

Sinus Floor Elevation Using a Bovine Bone Mineral (Bio-Oss) With or Without the Concomitant Use of a Bilayered Collagen Barrier (Bio-Gide): A Clinical Report of Immediate and Delayed Implant Placement

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Xenografts have been used extensively, either alone or in combination with autogenous bone, in sinus floor elevation techniques. However, controversy exists regarding the need to cover the lateral osteotomy site with a membrane. Also, the healing period before loading remains undefined when machined-surface implants are placed. Twenty-nine patients showing reduced bone volume in the posterior maxilla had 61 Brånemark System implants placed in 30 sinuses augmented with a lateral osteotomy approach. Sinuses grafted with Bio-Oss and covered with a collagen membrane Bio-Gide (M+) received 29 implants, while grafted but uncovered sites (M-) received 32 implants. An immediate procedure was followed to place 41 implants and a staged procedure was used for 20 implants. Abutment connection was made in 2 distinct postoperative periods: 6 to 9 months and over 9 months. The patients were followed for an average of 22.4 months. The survival rate of the implants was dependent on the postoperative healing time and membrane presence. In case of the immediate procedure and in M- sites, when residual bone height was less than 5 mm, more failures occurred when the loading was done at 6 to 9 months than after 9 months. No failures occurred in the M- series when a staged approach was followed. The overall survival rate was 78.1% for the M- sites and 93.1% for the M+ sites. No failures occurred (0/35) in the control implants placed in adjacent native bone. Implant survival rate was related to the quality of the reconstructed cortical plate and to implant length. The concomitant use of a collagen barrier to cover the osteotomy site, when machined-surface implants were used in sinus grafting, seemed to improve the quality of the graft healing and survival rate of the implants loaded between 6 and 9 months after placement. (INT J ORAL MAXILLOFAC IMPLANTS 2001;16:713-721)

Key words: bone grafting, endosseous dental implants, maxillary sinus, membranes

Inadequate bone volume and poor bone quality are frequent findings in the posterior maxilla and often represent challenging clinical situations for the placement of endosseous implants. A bone augmentation procedure usually becomes a prerequisite for completion of the treatment. Since sinus floor

elevation was first described by Boyne and James,¹ several techniques and grafting materials have been used, including autogenous bone,²⁻⁶ allografts,⁷ xenografts,⁸ or a combination of these materials.⁹⁻¹²

Implants of different shapes and surfaces have been placed in an immediate or staged procedure with variable degrees of success.¹³ However, controversy still exists concerning the need to use a barrier concurrently with a graft to contain the material, prevent its migration or dispersion into the soft tissues, and limit soft tissue invasion in the site, which would render the site unsuitable for implant placement.¹⁴

Several membranes have been used for graft containment. Originally, expanded polytetrafluoroethylene (e-PTFE) membranes (W.L. Gore, Flagstaff,

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AZ) were the most commonly used in bone regenerative procedures. However, because of the potential problems associated with nonresorbable barriers, namely postoperative infections following exposure, and the need to remove the material after healing, studies have been oriented toward the development of an alternative material that is resorbable and does not have the disadvantages of e-PTFE membranes.^{15,16}

The purpose of this investigation was to determine the clinical efficacy of a bioresorbable porcine-derived collagen barrier (Bio-Gide, Geistlich Pharma, Wolhusen, Switzerland) combined with a natural bovine mineral graft (Bio-Oss, Geistlich Pharma) in sinus floor elevation procedures to enhance healing. For this, the survival rate of the implants with or without the use of a barrier was evaluated using both delayed and immediate procedures, and was evaluated with respect to different parameters, such as height of ridge, time of graft maturation, reconstruction of the external cortical plate, and bone type.

MATERIALS AND METHODS

A total of 29 patients, 9 females and 20 males with a mean age of 56 years (range 38 to 75) at the initiation of the investigation, were treated. They demonstrated reduced bone volume in the posterior edentulous maxilla as diagnosed on preoperative panoramic and periapical radiographs.

