Four-year Follow-up of Larger-Diameter Implants Placed in Fresh Extraction Sockets Using a Resorbable Membrane or a Resorbable Alloplastic Material

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Purpose: *The aim of this randomized study was to evaluate and compare the long-term success rates of cylindric, screw-type titanium implants with a larger diameter (5.9 mm) that were placed in fresh extraction sockets in association with resorbable bone substitutes or a resorbable membrane.* ***Materials and Methods:*** *Eighty-three partially edentulous adult patients, selected from among those treated in 1997 and 1998 at the San Raffaele Institute in whom 1 or more implants had been placed into fresh posterior mandibular or maxillary sockets, were included in the study. A total of 111 implants were placed, 36 in mandibles and 75 in maxillae. Fifty-six implants were placed in combination with resorbable hydroxyapatite (HA group) and 55 with a resorbable membrane (MR group). Intraoral radiographs and follow-up examinations, including verification of implant stability via the Periotest, were carried out at second-stage surgery 3, 6, 9, and 12 months later; and then annually up to 4 years after placement of the definitive restoration. The radiographic examination was conducted by means of a standardized procedure to verify osseointegration.* ***Results:*** *There was 100% attendance at the follow-up examination after 4 years. At second-stage surgery, which was performed after 4 to 6 months' healing time, none of the implants showed any signs of mobility, peri-implantitis, or bone loss. Two implants failed in the MR group, one at 3 months and one at 9 months after placement; 1 implant failed in the HA group at 4 months after placement. After 4 years, the implant success rate was 97.3% (108 of 111 implants were considered successful). The success rate did not differ significantly between the HA group (98.2%) and the MR group (96.4%).* ***Discussion:*** *The use of larger-diameter implants served to minimize the anatomic discrepancies that would have evolved when substituting a molar with a standard-diameter implant. According to the accepted criteria for success, the 5-year success rate should be at least 85%; therefore both methods may be considered satisfactory.* ***Conclusion:*** *Implants placed in combination with a resorbable allogeneic material or with a resorbable membrane provided predictable long-term results when restored with a fixed partial denture.* INT J ORAL MAXILLOFAC IMPLANTS 2003;18:856–864

Key words: *artificial membranes, dental implants, guided tissue regeneration, hydroxyapatites, tooth extraction*

A number of scientific works have shown the predictability of osseointegrated implant dentistry that complies with the biologic principles proposed by Adell and others.[1–3] Among these principles was the need for complete healing of the alveolar bone before placing an implant into a fresh extraction socket, a process that usually requires from 6 to 12 months.[1–3] However, it has been observed that during this period, 44% or more[4,5] of the alveolar ridge can be resorbed, mostly in the first 6 months.[6] The degree of resorption generally depends on the dental region involved, on the lapse of time after extraction, and in some cases on the pressure exerted by the patient's removable denture.[5] This bone loss can prompt the clinician to introduce guided bone regeneration (GBR) techniques or the placement of implants 8 mm or less in length. Both situations have been associated with a lower rate of long-term implant success.[7–14]

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Some authors have argued that many advantages can result from placing dental implants into a fresh extraction socket. For example, it is easier to position them because of existing reference points, and they can be placed in some regions that are not suitable for a fixed restoration. It is also possible to preserve the alveolar bone and contour of the ridge and possibly reduce the risk of sinus penetration in the maxillary posterior region.[15,16] Moreover, further advantages for the patient include not only a shorter treatment time, reduction in the number of surgical appointments, and less morbidity, but also from better esthetic results related to optimal implant placement.

The introduction of GBR techniques has permitted the use of membranes in combination with implant placement in fresh extraction sockets.[17–21] The use of membranes to isolate the gingival epithelium and the connective tissue cells of the healing site can lead to an increase in osteogenesis, to stronger bone filling, and to osseointegration.[10,17,20,21] Recently, to avoid collapse of the alveolar ridge, the use of hydroxyapatite alloplastic graft materials[22–24] has been suggested, since this is a compound that is regarded as a good bone substitute in maxillofacial surgery.

From a clinical and practical point of view, it would be important to evaluate the existence of any differences among these bone-regeneration techniques when assessing long-term success, especially when implants are placed in fresh extraction sockets. In the current dental literature, there is a lack of experimental studies that have been carried out especially for examination of this problem. The aim of this study was to compare the potential for bone filling and success of osseointegration after 4 years around dental implants with a larger (5.9-mm) diameter that were placed directly into fresh extraction sockets in the posterior regions of the maxilla and mandible, in association with a resorbable membrane or with resorbable alloplastic materials.

