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

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

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

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

Key words: dental implants, atrophic maxilla, sinus lift, summers technique, guided bone regeneration, GBR, bone regeneration, implants

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

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

MATERIALS AND METHODS

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

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

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

One week before surgery, a professional oral hygiene session was given to each patient, and chlorhexidine digluconate 0.2% oral rinses were prescribed. One day before surgery antibiotics were prescribed: Augmentin (amoxicillin and clavulanate potassium) at a dosage of 1 g, or Azithromycin 500 mg as an alternative in case of allergy to penicillin. In brief, the treatment consisted of two-stage surgery for all patients.

First stage surgery

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

Second stage surgery

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



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



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

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

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

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

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

Follow-up

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

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

Outcomes

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



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



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

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

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

Statistical analysis

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



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

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RESULTS

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

There were 13 smokers (32.5%) and 27 non-

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



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



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

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

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

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

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

			Pre-surgery		Post-		1 year		Pre-surgery vs	Post-surgery vs 1-
			(RBH)		surgery		loading		post-surgery	y loading
variables		n	mean±SD	95% CI	mean±SD	95% CI	mean±SD	95% CI	P-value*	P-value*
	overall	39	8.34±0.96	8.03-8.64	10.03±1.21	9.64-10.41	10.32±1.05	9.98-10.65	<0.0001	0.0007
Candan	female	25	8.27±1.06	7.94-8.60	10.04±1.29	9.64-10.44	10.26±1.18	9.89-10.62	<0.0001	0.02
Gender	male	14	8.46±0.75	8.23-8.70	10.00±1.11	9.66-10.34	10.43±0.81	10.18-10.68	<0.0001	0.02
	P-value		0.55		0.93		0.63			
Smoking	no	27	8.30±1.01	7.98-8.61	9.98±1.06	9.65-10.31	10.25±0.94	9.96-10.54	<0.0001	0.006
Smoking	yes	12	8.42±0.86	8.16-8.69	10.12±1.53	9.64-10.59	10.46±1.28	10.06-10.86	<0.0001	0.056
	P-value		0.70		0.75		0.56			
Dana tura	11	14	9.00±0.71	8.78-9.22	10.86±0.99	10.55-11.16	11.07±0.81	10.82-11.32	<0.0001	0.08
вопе туре	III+IV	25	7.98±0.89	7.71-8.26	9.58±1.09	9.24-9.92	9.91±0.95	9.62-10.21	<0.0001	0.004
	P-value		0.0007		0.0008		0.0004			
Implant	premolar	16	8.94±0.79	8.69-9.18	10.63±1.12	10.28-10.97	10.84±0.96	10.55-11.14	<0.0001	0.048
location	molar	23	7.94±0.85	7.67-8.20	9.63±1.13	9.28-9.97	9.97±0.98	9.66-10.27	<0.0001	0.006
	P-value		0.0006		0.009		0.008			
	right	20	8.40±1.13	8.05-8.75	10.03±1.46	9.57-10.48	10.41±1.14	10.06-10.76	<0.0001	0.008
side	left	19	8.28±0.77	8.04-8.51	10.03±0.95	9.73-10.32	10.23±0.98	9.92-10.53	<0.0001	0.04
	P-value		0.69		1.00		0.59			

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

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

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

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

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

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

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

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

DISCUSSION

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

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

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

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

The results of the present study on residual bone height are in accordance with previous pre-clinical and clinical studies (22-24). A systematic review by Araujo et al. (24) aimed at determining the socket preservation effect on implant survival. The control subjects demonstrated significant bone resorption on the labial aspect and the sockets with biomaterial prevented resorption on buccal and palatal bone walls. The bone socket undergoes significant resorption more on buccal by 56% (2.2 \pm 0.2 mm, i.e., about 45 μ m/day) than on lingual side by 36% of the socket and these bone changes occur mostly in the first 2-3 months' phase of bone healing as a part of bone hemostasis and bone remodeling (22). The mean horizontal reduction in ridge width were reported to be~3.8mm and vertical reduction in ridge height was found to be~1.24mm (25). The SP approach can prevent this remodeling of bone in absence of tooth. These changes are well demonstrated in literature clinically and radiologically (23). Bone is a dependent hard tissue on tooth that contributes to maintaining the bone volume by transferring the occlusal forces through Sharpey fibers to the bundle bone (23). The bundle bone slowly disappears and is replaced by woven and lamellar bone during initial phase of wound healing. This is the possible reason why there is a significant change in bone height and width after extraction of the tooth and undergoes significant resorption (22).

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

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

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

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

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

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

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

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

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predictability and maintenance"). All the patients signed an informed consent agreement form, and the study protocol was in accordance with the principles laid down in the Declaration of Helsinki on medical protocol.

Authors' contributions

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

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ARTICLE

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Article

Development of a New Drill Design to Improve the Temperature Control during the Osteotomy for Dental Implants: A Comparative In Vitro Analysis

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Abstract: The present in vitro study evaluated a new drill design to improve the temperature control during the osteotomies for dental implant installation, comparing with two drill designs that use conventional external irrigation. Three blocks of synthetic cortical bone were used for osteotomy procedures. Three groups were created: control group 1 (Con1), where a conical multiple drill system with a conventional external irrigation system was used; control group 2 (Con2), where a single bur with a conventional external irrigation system was used; and, test group (Test), where the new single bur (turbo drill) with a new irrigation system was used. Twenty osteotomies were made without irrigation and with intense irrigation, for each group. A thermocouple was used to measure the temperature produced during the osteotomies. The measured temperature were: 28.9 ± 1.68 °C for group Con1; 27.5 ± 1.32 °C for group Con2; 26.3 ± 1.28 °C for group Test. Whereas, the measured temperatures with irrigation were: 23.1 ± 1.27 °C for group Con1; 21.7 ± 1.36 °C for group Con2; 19.4 ± 1.29 °C for group Test. The single drill with a new design for improving the irrigation and temperature control, in comparison with the drill designs with conventional external irrigation.

Keywords: dental implants; drill design; irrigation system; osteotomy; thermocouple

1. Introduction

The osteotomy protocols, regardless of the system used, determine that it should be performed with a low-temperature variation, never exceeding 47 °C, as it could denature bone tissue proteins and generate necrosis in that area [1]. Several studies have been developed with different irrigation systems and with different drill designs to improve and decrease trauma during the osteotomy procedure for installing implants and, consequently, reducing inflammatory reactions [2–4].

Recently, Salles and Collaborators (2015) [5], reported through an experimental study using an immunohistochemical analysis for the inflammatory factor NFkB (nuclear factor kappa-light-chain-enhancer of activated B cells), that irrigation plays an important role in controlling



this endonuclease and, obviously, in controlling the intensity of the inflammatory process. In this sense, other histological studies have also shown that the healing response of bone tissue around implants can be improved when using drilling systems designed to reduce the trauma caused during osteotomy procedures [6–8].

Regarding the instruments and techniques used to perform osteotomies for the installation of implants, different factors must be considered and analyzed, such as irrigation method (external or internal), drill design, drilling speed, the number of drills (single or multiples), drill material, drilling movement (continuous or intermittent), equipment used (rotary or oscillatory), force applied, among others. For these findings, the methods of evaluating the efficiency of the systems proposed for performing osteotomies, the most used is the evaluation of temperature control during the procedure. To perform these experiments, thermosensors installed near the location where the drilling or infrared sensors can be used, both of which have similar results, but may vary in practicality to the operator during the tests [2,4,9]. In addition, several substrates are used to perform this type of in vitro test, mainly, bone of animal origin and synthetic bone [10].

However, there is no consensus on the ideal system for osteotomy, both in terms of the number of drills, and in terms of their ideal design. In this sense, a device was developed and coupled to the drill shank, creating a new drill design, which has the function of boosting and directing the flow of the irrigating liquid into the bone tissue, thus increasing the effectiveness of refrigeration during the osteotomy procedure. Then, the present in vitro study evaluated this new drill design to improve the temperature control during the osteotomies, comparing with two drill designs (single and multiple sequence) that use conventional external irrigation.

2. Materials and Methods

In this study, two groups of drill systems with conventional external irrigation were used as control and, compared with the new drill design (TURBOdrill[®], Implants Diffusion International, Montreuil, France) that features a device attached to its stem to boost and direct the flow of the liquid used for irrigation. This device featured a titanium cylinder with an inverted propeller that received the liquid and, with the rotation of the drill, worked as a turbine. Then, the liquid was driven by the blades down into the socket. In addition, the device served as a stopper to control the exact drilling depth. Figure 1 presents the main characteristics of this new drill design.



Figure 1. Representative image of the details of new drill design (**a**), that present an accoupled cylinder with an inverted propeller to improve the irrigation. (**b**) The blue arrows indicate the liquid is driven by the propeller down into the blades. (**c**) Schematic image of the path taken by the irrigating liquid.

Thus, three experimental groups were formed, as described below:

Control group 1 (Con1): Multiple drill sequence for a conical implant of 10 mm in length and 4.1 mm in diameter, Straumann (Basel, Switzerland): drill diameters were 2.2 mm (used at 800 rpm), 2.8 mm (600 rpm) and 3.5 mm (500 rpm) [11].

Control group 2 (Con2): One single drill for a conical implant of 10 mm in length and 4.2 mm in diameter for conical IDAll implant, Implants Diffusion International (Montreuil, France). The speed recommended and used was 1500 rpm.

Test group (Test): One single drill (TURBOdrill[®]) for a conical implant of 10 mm in length and 4.2 mm in diameter for conical IDAll implant, Implants Diffusion International (Montreuil, France). The speed recommended and used was 1500 rpm. Figure 2 shows an image of the drills used for each group.



Figure 2. Image of the drill systems used for the osteotomies in the 3 groups.

Three synthetic cortical bone blocks manufactured in polyurethane foam with a density of 40 pounds per cubic foot (PCF), corresponding to 0.62 g/cm³ (Nacional Ossos, Jaú, Brazil), were used (one per group). The blocks presented the following dimensions: width of 9.7 cm, height of 5 cm and length of 10 cm. Initially, a perforation to install the sensor was performed with a conical carbide bur at 1 mm in diameter and 3 mm in depth, at a distance previously calculated so that after the osteotomy completed with the proposed system for each group, the final distance between the two perforations was 1 mm. Figure 3 shows these details.



Figure 3. The thermocouple type k positioned in the perforation and the drill positioned before starting the osteotomy (**a**) and after the osteotomy finished (**b**), where the arrow indicates the distance of 1 mm to the sensor.

A type K thermocouple device (Mod. TP-01, Lutron Electronics Co., Inc., Coopersburg, PA, USA) was used for measuring the temperature during the osteotomies, which was coupled to a digital thermometer (Lutron Electronics Co., Inc.) with a resolution of 0.1 °C. Whenever one osteotomy was completed, the next was only started after the temperature returned to the initial level of 18 ± 1 °C (baseline temperature).

For drilling, a drilling machine controlled by an automated system was used, which was used in other previous studies [4,12]. The device controls the milling speed, the load applied during the osteotomy, irrigation volume and intermittent movements. All osteotomies were performed by applying a load of 2 kg, intermittent movements (4 mm, 8 mm and, finishing at 10 mm) and with intense irrigation of 50 mL/min (in condition 2). Irrigation was carried out with distilled water. Then, within these described conditions, twenty osteotomies were performed without irrigation and another 20 with irrigation for each group.

The range of temperature variation was calculated using the maximum temperature value measured and the baseline temperature (Δ T). The data were compared statistically using the ANOVA One-Way test to verify differences between the 3 groups in the two proposed conditions (without and with irrigation). Additionally, Bonferroni's multiple comparison test was used to determine the individual difference between the 3 groups. All cases where *p* < 0.05 were considered statistically significant. All data were analyzed using GraphPad Prism version 5.01 for Windows (GraphPad Software, San Diego, CA, USA).

3. Results

The measured data of the temperature generated during the osteotomies were collected in an electronic sheet, and the differences between the initial and maximum temperatures were calculated. A normal distribution result was detected of the groups after applied the normality test.

Significant differences for the measured temperatures during the osteotomies without and with irrigation were detected, in both cases with p < 0.0001. Considering absolute values, the Con2 group and Test group (both using one single drill) yielded similar results (not significantly different) in the condition 1 (without irrigation). However, in the Con1 group, significantly higher temperatures were recorded concerning the other 2 groups in both conditions (without and with irrigation). The Box Plot graphs shown in Figure 4 presented the medians, quartiles and ranges of the 3 groups analyzed in both conditions (without and with irrigation) and the statistical comparison between the groups.



Figure 4. Box Plot graphs presenting the medians, quartiles and ranges of the 3 groups analyzed in both conditions tested (without and with irrigation, respectively) and the statistical comparison between the groups. * shows that they are statistically different.

The mean, standard deviation (SD), median and range values of the maximum temperature measured for each group in the 2 conditions proposed are summarized in Table 1.

Table 1. Mean, standard deviation (SD), median and range values of the maximum temperature measured for each group in the 2 conditions proposed. Values in centigrade degrees (°C).

Variables		Condition 1		Condition 2		
Groups	Mean and SD	Median	Range Values	Mean and SD	Median	Range Values
Con1	28.9 ± 1.68	28.8	25.8 to 32.1	23.1 ± 1.27	22.9	20.3 to 25.1
Con2	26.9 ± 1.31	27.0	24.7 to 30.2	21.7 ± 1.36	21.5	19.7 to 24.4
Test	26.3 ± 1.28	26.6	24.0 to 28.4	19.4 ± 1.29	19.7	17.3 to 21.8

The one single drill used in the Con2 and Test groups produced a smaller variation of temperature in comparison with the multiple sequence drills used in the Con1 group, as demonstrated follow the means \pm standard deviations concerning baseline values (Δ T). Firstly, the calculated variation of temperature data in the osteotomies without irrigation were: 10.40 ± 1.85 °C for Con1 group; 8.34 ± 1.23 °C for Con2 group; 7.77 ± 1.26 °C for Test group. Whereas, in the osteotomies with irrigation, the calculated values were: 4.54 ± 1.39 °C for Con1 group; 3.14 ± 1.34 °C for Con2 group; 0.93 ± 1.47 °C for Test group. A significant difference was recorded for Δ T between the groups in both conditions (*p* < 0.0001). However, when the groups were compared against each other, only in condition 1 did the Con2 and Test group shows no statistical differences. The calculated values of the temperature variation as well as the statistical comparison between the groups are shown graphically in Figure 5.

Regarding the time required for osteotomy in each group, the average was ~10 s for the Con2 and Test groups, and ~80 s for the Con1 group (including three consecutive drilling sequence plus the time for substitution the drills). The time needed to return to baseline temperature after each implant site preparation procedure was a mean of 10 ± 2 min.



Figure 5. Points graph of the calculated temperature variation (Δ T) between the initial temperature and maximums temperature for each group in both conditions tested and the statistical difference between the groups. * shows that they are statistically different.

4. Discussion

The control of trauma during the handling of peri-implant tissues in surgical procedures for the installation of implants is of fundamental importance to obtain satisfactory results and free of complications. Among the maneuvers performed during surgery to install implants, an osteotomy can be considered the most traumatic step, then this topic has been the subject of several studies and the development of new technologies to minimize the effects of this procedure. In this sense, a new drill design was developed featuring a titanium tube with an internal helix on its stem, which aims to direct the flow of irrigating liquid into the drill blades, improving the cooling of bone tissue during the drilling for osteotomy. Then, our objective was to compare this new drill design with two other drill systems, measuring and comparing the temperature during the drilling procedure performed in a block of synthetic bone. The results showed that the new drill design was more effective in the control of heat production during the osteotomies performed, in comparison with the other two drill systems used as control groups.

This new drill design uses the concept of a single cutter to perform an osteotomy, which, according to previous publications, when compared to conventional drill systems that use a multiple drill sequence, showed a better performance in controlling the temperature [12], and similar healing of bone tissue around the implants installed in prepared beds using a single drill [7,12,13]. In addition to these results from in vitro and preclinical studies in rabbits, a study in humans was presented demonstrating a high success rate (98% of implant survival) with the use of a single drill to install the implants, in which 350 implants were evaluated [14]. Conversely, as described by Li et al. [15], there is a great concern for the risk of heat generation during milling with a single cutter, mainly in higher density bone tissue and for the accumulation of bone chips inside the drill. This accumulation of residues inside the cutting part of the drill and its contact with the side of the drilling will result in additional heat generation [15]. In this sense, the device coupled to the stem of the new drill design, which works as a propeller turbine for the cooling liquid, in addition to increasing the temperature control of the drill blades, can eliminate the bone residues inside of the drill. Still, the intermittent movements applied during the performance of the osteotomy help this elimination of bone residues and are important in controlling the temperature [4].

Other authors have reported that the drilling procedures for osteotomy should be minimally traumatic, which would be highly recommended to preserve the bone tissue by preventing damage to its healing potential [16]. In addition, the drilling to perform the surgical bed (osteotomy) for the installation of endosseous implants, produces a large local inflammatory reaction, which can be controlled and/or reduced by the use of adequate irrigation technique [5]. The results obtained in the present study showed a lower temperature rise in the groups where a single drill was used to perform the osteotomy (Con2 group and Test group), in comparison with the group where a drilling system with multiple drills (Con1 group) was used. Comparing the data with irrigation, that is a more similar

condition with a clinical scenario, the Test group was 16% < Con1 group and 11% < Con2, whereas the Con2 was 6% < Con1 group.