Patient Selection

Patients were included in the study if no systemic or local contraindications were encountered; namely, no history of uncontrolled diabetes, no radiation therapy to the head and neck in doses over 5,000 rad, no chemotherapy in the 12 months preceding surgery, no active sinus infections, no uncontrolled periodontal disease, and no psychologic problems that would prevent long-term treatment. Smokers were advised to reduce or refrain from smoking. Only 3 of 29 patients smoked over 10 cigarettes/day; therefore, smoking did not represent an exclusion criterion in the present investigation.

Surgical Technique

One hour prior to the surgical procedure, all patients received 1 g of amoxicillin (Amoxil, SmithKline Beecham, Philadelphia, PA). They were premedicated with an oral dose of 5 to 10 mg of diazepam (Valium, Roche, Basel, Switzerland). Immediately before the procedure, they rinsed for 2 minutes with a 0.12% chlorhexidine solution (Oro-

clense, Germiphene, Brantford, Canada). An anesthetic agent (mepivacaine 2% + 1/100,000 adrenaline) was infiltrated locally.

A crestal incision, slightly displaced toward the palate, was made and a vertical releasing incision was placed in the canine area to facilitate flap elevation. A mucoperiosteal flap was elevated, exposing the lateral wall of the sinus. A bony window, 15×10 mm on average, was outlined with a no. 6 round carbide bur without perforating the Schneiderian membrane. Once mobility of the window was obtained, the sinus membrane was elevated starting from the inferior border of the osteotomy site. The lateral window was pushed inward and elevated superiorly, creating a new horizontal ceiling, along with careful dissection of the membrane from the medial and inferior wall of the sinus (Fig 1).

The grafting material (Bio-Oss) was hydrated with a saline solution and gently packed into the sinus until it filled the entire cavity (Fig 2). Immediate implant placement was indicated when enough native bone quality and quantity was available to achieve primary stability after placement. The procedure was delayed 6 to 9 months after grafting when it was considered impossible to anchor and stabilize an implant in the subsinus ridge. Screw-type machined-surface implants (Brånemark System, Nobel Biocare, Göteborg, Sweden) were used in all patients.

Distribution of the sites for membrane coverage was done at random. In patients in whom a membrane was used, the Bio-Gide barrier was cut to cover the osteotomy site and extend 2 to 3 mm beyond its borders. It was stabilized with Frios tacks (Friadent GmbH, Mannheim, Germany; Fig 3). Interrupted 4.0 silk sutures were used to achieve closure of a tension-free flap.

Postoperatively, the patients were given Amoxil (500 mg 4 times/day for 6 days), a nonsteroidal anti-inflammatory drug as needed, and a nasal decongestant twice daily for 10 days. Sutures were removed 10 days after surgery. The patients were instructed not to wear their removable prostheses for at least 3 to 4 weeks. The prostheses were relined with a resilient liner (Coe Soft, GC America, Alsip, IL) that was changed every 2 to 3 weeks during the treatment period.

A total of 30 sinuses were operated; 15 were filled with Bio-Oss and the osteotomy site was left uncovered (M-) and the other 15 had Bio-Oss covered with Bio-Gide (M+). Sixty-one implants were placed, 41 as an immediate procedure, and 20 as a staged procedure. Twenty-three of 41 immediate implants were placed in M- sites and 18 of 41 were placed in M+ sites. Nine of 20 delayed implants



Fig 1 Lateral window approach to the sinus cavity.



Fig 2 Sinus cavity filled with Bio-Oss.



Fig 3 Collagen barrier (Bio-Gide) in place covering the osteotomy site and stabilized with bone tacks.



Fig 4 Healing of the lateral osteotomy wall 10 months after grafting.

were placed in M- sites and 11 were placed in M+ sites. Thirty-five implants were placed in native adjacent maxillary bone and served as controls.

All implants were submerged. Abutment connection was done at 2 distinct postoperative periods: 6 to 9 months or over 9 months post-implant placement (Fig 4). Three to 4 weeks after soft tissue healing, the final abutments were connected, implant stability tested manually, and prosthetic treatment carried out. All prostheses were ceramometal restorations. Radiographic evaluation was done at abutment connection, 1 year postloading, and yearly thereafter (Figs 5 and 6). No implants were included in the data tabulation if they had not completed the 1-year post-loading clinical and radiographic evaluation. The average follow-up period was 22.4 months (range 12 to 40 months; Fig 7).