MATERIALS AND METHODS

In this randomized study, 83 adult patients, who needed 1 or more teeth in the posterior regions of the mouth extracted and replaced with dental restorations, were evaluated. The 44 women and 39 men, with an average age (± SD) of 46.2 ± 14.3 years, were selected from among those treated in 1997 and 1998, according to the following admission criteria: age between 21 and 75 years; compliance with home oral hygiene standards; extraction because of caries, dental fracture, periodontitis, or endodontic treatment failure; presence of a sufficiently wide, fresh extraction socket such that even after placement of a 5.9-mm-diameter implant there would still be a residual bone defect; and occlusion suitable for planned prosthodontic treatment. The criterion for exclusion was the presence of any dysmetabolic, chronic, and/or infectious disease. A detailed explanation of the treatment plan was given to each patient, and informed written consent was required for participation in the research.

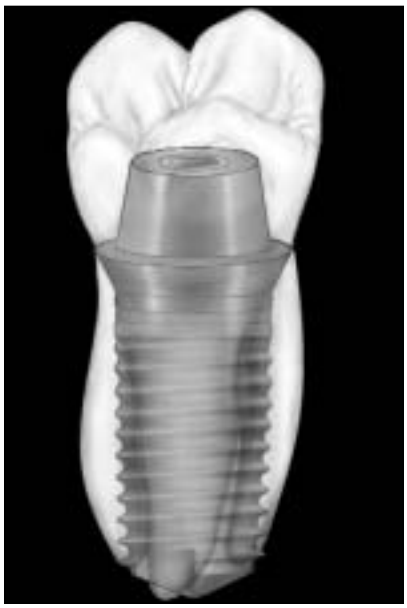
All implants were sandblasted, commercially pure titanium (Bioactive Covering, Winsix, London, United Kingdom), in the form of a self-threading cylindric screw, with a diameter of 5.9 mm and a length of 11 or 13 mm (Fig 1, Table 1). The fresh extraction sockets were categorized as type 1 in the Salama preoperative classification[25]:

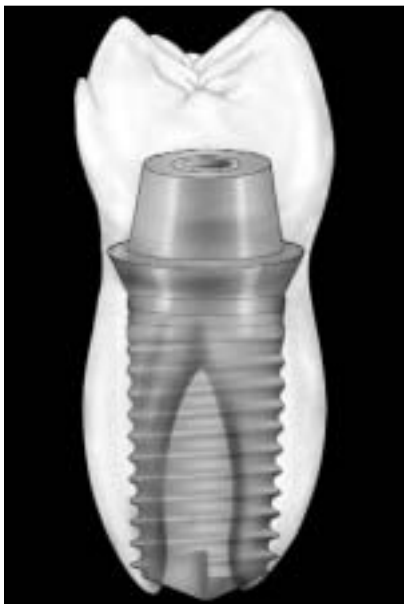
- Postextraction pocket with 4 walls and minimal bone resorption
- Presence of 3 to 5 mm of bone below the implant apex
- Acceptable discrepancy (< 2 mm) between the head of the implant and the cementoenamel junction of the adjacent teeth, if present, or the most coronal part of the socket
- Treatable gingival recession

In terms of marginal bone loss, the fresh extraction sockets were assigned to the classes A1 (no loss of periodontal attachment), B1 (loss of no more than one third of periodontal attachment), or C1 (loss of no more than half of periodontal attachment) according to the classification of Becker and coworkers.[26]

The patients were divided randomly into 2 groups: patients in the HA group received implants in combination with the use of synthetic hydroxyapatite (56 implants; Biosite; Vebas, Milan, Italy), and patients in the MR group received implants combined with a bioabsorbable membrane based on polyglycolic and polylactic acid copolymers (55 implants; Osseoquest; W.L. Gore, Flagstaff, AZ). Preoperative radiographic examinations included an orthopantomograph and periapical radiographs for evaluation of the anatomic residual ridge. A complete prosthetic evaluation leading to the fabrication of an appropriate prosthetic restoration was conducted.

All surgical and prosthodontic procedures were carried out by the same clinician. A total of 111 implants were placed, 36 in the mandible and 75 in the maxilla (Tables 1 and 2).





