Mario Roccuzzo Guglielmo Ramieri Marco Bunino Sid Berrone

Autogenous bone graft alone or associated with titanium mesh for vertical alveolar ridge augmentation: a controlled clinical trial

Authors' affiliations:

Mario Roccuzzo, Guglielmo Ramieri, Sid Berrone, Department of Maxillofacial Surgery, University of Torino, Torino, Italy

Marco Bunino, Private Practice, Pinerolo, Italy

Correspondence to:

Dr Mario Roccuzzo Corso Tassoni, 14 10143 Torino Italy Tel.: + 39 011 771 47 32 Fax: + 39 011 771 47 32 e-mail: mroccuzzo@iol.it

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Abstract

Objectives: The aim of this controlled clinical trial is to evaluate alveolar ridge augmentation using an autogenous onlay bone graft alone or associated with a titanium mesh (Ti-Mesh).

Material and methods: A group of 23 partially edentulous patients, presenting the need for vertical bone augmentation of at least 4 mm, were treated before implant placement. Surgical procedure was performed by the same operator and was identical at 12 test (bone graft + Ti-Mesh) and 12 control (bone graft alone) sites. During the first surgery, an autogenous bone graft was harvested from the mandibular ramus and secured by means of titanium screws. Particulate bone was added. In patients assigned to the test group only, a Ti-Mesh was used to stabilize and protect the graft.

Results: No major complications were recorded at recipient or donor sites. After a mean interval of 4.6 (SD 0.7) months, the mean vertical augmentation obtained was 5 mm (range 4–7 mm) for the test group and 3.4 mm (range 3–6 mm) for the control. The sites with Ti-Mesh coverage underwent bone resorption of 13.5%, while the sites with no coverage showed a corresponding value of 34.5%. The differences between the two groups were statistically significant. Implants were placed at all grafted sites.

Conclusion: The results of this study suggest that an onlay osseous graft protected by a Ti-Mesh demonstrated significantly less bone resorption when compared with an onlay bone graft alone. This benefit was reduced in case of short-term mesh exposure, with limited drawbacks.

Vertical regeneration of resorbed alveolar ridges is still a challenging surgical procedure, especially in case of extensive bone atrophy. Several augmentation techniques have been proposed, even in cases with limited bone support and inadequate nourishment. If implant stability or appropriate positioning cannot be achieved, ridge augmentation must be performed before implantation. Under these circumstances, various methods of bone grafting can be used with varying degrees of expected success. One of the major challenges, however, is to minimize the resorption of the grafted bone.

In order to do so, some authors (Buser et al. 1996; Tinti & Parma Benfenati 1998; Simion et al. 2004) have presented augmentation procedures in conjunction with a non-resorbable barrier membrane, while others (Chiapasco et al. 1999; Zeiter et al. 2000; Cordaro et al. 2002; Capelli 2003;

Schwartz-Arad & Levin 2005) have preferred the use of bone blocks without membranes.

Antoun et al. (2001) compared two techniques of bone augmentation with an onlay graft alone or associated with a membrane and concluded that the membrane group experienced significantly less resorption than the graft-alone group.

A recent study (Roccuzzo et al. 2004) presented a surgical protocol for vertical ridge augmentation in the maxilla and mandible using autogenous bone graft protected by a titanium mesh (Ti-Mesh), before implant placement. Data illustrated a 4.8 mm (range 4–7 mm) mean vertical bone augmentation reachable by means of this technique. The rationale of using a Ti-Mesh was to contain and stabilize the graft, allowing maximum bone regeneration and minimizing overall loss of bone volume. The advocated advantage of Ti-Mesh, however, could not be demonstrated as a negative control was not included in the preliminary research.

The aim of this controlled clinical trial study was to evaluate the reliability of Ti-Mesh in the prevention or limitation of bone resorption following grafting procedures in vertical defects.

Material and methods

Patient selection

Twenty-three (seven males and 16 females, mean age 48.6) healthy subjects providing 24 sites were included in the study. The patients were selected from those seeking implant rehabilitation and presenting, at preliminary visit with an orthopantomography, an insufficient corono-apical height of at least a portion of the alveolar process. The edentulous area in the maxilla or in the mandible, to be replaced with a fixed partial denture or a single crown, corresponded to a Cawood & Howell's Class IV, V or VI (Cawood & Howell 1988). The need for vertical augmentation of at least 4 mm was considered the condition required to be a part of this study.

