

Giovanni Serino
Salvatore Biancu
Giovanna Iezzi
Adriano Piattelli

Ridge preservation following tooth extraction using a polylactide and polyglycolide sponge as space filler: a clinical and histological study in humans

Authors' affiliations:

Giovanni Serino, Private Practice, Rome, Italy
Salvatore Biancu, Private Practice, Cagliari, Italy
Giovanna Iezzi, Adriano Piattelli, Dental School,
University of Chieti, Chieti, Italy

Correspondence to:

Prof. Adriano Piattelli
Via F. Sciucchi 63
66100 Chieti
Italy
Fax: + 39 0871 3554076
e-mail: apiattelli@unich.it

Key words: extraction sockets, polylactide-polyglycolide acid, human histology, bone loss prevention, wound healing

Abstract:

Background: The placement of different graft materials and/or the use of occlusive membranes to cover the extraction socket entrance are techniques aimed at preserving/reducing alveolar ridge resorption. The use of grafting materials in fresh extraction sockets has, however, been questioned because particles of the grafted material have been found in alveolar sockets 6–9 months following their insertion.

Aim: The aims of the study were to (i) evaluate whether alveolar ridge resorption following tooth extraction could be prevented or reduced by the application of a bioabsorbable polylactide–polyglycolide sponge used as a space filler, compared to natural healing by clot formation, and (ii) evaluate histologically the amount and quality of bone tissue formed in the sockets, 6 months after the use of the bioabsorbable material.

Material and methods: Thirty-six patients, undergoing periodontal therapy, participated in this study. All patients were scheduled for extraction of one or more compromised teeth. Following elevation of full-thickness flaps and extraction of teeth, measurements were taken to evaluate the distance between three landmarks (mesio-buccal, mid-buccal, disto-buccal) on individually prefabricated stents, and the alveolar crest. Twenty-six alveolar sockets (test) were filled with a bioabsorbable polylactide–polyglycolide acid sponge (Fisiograft[®]), while 13 sockets (controls) were allowed to heal without any filling material. The flaps were sutured with no attempt to achieve primary closure of the surgical wound. Re-entry for implant surgery was performed 6 months following the extractions. Thirteen biopsies (10 test and three control sites) were harvested from the sites scheduled for implant placement.

Results: The clinical measurements at 6 months revealed, in the mesial-buccal site, a loss of bone height of 0.2 mm (1.4 SD) in the test and 0.6 mm (1.1 SD) in the controls; in the mid-buccal portion a gain of 1.3 mm (1.9 SD) in the test and a loss of 0.8 mm (1.6 SD) in the controls; and in the distal portion a loss of 0.1 mm (1.1 SD) in the test and of 0.8 (1.5 SD) mm in the controls. The biopsies harvested from the test sites revealed that the new bone formed at 6 months was mineralized, mature and well structured. Particles of the grafted material could not be identified in any of the 10 test biopsies. The bone formed in the control sites was also mature and well structured.

Conclusion: The results of this study indicate that alveolar bone resorption following tooth extraction may be prevented or reduced by the use of a bioabsorbable synthetic sponge of polylactide–polyglycolide acid. The quality of bone formed seemed to be optimal for dental implant insertion.

Date:
Accepted 28 November 2002

To cite this article:
Serino G, Biancu S, Iezzi G, Piattelli A. Ridge preservation following tooth extraction using a polylactide and polyglycolide sponge as space filler: a clinical and histological study in humans. *Clin. Oral Impl. Res.* 14, 2003; 651–658

Copyright © Blackwell Munksgaard 2003

ISSN 0905-7161

Undisturbed extraction sockets heal uneventfully with bone tissue 1–2 months following extraction (Amler et al. 1960;

Evian et al. 1982). This healing process usually occurs with substantial reduction of the original height and width of the

alveolar bone, which in some cases may aesthetically compromise an implant, supporting prosthetics (McCall & Rosenfeld 1991). Several studies have proposed various ridge preservation techniques following tooth extractions, including placement of different graft materials and/or use of occlusive membranes to cover the extraction socket entrance (for a review, see Adriaens 1999). **The use of grafting materials in fresh extraction sockets has been questioned because they seem to interfere with the normal healing process in the sockets** in which oral implants have to be inserted (Pinholt et al. 1991; Becker et al. 1994; Becker et al. 1996; Buser et al. 1998). Indeed, studies in humans using demineralized freeze-dried bone allograft (DFDBA) (Brugnamì et al. 1996; Becker et al. 1994), deproteinized natural bovine bone mineral (Bio-Oss[®]) (Dies et al. 1996; Becker et al. 1996; Artzi et al. 2000; Carmagnola et al. 2001) or bioactive glass (Froum et al. 2002) have shown **the presence of particles** of the grafted material in the alveolar sockets **6–9 months** following their insertion. Furthermore, few studies have used **quantitative methods** to measure the efficacy of ridge preservation techniques following tooth extraction (Lekovic et al. 1997; 1998; Howell et al. 1997). **Lekovic et al. (1998)** reported that healing of extraction sites seems to occur with different degrees of bone resorption, which can be **partly prevented by the use of resorbable membranes made of glycolide and lactide polymers**.