The manufacture of cutters and their performance is directly related to engineering factors and mechanical functioning. For example, drills with double-positive cutters reduce the cutting pressure, consume less power and create less heat [17]. Then, the test carried out without irrigation (condition 1) serves, mainly, to analyze the efficiency of the different types of cutters. From the results obtained in the present study, when the samples were tested without irrigation, it was demonstrated that the 3 drill systems tested present high quality in their designs and excellent performance since the variation in general average from the initial temperature to final temperature was relatively low. Moreover, the heat generated in the drilling operation is also roughly proportional to the undeformed chip thickness and cutting forces [18].

Other authors have described that mechanical factors (drill and blade design, cutting precision, drill diameter) and technical factors (drilling protocol, speed and force applied, drill angulation, irrigation system and torque applied), are important in determining the physical stress generated [19,20]. Then, as the mechanical factors are determined by the manufacturer of the drilling system, it is the technical factors that may vary during its execution, as clinically this will depend directly on the operator. However, in our study, automated equipment was used so that there were no variations and/or errors during the execution of predetermined technical factors for each drilling systems tested. Regards to the technique applied for the groups, only the drill speed was different between them, which followed the recommendation of each manufacturer. In this sense, a variety of propositions were described in the literature [10], however, the drill design (project) must determine the ideal speed for each drilling system.

Another important factor to note is the characteristics of bone density used in our experiment. The cortical bone presented the mayor density and, as described by Sener et al. (2009) [21], that most heat changes are generated in the most superficial part of this compact bone. Then, the sensor was installed at a depth of 3 mm, although the bone block used had the same density throughout its structure. Still, regarding the drilling time, several authors have described that the drilling time can influence the temperature variation values during osteotomy [19]. In this point, the measured time for drilling in the Con1 group (multiple sequences), obviously was superior due to the need to replace the drills, because it is a sequence of 3 cutters, compared to the groups Con2 and Test that use only one drill. This possibility of performing osteotomy with a low-temperature variation using only one drill may prove beneficial to tissues reducing the local damage as well as the patients' discomfort.

Some limitations and clinical care of this in vitro study must be considered, such as the fact that an all-cortical bone model and automated equipment were used to perform osteotomies, as this does not reflect the clinical reality. On the other hand, when analyzing from the point of view of the proposed and tested techniques, the use of a single cutter for the preparation of the implant bed does not allow for direction corrections after its execution, unlike the use of multiple cutters, where it is possible correct any direction error during the passage from one to the other drill sequence. Thus, we can say that the use of a single cutter requires greater precision during its use. Another important observation is that the initial temperature of the specimens in this study was ~18 °C, while in the patient we have an initial temperature of ~37 °C, which gives us a variation limit of ~10 °C. Then, when we calculate the temperature variation values with the corporal temperature, in the Con1 group in the condition 1 (without irrigation), the temperature could exceed the critical limit and be causing bone necrosis $(\sim 37 \degree \text{C} + 10.4 \degree \text{C} = \sim 47.4 \degree \text{C})$. This scenario could occur due to a failure of the irrigation during the surgical procedure. However, in the other two groups a with an average temperature variation of 8.1 °C, even without irrigation, the value was below the critical point (~37 °C + 8.1 °C = ~45.1 °C). Still, in all groups when the osteotomies were performed using irrigation the values were far removed from the critical value.

5. Conclusions

Within the limitations of the present in vitro study, we can conclude that the single drill with the new design for improving the irrigation and temperature control, demonstrated that the new device coupled to the drills (TURBOdrill[®]) increases and directs the flow of the irrigation liquid and results in better temperature control during the osteotomy, in comparison with the drill designs that use conventional external irrigation.

Author Contributions: Conceptualization, J.C.P.F. and G.B.; Data curation, S.A.G. and B.A.D.; Formal analysis, S.A.G. and B.C.; Investigation, S.A.G., R.B. and B.A.D.; Methodology, S.A.G., J.C.P.F. and G.B.; Resources, G.B.; Software, R.B.; Supervision, R.B.; Validation, J.C.P.F.; Writing—original draft, S.A.G. and B.C.; Writing—review & editing, J.C.P.F. and B.A.D. All authors have read and agreed to the published version of the manuscript.

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RESEARCH ARTICLE Single vs sequential drilling in implantology: a systematic review

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RESEARCH ARTICLE

SINGLE VS SEQUENTIAL DRILLING IN IMPLANTOLOGY: A SYSTEMATIC REVIEW

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Abstract

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Background: Recent clinical protocols in implantology aim at shortening the treatment duration and reducing the trauma and discomfort of the surgical intervention, with good postoperative outcomes. The insertion of dental implants usually engages prior drilling procedures for making implant site. Conventionally, this drilling is done in a sequential way using gradual sizes of drills. However, sequential drilling may be timewasting and disagreeable for the patient (long intervention). Moreover, extended time of tissue exposure may be damaging for the healing response, and prolonging the exposure to the oral environment, which may produce infection. Currently, the clinical advances tend to simpler and minimally invasive procedures. In that respect, simplified drilling was proposed, which consists of minimizing the number of drills through the use of a pilot drill followed by a unique final drill or directly by using a single drill.

Purpose: The aim of this study is to compare, through a systematic review of the literature, the two procedures of drilling and conclude which can lead to a better cicatrization process.

Materials and method: A systematic review of the literature was conducted through the MEDLINE (PubMed) database between from "03/01/2009" to "03/01/2019". The following combination of MeSH terms was used in PubMed: "single drilling AND dental implant". Then a hand search was performed in Ebsco database. Two independent reviewers achieved the quality assessment of the articles retained and two other authors achieved screening, data abstraction and writing of the review.

Results: Most of the studies included in our review concluded no statistically significant differences between singleand sequential drilling, and stated that both of them are viable options.

Conclusion: Within the limitations of our review, it can be concluded that implant placement using a single bur method, is a reliable technique allowing the same outcomes as the conventional approach. Additionally, it allows decreasing the treatment's cost and duration.

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Introduction:-

Implant rehabilitation in dentistry is nowadays a well-documented therapy with 10-year success rates of more than 98% (Buser and al. 2012, Gehrke and al 2018). Osseointegration, which is considered as a direct contact between

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the bone tissue and the implant without the presence of fibers, is the key of success of this type of treatment. The successful osseointegration of a dental implant depends on achieving a good primary stabilization to bone. The preservation of bone cell vitality is a crucial condition for its healing and maturation process, and for setting-up a stable bone-to-implant contact. However, bone cell vitality depends on the quantity of surgical trauma and the damage caused by the thermal rising.

The insertion of dental implants normally engages prior drilling procedures for making implant site. Conventionally, this drilling is done in a sequential way using gradual sizes of drills. However, sequential drilling may be timewasting and disagreeable for the patient (long intervention). Moreover, extended time of tissue exposure may be damaging the healing response and prolonging the exposure to the oral environment, which may produce infection. Nowadays, the clinical advances tend to simpler and minimally invasive procedures. In that respect, simplified drilling was proposed, which consists of minimizing the number of drills through the use of a pilot drill followed by a unique final drill or directly by using a single drill.

Our work means through a literature review, to identify the best implant placement procedure, by a single drilling or a gradual drilling method, and which one leads to a better cicatrization process.

Materials and Method:-

Systematic Search Strategy:

Before the beginning of the systematic literature search, the protocol was agreed by the authors. An electronic search was performed through MEDLINE database (PubMed) (https://www.ncbi.nlm.nih.gov/pubmed).We meant to include only articles published in English during the last 10 years from "03/01/2009" to "03/01/2019". The following combination of MeSH terms was used in PubMed: "single drilling AND dental implant". Then a hand search was performed in Ebsco database. Two independent reviewers achieved the quality assessment of the articles retained and two other authors achieved screening, data abstraction and writing of the review.

Inclusion criteria:

Articles were included if they met all the following inclusion criteria:

- 1. Articles in English
- 2. In vitro studies or RCT
- 3. The variables must be defined and measured appropriately
- 4. The study methods must be valid and reliable
- 5. There must be enough detail in order to replicate the study
- 6. The density of the bone, the speed of the drilling, and the implant type must be detailed
- 7. The time of implant placement and loading must be cited (post extractive or in a healed site).

Exclusion criteria:

Articles were excluded if they don't meet the above-mentioned inclusion criteria.

Two authors extracted the data, and if there was a disagreement, the study was checked and discussed until consensus was reached.

Results:-

The systematic review was conducted following the steps as seen in the flow chart below (Figure 1).



Figure 1:- Flow chart showing the articles selection process.

The data collected was categorized and was organized according to the "PICO" approach as seen in the table below.

Authors	Year,	Population	Intervention	Comparison of outcomes	Results
	type of	-		-	
	study				
Mohlhenrich	2016	Artificial	-10 single (burA:	- With increasing drill	A single-bur system
SC,	In vitro	bone	Straumann,	diameter, the average	could generate more
et al	study	blocks:solid	Basel, of 2.8 mm,	temperatures were nearly	heat than sequential
		rigid poly-	3.5 mm, and 4.2	the same for the respective	drilling during implant
		urethane	mm)	surgical protocols.	site preparation in
		foam	and 10gradual	- Statistically significant	artificial bone types I
		(SRPF) with	implant sites with	differences between	and II. Therefore, bone
		different	diameters of 2.8,	surgical techniques were	density and drill
		densities:	3.5, and 4.2 mm	found for the 2.8mm drill	diameter influence
		(types I-IV;	were prepared in	in D1 (P = 0.0014) and D4	thermal increases.
		D1-D4)	four artificial	(P <0.0001), the 3.5mm	Particularly in lower
			bone blocks	drill in D3 ($P = 0.0087$)	density bone,
			- An infrared	and D4 (P <0.0001), and	conventional drilling
			camera was used	the 4.2-mm drill in D1 (P	leads to less
			for temperature	< 0.0001) and D4 (P =	temperature rising than
			measurements	0.0014)	sequential drilling
			(14-bit)		Further in vivo studies
					will be helpful to
					determine whether
					these results can be
					transferred to humans,
					in order to establish the

Table 1:- Summary of all the included articles with their respective outcomes.

					ideal drilling protocol.
Frösch L, and al	2018 in vitro study	Artificial bone blocks: polyurethane foam blocks	The four groups included single and sequential drilling with and without the use of a surgical guide -Temperature was measured with an infraredcamera	-Guided osteotomy preparation (GOP) showed statistically significant higher temperatures than conventional approach (CA): for the 2.2mm, the 3.5mm and the 4.2mm drill (p=0.032, p=0.005 and p<0.001, respectively) - Sequential drilling led to higher heat generation and longer duration of latent heat than single drilling.	When guided implant surgery is performed, a single drilling procedure could reduce heat production compared to a sequential procedure. Higher temperature changes were observed in GOP compared to CA, and in sequential compared to single drilling
Gehrke SA, and al	2018 in vitro study	Rabbit tibiae model	- using a single unique drill of 4.2mm conical implant, -using 3 consecutive cylindrical drills for a 4.1mm cylindrical implant -using 3 consecutive conical drills for a 4.3mm conical implant.	In the removal torque test, no significant difference was found between the 3 groups tested. Histomorphometric analysis showed no significant difference between groups in the bone-to-implant contact % ($p > 0.05$).	Osteotomy using a single bur did not show differences regarding the proposed and evaluated tests parameters for assessing the peri- implant behavior
R. A. Delgado- Ruiz and al	2017 in vitro study	10 bovine bone disks resembling type IV bone	 - 600 implant site preparations were performed using three test slow drilling speeds (50/150/ 300 rpm) and a control drilling speed (1200 rpm). - 3 different drill designs with similar diameter and length 	- Drilling at 50 rpm resulted in the lowest temperature increment (22.11 \pm 0.8 °C) compared to the other slow drilling speeds of 150 (24.752 \pm 1.1 °C) and 300 rpm (25.977 \pm 1.2 °C) (p < 0.042). - Slow drilling speeds required significantly more time to finish the preparation of the implant bed shown as follows: 50 rpm > 150 rpm > 300 rpm > control (p < 0.05)	- When using a single- bur protocol with tapered and multisteppedtwist drills, a slow drilling speed of 300 rpm in type IV bone density seems to be more efficient in terms of temperature increase and time reduction than using a single bur with a drilling speed of 50 rpm

Authors	Year	Population	Intervention	Comparison of outcomes	Results
Autors	2015	Topulation	-48 conical implants	- Both groups exhibited new	- The findings
Gehrke S.A and al	In vitro study	-Tibiae of 12 rabbits	of standard surface type and design and manufactured by the same company, 2 test groups were prepared: in the control group was used a conventional drill sequence with several uses, in the test group (tesG) used a single-use final drill.	bone in quantity and in quality; however, the tesGexhibited a higher level of new bone deposition than the control group.	suggest that the use of a single- use final drill leads to better and faster organization of the cortical bone area during the evaluated period
Gehrke S.A and al	2016 In vitro study	Synthetic blocks of bone (type I density)	- Group G1 - drilling with a single bur for a 4.2 mm conical implant; Group G2 and Group G3 - drilling with three consecutive burs for a 4.1 mm cylindrical implant and for a 4.3 mm conical implant respectively. Drilling procedures were performed without irrigation.	- The single drill (group 1) achieved a significantly higher insertion torque value (ITV) and implant stability quotient (ISQ) than the multiple drills for osteotomy (groups 2 and 3)	- A single bur system achieves greater precision in the osteotomy than a conventional drilling sequence while preparing implant site and can be considered as safe as the latter. It may increase the torque of insertion and consequently the initial stability of implants.
Guazzi P and al	2015 RCT	40patients: 20 patients 1-drill group and 20patients: multiple- drill group.	- The implant site was prepared using a single drilling step with a newly designed tapered-cylinder drill (1-drill group) or a conventional procedure with multiple drills (multiple-drill group) - Implants were loaded after 3 months and followed up: 4 months after implant loading	 Implants in the (1-drill group) lost 0.54 mm of peri-implant bone versus 0.41 mm for the implants in the multiple-drill group. Postoperatively, patients in the1-drill group vs patients in the multiple-drill group reported statistically significant differences for pain level, number of days in which the swelling persisted and the number of analgesic drugs taken. 	Both drilling techniques produced successful results over a 4- month post- loading follow- up period, but the single bur procedure required less surgical time and lead to less postoperative morbidity.
Marheineke N. and al	2017 In vitro	Osseous study model	- Six experimental groups were representing template-	Improved accuracy without template guidance was observed when experienced operators	- Single-step drilling protocols have

			guided and	were executing single-step	shown to
			freehanded drilling	versus multi-step technique.	produce more
			actions in a stepwise		accurate results
			drilling procedure in		than multi-step
			comparison to a		procedures
			single drill protocol		The outcome of
			Each ann anim antal		
			-Each experimental		any protocol can
			condition was studied		be further
			by the drilling actions		improved by use
			of respectively three		of guiding
			persons without		templates
			surgical knowledge as		
			well as three		
			experienced oral		
			surgeons.		
Bulloch S.E	2012	Bovine	Drilling was	No significant difference in	- Cannulated
and al	In	femoral	performed at a	thermal increase was found	single drill
	vitro	bone model	constant speed (2,100	between single	technique does
			rpm) and pressure	drill cannulated implant site	not cause an
			(2kg) under	preparation and sequential	increase in bone
			continuous room	drilling with or without the use	temperature
			temperature	of a drill guide for the 3.5-mm	greater than that
			irrigation Infrared	or 4.2-mm drilling sequences	seen with
			temperature	respectively	standard
			massuramentswara	respectively	sequential
			takan immadiataly		drilling with or
			hafers and		urifing with out o
			often duilling		without a
			after driffing.		surgical guide
			The 6 study groups		
			included standard		
			sequential drilling		
			protocols for 3.5 and		
			4.2mmfinal drills, and		
			cannulated single drill		
			technique for 3.5-mm		
			and 4.2-mm drills.		

Discussion:-

The results of our review revealed that there is large heterogeneity of methods of testing, protocols and also the materials tested (human bone, rabbit bone, bovine bone, Synthetic block, osseous study model) which make the comparison of the studies difficult.

It is known that the actual tendency in the dental field is to shorten the treatment duration and decrease the treatment costs. Single drilling allows to simplify the procedure of implant placement.

It has been shown to be a reliable method with no significant differences regarding the bone healing, complications, and patient's satisfaction, when compared to the conventional implant placement.

According to the study of Gehrke S.A and al 2018, the use of a single bur system achieves greater precision in the osteotomy than a conventional drilling sequence while preparing implant site and can be considered as safe as the latter. It may increase the torque of insertion and consequently the initial stability of the implants.

Many other studies agree with this finding: (Frösch L, and al 2018, Bettach R and al. 2018 Bulloch S.E and al 2012, Marheineke N. and al 2017)

Conversely, Mohlhenrich SC and al 2016, established that the single drilling procedure could generate more heat than traditional sequential drilling during implant bed preparation in artificial bone types I and II. Therefore, bone density and drill diameter influence thermal increases. Particularly in poorer density bone, conventional drilling seems to raise the temperature less. Nevertheless, since the study was conducted in a synthetic bone material, it is not identified if the results can be applied to humans.