All patients were healthy, with no systemic contraindication to intraoral surgery and implant placement. Following selection, they received proper oral hygiene instructions and, when necessary, scaling and root planing. At the end of the initial therapy, before entering the surgical procedures, all patients demonstrated an adequate plaque control. The patients agreed to participate in this study and gave their informed consent, in accordance with the Helsinki Declaration on human experimentation.

Surgical procedure

All surgeries were performed under local anesthesia, by the same operator (M. R.), and were identical at test and control sites. Premedication with oral diazepam 0.2 mg/ kg was given, when patient requested it, while I g of Augmentin[®] (GlaxoSmithkline, S.p.A., Verona, Italy) was prescribed I h prior to surgery. Randomization was performed by coin toss. The complete description of the clinical procedures can be found in Roccuzzo et al. (2004). Briefly, following local anesthesia, a midcrestal incision was made, maximizing keratinized mucosa on each side of the incision, in a mesio-distal direction. Oblique releasing incisions were made and full-thickness flaps were elevated to expose the bone. The flaps were elevated on the palatal/lingual and buccal aspect of the alveolar ridge and sutures were used for retraction. All fibrous tissue was removed, and perforations into the marrow space were produced by means of small surgical burs to facilitate vascularization of the graft.

Harvesting was performed from the ramus and angle of the mandible as described



Fig. 1. Clinical view of vertical ridge defect, control treatment patient (control site).

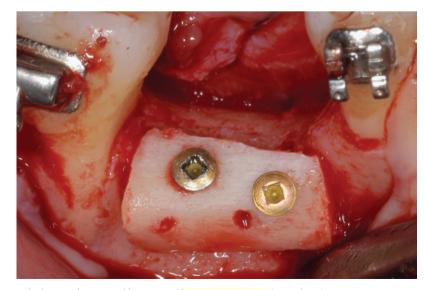


Fig. 2. The bone graft is secured by means of long titanium screws (control site).

by Misch (1997, 2000). Each block was secured by means of one or more 1.5 mm titanium screws (Institut Straumann AG, Waldenburg, Switzerland). The screws used were always long enough to traverse the residual alveolar process and keep the block firmly attached (Bahat & Fontanessi 2001c). Additional bone was harvested from and around the donor sites to increase the volume until the desired height and to create a regular morphology (Figs 1–3).

In patients assigned to the test group only, a 0.2-mm-thick Ti-Mesh (Institut Straumann AG) was used to stabilize and protect the graft as described previously (Roccuzzo et al. 2004). Each mesh was selected, trimmed and adjusted to the individual anatomy to protect the bone block and maintain the particulate bone *in situ*. Great care was taken to secure the Ti-Mesh to the residual ridge by means of as many fixation screws as necessary in order to reduce the micro-movements to the minimum (Figs 7 & 8).

Periosteal (horizontal (incisions) were made in order to extend the flap, as far as coronally needed, over the mesh. Horizontal mattress sutures were used to obtain tension-free closure of soft tissues and minute single-loop sutures were made to seal the incision line perfectly.

Data on patients, recipient sites, vertical component of the defect and complications after first surgery are reported in Table 1.

Post-surgical care

Immediately after surgery, the patients applied ice packs onto the treated area and it was recommended that they be kept in place for at least 4 h. Patients were also advised to discontinue tooth brushing and to avoid trauma in the site of surgery for the first 3 weeks. They were instructed to take **I**g of Augmentin[®] (GlaxoSmithkline, S.p.A., Verona, Italy) twice a day for 6 days and to use 0.2% chlorexidine digluconate (Corsodyl[®], GlaxoSmithkline) rinse I min three times a day for the same period of time, starting the day after surgery. They were seen at 1, 2, 4, 6, 8 and 12 weeks, to monitor their healing. If necessary, a professional supragingival prophylaxis was performed. Sutures were removed after 2 weeks. A removable prosthesis was never allowed, during healing, to avoid transmucosal pressure on the operated area.