Poly lactide and polyglycolide acids are considered to be suitable matrices for bone and soft connective tissue (Laurencin & Lane 1999). **Fisiograft[®]** (Ghimas, Bologna, Italy) is **a synthetic resorbable sponge formed by 50–50 lactide–glycolide polymer, and it has the fastest degradation rate of the D–L lactide/glycolide materials, with the polymer degrading in about 50–60 days** (Holland et al. 1986).

The aims of the present study were:

- (1) to evaluate if alveolar ridge resorption following tooth extraction could be prevented or reduced by the application of a bioabsorbable polylactide and polyglycolide sponge Fisiograft[®] (Ghimas, Bologna, Italy) **used as a space filler**, compared to natural healing by clot formation;
- (2) **to evaluate histologically the amount and quality of bone tissue formed** in

the sockets **6 months** after insertion of the material.

Material and methods

Forty-five patients (31 females and 14 males), ranging in age from 35 to 64 years and undergoing treatment of periodontal disease, participated in this study. The study was approved by the Ethics Committee of our university. All patients were **physically healthy**, with **no underlying systemic disease** as determined by medical history screening and with at least one tooth to be extracted and subsequently replaced with an endosseous implant at a later stage. Before entering the study, the patients were informed of the nature of the investigation, and signed an informed consent form. **All patients received basic periodontal therapy and exhibited good oral hygiene. If an abscess was present, systemic antibiotic therapy was given 2 weeks before the extraction of the scheduled tooth.**

The patients having **one tooth** scheduled for extraction were assigned to test and control groups at the time of their recruitment in the study as follows: **two patients to the test (T) group and one to the control (C) group**. In five patients with **two teeth scheduled for extraction, one site was assigned to T and the other to C**. In one patient with five teeth for extraction, three sites served as T and the other two as C.

Baseline clinical examination

Following **local anesthesia** and elevation of **buccal and lingual full-thickness flaps**, the teeth were **extracted**. The sockets were **thoroughly debrided to remove granulation tissue**. Measurements were taken to evaluate the distance between three landmarks (mesio-buccal, mid-buccal, disto-buccal) **marked on individually prefabricated acrylic stents, and the buccal alveolar crest**. The measurements were taken using a **depth gauge** (Astra Tech, Malmö, Sweden), with a **2-mm increment** and a large flat ballpoint. The direction of the depth gauge was guided by grooves on the acrylic stents. The flat ballpoint of the gauge was positioned on the bone crest. The measurements were approximated to the nearest millimeter. **The T sites were filled using a commercially available bioabsorbable sponge of polylactide–polyglycolide acid, Fisiograft[®]** (Ghimas, Bologna, Italy), while

natural healing by clot formation was allowed at **C sites**. The flaps in **both the T and C sites were sutured, with no attempt to achieve primary closure** of the surgical wound.

The patients rinsed with **chlorhexidine–digluconate 0.2%, twice/daily for a 2-week period. The sutures were removed 1 week following the extraction**. No antibiotic therapy was given, and an analgesic medication was recommended just in case of postoperative pain.

Six-month clinical examination

The installation of the fixture at T and C sites (**Astra Tech, Malmö, Sweden**) was performed 6 months after the extractions. Following local anesthesia, and elevation of full-thickness buccal and lingual flaps, the prefabricated stents were positioned. **New measurements were repeated** in a manner similar to that described during the baseline clinical examination. The distance between the three landmarks on stents, and the newly located position of the alveolar crest was recorded. The endosseous implants were then inserted.

Biopsies

As part of the implant site preparation, a **surgical trephine with 3 mm inner diameter and 6 mm length was used to harvest 6 × 3 mm of bone from the central part of the pre-existing sockets**. The holes were then enlarged and deepened to receive endosseous implants of **> 3.5 mm** in diameter and **> 10 mm** in length. The core of the bone was immediately fixed in 10% formalin.

Processing of specimens

The specimens were retrieved and stored **immediately in 10% buffered formalin** and processed to obtain thin ground sections with the Precise 1 Automated System (Assing, Rome, Italy). The specimens were dehydrated in an ascending series of alcohol rinses and embedded in a glycolmethacrylate resin (Technovit 7200 VLC, Kulzer, Wehrheim, Germany). After polymerization, the specimens were **sectioned longitudinally along the major axis** with a high-precision diamond disc at about 150 µm and ground down to about 30 µm. Three slides were obtained for each specimen. The slides were stained with basic fuchsin and toluidine blue. A double staining with von Kossa and basic fuchsin was carried out

to evaluate the degree of bone mineralization, and one slide per specimen, after polishing, was immersed in AgNO_3 for 30 min and exposed to sunlight; the slides were then washed under tap water, dried and immersed in basic fuchsin for 5 min, and then washed and mounted. Histomorphometry to evaluate the percentage of bone was carried out using a light microscope (Laborlux S, Leitz, Wetzlar, Germany) connected to a high-resolution video camera (3CCD, JVC KY-F55B) and interfaced to a monitor and PC (Intel Pentium III 1200 MMX). This optical system was associated with a digitizing pad (Matrix Vision GmbH) and a histometry software package with image capturing capabilities (Image-Pro Plus 4.5, Media Cybernetics Inc., Immagini & Computer Snc, Milano, Italy).