Clinical Parameters Used for Evaluation

Bone quality at the implant site was rated according to the classification of Lekholm and Zarb¹⁷ whether

an immediate or staged procedure was done. Height of the residual bone in the subsinus area was scored on periapical radiographs with a millimeter grid. The quality of primary anchorage of the implant was rated in Ncm, according to the torque with which the implant was seated using Nobel Biocare drilling equipment (DEC500).

Reconstruction of the external cortical plate at the osteotomy site at various postoperative periods after grafting was evaluated using a periodontal probe. A rating of P₀ was given when the cortical bone was totally reconstructed and there was no possibility of penetrating it at any point with a probe. A rating of P₁ was given when the bone could be probed at 3 distinct sites. A rating of P₂ was assigned when the cortical bone quality was inconsistent and poor and the area could be probed at 3 or more distinct points.

All perioperative and postoperative complications were recorded on the patient data sheet. Mucosal tears occurred in 5 of 30 sinuses treated. In

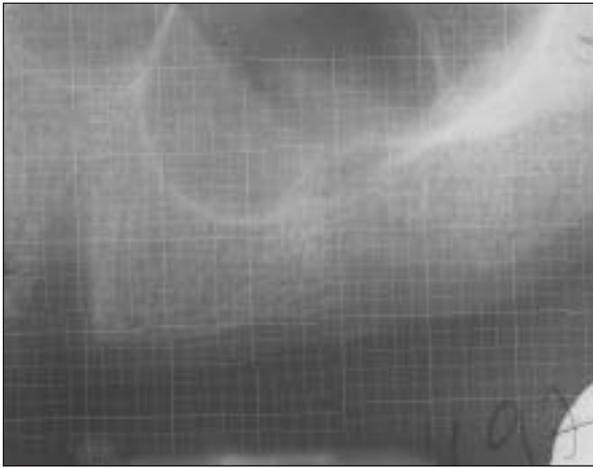


Fig 5 Preoperative radiographic image.

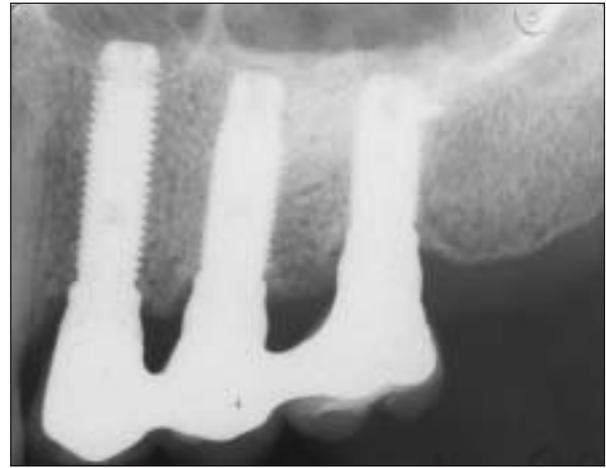


Fig 6 Two-year postoperative radiograph.

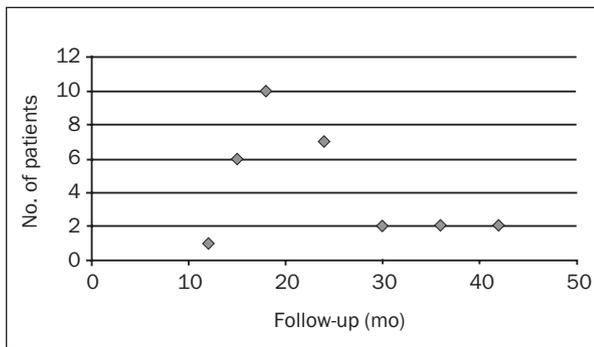


Fig 7 Distribution of patients according to duration of follow-up.

1 patient, surgery was delayed for 3 months because of a large tear. In 4 other patients, the tears were limited. They were patched with a portion of Bio-Gide membrane, and the procedure continued as described. In 1 patient, implant loss occurred. All others healed uneventfully. There were no infections or clinical complications in the present series.