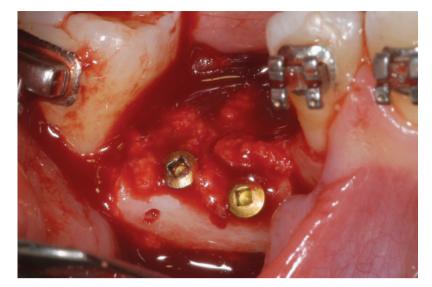


Fig. 3. Particulated bone is added to increase the volume both in height and in width (control site).



Fig. 4. Re-entry at 5 months after first surgery, fixation screws in place (control site).

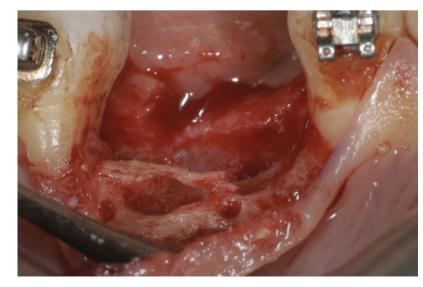


Fig. 5. Significant bone resorption is evident after screws' removal (control site).



Fig. 6. Abutment connection 10 weeks after implant placement (control site).

Patient	Age	Gender	Treatment	Recipient site	Vertical defe	ct (mm)
1.	55	F	Control	4.5 4.6		5
2.	60	F	Control	3.4 3.5 3.6		5
3.	68	F	Test	1.4 1.5 1.6	6	
4.	55	F	Test	4.5 4.6 4.7	4	
5.	50	Μ	Control	4.5 4.6		7
6.	40	F	Test	4.5 4.6	4	
7.	34	Μ	Test	1.3	8	
8.	43	F	Control	4.5 4.6		4
9.	55	Μ	Test	2.4 2.5 2.6	5	
10.	51	F	Test	4.5 4.6 4.7	4	
11.	46	F	Test	1.1 1.2	9	
12.	55	Μ	Control	1.3		9
13.	42	F	Control	1.1 1.2 2.1 2.2		6
14.	50	F	Test	4.6 4.7	4	
			Control	3.5 3.6		5
15.	40	F	Control	3.5		5
16.	37	Μ	Test	1.4 1.5	9	
17.	58	F	Test	1.6 1.7	7	
18.	20	F	Control	3.5		5
19.	47	Μ	Control	4.2 4.3		7
20.	50	Μ	Test	1.5 1.6 1.7	6	
21.	55	F	Control	3.4 3.5 3.6		6
22.	58	F	Test	2.6 2.7	7	
23.	48	F	Control	4.6 4.7		6
Mean	48.6				6.1	5.8
SD	10.2				1.9	1.3

Re-entry

After 4–6 months, a second surgery was performed at the recipient site. After the removal of titanium screws and mesh, if present, solid screw SLA implants were placed, according to the manufacturer's instructions (Institut Straumann AG) in a non-submerged fashion (Figs 4–6 & 10–12).

Whenever the vestibule was very much reduced in height, a connective tissue graft, harvested from the palate, was sutured onto the area in order to obtain thicker and wider marginal tissues around the implants, with no muscular tensions around their necks.

Clinical measurements

At the time of first surgery, after flap reflection and removal of all fibrous tissue, the dimension of the vertical alveolar ridge defect was measured by means of a periodontal probe (XP23/UNC 15, Hu-Friedy, Chicago, IL, USA), and rounded off to the nearest millimeter (Cordaro et al. 2002; Artzi et al. 2003; Roccuzzo et al. 2004). The cementoenamel junction of the adjacent tooth was used as a fixed reference point. One linear measurement was taken in each patient at the location where clinical evaluation revealed the maximum bone deficiency (Proussaefs et al. 2002a).

In addition, the distance between the site of measurement and the root surface of the nearest tooth was recorded to ensure that measurement, at the time of second surgery for implant placement, could be repeated, in the same location (Buser et al. 1996).

A paired-sample *t*-test was used to test the significance of differences between the two treatments. In cases where the requirements for parametric testing were not met, an analysis method was used that was tobust to distributional assumptions. Tests were performed two tailed and at the 5%significance level.

Results

At first surgery, the vertical bone augmentation was 5.7 ± 1.5 mm (range 4–8 mm) for the test group and 5.5 ± 1.2 mm (range 4–8 mm) for the control.