Subjects exited from the study

During the study period, nine subjects dropped out from the study for reasons unrelated to the therapy. At the end of the

study, data were available from 24 patients in the T group (26 T sites) and 12 C patients (13 C sites).

Statistical analysis

The measurements were expressed using mean values and standard deviations. The differences within the T and the C groups between the measurements recorded at baseline examination and 6 months later were analyzed using a paired *t*-test. A *P*-value < 0.05 was considered to be statistically significant.

Results

Clinical findings

The healing following tooth extractions occurred uneventfully in all the T and C sites. One week following the extractions, the clinical appearance of the soft tissues around the extraction sockets was similar

in the T and C groups. After 2 weeks, the sockets in the T and C groups were covered by soft tissue (Fig. 1A–D). The measurements taken at the time of re-entry surgery revealed an overall lesser resorption of the alveolar crest in the T group compared to what was observed in the C group, with a mean gain of 0.2 mm (SD 1.5) in the T sockets and a mean loss of 0.7 mm (SD 1.2) in the C sites. The difference between the values recorded at the baseline examination and at 6 months was found to be statistically significant in the C group. The measurements showed that there was, in the mesio-buccal portion (M-B), a loss of 0.2 mm (SD 1.0) in the T group and a loss of 0.6 mm (SD 1.0) in the C group; in the mid-buccal portion (mid-B) a gain of 1.3 mm (SD 1.9) in the T sockets and a loss of 0.8 mm (SD 1.6) in the C sockets, and in the disto-buccal portion (D-B) a loss of 0.1 mm (SD 1.1) in T and a loss of 0.8 mm (SD 1.5) in C (Table 1). The difference between the values recorded at the baseline

