonstrate a high insertion torque and exhibited minimal marginal bone loss. This finding is in agreement with Nkenke and colleagues.[22] They reported that implants placed in sites prepared with conventional preparation reached >50 N/cm^2 in >48% of the cases compared with 31.5% of the cases for implants placed with the osteotome technique.

However, as reported in the literature,[23–27] in this clinical study the implant site was prepared by the use of bone expanders that condensed the native bone for vertical and horizontal bone expansion, obtaining a survival rate of 94.93% for all placed implants at 24-month follow-up.

By series of gradual tapered instruments, the trabecular bone is compressed laterally in order to improve the quality and density of the implant osteotomy. Lateral bone compression during site preparation can improve the quality of type III bone to seem more like type II bone, so that implants may also be placed, with good success, in type IV bone compressed to type III bone as can be found in the maxillary molar region, especially when the bone width and height are insufficient. This surgical procedure is supported by data from an experimental study in animals showing that insertion of implants by means of bone expanders resulted in faster and greater bone apposition compared with implants inserted by conventional procedure.[28] The results revealed that the benefit of the osteotome technique is an increased bone-to-implant contact ratio in the early phase after the implant placement inducing an enhanced primary stability.

Primary stability is an essential factor for osseointegration process and for immediate loading procedure, as it increases the success rate of dental implants in type IV bone.[28]

It has been claimed that implant placement by the osteotome technique not only improves primary stability but also leads to accelerated bone healing compared with conventional implant placement in trabecular bone, as can be found, for example, in the human posterior maxilla.[29]

A statistically significant correlation between the cutting torque resistance of the implant penetrating the crestal portion of the compacted implant site and resonance frequency analysis has been reported.[29]

However, tapping of the expansion osteotomies with the hand mallet represents the greatest inconvenience of the technique, mainly when several implants are positioned in the same bone crest, and in some cases it may induce BPPV in patients who have experienced no previous episodes of this form of vertigo.[15,16]

In this study, two patients suffered vertigo when trying to sit up immediately after surgery and were diagnosed with BPPV.

Furthermore, incidence of this complication may have been higher. Because implant treatment is increasing in older patients and because of the widespread use of the bone expansion technique with osteotomes, incidence of BPPV can be expected to increase.

The low force of bending waves produced by the hand mallet (40 daN/2 ms) was found to depend on the density, area moment of inertia, and density-dependent elastic constants of bone.[30] It is important to account for the changes of these parameters along the bone and along with hyperextension of the neck during the operation, as these practices can displace otoliths.

In the patients of MMG, no symptoms were noted and no distress. The probable explanation may be represented by the magnetic wave and the subsequent shock wave, as they are calibrated by the timing of application of the force, inducing axial and radial movements applied on the tip of osteotome with a fast energy of 90 daN/8 μs.

The use of electrical mallet provided essential advantages both for operator and patient in comparison with hand mallet. During surgical procedure, electrical mallet delivered a precise control of bone expanders of the entry direction (or directionality) of the tip into the bone. This is an important concept as bone is generally formed of parts with different density and that the expander tends to be deflected when it moves from a bone part with a specific density to another bone part with a different density. The handling of the device is very simple as the mechanical oscillations transmitted to the osteotome are transmitted without difficulties to the bone.

Furthermore, within the limits of the present study, this procedure could improve the patient comfort avoiding BPPV.

However, further clinical trials are mandatory to evaluate the efficiency of the electrical mallet for osteotome procedure, but these results are encouraging to develop and continue in this methodology.

CONCLUSIONS

Within the limits of the present study, these results demonstrated a stable marginal bone levels over time and a significant increase in bone height between 6 and 12 months in osteotome technique. The use of electrical mallet provided some essential clinical advantages for the patients during surgical procedure in comparison with hand mallet.

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