Mohlhenrich SC and al 2016 also stated that bone density influences temperature development during implant bed preparation. In agreement with the results of Gehrkeand al. 2015, no differences in heat generation were found between the two surgical protocols using each drill diameter in type II bone. However, it was found that with decreasing density, higher temperatures could be expected using the single drilling. Thus, it was found that in low-density synthetic bone, sequential implant site preparation generates less temperature, and in high-density bone, single drilling, especially small-diameter osteotomy, generates less temperature.

It is still crucial to emphasize on some precautions like the speed of drilling. Delgado-Ruiz and al . 2017 concluded that drilling at a slow speed of 50 rpm resulted in the lowest temperature increment (22.11± 0.8 °C) compared to the other drilling speeds of 150 (24.752 ± 1.1 °C) and 300 rpm (25.977 ± 1.2 °C) (p < 0.042).

Moreover, slow drilling speeds required significantly more time to finish the preparation of the implant bed shown as follows:

50 rpm > 150 rpm > 300 rpm > control (1200 rpm) (p < 0.05). According to that study, also the diameter and design of drills are significantly important. In fact, it has been shown that using a single-bur protocol with tapered and multistepped twist drills of 3.2 or 3.6mm, with a slow drilling speed of 300 rpm in type IV bone density seems to be more efficient in terms of temperature increase and time reduction.

According to the RCT of Guazzi and al in 2015, both drilling techniques produced successful results over a 4-month post-loading follow-up period, but the single bur procedure required less surgical time and lead to less postoperative morbidity which seems interesting regarding to patient satisfaction and comfort. This team emphasized also on the importance of using sharp drills with high rotation speed(1,500 rpm) in combination with a large applied force and a good irrigation mode, this allows a faster site preparation and a minimum increase of temperature in comparison to lower rotation speed and pressure. Conversely, the use of worn burs makes it difficult to create a breach into the bone, with a consequent prolonged tissue exposure to heat, which, in turn, increases the risk of bone necrosis.

Marheineke and al raised the concerns on the impossibility of adjusting the axis of implant site if using a single bur method, while that Multi-step drilling technique carries the option of detecting and adjusting the axis of misaligned implant sites in early stages. Which needs a steeper learning curve, even for experienced surgeons, and encourages the combination of surgical guidance and single-drill technique allowing a precise implant placement and minimizing the operative discomfort for the patient.

Additionally, Gehrke S.A and al 2018 investigated the bone behavior and the osseointegration of both systems and showed that a single drill system did not change the biomechanical and/or biological of peri-implant tissue response more than a conventional drilling sequence does, while preparing implant site, and indicated that this approach is as safe as the sequential one, and may also increase the torque of insertion and consequently the initial stability of the implants.

Frösch and al . 2018 investigated the temperature development during single and sequential drilling with a conventional and guided approach. Higher temperature changes were observed in guided osteotomy preparation (GOP) compared to conventional approach (CA), and in sequential compared to single drilling. This is in line with several other studies that suggest the greater heat generation with guided procedures is caused by the surgical guide avoiding the irrigation fluid from entering the drilling site (Dos Santos et al. 2014, Markovic et al. 2016, Migliorati et al. 2013, Misir et al. 2009). Drilling with a cooling canal in the guide was proposed by Liu et al. 2016 and has been shown to reduce the temperature increase. Freehand placement is a good alternative but leads operator to a bigger risk of error and misalignment.

R. Bettach and al. 2018 stated that single drilling even in the immediate postextractive sites, either functionalized immediately or in a delayed mode, can be a predictable solution for the rehabilitation of patients in need of tooth extraction.

Conclusion:-

Based on the findings and considering the limitations of our review, it can be concluded that implant placement using a single bur method, is a reliable technique allowing the same outcomes as the conventional approach. Additionally, it allows decreasing the treatment's cost and duration.

Competing interests:

The authors declare no competing interest.

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CLINICAL STUDY Immediate Implant Placement Into Fresh Extraction Sites Using Single-Drilling Bur and Two Loading Procedures: Follow-Up Results

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Immediate Implant Placement Into Fresh Extraction Sites Using Single-Drilling Bur and Two Loading Procedures: Follow-Up Results

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Abstract: Modern clinical protocols in implantology aim at shortening the treatment time and reducing duration and discomfort of the surgical phase, while maintaining optimal treatment outcomes. The purpose of this study was to evaluate clinical outcomes of implants immediately placed in extraction sites, using a single drilling step for implant site preparation. One-hundred thirty-three patients (mean age 55.3 ± 12.7 [SD] years, range 20–83 years) were treated at 2 clinical centers. Two-hundred sixty-one implants were inserted in fresh postextraction sockets. One-hundred sixty-five implants were immediately loaded (IL) and 96 underwent delayed loading (DL). Implant survival, peri-implant bone level change and patients' satisfaction were assessed after at least 3 years of function. No patient dropout occurred. The mean follow-up was 63.61 ± 11.52 months (range 39.71 - 85.71 months) from prosthesis delivery. Two IL and 1 DL implant failed in 3 patients. Implant survival was 98.8% and 99% for IL and DL group, respectively. The mean marginal bone loss after 1 year was 0.48 ± 0.40 mm and 0.52 ± 0.34 mm for IL and DL group. No biological nor mechanical complications occurred. All patients demonstrated full satisfaction. The present protocol with single burs for site preparation produced satisfactory clinical outcomes independent of the loading timing. Further long-term comparative studies are needed to confirm the present findings.

Key Words: Dental implants, immediate implants, immediate loading, implant site preparation, postextraction socket

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F or many years, prior to dental implant placement, the compromised teeth were removed and the extraction sockets left unrestored until complete healing. Then, the implant was positioned and covered for several months to achieve osseointegration, before

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prosthesis delivery.¹ However, shortening the time between tooth extraction and implant placement would be favorably accepted by a large majority of the patients.

In addition to the reduced number of surgical sessions and the shortened treatment time, further advantages of immediate implant placement have been identified as the ideal positioning of implants in fresh extraction sites, the preservation of bony structures, and soft tissue aesthetics, as well as a simplification of the prosthetic phase.^{2–8} This contributes to increasing patient comfort and satisfaction and also patients' acceptance toward implant therapy.^{9–13}

On the other hand, limited bone apical to the socket, presence of infection at the extraction site, gaps between the surface of the implant and the socket walls, and alterations of the ridge dimensions during the healing period are all factors that may negatively affect the outcome of immediate implant placement, underlining the importance of a careful patient selection.^{14–17}

Lang et al¹⁸ in a systematic review published in 2012 observed a high survival rate of implants placed immediately into fresh extraction sockets, after at least 1 year of function. Despite this promising finding, the authors underlined the need for more long-term studies to determine the success of such treatment, especially in regard to the aesthetic outcome that can also be correlated to the resorption of buccal plate.¹⁸

The debate in timing of implant placement into extraction socket is still controversial, therefore a new classification defining the time for the positioning of implants has been proposed.¹⁹ This classification is based on morphologic, dimensional, and histological changes that follow tooth extraction and on common practice derived from clinical experience. In particular, postextraction implants are divided into type 1 (implants placed during the same surgical procedure as extraction), type 2 (implants placed after soft tissue healing, 4–8 weeks after extraction), type 3 (implants placed after radiographic filling of the socket), and type 4 (implants placed in healed sites, at least 3–4 months after extraction).¹⁹

Another critical phase of the surgical procedure is the implant site preparation. To ensure a successful osseointegration of dental implants, it is recommended to minimize surgical trauma to bone tissue.²⁰ In particular, the overheating of surrounding bone due to the attrition of burs during drilling can cause bone necrosis,²¹ thus influencing early peri-implant bone loss and implant survival.²² The conventional drill protocol for the correct preparation of the implant site consists of a sequence of incremental diameter drills, in the attempt to minimize bone damage during its instrumentation, but this technique may become time-consuming for both clinician and patient and cause prolonged tissue exposure of the surgical site and thermal trauma to bone tissue due to repeated drilling procedures.²¹ Therefore, a 4-bladed drill with a special design has been recently introduced in the market, allowing for the implant site preparation with a single drilling step in different types of bone. In a preliminary study, implants associated with the use of a single drilling step showed excellent success rate.24

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Moreover, the timing the implant is restored after placement is as well important in view of the modern tendency toward the reduction of the total treatment time without compromising the clinical and aesthetic outcomes. Single-stage surgery with immediate prosthetic loading can be adopted even at implants placed in fresh extraction sockets, allowing restoration the same day the implant is placed.²⁵ Recent systematic reviews of the literature assessed the outcomes of immediate restoration of single and multiple implants immediately placed in postextraction sockets.^{26,27} The results of these reviews validated the benefits offered by this protocol, but also emphasized that using such bimodal option the risk for implant failure is higher respect to immediately restored implants placed in healed ridges.

The aim of the present multicenter study was to evaluate the clinical and radiographic outcome of implants immediately placed into fresh extraction sockets using a single drilling step procedure, and restored according to the immediate or delayed loading procedure, after at least 5 years of function.

METHODS

The present investigation was designed as a prospective study. The protocol of the study was approved by the Institutional Review Board (IRCCS Galeazzi Orthopaedic Institute RC-3017, 30/06/2010) and patients were consecutively recruited from September 2010 to May 2014 at 2 private practice offices, 1 located in France and 1 in Northern Italy. The patients were treated following the principles embodied in the World Medical Association Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2000.²⁸ Three clinicians with more than 10 years of experience in implant dentistry performed surgical operations. After thorough explanation on the study procedures and purpose, all patients signed an informed consent form prior to being included.

Patients were selected according to the following inclusion and exclusion criteria.

Patients' inclusion criteria: at least 18 years of age; absence of general medical contraindications for oral surgery procedures (American Society of Anesthesiologists ASA-1 or ASA-2); absence of active infection at the involved site; full-mouth bleeding score, and full-mouth plaque score less than 25% at baseline; patient in need for extraction of a tooth to be rehabilitated by means of implant-supported prostheses; probing depth < 4 mm at the buccal, palatal, mesial, or distal aspects of the tooth to be extracted; presence of adequate quantity of native bone for achieving primary stability; available bone volume was evaluated through preoperative cone-beam computerized tomography; patients able to sign the informed consent form.

Patient's exclusion criteria: any systemic disease, condition, or medication that might compromise healing or implant osseointegration; inability or unwillingness to return for follow-up visits; inability or unwillingness to maintain a good level of oral hygiene throughout the study.

After diagnosis and treatment planning were formulated, the inclusion and exclusion criteria were checked and the patient's data recorded. Before subjects' enrolment, patient had to be fully informed about the study and had to personally sign and date the consent form. All patients meeting selection criteria who gave their consent to be enrolled in the study were divided into 2 groups: immediate loading (IL) group and delayed loading (DL) group. The allocation was chosen on the basis of patients' will and of clinical and radiographic evaluation before surgical intervention.

Surgical Procedure

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One hour before surgery, patients began a prophylactic regimen with 2 g of amoxicillin *per os.* Local anesthesia was obtained with articaine chlorohydrate (4%) and epinephrine (1: 100,000) (Alfacaina N; Weimer Pharma, Rastat, Germany).

The tooth that has been previously judged as hopeless was carefully luxated with the use of small elevators. The extraction of the mobilized tooth was carefully made using forceps to minimize the mechanical trauma to the surrounding alveolar bone and, when necessary, dedicated tips mounted on piezoelectric device were used to preserve as much as possible the alveolar bone.

The socket was thoroughly debrided to remove any granulation tissue and a single-tooth implant was placed in fresh postextraction sites. Implant site preparation was performed in all patients using cylindro-tapered drills with 4-bladed edges and a channel between the cutting thread (IDALL drills, Implant Diffusion International, Montreuil, France). These drills are available with 4 drilling lengths (10, 12, 15, 18 mm) characterized by different color codes, and 2 different diameters (4.2, 5.2 mm). Such 4-bladed drill is used without in-and-out movements and cooling is obtained by copious irrigation with physiological solution. All implants (IDALL, Implant Diffusion International, Montreuil, France) were made of TiAl6V titanium alloy with a sandblasted acid-etched and TiO₂-coated surface. Such implants had the following features: a switched platform, a cylindrical-tapered shape, an aesthetic gold polished neck, a morse taper connection, an anti-unscrewing groove, double twist threads and a catch base with large threads and tapered core. The recommended rotation speed of the implant during insertion is 35 rpm with a final torque between 25 rpm and 30 Ncm for the DL group cases and the same rotation speed value with both a final torque of 50 Ncm and a final Implant Stability Quotient value of 60 for IL group cases (measured by means of the Osstell Mentor, Osstell AB, Göteborg, Sweden).

Two options exist if the bone quality is misjudged and the implant stops at 50 Ncm before being finally seated; either unscrew the implant and choose a wider final drill, or manually, with a torque wrench, first tightening the implant into position, then loosening the fixture by reverse torque and finally using a machine at 50 Ncm seating the implant to its final depth. Those methods aim at eliminating the risk of over-tightening the implant. Before implant placement, the presence of dehiscence or fenestration on buccal wall was evaluated without elevating a flap. If the buccal bone width was inferior to 2 mm, the space between implant surface and the wall of buccal bone was filled with a bone substitute (deproteinized bovine bone mineral).

In the DL group a cover screw or a healing cap was attached to the implant. The flaps were repositioned and secured with nonabsorbable 5-0 silk sutures (Ethicon, Johnson & Johnson, Piscataway, NJ).

A standardized periapical radiograph was taken at the end of surgery. After the surgical phase, a standard pharmacologic protocol was prescribed, consisting of nimesulide 100 mg twice daily for pain control, if needed, and 0.2% chlorhexidine digluconate mouthwash twice daily for 1 week for plaque control. A soft diet was recommended as well as the avoidance of food contact with the surgically involved zone for a few days, if possible. The sutures were removed 1 week after surgery.

Prosthetic Phase

Implants of IL group were restored within 48 hours from the surgery with prefabricated provisory abutments and transfixed provisional crowns. Definitive restorations (made of ceramic) were inserted approximately 8 to 12 weeks after implant placement.

For the DL group, after at least 3 to 4 months of healing, a surgical re-entry procedure was performed. Full-thickness flaps were elevated to access the marginal portion of the implant site. The healing caps were replaced with permanent abutments, and the

implants were loaded with the final restoration. All prostheses were cemented. Complications were recorded as they occurred.

Radiographic Evaluation

Standardized intraoral radiographs were taken at entry, immediately after surgery (baseline), at the prosthetic phase, and at each follow-up visit (after 6 and 12 months of prosthesis function and yearly thereafter). Radiographs were taken using a long-cone paralleling technique and individual holders to ensure reproducibility. Each periapical radiograph was scanned at 600 dots per inch with a scanner (Epson Perfection Pro, Epson Italia, Roma, Italy). A dedicated image analysis software (ImageJ version 1.46, National Institutes of Health, Bethesda, MD; http://rsb.info.nih.gov/ij/) was used to perform measurements of marginal bone level around implants at the mesial and distal aspects. The implant neck was the reference for each measurement. The mesial and distal values were averaged to have a single value for each implant.

Outcome Variables Assessed

The primary outcomes were prosthesis success, implant survival and success, and patient satisfaction. Prosthesis success: the prosthesis was in function, with no signs of mobility, even in face of the loss of 1 or more implants (for partial and full prostheses). Prosthesis stability was assessed by using the pressure of 2 opposing instruments. The prosthesis was considered as failed when its function was compromised for any reason.

Implant survival criteria were: the implant was present in the patient's mouth, and there was no evidence of peri-implant radiolucency, no recurrence or persistent peri-implant infection, no complaint of pain and of neuropathies or paraesthesia.

Implant success was evaluated according to the traditional Albrektsson criteria (in addition to survival criteria, implant was stable, and radiographic bone resorption was within 1.5 mm during the first year and no greater than 0.2 mm per year thereafter).²⁹

A questionnaire similar to that used in previous studies^{30,31} was distributed to the patients 12 months after the prosthesis delivery to evaluate the patient's satisfaction for mastication function, phonetics, and aesthetic aspect. Each item was scored according to a Likert scale including 5 possible options: excellent, very good, good, acceptable, poor.

The secondary variables were the number and type of biological and mechanical complications, and peri-implant bone level changes measured on periapical radiographs at the mesial and distal aspect. The effect of implant location, smoking status, and bone quality evaluated according to the Lekholm and Zarb classification³² on the clinical and radiographic outcomes was also evaluated.

Statistical Analysis

The patient was the statistical unit to provide a general description of the population and to identify any possible differences between distribution of covariates in the study groups. The implant was the statistical unit for implant description and survival, marginal bone loss and prosthetic parameters. Data were synthesized using the mean value and standard deviation for quantitative variables, while absolute or relative frequencies were calculated for qualitative variables. To analyze the differences between variables the unpaired Student t test for continuous variables normally distributed and the Mann-Whitney test for continuous variables not following a normal distribution were used. Normality of distributions was assessed using the D'Agostino and Pearson omnibus test. The Pearson χ^2 test was applied to qualitative or discrete variables. The unpaired Student t test was used to compare the bone level change around immediately loaded versus conventionally loaded implants. Descriptive statistical analysis was performed



FIGURE 1. Distribution of implants in the maxilla.

by using GraphPad Prism 5.03 (GraphPad Software, San Diego, CA). Differences were considered significant at P<0.05, with a 95% confidence interval.