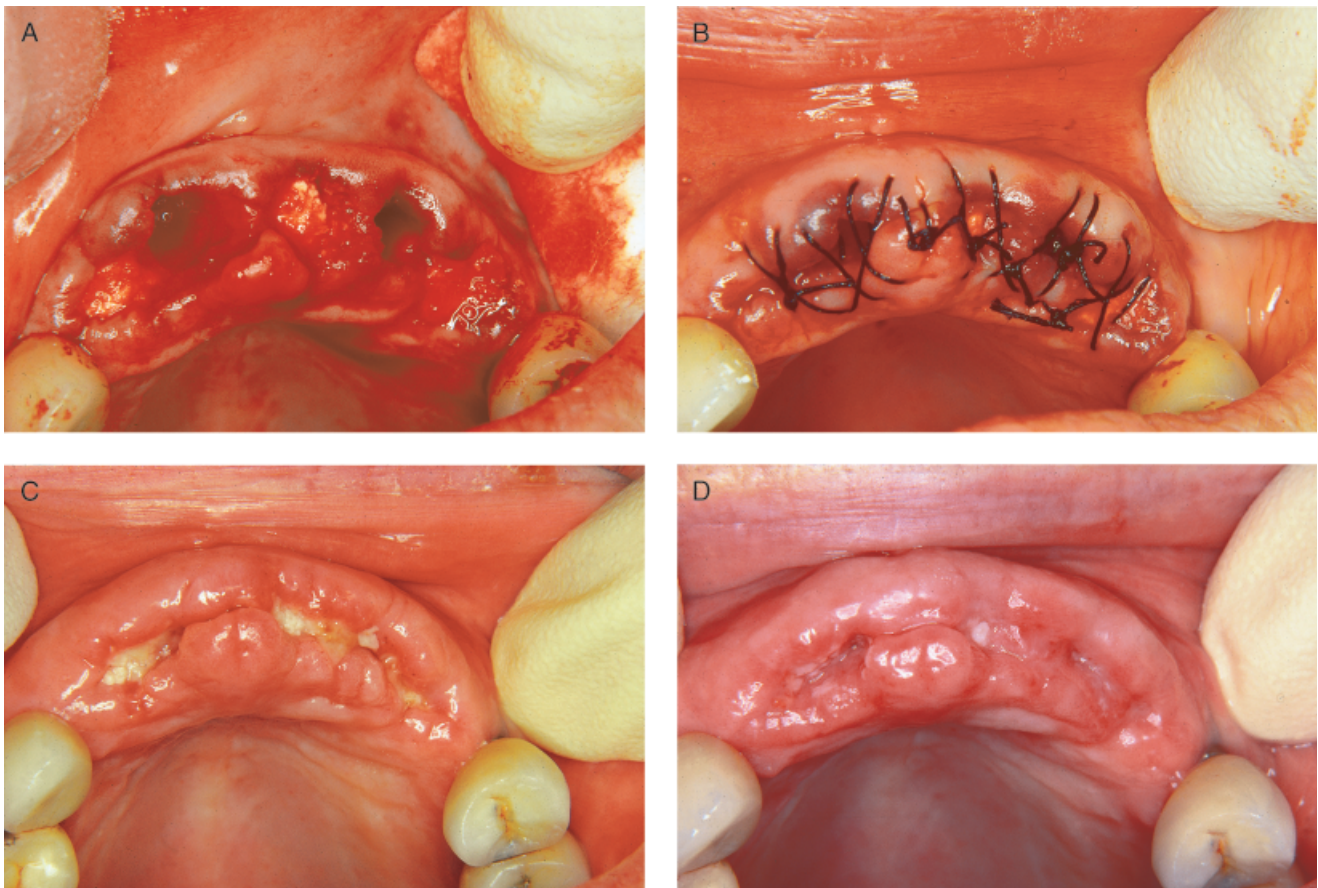


Fig. 1. Clinical photographs from test and control sockets following the extractions: (A) application of the graft material in the test socket 12, 21, 23, while the control sockets 11 and 22 are left empty; (B) sutures are in place with no attempt to achieve primary closure of the surgical wound either in test or in control sockets; (C) 1 week following the extractions, the clinical appearance of the soft tissue around the test and control socket is similar; (D) 2 weeks following the extractions, both the test and control sockets are covered by soft tissue.

Table 1. Difference between the measurements recorded at the baseline and at the 6-month examination of the distance between the socket bone crest level and the reference points on the acrylic stents

	Test sockets (n = 26)			Control sockets (n = 13)		
	M-B	Mid-B	D-B	M-B	Mid-B	D-B
All sites	- 0.2 (1.0)	+ 1.3 (1.9)* + 0.2 (1.5)	- 0.1 (1.1)	- 0.6 (1.0)	- 0.8 (1.6) - 0.7 (1.2)*	- 0.8 (1.5)

M-B = mesial-buccal; Mid-B = mid-buccal; D-B = distal-buccal. The values are expressed in mm (SD).
 + = bone gain; - = bone loss.
 *Statistical difference between the baseline and the 6-month values within the groups $P < 0.01$.

Table 2. Changes in the position of the buccal bone crest with respect to the reference points on the acrylic stents for all the test (T) and control (C) sites: ≥ 2 mm is the threshold chosen to express bone level change

	N	R	M-B	Mid-B	D-B		N	R	M-B	Mid-B	D-B
T1	35	F	/	+	/	C1	24	F	/	+	/
T2	23	E	/	+	/	C2	14	P	/	/	-
T3*	46	F	/	/	/	C3	14	P	/	-	/
T4	14	E	/	+	/	C4	34	E	/	/	/
T5*	14	F	/	/	/	C5	11	P	-	/	-
T6	21	P	-	+	+	C6	12	P	/	/	/
T7	15	F	/	+	/	C7	25	E	/	-	/
T8	23	F	/	/	/	C8*	22	F	/	/	/
T9	25	F	-	-	-	C9*	21	F	/	/	/
T10*	14	F	/	+	+	C10	34	F	/	-	-
T11	36	F	/	/	/	C11	15	C	/	-	-
T12*	16	F	/	/	-	C12	15	C	/	-	-
T13*	21	F	/	-	-	C13*	45	C	/	/	/
T14	14	F	/	/	/						
T15	46	C	/	+	/						
T16	35	F	-	+	-						
T17	24	F	/	/	/						
T18	25	F	+	+	+						
T19	36	C	/	/	/						
T20	23	F	-	+	-						
T21*	36	F	/	/	/						
T22*	21	F	/	/	/						
T23*	12	F	/	/	/						
T24*	23	F	/	+	/						
T25*	46	C	/	+	+						
T26	46	C	+	+	/						

+ = bone gain; - = bone resorption; / = no change.
 N = number of teeth; R = reason for extraction: F = fracture; P = periodontitis; C = caries; E = endodontic pathology.
 M-B = mesial-buccal; Mid-B = mid-buccal, D-B = distal-buccal.
 *Sites from which the biopsies were harvested.

examination and 6 months later at the mid-B portion of the T sockets was statistically significant ($P < 0.05$). Furthermore, six out of 26 T sockets had lost ≥ 2 mm bone height in at least one of the three sites of the buccal wall, and seven out of 13 in the C sockets (Table 2).

Particles of the grafted material were not identified in the T socket at the re-entry surgery. The new bone that filled the sockets was similar to the surrounding bone.

In three of the 26 T sockets and in two of the 13 C sockets, the bone in the central part, but not on the lateral sides, of the pre-existing sockets exhibited a low density. It was, however, possible to insert all implants with good primary stability. In all

these cases, the avulsed teeth had previously suffered from repeated abscesses.