Figs 1a and 1b The head of the implant should reflect the diameter of the teeth to be replaced. *(Left)* Anterior and *(right)* sagittal views of a standard molar.

Table 1 Implant Distribution According to Patient Sex, Implant Location, and Implant Length

Patient group/ location	Implant length	
	11 mm	13 mm
Female patients		
Maxillary right first molar	—	9
Maxillary right second molar	—	13
Maxillary left first molar	—	14
Maxillary left second molar	—	11
Mandibular left first molar	2	6
Mandibular right first molar	3	4
Total	5 (8.1%)	57 (91.9%)
Male patients		
Maxillary right first molar	—	10
Maxillary right second molar	—	8
Maxillary left first molar	—	10
Maxillary left second molar	—	7
Mandibular left first molar	—	3
Mandibular right first molar	2	9
Total	2 (4.1%)	47 (95.9%)

No significant difference was found in distribution by length according to the sex of the patient ($P > .839$).

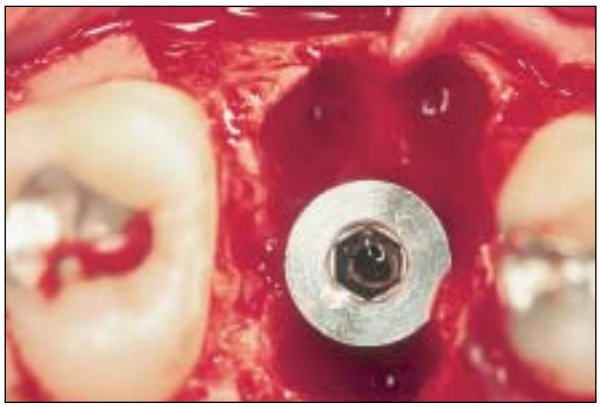
Table 2 Implant Distribution in the 2 Groups of Patients

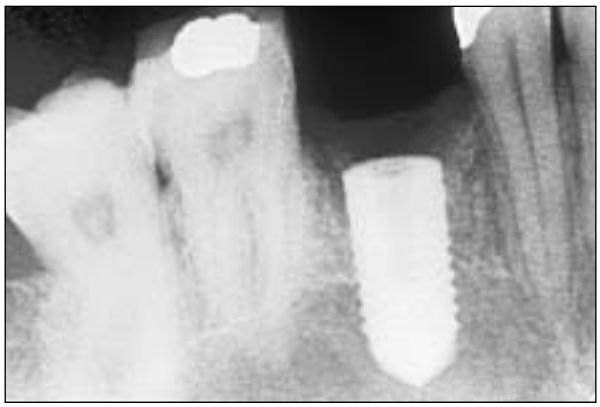
Implant location	Group	
	HA (n = 56/50.4%)	MR (n = 55/49.6%)
Maxilla		
Right first molar	7 (6.3%)	7 (6.3%)
Right second molar	11 (9.9%)	10 (9.1%)
Left first molar	12 (10.8%)	12 (10.8%)
Left second molar	8 (7.2%)	8 (7.2%)
Mandible		
Right first molar	8 (7.2%)	9 (8.1%)
Right second molar	—	1 (0.9%)
Left first molar	8 (7.2%)	8 (7.2%)
Left second molar	2 (1.8%)	—

No significant difference was seen between groups HA and MR ($P > .981$).

Surgical Procedures

The extractions were carried out atraumaticallly under local anesthesia, avoiding raising flaps, preserving the papillae, and where necessary, resorting to root resection to avoid destroying the alveolar septa. All traces of attached soft tissue were removed from the sockets using instruments, and then the apical portions of the socket itself were prepared to receive implants according to the instructions provided by the manufacturer. The biologic width of the adjacent teeth, if present, was considered, along with a projected average bone resorption rate of 1 to 1.5 mm for the first year after implant placement. To prevent exposure of the implant's polished neck, the implants were positioned 2 mm apical to the marginal bone level. Thus the implant sites were overcontoured by 2 mm. In the posterior regions, especially in first molar areas, miniature sinus lifts were performed: The residual bone was cored with a 6-mm trephine bur to reach approximately 1 mm from the schneiderian membrane, and then the membrane was lifted some 2 mm with slight pressure.