RESULTS

Twenty of the 153 patients screened for eligibility did not meet the selection criteria. A total of 133 patients were consecutively enrolled for this study (79 females and 54 males; mean age at surgery 55.3 ± 12.7 (SD) years, range 20–83 years). The study population included 19 smokers. A total of 261 IDALL implants (Implant Diffusion International, Montreuil, France) were immediately inserted in fresh postextraction sockets. One-hundred twenty implants were postextraction type 1 implants and 141 implants were postextraction type 2. One-hundred fifty-one implants were placed in the maxilla and 110 in the mandible. Figures 1 and 2 show the implant distribution in the jaws. One-hundred sixty-five implants were immediately loaded, while 96 underwent a delayed protocol. In the IL group, the majority of implants was postextraction type 1 (71%), while in the DL one 97% of implants were type 2. Tables 1 and 2 resume the implants in the 2 groups and demographics of patients and the statistics of the study population, respectively. The rehabilitations were 100 single-tooth, 38 fixed partial prostheses supported by 2 to 4 implants, and 11 full-arch fixed prostheses supported by 6 to 7 implants. Seventy-six prostheses (165 implants) were functionalized at the time of insertion according to an



FIGURE 2. Distribution of implants in the mandible.

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TABLE 1. Implant Dimensions

		No. of Implants			
Diameter (mm)	Length (mm)	Immediate Loading	Delayed Loading	Total	
4.2	10	19	17	36	
	12	77	52	129	
	15	55	11	66	
5.2	10	13	13	26	
	12	1	3	4	
	15	0	0		
Total		165	96	261	

immediate loading protocol. The mean follow-up was 66.88 ± 11.52 months from implant insertion (range 40.23-89.72) months) and 63.61 ± 12.10 months from prosthesis delivery (range 39.71-85.71 months). The mean healing time between implant insertion and prosthesis delivery in DL patients was 3.75 ± 1.56 months (range 1.94-9.66 months).

A total of 3 implants failed throughout the study. One implant (first maxillary premolar) was mobile at the prosthetic phase in the DL group and was removed. It was replaced with a larger one that osseointegrated and was rehabilitated without further complications. Two implants (1 upper and 1 lower central incisor) did not achieve osseointegration in the IL group and were removed within 2 months of insertion. Another IL implant (upper central incisor) developed an apical infection after 3 months of function. The apical cyst was surgically removed, a new guided bone regeneration procedure was performed and the site healed without compromising implant function. No further biological or technical complications were reported. Implant survival after 1 year of function was 98.8% in the IL group and 99.0% in the DL group. No significant difference in survival rate was found between the different loading modalities (P > 0.05).

The mean peri-implant bone level change evaluated after 1 year of function was -0.48 ± 0.40 mm (n = 130 implants) and -0.52 ± 0.34 mm (n = 68 implants) in the immediate and delayed loading group, respectively. For the remaining 60 implants still in function after 1 year, marginal bone loss could not be evaluated due to poor quality of the radiographs that did not allow a precise assessment of the peri-implant bone level. The differences in marginal bone remodelling between implants immediately loaded and implants loaded according to a delayed protocol were not statistically significant.

In 90.8% of patients (at 237 implants) adjunctive graft materials were used to fill the gap between the implant and the alveolar socket walls. Grafting was associated with the placement of barrier membranes to covering and protecting the grafted healing site around implants in 183 patients (70.1% of implants). Graft materials were: freeze-dried bone allograft (FDBA) plus collagen equine membrane (AT Collagen, Implant Diffusion International, Paris, France) (n = 147), tricalcium phosphate (TCP) plus collagen equine membrane (n = 33), TCP alone (n = 31), Plasma rich in growth factors alone (n = 15), FDBA alone (n = 3), TCP plus polytetrafluorethylene membrane (n = 1). In 24 patients no grafting was used and in 7 patients the material was not specified. In both IL and DL groups the majority of patients used the FDBA plus collagen equine membrane as graft material, 58% and 53%, respectively.

A total of 118 questionnaires (88.7% of patients) were returned and evaluated. Patients showed a high degree of satisfaction regarding function and phonetics after 12 months, independent of the loading protocol applied. The proportion of patients scoring the outcome as excellent or very good was 94.1% and 95.8% for

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TABLE 2. Descriptive Data Comparing Immediate Loading and Delayed Load-

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	IL 78 Pat/165 Impl	DL 55 Pat/96 Impl	P Value
Demographic variables (n = 21)			
Age (yr)			0.77
Range	20 - 78	33-83	
$\begin{array}{c} \text{Mean} \pm \text{standard} \\ \text{deviation} \end{array}$	55.40 ± 13.55	55.69 ± 11.40	
Gender			0.83
Female	47 (60%)	32 (58%)	
Male	31 (40%)	23 (42%)	
Smoking habit			1.00
Nonsmokers	67 (86%)	47 (85%)	
Smokers	11 (14%)	8 (15%)	
Implant placement status			
Jaw distribution			$< 0.001^{*}$
Maxilla	80 (48%)	71 (74%)	
Mandible	85 (52%)	25 (26%)	
Graft material			
FDBA alone	3 (2%)	0 (0%)	
FDBA + collagen AT	96 (58%)	51 (53%)	
equine membrane		\bigcirc \land	
TCP alone	31 (19%)	0 (0%)	
TCP + collagen AT equine membrane	19 (12%)	14 (15%)	
TCP + polytetrafluorethylene membrane	1 (1%)	0 (0%)	
PRGF	3 (2%)	12 (13%)	
Undefined	0 (0%)	7 (7%)	
None	12 (7%)	12 (13%)	
Prosthesis status			0.06
Single-tooth	56 (34%)	44 (46%)	
Fixed partial prosthesis	20 (12%)	18 (19%)	
Fixed full arch prosthesis	10 (6%)	1 (1%)	
Follow-up duration			
Implant positioning (mo)			0.15
Range	40.23 - 84.72	43.75 - 89.72	
Mean ± standard deviation	67.82 ± 10.26	65.30 ± 12.63	
Healing time (mo)			0.0015^{*}
Range	0.00 - 8.05	1.94 - 9.66	
Mean ± standard deviation	3.00 ± 0.89	3.75 ± 1.56	
Prosthesis loading (mo)			0.10
Range	40.20 - 81.73	39.71 - 85.71	
Mean \pm standard deviation	64.82 ± 10.04	61.54 ± 13.48	

IL, immediate loading; DL, delayed loading; FDBA, freeze-dried bone allograft; PRGF, plasma rich in growth factors; TCP, tricalcium phosphate. *Statistically significant difference between groups

phonetics and mastication function, respectively, with none of the patients scoring the outcome as poor. Regarding the aesthetic aspect, 101 of the patients (85.6%) judged it as excellent or very good while 3 patients (2.5%) scored the aesthetic outcome as poor.

DISCUSSION

Immediate placement of implants into extraction sockets has been extensively reported in the dental literature, but only a limited number of studies have evaluated the outcomes of immediate restoration of these implants. In the present study excellent clinical

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and radiographic results after a mean follow-up of 3 years were found.

In this study a 4-bladed drill with a special design, which allows preparing implant site with a single drilling step in different types of bone, was routinely used. With such drill type implant site preparation may be faster, reducing the overall surgical time. Prolonged tissue exposure during surgery could be detrimental to the postoperative course, because of the increased release of proinflammatory cytokines and consequent amplification of the inflammatory response.²³ Hence, any simplification of the technique for implant site preparation should be favorably accepted by both clinicians and patients. A few improvements of the drill design and drilling technique have been proposed in the past years to reduce the risk of overheating the implant site and to simplify the procedure.^{33,34} A previous study on 149 patients rehabilitated with a total of 350 implants placed in sites prepared with the same drill type reported a 98.0% implant survival after a mean follow-up of 21.5 months and a mean marginal bone loss of 0.58 mm.²⁴ In that study patients were rehabilitated by means of different oral surgery procedures such as guided tissue regeneration, sinus floor augmentation with either lateral or crestal technique, immediate, or delayed placement in postextraction sites.²⁴ In the present study only implants immediately placed in postextraction sites were considered. The drawback when using a single bur is that a great precision in drilling is required. In postextraction sites it is sometimes difficult to drill along the proper axis with precision as the socket is larger than the bur and frequently has an irregular shape, so it cannot serve as a guide for drilling. Therefore, in some cases it can be recommended to use a pilot drill first to drive the preparation of the implant site along the correct axis and then, the final high-performance drill. If many implants have to be placed in the same jaw it could be useful to using an individualized surgical guide.

All the implants used in this study are specially designed for achieving good primary stability and they are recommended for placement in the postextraction socket. They have a cylindrictapered shape, a switching platform, a smooth neck, double twist threads, an antiscrewing groove in the body, and penetrating and bone-condensing threads especially in the apical third. It has been shown that the implant length and thread profile may have an influence on the bone stresses, bone formation, and bone loss after implantation in postextraction sockets.³⁵ In particular, in a finite element simulation it was shown that shorter length implants can be related to higher bone remodeling (bone loss and growth) with respect to longer implants, and smoother thread profiles induced low stress values at the bone-implant interface, limiting bone resorption.³⁵ Furthermore, results from finite element analysis suggested that tensile and compressive peak stresses resulting from implantation in extraction sockets may be higher than implantation in healed bone,³⁶ which may lead to preservation of the mechanical stimuli to the alveolar bone and reduction of postoperative bone loss.37

The rough surface in the threaded part of the fixture is obtained through a sand-blasted, medium-grit, thermally acid-etched (S.M.A.) surface modification process. The smooth neck is designed to hinder bacterial plaque adhesion and reduce surface contamination and incidence of long-term infectious peri-implant disease. Though, it might pose a concern regarding marginal bone loss, as pointed out by some researchers. Hermann et al³⁸ in a study on canine mandible model reported that completely (all the way to the top) sand-blasted acid-etched surfaced, nonsubmerged implants are effective in decreasing the amount of peri-implant crestal bone loss and reducing the distance from the implant-abutment microgap to the first bone-implant contact as compared with implants with a machined collar. Furthermore, they reported that a slightly exposed sand-blasted acid-etched surface during implant placement did not

seem to compromise the overall hard and soft tissue integration and, in some cases, was associated with coronal bone formation in the canine model.³⁸ Conversely, a recent study by Bassetti et al³⁹, which investigated bone level changes around rough grooved neck and machined neck implant design, found no difference between the 2 types of implant neck. Such study was performed on 2-stage implants placed in the posterior edentulous mandible of patients. The authors concluded that the modification of implant neck texture had no significant influence on marginal bone loss, while only insertion depth may have a significant influence on the amount of peri-implant bone loss.³⁹

A literature review on this topic included 10 prospective studies that compared marginal bone loss around implants having a machined neck versus implants having a rough neck (either with or without microthreading to the top of the collar), after at least 12 months follow-up.⁴⁰ In 4 of those studies no significant difference in marginal bone loss was found between implants with rough or machined neck. Other studies found that microthreading was more advantageous than surface features for preserving the marginal bone around implants.⁴⁰

Another systematic review by Bateli et al⁴¹ investigated the effectiveness of various implant neck configurations in the preservation of peri-implant bone level. This review adopted broad study design selection criteria, but focused only on studies with at least 5 years of follow-up. The review included 20 studies, which proved to be rather heterogeneous, and provided no evidence regarding the effectiveness of any specific modification in the implant neck zone for preserving marginal bone or preventing marginal bone loss in the long term.⁴¹ In summary, there seems to be no consensus in the literature regarding the superiority of rough-surfaced neck as compared with machined neck for marginal bone level changes, while a possible advantage of microthreading has been pointed out. In the IDALL implants, microthreads are present in a double-twist configuration, until close proximity to the top of the implants, representing a possible beneficial solution for both marginal bone preservation and increase of the bone-implant contact as also suggested by previous investigations.42-45

In the present study marginal bone loss after 1 year of function averaged about 0.5 mm and rarely exceeded 1 mm around implants with smooth neck, such value being in line with most of the studies from the current implant literature evaluating implants with rough neck. A possible explanation for such a good result might be the presence of a switching platform. Such an approach has clinical, biological, and biomechanical rationale, as previously reported.^{46–49} Radiographical evidence from a number of clinical studies and results from recent systematic reviews showed very promising results, suggesting that such a configuration can be an effective method for preserving crestal bone around the neck of the implants.^{50–58} The platform switching solution is also accompanied by positive effects on the aesthetic outcome.⁵⁹

The implants used in the present study have a double implantabutment connection. The first one is a morse taper connection type, which has been associated with good preservation of the marginal bone crest, especially in conjunction with the platform-switching concept.^{60,61} The morse cone is a very reliable solution though in postextraction implants it poses some difficulties during removal of the provisional abutment, due to the risk of destabilizing the implant. Such a procedure can be performed using a special screw driver that goes through the provisional abutment and helps to extract it easily. The second implant-abutment connection consists of a tube-in-tube type connection down to the morse cone, similar to that proposed by other companies (eg, the Camlog), which allows a tight and precise fitting and represents a further secure connection. Two types of abutment were available from the Implant Diffusion International Company, 1 with the morse cone and the came (tube-

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in tube) as an index, and 1 just using the came connection. However, when dealing with postextraction implantation it is recommended to use provisional abutments with just the came connection, to facilitate handling of the provisional abutment during the surgical step. After that, the surgeon may choose between the 2 abutment types.

Another debated question is the timing of loading since implant placement in postextraction sites. In the present study we found no difference in implant failure and complication rate as related to the timing of prosthesis delivery, suggesting that implants inserted immediately in postextraction sites and achieving a good primary stability can be functionalized immediately, without a major risk of adverse events. In the present study there is no concurrent comparison with implants inserted in healed sites, which should represent the ideal comparison group, but in terms of implant survival and marginal bone loss, the results achieved in this study after a minimum of 2 years of function are excellent and well comparable to the gold standard. A recent systematic review focused on immediate loading of postextraction implants in the aesthetic region concluded that the clinical outcome of such implants is excellent, being implant survival equal to 97.6% after 1 year of function. However, from the analysis of comparative studies survival of such implants resulted inferior to that of implants placed in healed sites (95.6% versus 99.4%).²⁷ This review, which included 7 randomized studies and 35 case series accounting for 1170 patients with mean follow-up ranging between 12 and 65 months, reported that no failure of immediately loaded postextraction implants occurred later than 1 year of function.²⁷ In another review, immediate loading of immediately placed implants was found to be related to higher failure rate as compared with delayed implants, especially when implants with minimally rough surface were used.⁶

A recent clinical study assessed the reliability of immediate implantation in postextraction socket and immediate loading protocols in the edentulous jaws, based on 591 implants inserted in 80 patients with at least 4 years of follow-up.⁶³ According to a multivariate Cox regression analysis, the highest risk of failure was associated with implants immediately placed and immediately loaded in the maxilla (89.4% survival rate), while those placed in the mandible showed an excellent survival rate (98.6%).⁶³ In that study no difference was found as related to the position in the jaw (anterior versus posterior regions) and other variables like bone quality, insertion torque, implant design (cylindrical versus conical), while analyzing the reason for extraction, it emerged that implants inserted in the socket of teeth affected by endo-periodontal lesions had worse outcomes than those replacing teeth extracted due to caries or periodontal disease.⁶³

Conversely, another recent randomized controlled trial-based systematic review comparing immediate versus conventional implant loading found no significant difference in marginal bone level change and implant survival up to 5 years follow-up between immediate functional versus nonfunctional loading, as well as between immediate versus conventional loading in implants placed in both healed and postextraction sites.⁶⁴ That review concluded that, in spite of the limited evidence, that cannot allow drawing definitive conclusions, the loading protocol—that is, immediate or conventional loading—is irrelevant for clinical outcome data such as implant survival or marginal bone level stability.⁶⁴

Due to the very low number of implant failures recorded in the present study, no association could be established with possible risk factors related to the patient (age, gender, smoking status, systemic condition), the surgical procedure (guided bone regeneration, type of graft material, flap or flapless procedure, implant position in the socket, insertion torque, implant length, and diameter), prosthesis type (single tooth or multiple-element prosthesis), or the surgical site (jaw, location, postextraction defect characteristics, presence of infection at the alveolar site, reason for extraction).

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In conclusion, the excellent outcomes of the present study could be attributed to the proper surgical technique adopted, to the skillfulness of the surgeons involved, to the careful and appropriate presurgical planning, to the adequate level of oral hygiene and motivation of the patients, to the validity of the implant system, of the special bur and the materials adopted, or to a combination of the above.

The present results are in line with recent reviews and clinical studies, indicating that the immediate postextraction implants, either functionalized immediately or in a delayed mode, represent a predictable solution for the rehabilitation of patients in need of tooth extraction.

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ARTICLE

Evaluation of the insertion torque, implant stability quotient and drilled hole quality for different drill design: an in vitro Investigation

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Evaluation of the insertion torque, implant stability quotient and drilled hole quality for different drill design: an in vitro Investigation

Key words: dental implants, resonance frequency analysis, bone density, insertion torque, drill precision

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Abstract

Objective: The purpose of the present study was to compare the insertion torque and implant stability quotient between different drill design for implant site preparation.