Histological findings

In the biopsies harvested from the T sites, mature bone with signs of remodeling was present (Fig. 2). In some areas, it was not yet possible to observe mineralized bone. The histomorphometric analysis revealed that the percentage of the area occupied by mineralized bone was $\geq 67\%$ in eight out of 10 biopsies; 43% and 38% were the percentages recorded in the remaining two (Table 3). At higher magnification, it was possible to observe, only in a few areas, a few scattered osteoblasts. Particles of the grafted material could not be identified.

These findings were consistent in all the 10 harvested biopsies.

At the C sites, the percentage of mineralized bone did not exceed 56% (Table 3); the bone presented wide marrow spaces (Fig. 3).

Discussion

The results of this study indicate that loss of alveolar bone height following tooth extraction was lower in the sockets where a bioabsorbable synthetic sponge made of polylactide and polyglycolide acid was inserted compared to what was observed in the alveoli where natural healing by clot formation was allowed. Six months follow-

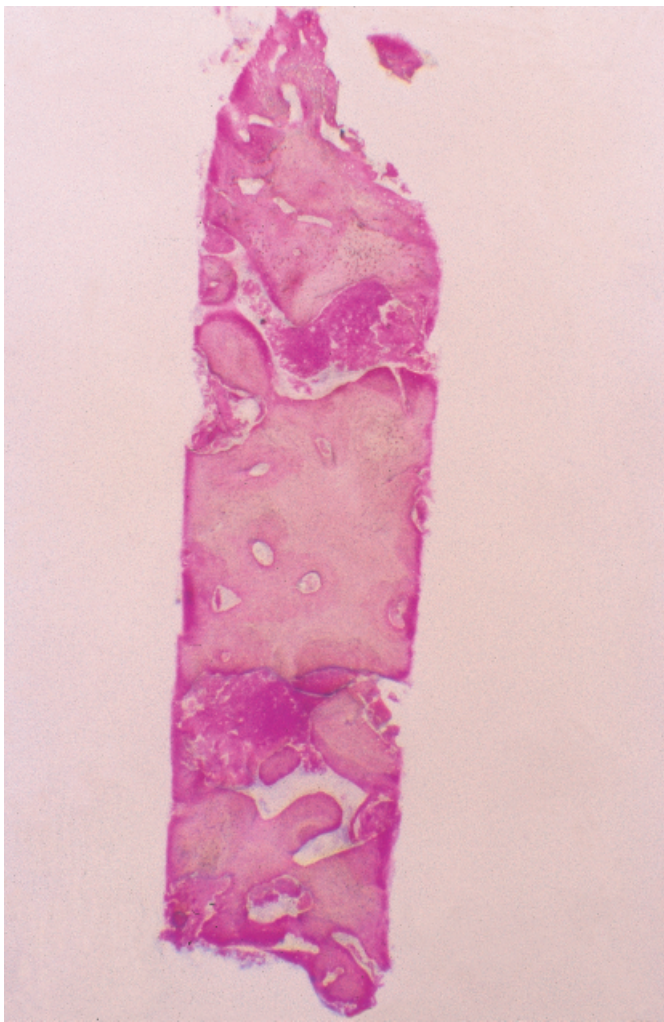


Fig. 2. Photomicrographs illustrating a biopsy harvested from a test socket, 6 months following the application of the graft material. The bone is mature and compact. Magnification $\times 10$.

Table 3. Histomorphometric analysis: percentage of the area occupied by mineralized bone (B), and graft material (G) for 10 biopsies from the test sockets (T) and three biopsies from the control sockets (C)

Site	% B	% G	Site	% B
T1	67	0	C1	56
T2	78	0	C2	37
T3	38	0	C3	38
T4	71	0		
T5	77	0		
T6	43	0		
T7	73	0		
T8	72	0		
T9	78	0		
T10	70	0		

ing tooth extractions, no particles of the grafted materials could be identified in the alveolar sockets, and the new bone formed was mature and well structured.

We noted that the grafted sockets had healed with less bone resorption than the control sockets, especially at the mid-

buccal portion, where the buccal plate of the socket was often found to be partially or completely destroyed by tooth pathology. One possible explanation for this is that in the T sites, the sponge served as a supporting element to prevent the collapse of the surrounding soft tissues in the fresh extrac-

tion sockets once the teeth were avulsed. However, in the interpretation of these results, it should be taken into consideration that buccal bone walls are much thinner and less corticalized in the upper compared to the lower jaw, so that the sockets in the lower jaw may have a higher potential to regenerate the missing wall. In our experiment, 35% of the sockets in the test group were located in the lower jaw compared to only 23% in the control group. On the other hand, the fracture of teeth, which was often the cause of loss of the buccal wall, was present in 70% of the T sockets and in 30% of the C sockets (Table 2), and 79% of the teeth fractures in the T sockets had involved maxillary teeth.