RESULTS

A total of 61 implants were placed, with 32 in M- sites and 29 in M+ sites; 41 were placed immediately with sinus floor elevation and 20 were placed as a staged procedure between 6 months and 23 months after grafting.

Of the 41 implants placed immediately, more failures occurred in the M- sites (7 of 23) than in the M+ sites (1 of 18; Table 1). In the M- sites, most of the failures (6 of 7) were reported when the implants were exposed and loaded 6 to 9 months postoperatively. The only failure noted in the M+ sites occurred when the implant was loaded 6

months postoperatively. For the immediate procedure, the survival rate of the implants appeared to be dependent on the presence of a membrane and the postoperative healing time in M- and M+ sites (Table 1). There were more failures when the implants were placed in M- sites and loaded 6 to 9 months postoperatively.

Of the 20 implants placed in a delayed procedure, no failures (0 of 9) were recorded in the M- sites, while only 1 implant in the M+ sites failed (1 of 11) 8 months after placement (Table 1). In this procedure, survival of the implants was found to be independent of both the presence or absence of a membrane and the postoperative healing time.

In the case of immediate implant placement, when height of the residual ridge was considered as a variable, only 1 implant failed (1 of 18) in M+ sites when the ridge height was more than 5 mm, and no failures occurred where the ridge height was less than 5 mm; 7 implants failed (7 of 23) in M- sites when the ridge height was less than 5 mm (Table 2). The survival rate was found to be related to the height of the ridge and the presence or absence of a membrane (Table 2). More specifically, the survival rate was related to the height of the ridge in M- sites but not in M+ sites.

When bone quality was considered as a variable, there was no relationship between bone quality and survival rate of the implants placed with the delayed procedure (DP; Table 3a). In the case of immediate implant placement (IP), although more failures occurred when the residual ridge height was less than 5 mm than in sites where more than 5 mm was present (whether bone quality was of type III or IV), no relationship was found between the survival rate and these 2 variables because of the limited number of implants in each clinical situation (Table 3b).

Table 1 Relationship Between Length of Postoperative Healing Period of the Graft and Survival Rate of the Implants

Postoperative healing	Immediate procedure						Delayed procedure					
	M-			M+			M-			M+		
	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)
< 9 mo	12	6	50.0	8	1	87.5	4	0	100.0	8	1	87.5
> 9 mo	11	1	90.0	10	0	100.0	5	0	100.0	3	0	100.0
Total	23	7	69.9	18	1	94.4	9	0	100.0	11	1	90.9

M- = sinus grafted without membrane coverage; M+ = sinus grafted with membrane coverage.

Table 2 Relationship Between Residual Ridge Height and Survival Rate of Immediately Placed Implants

Ridge height	M+			M-		
	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)
< 5 mm	7	0	100.0	16	7	56.3
> 5 mm	11	1	90.0	7	0	100.0
Total	18	1	94.4	23	7	69.3

M- = without a membrane; M+ = with a membrane.

Table 3a Bone Quality Versus Survival Rate with Respect to Delayed and Immediate Implant Placement*

Bone quality	Delayed placement			Immediate placement		
	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)
III	7	0	100	29	5	82.8
IV	13	1	92.3	12	3	75

*As determined by one surgeon.

Table 3b Bone Quality and Height of Residual Ridge with Respect to Survival Rate in Patients Having Immediate Implant Placement

Bone quality/ ridge height	No. placed	No. failed	Surviving (%)
III			
4 mm	3	0	100.0
5 mm	10	3	70.0
6 mm	7	1	85.7
8 mm	7	0	100.0
IV			
4 mm	4	2	50.0
5 mm	6	2	66.7
6 mm	2	0	100.0
8 mm	2	0	100.0

Table 4 Reconstruction of the External Cortical Plate for Sites Covered by a Membrane Versus Sites Not Covered with Respect to Survival Rate

Cortical consistency	All sites			M-			M+		
	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)
P ₀	9	0	100.0	4	0	100.0	5	0	100.0
P ₁	37	2	94.6	18	1	94.4	19	1	94.7
P ₂	15	7	53.3	7	6	14.3	8	1	87.5
Total	61	9	85.3	29	7	75.9	32	2	93.8