Materials and Methods: Synthetic blocks of bone (type) density) were used for drilling procedures. Three groups were evaluated: Group G1 - drilling with a single bur for a 4.2 mm conical implant; Group G2 and Group G3 - drilling with three consecutive burs for a 4.1 mm cylindrical implant and for a 4.3 mm conical implant respectively. For each group, 15 drilling procedures were performed without irrigation for 10-mm in-depth. The drilled hole quality (HQ) after the osteotomy for implant site preparation was measured in the five-first holes through a fully automated roundness/cylindricity instrument at three levels (top, middle, and bottom of the site). The insertion torque value (ITV) was achieved with a computed torquimeter and the implant stability quotient (ISQ) values were measured using a resonance frequency apparatus.

Results: The single drill (group 1) achieved a significantly higher ITV and ISQ than the multiple drills for osteotomy (groups 2 and 3). Group 1 and 3 displayed significantly better HQ than group 2. **Conclusions:** Within the limitations of the study, the results suggest that the hole quality, in addition to the insertion torque, may significantly affect implant primary stability.

Introduction

Implant stability at the time of surgery is crucial for the long-term success of dental implants. Primary stability is considered of paramount importance to achieve osseointegration (Degidi et al.2013). Primary implant stability can be defined as a function of the local bone quality and quantity, the geometry of the implant, the placement and surgical technique used, and the precise fit in the bone (Bilhan et al. 2010). Thus, the orchestration of the above elements is crucial for the long-term success of the implant (Dilek et al.2008; Stacchi et al.2013) Two main factors that influence primary stability of an implant during placement are the amount of bone-implant contact and the role of compressive stresses at the implant tissue interface.

Such stresses may be beneficial for enhancing the primary stability of an implant, but

excessive compression of the blood vessels in the bone tissue surrounding the implant may result in necrosis and local ischemia of the bone at the implant-tissue interface (Nedir et al. 2004; Isoda et al. 2012) In the same respect, secondary stability can also be determined by the bone tissue response to the surgical trauma and the implant surface. In this respect, the quality of the cutter is of fundamental importance, as the intensity of the trauma caused by the osteotomy procedure may determine the bone response. Gehrke 2015) histologically showed better bone response when the final drill used in the osteotomy was new and efficient in cutting (single use).

Shorter healing periods are usually needed for implants with adequate primary stability to achieving osseointegration. On the other hand, implants with poor primary stability need longer healing periods to achieve sufficient gain in secondary stability, to support prosthetic rehabilitation. This suggests the possibility of determining the length of the healing period on an individual basis, making implant treatment safer, more effective, and less time-consuming in some cases (Esposito et al. 1998) Generally, clinicians evaluate primary stability using the percussion test or using their own perception during the insertion process. However, the lack of precision has motivated the development of different methods to objectively evaluate primary stability; in particular, peak insertion torque (IT) and resonance frequency analysis (RFA) are the most used globally. Clinically, RFA values or implant stability quotient (ISQ) values have been correlated with changes in implant stability during osseous healing. Thus, IT and ISQ values are thought to have a positive correlation (Degidi et al. 2009, 2012). However, the formula of higher IT translating into higher primary stability may not always be true because the quantity and quality of bone varies significantly among patients. Therefore, the purpose of the present study was to investigate the IT, RFA and drilling quality (hole precision, that is the linearity and roundness of the borders of the prepared site at any depth, which should be as close as possible to a cylinder or a cone, depending on the profile of the drill used) of three different dental implant design using artificial bone block. The null hypothesis was that using a single drilling step, no difference in drilling quality (hole precision), IT and RFA of the implants occurs, with respect to using conventional multiple-step drilling.

Materials and methods

Bone specimen and groups division

To standardize the bone characteristics, bone blocks of solid rigid polyurethane foam (Nacional Ossos, São Paulo, Brazil), in accordance with the ASTM F1839/08 (Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments. ASTM International, West Conshohocken, PA, 2012) with a thickness of 40 mm, a width of 10 mm, and a length of 180 mm were used, foam is available in a range of sizes and densities, in this study it was 0.64 grams per cubic centimeter (40 pcf = 40 pounds per cubic foot).

Three groups were considered and are showed in the Fig. 1:

Group 1: One drill 4.2 mm diameter by 10 mm length (1500 rpm) for conical



Fig. 1. Image of the sets (drills and implant) used for each group.

Group 3

implant, (IdAll Implants Diffusion International (Montreuil, France).

Group 2: Drill sequence for a cylindrical 4.1 mm standard implant diameter by 10 mm length, Straumann (Basel, Switzerland): drill diameters were 2.2 mm (used at 800 rpm), 2.8 mm (600 rpm) and 3.5 mm (500 rpm).

Group 3: Drill sequence for a conical 4.3 mm Nobel Replace® implant diameter by 10 mm length, Nobel Biocare (Sweden): tapered 2 mm (2000 rpm), 3.5 mm (800 rpm) and 4.3 mm (800 rpm).

Osteotomy preparation and hole quality analysis

An apparatus was prepared ad hoc for this experiment. It was composed of a control panel with a programmable logic controller (PLC) and a step motor with a man-machine interface (MMI). These devices were used to produce continuous drilling movements. which were pre-determined (position, depth, and load) with high precision by the investigator. A device was used to stabilize bone samples while drilling. Fifteen osteotomies of each group were prepared with a gentle surgical technique using a surgical drill at a rotational speed recommended hv the manufacturer of each implant system. In the present study, a load of 2 kg was used, according to the procedures of other authors (Lavelle & Wedgwood 1980; Misir et al. 2009)) After the perforations (15 osteotomies), the five-first holes of each group were selected and submitted to a revolutionary concept in automated roundness inspection to measure the hole precision (Talyrond 585, Taylor Hobson, Chicago, IL, USA) (Fig. 2). The five holes were analyzed at three



Fig. 2. Image of the apparatus used to measure the hole precision in the samples.



Fig. 3. Different evaluations and measurements with different drills.

levels, top (p1), middle (p2) and bottom of the hole (p3), showing in the scheme of the Fig. 3. A percentage average of the data was



Fig. 4. Image of the computed torquimeter used to measure the insertion torque.

Table 1.	Data of	the impl	ant stability	quotient
(ISQ) me	asured in	n differen	t groups	

	Mean & SD	Median	Range
Group 1	$84 \pm 2.29 \\ 75 \pm 2.51 \\ 74 \pm 2.41$	84	81–87
Group 2		75	70–79
Group 3		74	69–78

made in relation of the roundness precision (mean difference of the actual hole profile respect to an ideal circle).

Fixture installation, IT and RF measurements

Ten implants of each group were installed in the last 10 osteotomies not used for the roundness measurement. For the implants installation a Torque Testing Machine - CME (Técnica Industrial Oswaldo Filizola, São Paulo, Brazil), which is fully controlled by software DynaView Torque Standard/Pro M (Fig. 4), with test speed of 5 rpm and angular measuring system with a resolution of 0.002, was used by avoiding possible differences caused by human movement during implant installation. Furthermore, the implants were inserted with a controlled force of 10N, in accordance with standard ASTM F543-2 (2007). The peak IT was measured automatically for all of the implants. Following the final level seating of the implants, all samples underwent resonance frequency analysis (RFA) to measure the implant stability. A Smartpeg[™] (Integration Diagnostics AB, Göteborg, Sweden) was screwed into each implant and tightened to approximately 5N. The transducer probe was aimed at the small magnet at the top of the Smartpeg at a distance of 2 or 3 mm and held stable during the pulsing until the instrument beeped and displayed the ISQ value. The implant stability quotient (ISQ) values were measured by Osstell[™] Mentor (Integration Diagnostics AB, Göteborg, Sweden). The ISQ values were measured in two different directions, and the 20 values (2 per implant) were used to obtain a mean ISQ value per group (Huang et al. 2002; Turkyilmaz 2006; Kahraman et al. 2009; Roze et al. 2009; Hong et al. 2012).

Statistical analysis

The D'Agostino & Pearson omnibus test was used to test normality of distributions



Fig. 5. Bar graph showing the comparisons of the ISQ values and p values between groups.

of each group. Statistical analyses were performed using a one-way analysis of variance (ANOVA) to determine the differences between the three groups comparing the three methods (RFA, IT and hole precision) for each of the parameters evaluated. For the comparisons between groups at each observation methods, the Student's unpaired t-test was applied. P < 0.05 was considered as the significance level. The data were processed in the software Unscrambler®, 6.11(CAMO version A/S, Trondheim, Norway).

Results

Resonance frequency analysis (RFA)

The mean resonance frequency values for the three investigated implant designs, standard deviation (SD) and range are summarized in Table 1. Using a one-way ANOVA test comparing the three groups, the test showed high significance ($P = 5.6 \times 10^{-20}$), and it is thus concluded that there is an important effect among the groups, with significance set at P < 0.05. The variations in the RFA among the groups, applying the t-test, are shown in the bar graph of Fig. 5 along with the p-values. The single drill (group 1) achieved a significantly higher ISQ than the multiple drills for osteotomy (groups 2 and 3).

Insertion torque value analysis

During the insertion torque testing, all of the implants were stable and anchored in bone. The mean resistance to insertion torque values, standard deviation and range are summarized in Table 2. The groups were compared using a one-way ANOVA test; because F crit (= 3.35) is smaller than F calc (= 22.95), the test is highly significant (p = 1.5×10^{-6}), and it is thus concluded that there is an important effect among the groups, with significance set at P < 0.05. When the values were compared among the groups using the t-test, statistically significant differences were found as shown in the graph of Fig. 6 with the respective p-values. Again, group 1 showed significantly higher IT values than groups 2 and 3.

Table 2. Data of the implant insertion torque (IT) in Ncm, measured in different groups

	Mean & SD	Median	Range
Group 1	71.5 ± 4.1	71.8	61–75.8
Group 2	61.6 ± 3.6	61.8	55–68
Group 3	$\textbf{62.0} \pm \textbf{3.5}$	61.4	56.1-66.3



Fig. 6. Bar graph showing the comparisons of the removal torque values and p values between groups.

Hole precision analysis

These data showed an average accuracy of circularity measured in 3 points for group 1 of 93% (Fig. 7), in the group 2 of 76% (Fig. 8) and for the group 3 of 88% (Figs. 9). Groups 1 and 3 showed significantly better precision as compared to the group 2 (P < 0.05).

Discussion

The aim of the present study was to compare different drill systems used for implant site preparation through the insertion torque (IT), primary stability and hole quality of dental implants inserted in artificial cortical bone blocks. The best results for each of these outcomes were achieved by the IDAll implants, for which the implant site preparation was made using a single, high performance drill. This might be a possible explanation for the excellent clinical results recently presented (98% of implant survival) in the evaluation of 350 implants installed with a single drilling step in several clinical procedures (Bettach et al.2015).

In general, the insertion torque determines the primary implant stability, which is considered the most important factor for a successful implant treatment. The distinct ranges of implant primary stability have been distinguished by the resonance frequency method (Martinez et al. 2001; Molly 2006; Sim & Lang 2010; Katsoulis et al. 2012;). Thus, IT was related with the RFA using the Osstell as a method to measure implant stability. The results of the present study interestingly showed that the IT and



Fig. 7. Graph of the circularity test of the IDI implants (Group 1).



Fig. 8. Graph of the circularity test of the Straumann implants (Group 2).

initial stability increased according to the hole quality, suggesting a positive correlation between these parameters, that could be further investigated in subsequent investigations. It may be speculated that the more precise the cylindrical/conical hole produced by the drill, the better the fit with the implant and, consequently, the higher the possibility of achieving an optimal implant primary stability, with favorable consequences on osseointegration and load-bearing capacity. Conversely, an implant with a poor fit to the drilled site may achieve poor stability and have an increased risk of excessive micromovements at the bone-implant interface, with deleterious effects on osseointegration.

The initial stability is known to be highly dependent on the local bone density. The IT also increases according to the thickness of the cortical bone, and a slight increase was observed for initial stability. This suggests that the volume of high dense cortical bone affects the initial stability and it corroborates a recent study in which the same artificial bone model was used (Cleek et al. 2007; Motoyoshi et al. 2007; Salmória et al. 2008). Then, to there were variations in the type of bone (quality) during measurements, we used a completely cortical bone block.

The osteotomy using different methods (piezoelectric vs. conventional drilling) has demonstrated different clinical results (Da Silva Neto et al. 2014) i.e., the stability of implants placed using the piezoelectric method was greater than that of implants placed using the conventional technique. These data may indicate that the surgical technique has an important function in the implant stability (Bilhan et al. 2010). Drill design should allow for the less traumatic surgery as possible, and this consideration should determine drill characteristics as flute geometry and design, sharpness of the cutting tool, diameter, as well as drilling protocol features such as drilling speed, axial force (pressure applied to the drill), bur angulation, irrigation, torque and thrust forces, use of multiple burs with incremental diameter vs. one-step drilling (Oh et al. 2011; Augustin et al. 2012) Also bone characteristics like cortical bone thickness and bone density, as well as the time needed for implant site preparation may affect heat generation during drilling (Tehemar 1999; Chacon et al. 2006; Gronkiewicz et al. 2009).

In previous study in which the temperature generation using single IDI drills was compared to the multiple drills of other two systems, the results showed no significant difference in the heat produced in the bone surrounding the implant site, measured with a thermocouple (Gehrke et al. 2015). While there might have been a slight overestimation of the temperature in the groups using multiple drills, due to a reduced recovery between consecutive drilling steps, this



Fig. 9. Graph of the circularity test of the Nobel Replace® implants (Group 3).

allowed for a standardization of the protocol. The possibility of shortening the overall drilling procedure may prove beneficial to tissues reducing the local damage as well as the patients' discomfort. In fact, prolonged tissue exposure may be detrimental to the postoperative course due to the increased release of pro-inflammatory cytokines and consequent amplified inflammatory response (Penarrocha et al. 2006).

The blocks of synthetic bone used in the present study have been specifically designed to reproduce the physical properties of the cortical bone in terms of hardness, density, elasticity (Young module), in accordance with the ASTM F1839/08. The physical features of these synthetic bone blocks are homogeneous throughout their volume, so as to obtain a good standardization of the procedures and avoid introducing possible sources of bias in the measurements. The use of synthetic bone blocks, as well as

other standardized procedures, has been recommended by a recent systematic review aiming at evaluating, through an analysis of published papers on this topic, the main factors affecting the temperature increase and drill wear during implant site preparation (Möhlhenrich et al. 2015). On the other hand, due to natural inhomogeneities in the human jawbones, there might be differences between such synthetic model and the in vivo situation. Finally, only blocks of bone type 1 were used, which is not so common in clinical situations. This was done because it is in this type of bone where the cutting precision is more important and also where the insertion torque and ISQ values are more uniform between groups.

Biologic and anatomical consequences such as the osteotomy quality of cortical bone seem to be significant factors affecting primary stability, and estimation of bone density and the optimal selection of drill system are important.

Conclusion

The present study, within the limitations, showed that a single bur system achieves greater precision in the osteotomy than a conventional drilling sequence while preparing implant site and may be considered as safe as the latter. Furthermore, it may increase the torque of insertion and consequently the initial stability of the implants. More studies, both *in vitro* possibly on human bone samples, and in vivo, will help to achieve a better understanding the importance of hole quality during the preparation of implant sites.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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ARTICLE

Osteotomy at Low-Speed Drilling without Irrigation Versus High-Speed Drilling with Irrigation: an Experimental Study

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Osteotomy at Low-Speed Drilling without Irrigation *Versus* High-Speed Drilling with Irrigation: an Experimental Study



Osteotomia a Baixa Rotação sem Irrigação Versus Alta Rotação com Irrigação: Estudo Experimental

João GASPAR¹, Gonçalo BORRECHO², Pedro OLIVEIRA¹, Francisco SALVADO³, José MARTINS dos SANTOS¹ Acta Med Port 2013 May-Jun;26(3):231-236

ABSTRACT

Introduction: Excessively traumatic surgery can adversely affect the maturation of bone tissue and consequently diminish the predictability of osseointegration so the mechanical and thermal damage should be minimized during surgical procedure. The purpose of this study is to evaluate immediate histological alterations in rabbit tibias, produced by low speed drilling (50 rpm) without irrigation and conventional drilling (800 rpm) under profuse irrigation.

Material and Methods: Thirty-six implant osteotomies were created in the tibias of 6 White female rabbits. Drilling began with a 1.5 mm round bur, followed by 2.0 mm, 2.5 mm and 3.5 mm helical drills. The posterior tibial cortex was evaluated as the positive control, and it was preserved during the surgical procedure. The receptor beds were collected for histological analysis.

Results: All defects showed regular edges. Hematoxylin eosin (HE) sections showed that both techniques preserved the bone structure and the presence of living cells. No histological differences between the two surgical drilling techniques were found.

Conclusions: Based on our results, we can conclude that the effects of implant site preparation on bone by low speed drilling (50 rpm) without irrigation and conventional drilling (800 rpm) under abundant irrigation are similar. Both surgical drilling techniques preserve bone-cell viability and the clinician can decide which drilling technique to use, based on other criteria.

Keywords: Osteotomy; Osseointegration; Rabbits; Therapeutic Irrigation; Tibia; Wound Healing.

RESUMO

Introdução: A cirurgia traumática pode afetar a maturação do tecido ósseo e, diminuir a previsibilidade de osteointegração, pelo que a lesão mecânica e térmica deve ser minimizada. O objectivo deste estudo foi avaliar as alterações histológicas imediatas provocadas pela osteotomia a 50 rpm sem irrigação e a 800 rpm com irrigação, no osso do coelho.