In all patients, healing proceeded with neither major complications nor dropouts during this first period of observation. Postoperative discomforts included swelling, hematoma and pain, and did not require specific additional treatment. Temporary paresthesia was observed in one case, with no incidence of anesthesia or dysesthesia. On the test sites, exposure of the Ti-Mesh was noticed in four of the 12 patients (Fig 9). In these cases, weekly examinations were carried out. Patients were instructed to apply 1% chlorhexidine gel twice a day (Corsodyl[®] Dental Gel, GlaxoSmithkline). In one of these four cases, closure of the dehiscence occurred spontaneously after a few weeks. In another case, soft tissue dehiscence was extensive and required early removal of the mesh, 5 weeks after first surgery. At reentry, grafts appeared well incorporated into native bone in all 12 cases. The presence of a slightly insufficient volume was found in two patients. In these cases, supplementary bone was added at the time of implant placement.

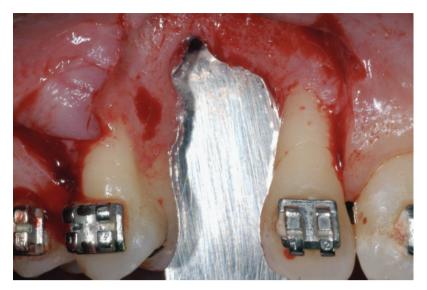


Fig. 7. Surgical exposure of the vertical bone defect, test treatment patient (test site).

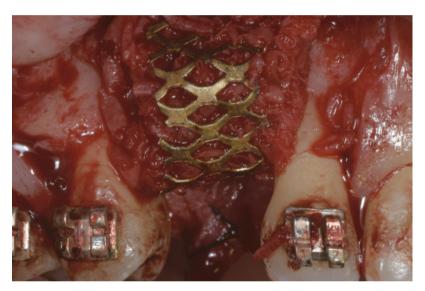


Fig. 8. Ti-Mesh is fixed in order to contain and to protect the bone graft (test site).



Fig. 9. Soft tissue dehiscence and mesh exposure 2 months after surgery (test site).

On the control sites, grafts appeared well maintained and incorporated into native bone in six of the 12 cases. In particular, at re-entry, grafts in three patients revealed discoloration. The outer necrotic portion was removed with a bur and additional bone was inserted. In the other two cases, a significant graft resoprtion, i.e. $\geq 50\%$, was recorded. Finally, during osteotomy preparation for implant placement in one patient, the block graft became completely dislodged and was removed.

The overall mean vertical adgmentation obtained was 4.8 ± 1.5 mm (range 4-7 mm) for the test group and 3.6 \pm 1.4 mm (range 3-6 mm) for the control. The sites with Ti-Mesh coverage underwent bone resorption of 13.5%, while the sites with no coverage showed a corresponding value of 34.5%. The differences between the two groups were statistically significant.

Data regarding healing time, augmentation, bone resorption and complications are listed respectively, in Tables 2 and 3.

Discussion

The aim of this paper was to evaluate a technique for vertical ridge augmentation in the maxilla and mandible using autogenous onlay bone graft alone or associated with a Ti-Mesh in a group of partially edentulous patients.

The results showed significantly less bone resorption when the graft was protected with the Ti-Mesh than with a bone graft alone. The most likely hypothesis lies in its protective effect during healing time. This is accordance with a previous similar controlled study with non-resorbable membranes (Antoun et al. 2001).

The easy handling of the Ti-Mesh allowed application for three-dimensional reconstruction of large bony defects even in the case of significant vertical deficits. The advantages of Ti-Mesh over e-PTFE membranes are, however, especially evident in case of soft tissue dehiscence during healing. Non-resorbable membrane barriers, when exposed, result in infection that can jeopardize the results (Buser et al. 1996). On the contrary, exposure of the Ti-Mesh did not appear to affect the final outcome as the ridge was augmented to receive the implants needed in the

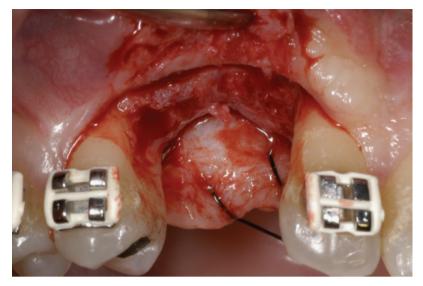


Fig. 10. At re-entry, after mesh removal, (significant vertical bone gain is evident (test site).