Figs 2a and 2b Case 1. Placement of the implant into the socket, with the coronal portion 2 mm more apically than the level of the bony ridge crest, immediately after tooth-extraction. *(Left)* Occlusal view; *(Right)* periapical radiograph.

Following this, the aim was to place the implants in the center of the residual alveolar cavity, so as to be equidistant from the bony walls (Figs 2a and 2b).

In the HA group at this stage, the graft was located in direct contact with the bleeding bone surface and the material was condensed to eliminate any bubbles (Fig 3). For the MR group, after the clinician raised a full-thickness flap, the membrane was placed in complete contact with the surface surrounding the socket area, avoiding contact between the mesial and distal edges and nearby teeth, where present, and extending its design to cover at least 3 mm of bone crest at the level of the buccal and lingual surfaces (Fig 4).

Particular attention was paid to suturing; the surgeon tried to appose the 2 flaps by first intention with horizontal mattress sutures (Gore-Tex; W. L. Gore, Flagstaff, AZ), used vertical or interrupted sutures for papillae, and resorted to fibrin glue (Tissucol; Immuno, Pisa, Italy) where necessary. After surgery, a radiograph was obtained to document the existing relationship between the implant and the bony socket (Figs 5a and 5b). This was followed by a prescription for 1 g of amoxicillin plus clavulanate potassium (Augmentin; Smithkline Beecham, New York, NY) every 12 hours for 6 days and 100 mg of nimesulide when required. In addition, postoperative rinsing twice a day with 0.2% chlorhexidine digluconate (Dentosan Mese; Pagni Raffaello, Florence, Italy) and the topical application of a corticosteroid/chlorhexidine–based gel (Corsodyl; Smithkline Beecham Farm, Bollate, Italy) were prescribed for 2 weeks following surgery. The week after surgery, sutures were removed and dental prophylaxis was introduced as appropriate.

The patients were then seen once a week for the next 3 weeks for prophylaxis, instruction in oral hygiene, and monitoring of the healing process (Fig 6a). During this time patients were restricted from using removable provisional partial dentures to avoid traumatizing the treated area, since the dentures were not esthetically required. Subsequently, patients received postsurgical therapy once a month (mandibular implant patients for 3 months; maxillary implant patients for 5 months). After 4 and 6 months, respectively, second-stage surgery was performed for implant exposure (Fig 6b), and periapical radiographs were obtained to document healing status.

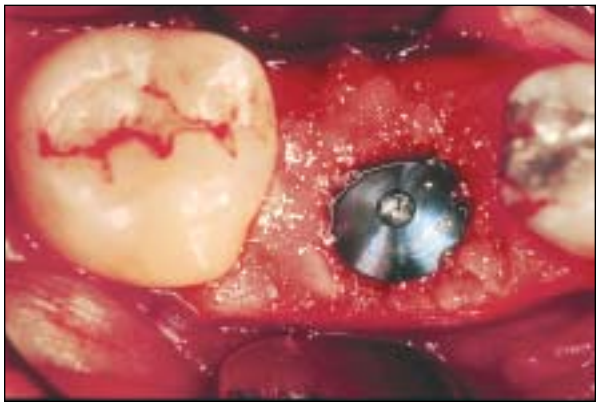
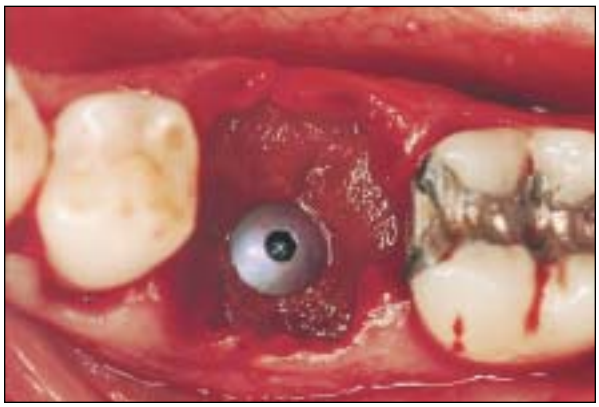


Fig 3 Case 2. Biostite was plugged between the walls of the socket and the implant.