Material e Métodos: Foram efectuadas 36 perfurações (18 com cada técnica) nas tíbias de seis coelhos adultos. A sequência de brocas utilizada foi: uma broca esférica com 1,5 mm de diâmetro, uma broca piloto com 2,0 mm de diâmetro, e uma broca com 3,5 mm de diâmetro. A cortical posterior das tíbias foi preservada, constituindo o osso de controlo. Procedeu-se à recolha das tíbias com os defeitos a analisar, para observação com microscópio óptico e análise qualitativa.

Resultados: Os defeitos ósseos apresentaram bordos regulares. Observou-se tecido ósseo viável, vascularizado e com presença de osteócitos junto aos defeitos. A estrutura haversiana e lamelar do tecido encontrou-se mantida, bem como a rede vascular. A matriz extracelular não apresentou alterações. Os resultados indicam não haver diferenças histológicas entre as osteotomias a 800 rpm com irrigação e a 50 rpm sem irrigação.

Conclusão: O nosso estudo sugere que as alterações no tecido ósseo provocadas pela osteotomia a 50 rpm sem irrigação e a 800 rpm com irrigação são semelhantes, e que ambas as técnicas mantêm o tecido ósseo viável para a colocação de implantes e respectiva osteointegração, cabendo ao clínico a escolha, em função de outras variáveis.

Palavras-chave: Coelhos; Irrigação Terapêutica; Osteointegração; Osteotomia; Tibia.

INTRODUCTION

Oral rehabilitation with endosseous implants represents a safe and viable treatment option with high success rates; however, it depends on osseointegration.¹⁻³ There are many parameters that must be taken into account during implant site preparation which should be as atraumatic as possible, for osseointegration to occur.^{1.4-7} Excessively traumatic surgery can adversely affect the maturation of bone tissue at the bone/implant interface and consequently diminish the predictability of osseointegration⁸ so the mechanical and thermal damage should be minimized during surgical procedure.^{7,9} The viability of the bone tissue depends on several factors: rotational speed^{6,10-12}; irrigation^{7,13-15}; type of osteotomy (continuous or intermittent)⁸; temperature¹⁶; pressure applied during drilling¹⁷; shape, size and cutting edge of the drills¹⁸; duration of bone heating and density of the bone.^{7,8,19}

Implantology and its surgical techniques are in constant evolution. Most implant systems recommend similar drilling protocols (from 800 to 1500 rpm), using profuse irrigation in order to avoid overheating generated by the drill. Recently there has been suggested a new concept of low speed drilling (50 rpm) without irrigation as an alternative to the conventional procedure with irrigation.²⁰ This technique can provide some advantages including collecting autologous bone²¹ without the need for additional surgery.²² It is possible to recover directly the bone cut by the drills without contamination by saliva, which can be used for an autograft.²⁰ Low-speed drilling can also give the operator more

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precise information of the path of the drill so that the operator can correct it if necessary. Thus, by drilling at low speed it is possible to better control the osteotomy.²¹

The purpose of this study is to evaluate the immediate histological alterations, in rabbit tibias, produced by low speed drilling (50 rpm) without irrigation and conventional drilling (800 rpm) under abundant irrigation.

MATERIAL AND METHODS

Sample

This study used 6 White adults female rabbits (*Oryctolagus cunilicus*, New Zealand White) with body weights of 4.0 kg \pm 0.5 kg. The animals were acquired in a local rabbit breeder.

The animals were placed in individual cages appropriate for the species in the ward for animals of Instituto Superior de Ciências da Saúde Egas Moniz. They were fed a standard ration and had free access to water originating from the municipal supply. The animals were treated according to the European Union Directive on Animal Welfare for Scientific and Experimental (86/609/CE) and to the transposition into Portuguese legislation to the same effect (Decree-Law 197/96).

Material

IDI implant drill system (IDI[®], France) was used in this study. The drills are made of stainless steel (Sandvik 4C27A, ASTM 420F), highly resistant to wear, with great cutting capacity.

An electric motor (W.H. Implantmed[®]) connected to a 20:1 reduction contra-angle was used to perform the osteotomies.

Surgical procedure

The animals were anesthetized by intramuscular administration of a combination of 0.12 mg/kg of medetomidine hydrochloride and 20 mg/kg of ketamine. The heart and respiratory rate were monitored during the entire anesthetic period.

After skin exposure, an incision in the medial portion of the right and left tibias of each rabbit was made, followed by detachment of the periosteum to perform the osteotomies.



Figure 1 – Osteotomy at 50 rpm without irrigation.

Six osteotomies were made for each animal: three at 800 rpm with saline irrigation (right tibia) and three at 50 rpm without irrigation (left tibia) (Fig.s 1 and 2). It was maintained a distance of about 6 mm between the defects.

The drill sequence used was: 1.5 mm round bur, followed by 2.0 mm, 2.5 mm and 3.5 mm helical drills.

The pressure exerted on bone during drilling was not measured; however, all the osteotomies were performed by the same operator with low pressure and intermittently so that there is a standardization throughout the procedure. The posterior tibial cortex was evaluated as the positive control and it was preserved during the surgical procedure. After surgical procedure, the animals were sacrificed with a lethal dose of thiopental sodium intraperitoneally. The tibias were collected and the defects were fixed in 10% formaldehyde solution.

The samples were then processed, sectioned transversely and stained with hematoxylin and eosin for light microscopy observation, photography and qualitative analysis. There were made two histological sections from each one of the 36 defects, a total of 72 sections.

RESULTS

Histological analysis of the 36 osteotomies was made by observation with an optical microscope. All defects showed regular edges. As intended, the posterior tibial cortex was preserved in all parts.

All the histological sections showed more exact cutting line in the compact bone than in the cancellous bone.

For the cancellous bone, there was observed greater bone destruction in defects produced at 800 rpm with irrigation, with the presence of splinters, bleeding and disruption of bone marrow (Fig. 3).

On the other hand, with drilling at 50 rpm without irrigation, the cancellous bone was more preserved and 'cleaner' (Fig. 3).

For the cortical bone, no differences were found between the osteotomized bone and the posterior cortex (control), with both drilling techniques (Fig. 4).

Microscopic examination showed that both techniques preserved the bone structure. The lamellar and haversian systems were maintained as well as the vascular network.



Figure 2 – Bone collected during low-speed drilling (50 rpm) without irrigation.



Figure 3 – A - Osteotomy at 800 rpm with irrigation (H-E, 40x) It is observed disruption of bone marrow (2) and a splinter (3). 1: cortical bone; 2: cancellous bone; 3: splinter B - Osteotomy at 50 rpm without irrigation (H-E, 40x) It is observed preservation of cancellous bone.

1: cortical bone, 2: cancellous bone.

The extracellular matrix did not show changes (Fig. 5). Near the defects the osteocytes showed no morphological alterations.

In summary, the current results indicate that no histological differences between the two surgical drilling techniques were found (Fig. 6).

DISCUSSION

In implantology, traumatic surgery may lead to the formation of connective tissue around the implant, which will hamper its anchorage to the bone.²³ Heat is always generated during implant drilling.⁶ A significant increase in temperature can result in considerable damage in the bone tissue. Apart from thermal damage, osteotomy may also cause mechanical damage to the surrounding bone.²¹ Thus, to preserve the viability of the bone⁸ and to avoid excessive heat generation during implant site preparation, it is essential to practice a proper surgical technique.⁶

Our study, as well as several similar experimental studies,^{1,8,11,23,24} was conducted in rabbit tibias. The maxilla and the mandible are bones of intramembranous origin, unlike the tibia which is of endochondral origin. However, in the adult, the structure of the bone tissue formed by the two ossification mechanisms is indistinguishable²⁶ so the conclusions were not affected.

Clinically, there is no way to accurately measure the pressure that is applied to the handpiece during osteoto-



Figure 4 – Posterior cortical preserved (control) (H-E, 40x) 1: cortical bone, 2: cancellous bone.

my. Therefore, by keeping the rotational speed constant it is likely for the operator to apply more pressure during the drilling of cortical bone, thus producing more frictional heat and a rise in temperature of the bone tissue.¹ In this study, osteotomies were performed in dense cortical bone (type I),⁸ which apparently viable in the immediate in both drilling techniques. Thus, in less dense bone, it is expected that results are at least similar, because of lower production of frictional heat.

In the literature, there seems to be no consensus on the most recommended method of irrigation. Some authors^{14,26} reported advantages of using internal irrigation; on the other hand, according to Benington et al,⁷ it seems not to exist significant differences between the two methods. In this study, external irrigation was used (in the case of the osteotomies at 800 rpm). The osteotomies were performed at low pressure and intermittently, to avoid interference between the output of bone fragments and the intake of the cooling liquid; thus the irrigation could reach the implant bed and the tip of the drill, in order to reduce the friction caused by this. Continuous drillings in deep osteotomies can produce potentially damaging temperatures to the bone tissue.²⁷ According to Sharawy et al,⁶ it may be beneficial a waiting period between each drill sequence in an osteotomy so as to cool the bone thus avoiding an excessive heat production. Implant and surgical drilling technique interplay that provides low levels of compressive stress immediately after placement, high degrees of implant primary stability and low degrees of micromotion have been regarded as potential benefits in the quest for atemporal implant stability during the early stages of osseointegration.28 Therefore, the differences we have found in the cancellous bone between the two drilling techniques may not be relevant since implant primary stability is essentially given by the anchorage in the cortical bone.

Drill wear caused by repeated use may result in increased heat production¹⁸ and further damage to the bone tissue, thus affecting the process of osseointegration of implants.⁸ In our study, we used two new drill sequences: each sequence completed 18 osteotomies.



Figure 5 – A - Osteotomy at 800 rpm with irrigation (H-E, 400x) Cortical bone near the surgical defect. It is observed normal bone tissue.

1: cortical bone; oblique arrows: lacunae filled with osteocytes; horizontal arrows: Haversian canals

B - Osteotomy at 50 rpm without irrigation (H-E, 400x)

Cortical bone near the surgical defect. It is observed normal bone tissue.

1: cortical bone; oblique arrows: lacunae filled with osteocytes; horizontal arrows: Haversian canals

The aim of this study was to evaluate histologic alterations (in the immediate period) caused by two types of osteotomy: 800 rpm with irrigation, commonly used by many clinicians and in previous studies^{29,30} and 50 rpm without irrigation, a more recent alternative to conventional procedures, which can bring some advantages.^{20,21} Giro et al³¹ evaluated the effect of the surgical technique on implant integration, by performing osteotomies at 50 rpm without irrigation and 900 rpm with irrigation. The authors concluded that both techniques showed similar results and did not affect the integration of implants.³¹

Kim et al²¹ measured the temperature change during implant site preparation by drilling at 50 rpm without irrigation with three different drill systems, and in neither case was excessive heat production. Irrigation can have a negative effect by washing away and dissolving osteoinductive signaling proteins and other biomolecules present in bone extracellular matrix, which have an important role in bone

remodeling.20

One of the advantages of the concept of low-speed drilling without irrigation is the easy control of the drilling path; however, it has the disadvantage of being a more time consuming procedure. During conventional high-speed drilling, there may be an unintentional deviation of the drilling path. Low-speed drilling can inform the operator more precisely that the path has changed so that the operator can correct it if necessary.²¹ Furthermore, the potential risk of damaging the inferior alveolar nerve or invading vital structures such as the maxillary sinus is minimized with this technique.³²

The recovery of autologous bone through suction filters (in the conventional drilling procedure with irrigation) is more difficult; in addition, the presence of microorganisms is typically quite high, due to the presence of saliva,²¹ with the risk of complications associated with infection of collected bone particles. Therefore, decontamination methods (with chlorhexidine or clindamycin) of collected bone particles through suction filters should be considered to reduce the risk of graft failure due to bacterial contamination.³³ Lowspeed drilling without irrigation is particularly recommended when an autograft is indicated since it allows to collect the bone directly from the drill, reducing contamination by saliva. The bone particles collected by this method are larger and viable, with osteocytes and bone architecture maintained.²⁰

This study only evaluated histologic alterations in bone tissue in the immediate period: It was observed bone tissue with regular edges, maintaining the characteristic lamellar structure with apparently normal osteocytes in both techniques. In our observations we haven't found alterations in the architecture of bone tissue that could determine severe anatomic alterations of the involved site. It was not possible to determine if there was bone necrosis in either case since the period of time between the surgery and the histological evaluation was too short.

It would be interesting to proceed with the study of bone tissue changes with an evaluation in a late period (to evaluate whether the changes would also be superposable), or with implant placement and evaluation of integration thereof.

CONCLUSION

Based on our results, we can conclude that the effects of implant site preparation on bone by low speed drilling (50 rpm) without irrigation and conventional drilling (800 rpm) under profuse irrigation are similar. Both surgical drilling techniques preserve bone-cell viability and the clinician can decide which drilling technique to use, based on other criteria.

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Figure 6 – A - Osteotomy at 800 rpm with irrigation (H-E, a: 100x; b: 400x)

The edges of the defect are regular, with viable bone tissue. It is observed gaps filled by osteocytes (oblique arrows) and lamelar and haversian systems maintained (horizontal arrows).

1: cortical bone

B - Osteotomy at 50 rpm without irrigation (H-E, c: 100x; d: 400x)

The edges of the defect are regular, with viable bone tissue. It is observed gaps filled by osteocytes (oblique arrows) and lamelar and haversian systems maintained (horizontal arrows).

1: cortical bone;

2: preserved cancellous bone.

CONFLICT OF INTERESTS

None stated.

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Implant Survival after Preparation of the Implant Site Using a Single Bur: A Case Series

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ABSTRACT

Background: Implant site preparation usually consists of several consecutive drilling steps, performed using different burs with increasing diameter.

Purpose: The purpose of the present study was to report the clinical outcomes of edentulous patients that underwent implant treatment, in which a special bur that allows preparation of the implant site in a single drilling step was used.

Material and Methods: One hundred forty-nine patients (79 males, 70 females, mean age 51.8 ± 12.2 [SD] years, range 20–80 years) have been rehabilitated using different oral surgery procedures. A total of 350 implants were inserted (171 in the maxilla and 179 in the mandible). A barrier membrane was used for covering a total of 126 implants. Fifteen implants were placed by using the osteotome technique and 52 by using the lateral sinus lift procedure. Eighty-nine implants were placed in postextraction sockets. Thirty-six implants underwent immediate loading. Implant survival, peri-implant bone level change, and patients' satisfaction were the main variables assessed.

Results: No patient dropout occurred. The mean follow-up on a patient basis was 21.5 ± 3.1 months (range 12–27 months). A total of seven implant failures were recorded in six patients, leading to a mean implant survival of 98.0% (96.0% on a patient basis). The mean peri-implant bone loss after 1 year was 0.58 ± 0.44 mm (n = 282). Apart from implant failures, no biological nor mechanical complications occurred. All patients demonstrated full satisfaction.

Conclusions: The use of a single bur for implant site preparation allows the reduction of the time needed for the surgical procedure, without compromising the clinical outcomes. Further, long-term comparative studies are needed to confirm the results of this study.

KEY WORDS: dental implants, implant site preparation, implant survival, surgical drills

INTRODUCTION

The use of dental implants for the treatment of edentulism continues to increase worldwide and over the years has evolved into a predictable procedure, which is rapidly becoming the preferred method of tooth

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replacement. In addition to function restoration, there is increased awareness of and demand for esthetics in traditional restorative dentistry as well as implant-related care. Predictable delivery of highly esthetic, naturally appearing implant restorations is dependent on a number of factors, some of which are related to the morphology and to hard and soft tissue quality of the intended implant site and others to the implant features or to some steps of the surgical protocol.

Implant site development is a very important phase of the surgical procedure. A minimally traumatic procedure is recommended for preserving as much as possible the healing potential of bone and soft peri-implant tissues and to reduce crestal bone loss as well. Hence implant site preparation becomes critical for achieving a predictable osseointegration and for obtaining a pleasing natural implant restoration. Among the factors correlated to implant site preparation, the rising of the

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temperature during drilling has long been identified as critical to preservation of the surrounding tissue.¹⁻⁴ A temperature of 47°C for 1 minute in fact has been reported to cause bone necrosis at the drilling site.³ The latter may hinder osseointegration process and is one of the most credited reasons for excessive early periimplant bone loss, which may compromise implant stability as well as facilitate bacterial infiltration and peri-implantitis.⁵ Control of the heat generation may be achieved using irrigation with cool water, and adopting a correct combination between the drill rotation speed, the drilling time, the bur angulation, and the pressure applied during site preparation.⁶⁻⁹ In particular, it has been suggested that a combination of high rotation speed and a large applied force may be desirable as this allows a faster site preparation and a minimum increase of temperature as compared with lower rotation speed and pressure.^{6,7} Such factors, in turn, are dependent on the bone quality at the intended implant site, by the site depth and by the features of the bur, like diameter, shape, and above all the sharpness of the threads.⁹⁻¹⁶ Sharp burs may reduce friction force generation which is likely to produce heating of the site. Drill wear may also be an issue in heat generation at the drilling site.^{17,18}

Correct preparation of the implant site ensures efficient and accurate installation. Incremental site preparation using a sequence of increasing diameter drills has long been characterized as an implant site preparation technique. However, using a host of drills for any single implant may become boring for clinicians, especially when multiple implants are to be placed, and for the patient as the duration of the intervention may be excessively long, causing discomfort. Furthermore, prolonged tissue exposure may be detrimental to the postoperative course due to the increased release of pro-inflammatory cytokines and consequent amplified inflammatory response.¹⁹ Therefore, any simplification of the techniques for site preparation can be favorably accepted by both clinicians and patients. Some improvements of the drill design and drilling technique have been proposed in order to reduce the risk of overheating the implant site and simplify the procedure.²⁰⁻²² Recently, a four-bladed drill with a special design, which allows to prepare implant site with a single drilling step in different types of bone, has been introduced in the market.