Fig. 11. Fixture placement according to the principle of prosthetic-driven implantology (test site).



Fig. 12. Abutment connection 12 weeks after implant placement (test site).

desired position. This is in accordance with von Arx et al. (1996), Bahat & Fontanessi (2001c), Proussaefs et al. (2003), and Roccuzzo et al. (2004).

In the current study, the Ti-Mesh was removed at the time of implant placement in all cases except in one patient who presented an extensive mesh exposure. The presence of a thin layer of soft tissue around the mesh did not facilitate its removal in a separate approach as suggested by Proussaefs et al. (2003). The positive results of this protocol suggest the clinical use of Ti-Mesh in spite of the slight increase of surgical time and the cost of the procedure.

Exposure of the block graft, not protected, during healing as recently described by Capelli (2003), was never observed in this group of patients. Nevertheless, the presence of a graft insufficiently remodeled and revascularized was found, at re-entry, in four control patients (Fig. 2). The reason for this is not fully understood. Similar findings were described by Buser et al. (2002) and could be caused by an insufficient contact among the block grafts and the recipient sites or could be connected to the extremely cortical nature of the blocks themselves. In all cases, the grafts were harvested from the most posterior region of the mandible where the cancellous component is almost completely absent. Grafts from the chin, which could offer more cancellous bone to facilitate revascularization, was reported to present discomfort for the patients by Nkenke et al. (2001) and Raghoebar et al. (2001). In contrast, the ramus donor site resulted in fewer complications in accordance with Misch (1997, 2000), Nkenke et al. (2002), and Clavero & Lundgren (2003). Specifically, only one patient from this group presented temporary paraesthesia of lip area.

Late soft tissue dehiscence and consequent bone graft exposure was observed in four patients, several weeks after implant placement. The reason for this fact, never described before in the literature to the best of our knowledge, is far from being understood. In all these cases, however, the exposed bone was reduced by means of a bur and was covered by a thick connective tissue graft to promote secondary healing of the mucosa. The preliminary results of this empirical protocol to solve the problem tentatively seem positive as none of the

Table 2. Healing time, augmentation, bone resorption and complications at test sites	Table 2. Healing time	augmentation, bone	e resorption and com	plications at test sites
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Patient	Healing time (months)	Vertical augmentation (mm)	Complications before implant placement	Graft resorption (mm)	Adjunctive therapy	Complications after implant placement
3.	5	6	_	1	-	-
4.	4.5	4	-	0	CTG	_
6.	5	4	-	0	CTG	-
7.	4	8	Minimal mesh exposure	1	CTG	-
9.	4	5	-	1	Additional bone	-
10.	6	4	Estensive mesh exposure	2	Additional bone	-
11.	3.5	8	-	1	-	-
14.	4	4	-	0	CTG	Soft-tissue dehiscence
16.	4.5	7	Minimal mesh exposure	0	-	-
17.	5	6	-	1	-	-
20.	4	6	-	2	-	-
22.	5.5	6	Partial mesh exposure	2	-	-
Mean	4.6	5.7		0.9		
SD	0.7	1.5		0.8		

Table 3. H	Healing time.	augmentation.	bone resor	otion and	complications at	control sites

Patient	Healing time (months)	Vertical augmentation (mm)	Complications before implant placement	Graft resorption (mm)	Adjunctive therapy	Complications after implant placement
1.	5	5	Incomplete integration of graft	2	Additional bone	Soft-tissue dehiscence
2.	4	4	-	0	CTG	-
5.	4	6	Incomplete integration of graft	1	CTG	Soft-tissue dehiscence and graft resorption
8.	5.5	4	-	1	-	_
12.	4.5	8	-	2	-	-
13.	5	6	-	2	-	-
14.	4	5	Graft mobilization at implant placement	N/A	Additional bone + CTG	-
15.	4	4	Temporary paresthesia	1	-	$ \bigcirc$ \bigcirc
18.	5	5	Significant graft resorption	4	Additional bone	Small sequestra expelled
19.	4	7		2	-	_
21.	5	6	Incomplete integration of graft	3	Additional bone	-
23.	6	6	Significant graft resorption	3	Additional bone + CTG	-
Mean	4.7	5.5		1.9		
SD	0.7	1.2		1.1		

patients presented further complications in the area.