Table 5 Relationship Between Length and Diameter of Implants Placed in Grafted Sinuses and the Survival Rate

Length	Implant diameter												Total		
	3.75 mm			4 mm			5 mm (regular platform)			5 mm (wide platform)					
	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)
8 mm	-	-	-	-	-	-	1	1	0.0	-	-	-	1	1	0.0
10 mm	1	0	100.0	11	2	81.8	9	3	66.7	1	1	0.0	22	6	72.3
11.5 mm	-	-	-	1	0	100.0	-	-	-	-	-	-	1	0	100.0
12 mm	-	-	-	-	-	-	5	0	100.0	-	-	-	5	0	100.0
13 mm	3	0	100.0	27	1	96.3	-	-	-	-	-	-	30	1	96.7
15 mm	-	-	-	2	1	50.0	-	-	-	-	-	-	2	1	50.0

Table 6 Survival Rates of Control Versus Test Implants

Implant type*	M-			M+		
	No. placed	No. failed	Surviving (%)	No. placed	No. failed	Surviving (%)
Total	51	7	86.3	45	2	95.6
Control	19	0	100.0	16	0	100.0
Test	32	7	78.1	29	2	93.1

*Control = implants placed in sound bone adjacent to grafted site;
test = implants placed in grafted sites.

No relationship was found between implant stability at placement and the survival rate. However, it should be mentioned that no implant was unstable when placed. The assessed primary anchorage of the implants varied between 10 and 40 Ncm. Two failed implants were finally seated at 20 Ncm, 3 at 30 Ncm, 1 at 40 Ncm, and 1 at less than 10 Ncm.

No failures occurred (0/9) when the quality of the reconstructed cortical bone was rated P₀, 2 failures in 37 implants occurred in bone quality P₁, and 7 failures of 15 implants were recorded in bone quality P₂ (Table 4). The relationship between length of the implants placed in grafted sinuses and the survival

and failure rates was also evaluated. Seven of 9 failures were implants shorter than 10 mm (Table 5).

When the survival rate of the implants placed in native adjacent maxillary bone (control group) was compared to the survival rate of implants placed in grafted sinuses (test group), no failures (0/35) occurred in the control group, while 9 of 61 implants failed in the test group (Table 6). More failures occurred in the M- group (7 of 32 or 21.9%) than in the M+ group (2 of 29 or 6.9%), and most of the failures occurred when the implants were placed immediately after grafting, loaded 6 to 9 months later, and no membrane was used.

DISCUSSION

Several variables may be involved in implant failure when sinus grafting is performed, namely, patient age, vascularity of the site, volume of the grafted area,¹⁸ shape and surface texture of the implants, height of the residual ridge, quality of the residual or reconstructed bone, postoperative healing time, nature of the grafting material, and coverage of the osteotomy site with a membrane. Machined-surface implants have rarely been placed in sinus augmentation procedures when bone substitutes were used as the grafting material.^{19,20} In most studies,^{3,21-24} rough surfaces were selected and high success rates reported, varying between 90.3% and 100%. Hürzeler and colleagues found no difference in the implant survival rate when using 5 different grafting materials.²⁵ The addition of autogenous bone did not seem to improve the outcome. More implant failures have been reported in a machined surface group than in a plasma-sprayed group.¹² The failures were attributed to insufficient bone-to-implant contact in sinuses grafted with a mixture of demineralized freeze-dried bone allografts and Bio-Oss. Conversely, Zitzmann and Schärer¹⁹ obtained 100% success in Bio-Oss-grafted sinuses using Brånemark System implants in a 1- or 2-stage procedure.

According to the present results, a higher failure rate may be expected if the implants are placed in a 1-step procedure when the residual bone height is less than 5 mm and the implants are loaded 6 to 9 months after placement in osteotomy sites not covered by a membrane (M-), even if the primary anchorage was acceptable. However, if the period of healing is extended over 9 months, the survival rate increases dramatically. Similar results have been reported using rough-surfaced implants¹² when implant loading was done at 9 months.