The purpose of the present report is to describe our clinical experience with such type of drill in a number of clinical applications for the implant treatment of partially and totally edentulous patients. Here, clinical and radiographic outcomes as well as patient satisfaction after at least 1 year of follow-up are reported.

MATERIALS AND METHODS

This report is based on a series of patients consecutively treated at a single private practice office in Paris. All patients were rehabilitated by means of implantsupported prostheses, for different indications. All cases were treated by a single clinician with more than 10 years of experience in implant dentistry. The patients were treated following the principles embodied in the World Medical Association Helsinki Declaration of 1975 for biomedical research involving human subjects, as revised in 2000.²³

Patients' inclusion criteria were the following:

- at least 18 years of age;
- absence of general medical contraindications for oral surgery procedures (American Society of Anesthesiologists ASA-1 or ASA-2);
- full-mouth bleeding score and full-mouth plaque score less than 25% at baseline;
- partially or totally edentulous or in need for extraction in order to be rehabilitated by means of implant-supported prostheses;
- absence of ongoing infection at the intended implant site or sinus pathologies for those scheduled for maxillary sinus augmentation; and
- able to sign the informed consent form.

Patients were excluded if they presented one of the following exclusion criteria:

- any systemic disease, condition, or medication that might compromise healing or implant osseointegration;
- inability or unwillingness to return for follow-up visits; and
- inability or unwillingness to maintain a good level of oral hygiene throughout the study.

The following clinical procedures were performed, according to conventionally accepted protocols: guided bone regeneration (GBR) with implants placed simultaneously or in a second surgical phase; maxillary sinus elevation using the crestal approach (osteotome technique); maxillary sinus elevation using the lateral approach with implants placed simultaneously or in a second surgical phase; single-tooth implants placed in fresh postextraction sites (type I according to the Hammerle classification²⁴) with either immediate or delayed restoration; single-tooth implants placed in extraction sockets after healing of soft tissues (type II implants); multiple tooth extraction and immediate implant placement and restoration (partial prosthesis); full bridges with immediate loading. All patients underwent cone beam CT before surgery as a routine diagnostic approach in order to carefully evaluate the available bone at the intended surgical site and planning the correct implant size and three-dimensional orientation.

All patients received prophylactic antibiotic therapy consisting of 2 g of amoxicillin (or clindamycin 600 mg if allergic to penicillin) 1 hour before the implant placement procedures. All patients rinsed for 1 minute with chlorhexidine digluconate mouthwash 0.2% prior to the surgery. Local anesthesia was induced using articaine with adrenaline 1:100.000.

The surgical procedure started with a minimal full-thickness flap elevation with marginal incisions extended to one tooth mesial and one tooth distal to the implant site without vertical incisions.

In case of implants immediately inserted in fresh postextraction sites, after atraumatic tooth extraction the socket was debrided and the implant carefully placed in the correct prosthetically driven position, with the implant platform leveled 1 mm below the marginal level of the buccal wall.

Implant site preparation was always performed using specially designed cylindro-tapered drills with four bladed edges (ID^{ALL} drills, Implant Diffusion International, Montreuil, France) (Figure 1). These drills are available with four drilling lengths (10, 12, 15, 18 mm) characterized by different color codes, and three different diameters (3.8, 4.2, 5.2 mm). They allow a single drilling procedure before implant placement in soft and normal bone (types II–IV), and up to two drilling steps with two increasing diameters in dense bone (type I). The drilling sequence is shown in Figure 2, A–C. The recommended rotation speed is 1,500 rpm and cooling is obtained by copious irrigation with physiological solution. Such four-bladed drill is used without in-andout movements.

All implants (ID^{ALL}, Implant Diffusion International) were made of TiAl6V titanium alloy with a sandblasted acid-etched and TiO2 coated surface. Such implants had the following features: a switched platform, a cylindrical-tapered shape, an aesthetic gold



Figure 1 Four-bladed drill used in the present study. The red band indicates 10-mm drilling length.

polished neck, a morse taper connection, an antiunscrewing groove, double twist threads, and a catch base with large threads and tapered core. They are recommended for use in postextraction sockets and are specially designed for self-tapping, in order to optimize the achievement of primary stability in any type of bone density, and favoring the immediate loading protocols. The recommended rotation speed of the implant during insertion is 15 to 20 rpm.

After implantation, the surgical flaps were sutured, achieving a soft tissue primary closure. Sutures were removed 1 week later and the patients were seen monthly for prophylaxis. All patients continued to take the antibiotic postoperatively -1 g amoxicillin (or 300 mg clindamycin) twice a day for 5 days. They also took nonsteroidal anti-inflammatory drugs if needed. Chlorhexidine digluconate mouthwash twice a day was prescribed for 3 weeks postsurgery.

Follow-Up

Patients were scheduled for follow-up visits at 6 months after loading, 12 months, and once a year thereafter, up to



Figure 2 Drilling sequence. *A*, Flap elevation with ridge exposure. *B*, Site preparation using one single bur. *C*, Implant insertion at low-speed rotation.

5 years. Orthopantomograms and periapical radiographs were taken at implant insertion; periapical radiographs were then taken at the prosthesis delivery and at each scheduled follow-up visit. Periapical radiographs were taken using a long-cone paralleling technique and an individual X-ray holder (bite block) to ensure reproducibility.

The outcome variables under study were:

- Prosthesis success. The prosthesis is functional, even if one or more implants have failed. No mobility nor pain is present. At each follow-up visit, prosthesis stability was tested by means of two opposing instruments' pressure.
- Implant survival. The implant is in function and stable. No evidence of peri-implant radiolucency, no suppuration or pain at the implant site, or ongoing pathologic processes is present.
- Implant success. The success criteria proposed by Buser and colleagues²⁵ and Cochran and colleagues²⁶ were adopted for each implant, at each follow-up visit. These criteria were: (a) no clinically detectable mobility when tested with opposing instrument pressure; (b) no evidence of peri-implant radiolucency; (c) no recurrent or persistent peri-implant infection; (d) no complaint of pain; and (e) no complaint of neuropathies or paresthesia.

- Occurrence of complications. They include both biological complications, such as peri-implant mucositis, peri-implantitis, fistula or abscess, and mechanical or prosthetic complications like fracture of the implant and/or of any prosthetic component, screw loosening.
- Marginal bone level change. Intraoral radiographs were scanned at 600 dpi with a scanner (Epson Perfection Pro, Epson Italia SpA, Roma, Italy) and the peri-implant bone level was assessed with an image analysis software (UTHSCSA Image Tool version 3.00 for Windows, University of Texas Health Science Center in San Antonio, TX, USA) by an experienced evaluator. The known distance between the screw threads or the length of the implant was used to calibrate each image. The implant platform was used as the reference for each measurement. Radiographs taken at the prosthesis delivery served as the baseline for evaluation of the marginal bone level change over the study period. The linear axial distance between implant platform and the most coronal bone-to-implant contact was measured. In order to have a single value for each implant, mesial and distal values were averaged.
- Oral hygiene level. The presence of plaque and bleeding on probing was evaluated at four surfaces per each tooth or implant and expressed as percentage of positive sites over total sites (full-mouth score).
- Postoperative course. One week after surgery, patients were asked to take a few minutes for a survey investigating the most common items related to quality of life in the postsurgical period. Such items were: pain (on a 0–100 visual analog scale), tissue swelling, analgesic drugs taken.
- Patient satisfaction. Aesthetics, mastication function, and phonetics were assessed after 1 year of loading using a questionnaire. Each item was rated according to a five-point Likert-type scale choosing among the following possible answers: excellent, very good, good, sufficient, or poor.

Statistical Analysis

The 1-year outcomes of the different types of rehabilitation were compared using the Pearson's chi-square test, considering the implant as the analysis unit, and assuming p = .05 as the significance level. In particular, the following comparisons were made: implants in fresh extraction sites versus healed sites; implants simultaneous to GBR procedure versus implants placed in a second surgical session respect to GBR; postextraction implants with immediate versus delayed restoration; lateral approach for maxillary sinus augmentation with simultaneous versus delayed implant placement; crestal approach versus lateral approach for maxillary sinus augmentation. Kaplan–Meier statistics (life table analysis) was used to assess the implant cumulative survival rate throughout the study.

RESULTS

Based on the selection criteria, 149 patients (79 females and 70 males) were treated from September 2010 to December 2011. Patients' mean age was 51.8 ± 12.2 years (range 20–82 years). Each patient accounted for a single prosthetic rehabilitation. A total of 350 implants have been inserted. All implant sites were prepared using a single drill. Table 1 resumes the number of implants placed for each type of rehabilitation. One hundred seventy-one implants have been placed in the maxilla and 179 in the mandible. Figures 3 and 4 show the distribution of implants per each site in the maxilla and mandible, respectively. The mean follow-up was 21.6 ± 3.1 months (range 12–27 months). No patient dropped out to date.

Bone type distribution according to the Lekholm and Zarb classification²⁷ was: 39% type II, 52% type III, 9% type IV.

A total of seven implant failures were recorded, for an overall implant cumulative survival of 98.00% on an implant basis (Table 2), and of 95.97% on a patient basis. Prosthesis success was 99.3%. All failures occurred within 4 months of implant placement. Two of them occurred in a 59-year-old woman who smoked more than 10 cigarettes/day. She underwent immediate implant placement in fresh extraction sockets and immediate restoration with provisional crowns. The other five failures did not compromise prosthesis function. One of them occurred in a patient with a full bridge that was placed in function according to an immediate loading protocol. The remaining four failures were recorded during healing phase. The failed implants were replaced by implants of similar size that achieved osseointegration and were restored without further complications. No biological or mechanical complication was recorded to date.

TABLE 1 Summary of the Outcomes of the Different Surgical Procedures				
Type of Rehabilitation	No. of Implants	No. of Failures	Implant Survival (%)	
Implants in healed sites	32	0	100	
GBR and implants the same day	54	1	98.1	
GBR and implants in two different surgical steps	72	1	98.6	
Osteotome technique for sinus lift	15	1	93.3	
Lateral sinus lift with delayed implant placement	38	0	100	
Lateral sinus lift with simultaneous implant placement	14	0	100	
Type II postextraction implants	27	0	100	
Type I postextraction implants with delayed restoration	14	1	92.8	
Type I postextraction with immediate delivery of provisional crown	28	2	92.8	
Postextraction on partially edentulous with provisional crown	20	0	100	
Full bridge with immediate loading	36	1	97.2	
	350	7	98.0	

GBR, guided bone regeneration.

No significant difference in implant survival was found between postextraction implants and implants placed in healed sites (p = .84), nor between postextraction implants submitted to immediate or delayed restoration (p = .93). Also for reconstructive procedures like sinus augmentation and GBR, no difference in survival was found between implants placed simultaneously or in a subsequent surgical session (p = 1.00 for both procedures), nor between lateral and crestal approach to maxillary sinus augmentation (p = .51).

The mean peri-implant bone loss evaluated after 1 year of function was 0.58 ± 0.44 mm (n = 282 implants). The remaining 61 implants could not be evaluated due

to poor quality of the radiographs that did not allow a precise assessment of the peri-implant bone level.

Postsurgical quality of life survey was available for 145 patients (97.3%). Only patients submitted to the maxillary sinus augmentation procedure with lateral approach had pain levels higher than 30/100 in the first 4 days, and took analgesics in the same period. They also reported swelling in the first 3 days. Conversely, patients undergoing other surgical procedures reported pain levels of less than 20/100 since the first day postsurgery, and took negligible amounts of analgesics. Also, the swelling was negligible in the first 2 days and absent thereafter.



Figure 3 Implant distribution in the maxilla.



A total of 138 questionnaires (92.6% of patients) were evaluated. Patient satisfaction after 1 year of function was very high. A score of "excellent" or "very good" (pooling together these two answers) was reported in 97.8%, 94.9%, and 99.3% for aesthetics, mastication function, and phonetics, respectively.

DISCUSSION

This study reports excellent clinical and radiographic results using a special drill for the preparation of the implant site. It may be speculated that such a fast drilling phase, causing a decrease of the overall surgical time in which tissues remain exposed, also reduces tissue suffering. This may lead to better tissue preservation, reduced postoperative discomfort, and better patient acceptance of the treatment.

Excessive heating of the surgical site during drilling has been advocated to be detrimental for tissue healing, causing excessive bone loss.^{1–5} The temperature increase is also related to bone density that is to the hardness of

the bone tissue and its resistance to drilling. The latter depends on the local bone composition, namely the ratio between cortical and cancellous bone.13,14,28 The thicker the cortical layer, the harder the bone and the higher the risk of causing elevated temperatures when drilling. For this reason, it has been recommended to adopt different protocols for implant site preparation, in relation to bone tissue density.^{13,14} Conventional protocols consist of different numbers and types of drills used and different rotation speed. It has been observed that the use of sharp drills, in combination with high rotation speed, allows the creation of the implant site in a very short time, reducing the risk of developing excessive heat.^{15,20,22} Conversely, the use of worn burs makes it difficult to create a breach into the bone, with a consequent prolonged tissue exposure to heat, which, in turn, increases the risk of bone necrosis. According to the manufacturer, the drills used in the present study can be used at least 50 times in dense bone without reducing their performance, without showing signs of wear and

TABLE 2 Life Table Analysis						
Months from placement	No. of implants	No. of failures	No. of dropout	Interval survival (%)	Cumulative survival (%)	
0–6	350	7	0	98.0	98.0	
6–12	343	0	0	100	98.0	
12–18	338	0	0	100	98.0	
18–24	326	0	0	100	98.0	
24–30	140	0	0	100	98.0	

deformation and without causing excessive high temperatures at the drilling site. This well compares with a previous in vitro study reporting that stainless steel and ceramic burs can be safely used up to 100 times before showing signs of wearing that might compromise their cutting efficiency.¹⁷

With the drill type used in the present study, no excessive bone loss around implants has been observed and 98% of the implants have remained stable during the observation period.

The drills used in the present study, however, have some limitations. In fact, with the incremental site preparation technique it is possible to correct the axis properly, in case the first few drills have created a misaligned implant site. Hence, with modification of the drilling axis of the larger burs the final site can fit the original project of the treatment plan. With a reduced number of steps, down to a single drilling phase, a greater precision is required as it is not possible to correct misalignments. Therefore, it can be recommended to adopt a surgical mask to drive the bur properly, at least for the early procedures, for a learning curve is required even in case of experienced surgeons.

In the present study, very restrained postsurgical symptomology was reported. The pain levels, swelling, and the amount of analgesics taken by the patients were very low, with patients demonstrating a high acceptance of the treatment. The 1-year questionnaire also proved that the treatment was very satisfying to patients, which expressed positive judgments for both esthetic and functional aspects. These excellent results may be at least in part due to the minimally invasive implant site preparation procedure proposed in this study. Speeding up and simplifying the clinical procedure may allow a better control of tissue suffering and of the related local inflammatory process, minimizing postoperative pain and swelling. Furthermore, minimally invasive procedures may preserve the healing potential of the tissues, improving and accelerating implant osseointegration and soft tissue healing, with positive consequences for both implant functionality and aesthetic appearance of the restoration.

Furthermore, no significant difference in clinical outcomes was found among different types of implantbased rehabilitations. It may be speculated that the present minimally invasive surgical procedure for implant placement may contribute to achieve a highly predictable clinical outcome in several types of implantbased clinical applications.

CONCLUSION

One-step drilling may lead to excellent outcomes, with advantages for the surgeon in terms of simplification of the implant site preparation technique and speeding up of the surgical procedure, and for the patient as well, due to faster treatment time and decreased postsurgical tissue suffering, which may lead to better acceptance of the implant therapy.

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ARTICLE

Temperature Changes in Cortical Bone after Implant Site Preparation Using a Single Bur versus Multiple Drilling Steps: An In Vitro Investigation

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Temperature Changes in Cortical Bone after Implant Site Preparation Using a Single Bur versus Multiple Drilling Steps: An In Vitro Investigation

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ABSTRACT

Objectives: The study aims to test the hypothesis of no differences in temperature variation by using a single bur for implant site preparation as compared with conventional drilling sequence using multiple burs with incremental diameter.

Materials and Methods: Synthetic blocks of bone (type I density) were used for drilling procedures.

Three Groups Were Evaluated: Group 1 and Group 2 – drilling with three consecutive burs for a 4.1 mm cylindrical implant and for a 4.3 mm conical implant, respectively; Group 3 – drilling with a single bur for a 4.2 mm conical implant. For each group, 20 drilling procedures were performed without irrigation and 20 with external irrigation. The temperature in the cortical bone during osteotomy for implant site preparation was measured through a thermocouple.