Horizontal augmentation was also achieved whenever clinically necessary, but it was not calculated in order to simplify clinical measurements. A precise assessment of the amount of bone augmentation obtained remains a demanding task due to the evident difficulties in measuring. A CT scan performed after surgery, as suggested by Antoun et al. (2001), could make the measurement of the bone gain more reliable. It was, however, considered unnecessary and therefore in contrast with the ethical recommendation of the directive of the council of the European Communities about the responsible use of ionizing radiation in medicine.

The precision of a method as described by Proussaefs et al. (2002b) is questionable as the mucous thickness and morphology varies considerably and with several modifications from one side to another contighous one. Moreover, in our series, the variation in soft tissue was even larger in those cases where a connective tissue graft was added to benefit the site.

With regard to patients' compliance, it is important to note that oral hygiene conditions were carefully evaluated before and after surgeries and probably account for the low levels of complications regarding possible infections, even in cases of mesh exposures.

Recently, two studies (Maiorana et al. 2005; Proussaefs & Lozada 2005) have proposed the use of inorganic bovine material to reduce autogenous bone graft resorption. In particular, Proussaefs & Lozada (2005) presented an average of 4.75 ± 1.29 mm of vertical ridge augmentation, with 17.4% resorption 4–6 months

after bone grafting. These results are similar to those found in the test group of this research. Further comparative studies should be encouraged to better understand the pros and cons of the respective techniques.

The results or this clinical investigation suggest that vertical ridge augmentation with Ti-Mesh and autogenous bone is predictable and does not go through major resorption. Implants were placed at all grafted sites. It is clear, however, that both procedures are not free from complications. Aside from technical problems, biological considerations, i.e., the vascularization of the bone transplants, the quality of bone blocks, the blood supply to soft tissue, etc, should be further investigated. These considerations, along with the results from this study, favor the use of a delayed approach when using autogenous

bone grafts and titanium implants for reconstruction of the severely atrophied max-

illa, in accordance with Buser et al. (1996), Triplett & Schow (1996), Chiapasco et al. (1999), Bahat & Fontanessi (2001a, 2001b) and Cordaro et al. (2002).

No surgical techniques are currently available to regain predictably lost crest height in esthetic areas (Buser et al. 2004). One of the greatest clinical advantages of the proposed procedure is the lack of major complications if soft tissue dehiscence and subsequent mesh exposures do occur. This method, therefore, can be represented as an important reference forward in the definition of ideal augmentation protocols, especially in clinical situations with reduced vertical bone on adjacent teeth.

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More years of observation are, however,

necessary (Weber et al. 1997) to verify the stability of augmention over a long period of time and to compare the rate of resorption of peri-implantal bone with that obtained by means of similar or other techniques (von Arx et al. 1998; Simion et al. 2001, 2004; Chiapasco et al. 2004).

要旨

目的:本対照付き臨床試験の目的は、自家 骨オンレー移植単独あるいはチタン・メッ シュ(Ti-Mesh)との併用を用いて歯槽堤 増生を評価することであった。 材料と方法:少なくとも4mmの垂直的骨 増生を必要とする23名の部分無歯顎患者 をインプラント埋入前に治療した。手術は 同じ術者が行い、12箇所の試験部位(骨 移植+Ti-Mesh)と12箇所の対照部位(骨

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移植のみ)で同一の術式を用いて行った。 初回手術中に自家骨移植片を下顎枝から採 取し、チタン・スクリューで固定し、粒子 状骨片を追加した。試験群の患者のみ、 Ti-Meshを用いて移植片を固定し、保護し た。

結果:受給側も供給側も主だった合併症は 観察されなかった。平均4.6(SD0・7) ケ月の間隔後、平均垂直増生量は試験群で 5.0mm(4-7mmの領域)であり、 対照群では3.4mm(3-6mmの領域) であった。Ti-Meshで被覆した部位は骨吸 収13.5%で、被覆しなかった部位は3 4.5%であった。2群間の差異は統計学 的に有意であった。インプラントを全ての 移植部位に埋入した。

結論:本研究の結果は、チタン・メッシュ で保護したオンレー骨移植はオンレー骨移 植のみに比較して、骨吸収量が有意に少な かった。この効果は短期間でメッシュが露 出した際は、やや減少した。

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