Lekovic et al. (1998), in a clinical study involving 16 patients, also reported a lesser vertical bone resorption in the sockets covered by a resorbable membrane made of glycolide and lactide polymer compared to the negative control sockets in the same patients (0.4 mm in the test sites, compared to 1.5 mm in the control sites). However, the use of the membrane technique may present some clinical disadvantages such as (1) difficulty in obtaining the complete coverage of the membrane, which may eventually be exposed to the oral environment and consequently be colonized by bacteria (Selvig et al. 1990; Simion et al. 1994a; Nowzari et al. 1995), and (2) the risk of collapse of the membrane in the socket if the membrane is not supported by filling graft materials (Simion et al. 1994b; Buser et al. 1998). In our study, both in the T and C groups, the primary closure of the wound healing was intentionally not achieved. Signs of infections were not recorded. This may be due to the good supragingival plaque control exhibited by the patients and also shows that glycolide and lactide polymer were well tolerated by the gingival tissue. This finding is in agreement with Lekovic et al. (1998). Most grafting materials have been used as filling materials in fresh extraction sockets to avoid collapse of the membrane. Studies in humans using DFDBA (Becker et al. 1994; Brugnamì et al 1996; Froum et al. 2002), deproteinized natural bovine bone mineral (Bio-Oss®) (Dies et al. 1996; Becker et al. 1998; Artzi et al. 2000; Carmagnola et al. 2001) or bioactive glass (Froum et al. 2002) showed the presence of particles of the grafted material in the

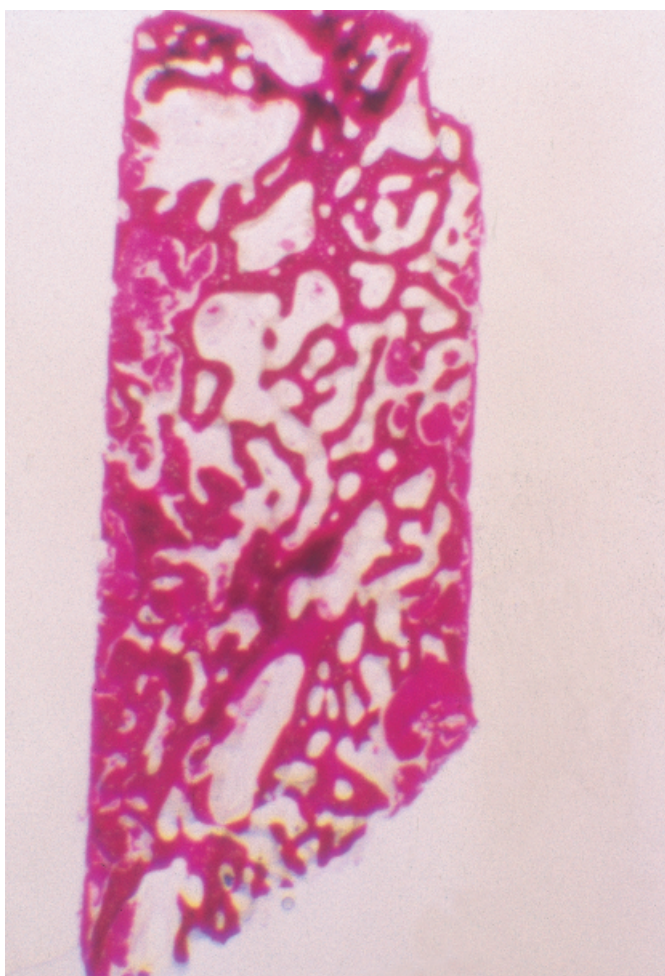


Fig. 3. Photomicrographs illustrating the biopsy harvested from a control socket, 6 months following the extractions. The bone has wide marrow spaces. Magnification $\times 20$.

sockets 6–9 months following their insertion. On the contrary, in our study, particles of the grafted material could not be identified by the histological analysis of the biopsies harvested 6 months following the extractions. This may be related to the fact that Fisiograft[®], formed by 50–50 lactide–glycolide polymer, has the fastest degradation rate of the D–L lactide/glycolide materials, with the polymer degrading in about 50–60 days (Holland et al. 1986). The bone that filled the sockets was similar to the surrounding bone and it was not possible to identify the previous socket wall. The histological analysis indicated that the new bone formed in the T sites was mature with signs of remodeling. The bone in the apical portion of the biopsies (corresponding to a depth of about 3 mm from the bone crest) was dense, with few marrow spaces. In the coronal part of the biopsies, the bone was also well structured, with no signs of ingrowth of tissues other than

bone; the sponge may be functioning as a barrier to the ingrowth of surrounding tissue that could have impeded the process of bone regeneration.

At the C sites, the percentage of mineralized bone did not exceed 56% (Table 3) and did not differ in the coronal compared to the apical portion of the biopsy. However, due to the small number of control biopsies, comparisons with the T sites cannot be made.

At the re-entry surgery, however, we noted that in three of the 26 T sites, and in two of the 13 C sites, the density of the bone in the central part of the sockets was reduced. In all these five cases, the teeth that were extracted presented a history of repeated infection with abscess formation. However, the bone at the buccal and lingual site of the ridge in these five cases was of normal consistency. This observation seems to corroborate the findings of Boyne (1997), who noted that bone apposi-

tion in an extraction socket initiates along the lateral wall of the socket.