In this study, the survival rate was found to be greatly improved when the implants were placed as a delayed procedure (Table 1). Some reports have favored a delayed procedure,²⁶ while others found no difference in the outcome using either approach,²³ in spite of histologically greater bone-to-implant contact (BIC) observed in the delayed group²⁵ and just 27% BIC when the immediate protocol was applied.²⁷

The percent of BIC gained during a 6- to 9-month period may not have been sufficient to be compatible with function, even when the implants were initially stable. Coverage of the grafting material by a membrane improved the quality of the results in the present investigation. However, the difference between the M- and M+ groups was remarkable only in the 6- to 9-month healing

period and when the immediate approach was used. High success rates have been reported in membrane-covered osteotomy sites,¹⁹ as compared to uncovered sites.²⁶ Conversely, others¹⁸ have found no difference in the survival rate using both approaches, in spite of a greater percentage of vital bone formation in the covered sites.

When external cortical plate healing was related to coverage of the osteotomy site by a resorbable membrane, there was no difference between the quality of the reconstructed cortex in the M+ and M- sites (Table 5). Yet the highest failure rate was found when the implants were loaded 6 to 9 months postoperatively in the M- sites, which may indicate that the healing may be more advanced in the deeper part of the graft as compared to the more superficial part when a membrane is used. It has been observed that bone density near the floor of the sinus is greater than that of the lateral osteotomy site.²⁸ Bone growth starts from the bony walls surrounding the cavity and progresses toward the center.¹⁸ The lateral osteotomy site is one of the last areas to mineralize. If quality of the bone at the external cortical site is optimal, one may assume that it is of greater density in the deeper parts of the graft.²⁹ The cortical reconstruction index proved to be very predictable when related to survival or failure of the implants (Table 5). It may be advisable to probe the external cortex at the time of abutment connection, as this may predict the outcome of implant therapy.

When the height of the residual bone was considered as a variable, 7 of 8 failures occurred when 5 mm or less of residual bone was present, in spite of acceptable primary stability, in the M- series. No implants failed in the M+ series with less than 5 mm of residual bone (Table 2). Coverage of the osteotomy site in such cases seems to have improved the healing, at least in its early phase. Height of the residual ridge bone has been a matter of concern to the clinician. With hydroxyapatite-coated^{21,30} or plasma-sprayed implants²² and allograft, hydroxyapatite, or autografts, high success rates have been reported in the literature where initial bone height was between 3 and 5 mm. However, with machined-surface screw-type implants, it may be more difficult to obtain primary anchorage with limited residual bone and to achieve sufficient bone-to-implant contact to maintain function. A 2-stage surgical procedure in these situations may be a better approach if higher success rates are to be achieved.

When implant survival in the grafted sinuses was compared to that in the adjacent native maxillary bone (control group), no failures were reported in the control group, as compared to 21.8% failure in

the M- group and 6.8% failure in the M+ group (Table 7). Similar results have been reported using machined³¹ or rough-surfaced implants.²²

In the present investigation, implant survival was also found to be related to the length of the implants. Five of 7 implants failed when the length was 10 mm or less. Previously, similar results have been reported.³² However, it must be emphasized that many variables may influence the outcome, namely, implant configuration and surface topography, quality and height of the residual bone, quality and height of the reconstructed bone,³³ and the amount of bone-to-implant contact. When machined-surface implants are used, it may be advisable to use implants longer than 10 mm to improve the success rate.

CONCLUSION

In spite of the relatively small number of implants placed in the different test groups, it was possible to demonstrate clinical differences using several parameters of evaluation. Under conditions of this study and the patient population investigated, the following conclusions may be drawn:

1. Machined-surface implants can be used predictably in sinus floor elevation using bone substitutes if a postoperative healing period longer than 9 months is observed.
2. Immediate implant placement in sites where the residual bone height was less than 5 mm, the healing period was less than 9 months, and the lateral osteotomy site was not covered by a membrane led to the highest failure rate.
3. Better results were obtained when implants were placed as an immediate procedure in M+ sites as compared to M- sites when the postoperative healing period was less than 9 months. No differences were observed when the healing period was over 9 months or when the implants were placed as a delayed procedure.
4. A relationship was found between the external cortical plate reconstruction index and the implant survival rate. This index may possibly be used to determine the optimal time of implant loading.

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