Follow-up Evaluations

After the definitive restoration was placed, all patients were invited to attend planned clinical follow-up appointments every 3 months for an overall period of 4 years from the time of implant placement. During these appointments, an objective examination of soft tissues was carried out, the marginal precision between restoration and abutment was evaluated using a microscope at 4× magnification, and if necessary, corrections were made. In



Figs 4a and 4b Case 3. The membrane was cut and positioned so as to cover both the dental implant and the surrounding bone. *(Left)* Occlusal view of the surgical site; *(right)* membrane with inserted pin for anchorage.

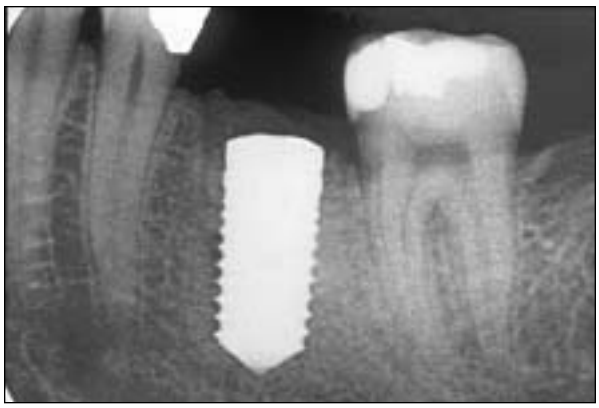


Fig 5a Case 2. Radiograph of the implant taken immediately after placement in the socket, during the first surgical stage. In the coronal third, the condensation of the biomaterial is clearly visible.

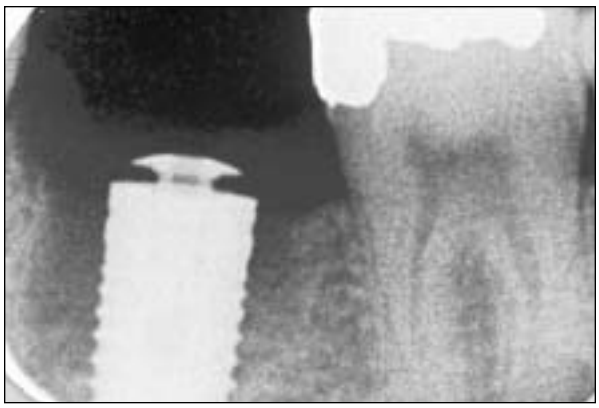


Fig 5b Case 3. Radiograph of the implant taken immediately after placement in the socket, during the first surgical stage. In the coronal third, a radiolucent space is clearly visible, given the non-opacity of the membrane.

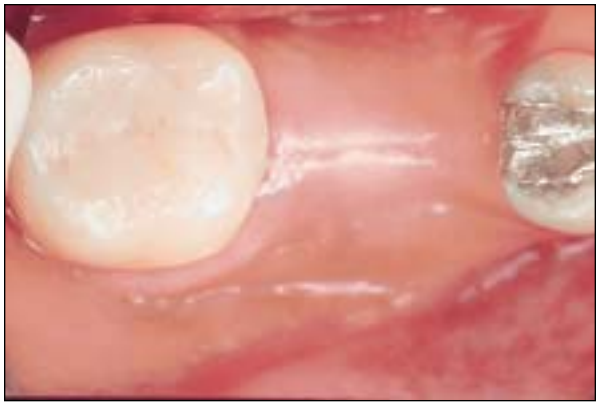


Fig 6a Case 2. Healing of hard and soft tissues at 3 month follow-up.

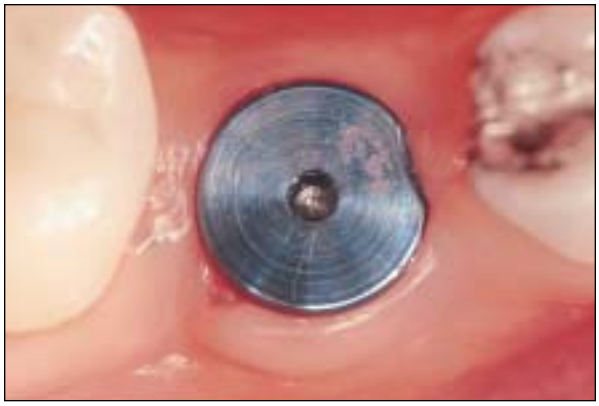


Fig 6b Case 2. Implant exposure and placement of the healing screw.