Finally, it is important to consider that Fisiograft[®] is a synthetic material, not derived from animals or humans, and for this reason it may be well accepted by patients.

Conclusion

The results of this study indicate that alveolar bone resorption following tooth extraction may be prevented or reduced by the use of bioabsorbable synthetic sponge of polylactide–polyglycolide acid inserted into the tooth socket. The use of this material in the form of a sponge seemed to be of clinical advantage in sockets where the buccal bone is completely or partially lost as a consequence of dental pathology. No adverse reactions that could be related to the use of this synthetic material were reported. The quality of the bone formed seemed to be good for dental implant anchorage. However, the treatment of alveolar sockets with a history of repeated abscesses has to be optimized.

Résumé

Le placement de différents matériaux de greffe associés ou non à l'utilisation de membranes occlusives pour recouvrir les alvéoles d'avulsion sont des techniques qui ont pour but de préserver ou de réduire la résorption du rebord alvéolaire. L'utilisation de matériaux de greffe dans les alvéoles fraîches d'avulsion a cependant été examinée parce que des particules du matériel de greffe ont été trouvées dans ces alvéoles six à neuf mois après leur placement. Les buts de cette étude ont été (1) d'évaluer si la résorption du rebord alvéolaire suivant l'avulsion dentaire pouvait être évitée ou réduite par l'application d'une éponge bioabsorbable en acide polyglycolide-polylactide utilisée comme mainteneur d'espace, comparée à une guérison naturelle avec formation d'un caillot, (2) d'évaluer histologiquement la quantité et la qualité du tissu osseux formé dans les alvéoles six mois après l'utilisation du matériel bioabsorbable. Trente-six patients qui suivaient un traitement parodontal ont participé à cette étude. Tous les patients ont été soumis à une avulsion de une ou plusieurs dents defectueuses. Après l'élévation de lambeaux d'épaisseur totale et l'avulsion de dents des mesures ont été relevées pour évaluer la distance entre trois marques (mésio-vestibulaire, médiane et disto-vestibulaire) sur des gouttières individuelles préfabriquées, et le rebord alvéolaire. Vingt-six alvéoles d'extraction (tests) ont été remplies avec l'éponge bioabsorbable (Fisiograft[®]), tandis que treize autres (contrôles) ont dû guérir sans ajout d'aucun matériel. Les lambeaux ont été suturés sans fermeture complète du site chirurgical. La réentrée pour la chirurgie implantaire a été effectuée six mois

après les avulsions. Trente biopsies (10 tests et 3 contrôles) ont été obtenus des sites prévus pour le placement implantaire. Les mesures cliniques à six mois ont révélé dans le site mésio-vestibulaire une perte osseuse verticale de 0.2 ± 1.4 mm au niveau des tests et 0.6 ± 1.1 mm au niveau des contrôles; dans la portion moyenne un gain de 1.3 ± 1.9 mm dans les tests et une perte de 0.8 ± 1.6 mm dans les contrôles; une perte de 0.1 ± 1.1 mm au niveau des tests et de 0.8 ± 1.5 mm au niveau des contrôles a été enregistrée dans la portion distale. Des biopsies prélevées des sites test ont révélé que le nouvel os formé à six mois était minéralisé, mûr et bien structuré. Des particules de matériel greffé ne pouvaient pas être identifiées dans aucune des dix biopsies. L'os formé dans les sites contrôles était également mûr et bien structuré. Les résultats de cette étude indiquent que la résorption osseuse alvéolaire suivant l'avulsion dentaire peut être empêchée ou réduite par l'utilisation d'une éponge synthétique bioabsorbable en acide polyglycolide-poly lactide. La qualité de l'os formé semble être optimale pour l'insertion implantaire.

Zusammenfassung

Erhaltung des Kieferkammes nach Zahnextraktion mittels eines Schwammes aus Poly lactid und Poly glycolid als Platzhalter: eine klinische Studie am Menschen

Hintergrund: Die Platzierung von verschiedenen Transplantationsmaterialien und/oder die Verwendung von dichten Membranen zur Abdeckung von Extraktionswunden stellen Techniken dar, die zur Vermeidung/Verminderung von Alveolarkammresorptionen dienen. Die Verwendung von Transplantationsmaterialien in frischen Extraktionswunden wurde jedoch in Frage gestellt, da Partikel des Transplantationsmaterials noch 6–9 Monate nach Platzierung in der Extraktionswunde gefunden werden können.

Ziel: Die Ziele der Studie waren: (i) zu evaluieren, ob die Resorption des Alveolarkammes nach Zahnextraktion durch die Applikation eines bioabsorbierbaren Schwammes aus Poly lactid und Poly glycolid als Platzhalter im Vergleich zur natürlichen Heilung durch Bildung eines Blutkoagulum verhindert oder reduziert werden kann; (ii) histologisch 6 Monate nach dem Einsatz des bioabsorbierbaren Materials die Menge und Qualität des in den Extraktionsalveolen gebildeten Knochengewebes zu untersuchen.