Results: The mean temperatures and standard deviations for the drilling without irrigation were: 25.5 ± 1.24 °C for Group 1; 28.1 ± 1.76 °C for Group 2; 26.5 ± 1.79 °C for Group 3. Considering the drilling with irrigation, the mean values and standard deviations were: 20.4 ± 1.17 °C for Group 1; 22.2 ± 1.38 °C for Group 2; 20.2 ± 0.83 °C for Group 3. Groups 1 and 3 yielded similar results, while Group 2 displayed significantly higher temperature increase than the other two groups.

Conclusions: The single bur drilling protocol did not produce greater bone heating than the conventional protocol and may be considered a safe procedure.

KEY WORDS: bone surgery, cortical bone, dental implants, irrigation methods, osteotomy, thermocouple



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INTRODUCTION

One of the issues that may contribute to a successful osseointegration of dental implants is to minimize surgical trauma to bone tissue.¹ While preparing implant site, the overheating of surrounding bone due to attrition of burs during drilling can cause local bone necrosis, through the deterioration of the organic component of the bone.^{2,3} This situation can have a direct implication in osseointegration process, influencing periimplant bone loss rate and implant survival.^{4–7}

Albrektsson and colleagues suggested that the success of osseointegration depends on six factors: implant biocompatibility, design, surface, state of the host bed, surgical technique, and loading conditions.⁸ More specifically, the critical modifiable factors are the macro and microgeometry, excessive surgical trauma,

prosthesis overload, misfit of suprastructures, or surgical site infection.^{9,10}

Several studies have evaluated the effects of overheating on surrounding bone, such as necrosis, fibrosis, bone cystic degeneration, and a general decrease of the osteoblastic activity.^{4,11,12} These are mainly caused by physical characteristics of the bone itself, which has a very low thermal conductivity that prevents the heat dissipation while drilling. Also, the inner structure of the bone has importance in determining the reaction to heat stress. In fact, it was known that medullar bone, due to its greater vascularization, has a higher capacity of dissipating heat than cortical bone.^{1,12}

It was demonstrated that the temperature limit without damaging the tissues during the preparation of the implant site is between 44°C and 47°C. and that the drilling time must be less than 1 minute.^{13,14} The heat production during drilling has also been evaluated as a function of drill design,^{15–18} repeated utilization of drill units,¹⁹ and irrigation method.^{20,21}

Several devices and techniques were proposed in order to control the thermal damage to bone, reducing the heat due to drilling. External irrigation is directed to the bur and dispersed over the cortical bone while preparing implant site.^{8,20,22} Internal irrigation consists of water delivered through a canal that is internal to the bur itself, ending with a hole and allowing to directly cool the bur–bone interface.^{20,23} A combination of both irrigation systems was also described in literature.²⁴

Moreover, many devices and techniques were adopted to measure the physical amount of heat generated during the drilling. Infrared thermography was described as an indirect method allowing the measurement of the temperature, detectable on the surface of a body through a color scale.^{18,22} Also, thermocouples were used, placed close to the site of bone drilling.^{8,15,24,25} Thermocouples are based on the differential of electrical potential between two metals and they are a sensible detector for measuring temperature.

Even though there are studies investigating the effect of different drilling protocols on osseointegration, little or no data are available regarding the rate in which the drilling site diameter is incrementally increased prior to implant placement. As anecdotally, this procedure has been performed in an incremental drill diameter fashion in an attempt to minimize bone damage during its instrumentation. There is no evidence in the literature on the optimal drilling protocol that would result in successful osseointegration in clinical reality. Recently, a published study showed an excellent success rate with the installation of implants using simplified osteotomy in which a single drilling step is performed.²⁶ This also brings considerable advantages in terms of time, considering that several drilling protocols require a number of time-consuming steps. However, a balance should exist between the accuracy of the implant site in terms of angulation, size, and shape for an optimal implant accommodation, and the total time required. The latter should not be too long for avoiding prolonged exposure of the surgical site and thermal trauma to bone tissue due to repeated drill procedures. It appeared of great interest to investigate if reducing the number of drilling steps and, in particular, using a single highperformance drill, would provide results comparable with the conventional drilling sequence in terms of bone heating.

Thus, the aim of the present in vitro study was to measure the bone temperature during the drilling, comparing a simplifying protocol consisting of one single drill versus multiple conventional drilling for implant site preparation. The null hypothesis was that in using a single drilling step, no difference in heating of the bone surrounding the implant site occurs, with respect to using conventional multiple-step drilling.

MATERIALS AND METHODS

An apparatus was prepared ad hoc for this experiment. It was composed of a control panel with a programmable logic controller and a step motor with a manmachine interface. These devices were used to produce continuous drilling movements, which were predetermined (position, depth, and load) with high precision by the investigator. A device was used to stabilize bone samples while drilling. The surgical osteotomies were adjusted as recommended by each manufacturer, with a saline solution irrigation flow of 50 mL/min (at room temperature ~19°C), as coupled to a handpiece with a 20:1 reduction and a predetermined load of 2 kg, linked to the step motor. In the present study, a load of 2 kg was used, according to the procedures of other authors.^{23,24} The speed used was as recommended by each implant system. As a whole, the entire apparatus reduced the possibility of human error during the experiment.

Three groups were considered:
Group 1: Drill sequence for a cylindrical 4.1 mm standard implant, Straumann (Basel, Switzerland): drill diameters were 2.2 mm (used at 800 rpm), 2.8 mm (600 rpm), and 3.5 mm (500 rpm).²⁷ The length was 12 mm.

Group 2: Drill sequence for a conical 4.3 mm NobelReplace[®] implant, Nobel Biocare (Göteborg, Sweden): tapered 2 mm (2000 rpm), 3.5 mm (800 rpm), and 4.3 mm (800 rpm).²⁸ The length was 13 mm.

Group 3: One drill 4.2 mm (1500 rpm) for conical IDAll implant, Implants Diffusion International (Montreuil, France). The length was 12 mm.

For each group, 20 perforations were made without and with irrigation, using a new drill for each situation. The perforations without irrigation were used as control of the process used in this study. The time needed to complete the drilling was recorded.

For this experiment, three synthetic bone blocks of type I density (Nacional Ossos, São Paulo, Brazil), with a thickness of 40 mm, a width of 130 mm, and a length of 180 mm, were used. Foam is available in a range of sizes and densities; in this study, it was 0.64 g/cm^3 (40 pcf = 40 pounds per cubic foot).

For the temperature measurements, a type K thermocouple device (Mod. TP-01, Lutron Electronics Co., Inc., Coopersburg, PA, USA) was coupled to a digital thermometer (Lutron Electronics Co., Inc.) with a resolution of 0.1°C and installed into a hole (1 mm diameter and 2 mm in depth) placed 1 mm lateral to the perforations. This configuration is illustrated in Figure 1. After completion of one implant site preparation procedure, the subsequent was not performed until the temperature was returned to normalcy (19°C).

Parameters Evaluation and Statistical Analysis

Temperature was measured for each sample immediately before drilling (baseline value) and immediately after. For the multiple drilling samples, the measurements were performed after the last drilling step. Afterwards, the differences between the two measurements were computed. Mean values, confidence intervals (95% CI), and ranges were calculated for each group.

Shapiro–Wilk test was used to test normality of distributions of each group. The analysis of variance was used to evaluate differences among all groups. Student's unpaired *t*-test was applied to test differences between single and multiple drilling and between data obtained with or without irrigation. P < .05 was considered as the significance level.



Figure 1 The thermocouple in position and the distance of the drilling.

RESULTS

The mean temperatures measured in the three groups and the mean differences with respect to baseline values (ΔT) with 95% CI considering the drilling without irrigation were: 25.54 ± 1.24°C (range: 22.2–27.9°C; $\Delta T = 6.67 \pm 1.17$; 95% CI: 6.16, 7.18) for Group 1; 28.11 ± 1.76°C (range: 26.4–32.1°C; $\Delta T = 8.70 \pm 1.63$; 95% CI: 7.98, 9.42) for Group 2; 26.48 ± 1.79°C (range: 23.3–30.3°C; $\Delta T = 7.83 \pm 1.77$; 95% CI: 7.05, 8.61) for Group 3. Considering the drilling with irrigation, the corresponding results were: 20.40 ± 1.17°C (range: 19.6– 25.1°C; $\Delta T = 1.84 \pm 1.28$; 95% CI: 1.28, 2.40) for Group 1; 22.21 ± 1.38°C (range: 20.7–26.8°C; $\Delta T = 3.07 \pm 1.42$; 95% CI: 2.44, 3.69) for Group 2; while it was 20.25 ± 0.82°C (range: 18.9–22.3°C; $\Delta T = 1.73 \pm 0.95$; 95% CI: 1.31, 2.15) for Group 3.

Considering absolute values, Group 1 and Group 3 yielded similar results (not significantly different) in all experimental conditions. In Group 2, significantly higher temperatures were recorded with respect to the other two groups both with and without irrigation (Figures 2 and 3). Figures 4 and 5 show the graph with averages, quartiles, maximum and minimum values of the analyzed groups. No significant difference was recorded for ΔT between Group 1 and Group 3 with irrigation (the experimental condition most similar to the clinical situation), while the ΔT for Group 2 was significantly higher than the other two groups.



Figure 2 Bar graphs of the absolute values and statistical comparisons between groups without irrigation (*no significant difference).

The time for drilling was on the average 10 seconds for Group 3 and 80 seconds for Groups 1 and 2 (including three consecutive drilling steps plus the time for changing the drills). The time needed to return to baseline temperature after each implant site preparation procedure was approximately 5 to 10 minutes.

DISCUSSION

In the present study, a single drilling step was compared with conventional multiple drilling sequence regarding heat generation during the preparation of implant sites.

The results demonstrated that the use of a bur specially developed for preparing the implant site through a simplified drilling phase did not generate more heat in the bone surrounding the implant site than the conventional multiple sequence of burs for drilling. This might be a possible explanation for the excellent clinical results recently presented (98% of implant survival) in the evaluation of 350 implants installed with the use of a single drill in several clinical procedures.²⁶

This consideration might be relevant to suggesting a standardized method for preparing implant site because it is derived from an investigation conducted with an experimental mechanical device, adequately programmed and standardized. Some authors have previously performed experimental osteotomies with



Figure 3 Bar graphs of the absolute values and statistical comparisons between groups with irrigation (*no significant difference).



Figure 4 Variation of temperature in the groups without irrigation.

different protocols, such as a saw blade and only external irrigation, in samples of blocks of bovine mandible, in vitro and in vivo.^{29–31} Ercoli and colleagues performed osteotomies in samples of bovine ribs in vitro, comparing seven brands of drills, with only external irrigation.²⁹ In the present study, only external irrigation was adopted.

Considering the effect of drill design on heat generation in cortical bone, many aspects were highlighted as important to reduce the physical stress. Drill design should allow for the less traumatic surgery as possible, and this consideration should determine drill characteristics as flute geometry and design, sharpness of the cutting tool, diameter, as well as drilling protocol features such as drilling speed, axial force (pressure applied to the drill), bur angulation, irrigation, torque and thrust forces, use of multiple burs with incremental diameter versus one-step drilling.^{17,32} Also, bone characteristics, like cortical bone thickness and bone density, as well as the time needed for implant site preparation, may affect heat generation during drilling.

In this study, the Implant Diffusion International (IDI; Montreuil, France) drills were used at higher rotation speed as compared with the final drills of the other two systems. It has been suggested that high rotation speed in combination with a large applied force allows a faster site preparation and a minimum increase of temperature as compared with lower rotation speed and pressure.^{33,34} In the present experimental protocol, the pressure applied to the drill was the same for all the three groups, but with the IDI drills the site preparation was completed within 10 seconds, while with the two



Figure 5 Variation of temperature in the groups with irrigation.

other system the procedures took significantly longer. However, the time needed for drilling in Groups 1 and 2 might be considered faster as compared with the clinical situation. While this may have caused a slight overestimation of the temperature due to a reduced recovery between consecutive drilling steps, this allowed for a rigorous standardization of the protocol. The possibility of shortening the overall drilling procedure may prove beneficial to tissues reducing the local damage as well as the patients' discomfort. In fact, prolonged tissue exposure may be detrimental to the postoperative course due to the increased release of pro-inflammatory cytokines and consequent amplified inflammatory response.³⁵

The time required to return to baseline temperature (5–10 minutes) may seem quite large. This could be related to the bone heat dissipation properties which are hypothetically low in the cortical bone blocks used in this in vitro study, but should be far greater in the in vivo situation due to the bone vascularization system, which largely contributes to heat dissipation.

In the present study, different drill designs and systems were compared. The results suggested that a simplified drilling system generated similar heat to the cortical bone than using a conventional drilling. When compared in vivo, histologically, Jimbo and colleagues suggested that bone response to the implants installed with a simplified protocol is comparable with the conventional drilling protocol.³⁶

Even though this consideration may appear obvious, the entity of the difference between the two systems is relevant and cannot be disregarded, aiming to reduce the heat generation as much as possible.

Though some authors declared that studies about comparisons between different cooling systems provided insufficient data for definitive conclusions,³² many published studies investigated different systems aiming at reducing heat generation in the bone tissue while drilling.

Benington and colleagues, in 1996 and in 2002, described that an external irrigation system can significantly reduce heat generation during drilling procedure.^{20,37} In the present study, the use of irrigation allowed for decreasing bone temperature by 5 to 6°C as compared with drilling procedures performed without irrigation in all groups.

Sener and colleagues, in 2009, evaluated the difference in temperature at various depths while preparing implant site with an external irrigation device, describing that the majority of heat was generated in the superficial part of the cavity, due to the characteristics of compact bone.¹¹ This issue can justify the position of thermocouples in our experimental model, which were placed within the superficial 2 mm of the bone samples.

Another study compared different shapes of surgical drills with external irrigation, suggesting that conical drills allowed for a lower heat generation if irrigated with an external device while drilling.¹⁸

One study of Carvalho and colleagues, in 2011, pointed out that the use of abundant irrigation was able to reduce the impact of drill design or drilling methods on heat generation.¹⁹ In fact, it was observed that during the whole in vitro experiment, the measured temperature never approached a level (47°C) that can cause an irreversible damage to the bone. This observation was confirmed also in our study, where the results of temperature measurements were always lower than the previously cited threshold value.

Augustin and colleagues, in 2012, examined the performances of a drill with an internal irrigation system in terms of heat generation.³⁸ Even though it was observed that an increase in drill diameter resulted in an increase of heat generation, the measured temperature never overcome the critical 47°C.

Other authors suggested that ceramic drills can produce less heat while drilling than steel drills, further highlighting the importance of drill material and characteristics in heat generation.⁷ As far as we know, no published study has ever compared a single drilling protocol versus conventional multiple incremental drilling systems.

Even though the findings of the present work are statistically significant, several limitations emerged. First, sample size is relatively small, as well as the number of drillings even though the use of standardized experimental design can increase the external validity of the results. Then, a surgical guide was used and this was shown to influence the temperature measured at the cortical bone level. The blocks of synthetic bone used in the present study have been specifically designed to reproduce the physical properties of the cortical bone in terms of hardness, density, elasticity (Young's modulus). The physical features of these synthetic bone blocks are homogeneous throughout their volume, so as to obtain a good standardization of the procedures and avoid introducing possible sources of bias in the measurements. However, due to natural inhomogeneities in the human jawbones, there might be differences between

such model and the in vivo situation. Finally, only blocks of bone type 1 were used, which is not so common in clinical situations. This was done because such type of bone is at greater risk for developing excessive heating during drilling, as compared with softer bone type, and we aimed at testing the most risky situation.

Furthermore, we found that the baseline temperature for Group 2 was significantly greater than the other two groups, whose baseline values were similar. The latter issue, however, was overcome by using the temperature difference for the comparisons instead of the absolute values, thereby disregarding any inhomogeneity among baseline values.

Group 2 also displayed the highest temperature difference among the investigated drilling systems. This may have been caused by peculiar features of the drills or the protocol recommended by the manufacturer, though the magnitude of the bone heating under irrigation is still small, like the other two drilling systems, and should allow for a safe drilling in the clinical situation.

In the translation to clinical reality, it must also be acknowledged that the single drilling step procedure has some limitations. In fact, with the multiple-step drilling technique it is possible to modify the axis appropriately, in case the first drills have created a misaligned implant site. Therefore, through correction of the drilling axis of the larger burs, the final implant site can match the original project of the treatment plan. By reducing the number of steps, down to a single drilling phase, a far greater precision is needed as it is not feasible to correct misalignments. Hence, it may be advisable to adopt a surgical template to drive the bur properly, at least during the very first procedures, because a learning curve is necessary even for the experienced surgeon. Further studies should be performed to investigate the precision of single drilling as compared with multiple incremental drilling protocol in creating a proper implant site.

CONCLUSION

The present study showed that a single bur system did not generate more heat than a conventional drilling sequence while preparing implant site, and may be considered as safe as the latter. Moreover, the use of drills with irrigation is effective in reducing the heat generation at the cortical bone level. More studies, both in vitro (possibly on human bone samples) and in vivo, will help to achieve a better understanding of heat generation phenomenon during the preparation of implant sites, as well as to establish the ideal drilling protocol for different bone types.

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