this context, the patient's oral hygiene was also verified. To assess the osseointegration of all implants, a protocol was established, including mobility testing by means of Periotest (Siemens, Bensheim, Germany) and periapical radiographs (Digora; Soredex, Helsinki, Finland), which were carried out on every patient at 3, 6, 9, and 12 months and then annually until the fourth year. The degree of resorption of bone tissue was evaluated, using for reference the level of the bony ridge crest and the circular ring located 1.4 mm from the edge of the implant at the mesial and distal positions. Implant success was defined on a radiographic basis, in accordance with the criteria of Albrektsson and associates.[2]

Statistical Analysis

The results are presented as a number and/or percentage of observations. For continuous variables, comparisons between the 2 groups of implants were done using the Student *t* test for nonmatching data. The chi-square test and the Fisher exact test were used to compare discrete variables. *P* values below .05 were considered to indicate statistical significance (2-tailed test).

RESULTS

The distribution in terms of age and sex did not differ between the 2 groups of patients, who were also comparable in terms of the linear dimensions of the implants and the area of the mouth under consideration ($P > .839$) (Table 1).

At the end of the healing period, at implant exposure, no implants showed visible signs of mobility, peri-implant infection, or bone loss. In particular, all Periotest values were in a range from –5 to 0 for both the HA and MR implant groups. The distance between the groove of the implant neck and the first visible part of the bone did not prove to be significantly different between the 2 implant groups, varying from 0.70 to 0.80 mm in the HA group and from 0.73 to 0.80 mm in the MR group ($P = .772$).

Table 2 shows, for the 2 groups of patients, the distribution of implants according to area of placement. Distribution was comparable in the 2 groups ($P > .981$). There was 100% attendance at the follow-up after 4 years. The overall incidence of implant success 4 years after placement was 97.3% and did not differ significantly between the HA group (98.2%) and the MR group (96.4%) ($P = .986$).

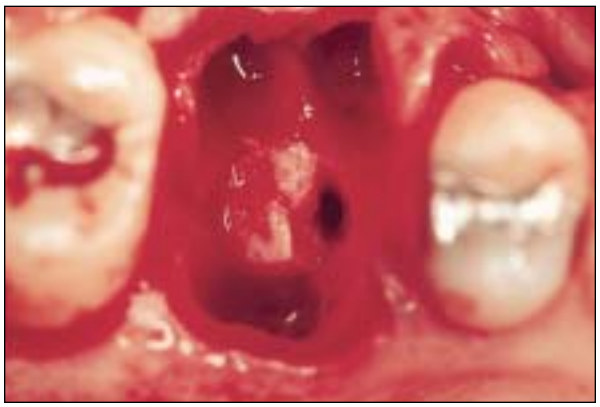
The 2 implant failures in the MR group occurred in the same patient; one took place in the mandibular right first molar region before loading, and the other happened in the mandibular left first molar region 3 months after loading. There were no particular inflammatory reactions, only a loss of implant stability. Possible relevant factors included the patient's history of previous odontogenic cysts and a smoking pattern of more than 10 cigarettes per day. The only failure in the HA group occurred with an implant in the maxillary left second molar region in a patient with low-density bone.

DISCUSSION

The main aim of this investigation was to evaluate the osseointegration success of implants with a larger diameter when placed into fresh extraction sockets in combination with a resorbable biomaterial or with a resorbable membrane.

The use of larger-diameter implants served to minimize the anatomic discrepancies that would have come about when substituting a molar with a standard-diameter implant.[27,28] Problems with a standard-diameter implant could involve not only the emergence profile, but also screw loosening, breakages, or a lack of primary stability.[29–31] The discrepancy between the cross-section of the implant and that of the tooth root is often the cause of marked undercuts at the emergence profile level, an area that can be inaccessible for hygiene purposes. Furthermore, an unbalanced relationship can result relative to the larger diameter (10 to 12 mm) of the crown in a mesiodistal direction, along with multiplication of the flexure moments exerted on the implant by the application of eccentric loads, which can cause fractures in the coronal part of the implant.[32] The use of 5.9-mm-diameter implants made it possible to increase stability and to almost completely fill postextraction defects, thus enhancing the prognosis.

The rationale behind the slight lifting of the sinus for implants placed in posterior maxillary areas is seen in the evidence that the alveolar process is wider in the molar/premolar region. However, often there are ridge height problems, and the maxillary sinus sometimes hosts apices of the second premolars and first molars. Therefore, given that according to the criteria of Adell and associates[1] 6 months of healing are required in the maxilla before loading the implants and exerting pressure stimuli on the bone, an attempt was made to avoid the risk of physiologic resorption of the alveolar ridge, as occurs after extraction through lack of bone stimulation and the expansion of the maxillary sinus. The technique used, which is relatively atraumatic, may be considered a variation of that developed by Summers.[33] In the present experience, the use of a



Figs 7a and 7b Case 1. *(Left)* Trephine bur that was used to drill the maxillary bone in conjunction with a mini–sinus lift; *(right)* surgical application.

trephine bur (ACE, Brockton, MA) (Fig 7) with the same diameter as the implant was justified by the need to preserve the septum of the original dental socket, which would otherwise have been lost because of the pressure exerted by osteotomes.

Generally, the most commonly used strategies for avoiding alveolar resorption are alveolar grafts, GBR, or a combination of these. In the study in question, the use of semisynthetic hydroxyapatite allograft was compared to the use of a resorbable membrane. For the first method, usually autologous bone taken from intraoral sites is preferred, but considering that the socket is a favorable defect, having 5 walls and high regenerative capacity, it is also suitable to use a material that resorbs at the same pace at which new bone formation occurs in the peripheral site of the socket. The product used in this group (Biostite) is a controlled-resorption alloplastic material. Its fundamental and innovative characteristic is the presence not only of hydroxyapatite (88%) but also of collagen (9.5%), which stimulates fibrinogenesis and inhibits the dispersion of hydroxyapatite cells and of chondroitin-4-sulfate (2.5%), a glycosaminoglycan that allows a sufficient concentration of calcium phosphate for mineral nucleation. Thus Biostite would seem to be both osteoconductive and osteoinductive.[34–37]

In all but one of the cases examined, satisfactory clinical healing was attained, without any foreign body reaction and with rapid bone formation, as far as can be deduced from repeated radiographic examination. Failure of the implant in the maxillary left second molar region, even before functional loading, was probably related to the fact that it was placed in soft (type 4) bone, which would appear to be a risk factor for implant success.[38,39] Although it was difficult to evaluate bone density, it is probable that this patient's bone was of low density, judging by the ease with which the terminal part of the implant engaged.

The basis for GBR, on the other hand, consists of the selective exclusion of extraskeletal connective tissue from the alveolar area during the healing phase, as it has a slower cellular turnover rate.[33] Insertion of a barrier between the bone and the connective tissue can prevent penetration of this into the socket, and thus bone cells do not have to "compete" and can fill the space around the implant. The resorbable membranes placed in the MR group, which were derived from the combination of resorbable copolymers of polyglycolic and polylactic acid, allowed optimum tissue integration and were resorbed within 16 to 24 weeks, ie, within usual bone maturation times. The main advantage of using resorbable membranes is that a second operation for removal of the membranes can be avoided. In patients treated with this method, radiographic examination showed complete bone filling around the implants. The 2 failures reported in the MR group, both in the same patient, are most probably not the result of technique, but of the patient's previous history of odontogenic cysts, as well as, perhaps, to the fact that she smoked over 10 cigarettes per day. Smoking was not an exclusion criterion for this study. The patients were asked to stop smoking for at least the first 2 weeks immediately following implant placement.

In both groups a fundamental factor in success was the achievement of healing of the flaps by first intention, ensured by means of Gore-Tex sutures. These allow maximum clot stability and maintain stable initial tension.[40] In cases where this was not possible, fibrin glue was used (Tissucol); this can stimulate reparative processes because of its ability to interact with coagulation mechanisms. With the 2 surgical procedures adopted, the combination of implants placed in fresh extraction sockets with a

resorbable biomaterial resulted in a 4-year success rate of 98.2%, while that for implants placed in fresh extraction sites combined with a resorbable membrane was 96.4%. Albrektsson and associates[2] suggested that for an implant procedure to be considered satisfactory, the 5-year success rate should be at least 85%. Using this criterion, both methods may be considered to be satisfactory.

CONCLUSIONS

This study showed implant success rates, at 4 years after implant placement, of 98.2% for implants placed in fresh extraction sockets in combination with resorbable synthetic hydroxyapatite and 96.4% for implants placed in fresh extraction sockets in combination with a resorbable membrane. The results, therefore, suggest that both strategies used in this investigation to replace posterior teeth in either the maxilla or mandible can be successfully used for long-term support of fixed partial dentures.

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