Material und Methoden: Sechszwanzig Patienten, welche in parodontaler Behandlung waren, nahmen an der Studie teil. Bei allen Patienten war die Extraktion eines oder mehrerer angeschlagener Zähne vorgesehen. Nach der Präparation von Mukoperiotappen und Extraktion der Zähne wurden Messungen vorgenommen, um die Distanz zwischen 3 Fixpunkten (mesio-bukkal, bukkal, disto-bukkal) auf individuell vorgefertigten Schienen und dem Alveolarkamm festzuhalten. Sechszwanzig Alveolen (Test) wurden mit einem Schwamm aus Poly lactid-Poly glycolid (Fisiograft®) aufgefüllt, während 13 Alveolen (Kontrolle) ohne Füllmaterial ausheilten. Die Lappen wurden vernäht. Es wurde kein primärer Wundverschluss angestrebt. Die Wiedereröffnung für die Implantatplatzierung wurde 6

Monate nach den Extraktionen durchgeführt. Von den Implantatstellen konnten 13 Biopsien (10 Test- und 3 Kontrollstellen) gewonnen werden.

Resultate: Die klinischen Messungen nach 6 Monaten zeigten einen Verlust an Knochenhöhe an der mesio-bukkalen Seite von 0.2 mm (1.4 SD) bei den Test- und 0.6 mm (1.1 SD) bei den Kontrollstellen; bukkal konnte bei den Teststellen ein Gewinn von 1.3 mm (1.9 SD) und bei den Kontrollstellen ein Verlust von 0.8 mm (1.6 SD) gesehen werden; distal zeigte sich bei den Teststellen ein Verlust von 0.1 mm (1.1 SD), während die Kontrollstellen eine Verlust von 0.8 mm (1.5 SD) aufwiesen. Die Biopsien der Teststellen zeigten, dass der neu gebildete Knochen nach 6 Monaten mineralisiert, maturiert und gut strukturiert war. In keiner der 10 Testbiopsien konnte noch Transplantationsmaterial nachgewiesen werden. Der Knochen der Kontrollstellen war ebenfalls maturiert und gut strukturiert.

Schlussfolgerung: Die Resultate dieser Studie zeigen, dass die Resorption des Alveolarkammes nach Zahnextraktion verhindert oder reduziert werden kann, wenn ein bioabsorbierbarer synthetischer Schwamm aus Poly lactid-Poly glycolid verwendet wird. Die Qualität des gebildeten Knochens schien für die Platzierung von dentalen Implantaten optimal zu sein.

Resumen

Antecedentes: La colocación de diferentes materiales de injertos y/o el uso de membranas oclusivas para cubrir la entrada del alvéolo de extracción, son técnicas que intentan preservar/reducir la reabsorción de la cresta alveolar. El uso de materiales de injerto en alvéolos frescos de extracción ha sido sin embargo cuestionado porque se han encontrado partículas del material injertado en los alvéolos de 6–9 meses tras su inserción.

Intención: Las intenciones del estudio fueron (i) evaluar si se podía prevenir o reducir la reabsorción de la cresta alveolar tras la extracción dentaria mediante la aplicación de una esponja biorreabsorbible de poliáctido-póliglicólido usada como relleno de espacio, en comparación con la cicatrización natural por formación de coágulo; (ii) evaluar histológicamente la cantidad y calidad del hueso formado en los alvéolos, 6 meses tras el uso del material biorreabsorbible.

Material y métodos: En este estudio participaron treinta y seis pacientes sometidos a tratamiento periodontal. Todos los pacientes estaban programados para extracción de uno o más dientes comprometidos. Tras la elevación de un colgajo de grosor completo y la extracción de los dientes, se tomaron medidas para evaluar la distancia entre 3 puntos de referencia (mesio-vestibular, medio-vestibular, disto-vestibular) en tallos fabricados individualmente y la cresta alveolar. Se rellenaron yentiséis alvéolos (prueba) con una esponja de ácido poliáctido-póliglicólido (Fisiograft®), mientras que 13 alvéolos (control) fueron permitidos cicatrizar sin material de relleno. Se llevó a cabo la reentrada a los 6 meses tras las extracciones. Se tomaron 13 biopsias (10 en lugares de prueba y 3 de control) de los lugares previstos para colocación de implantes.

Resultados: Las mediciones clínicas a los 6 meses, revelaron en el lugar mesio-vestibular una pérdida de altura ósea de 0.2 mm (1.4 SD) en las pruebas y de 0.6 mm (1.1 SD) en los controles; en la porción medio-vestibular se registró una ganancia de 1.3 mm (1.9 SD) en las pruebas, y una pérdida de 0.8 mm (1.6 SD) en los controles; en la porción distal se encontraron unas pérdidas de 0.1 mm (1.1 SD) en las pruebas y de 0.8 mm (1.5 SD) en los controles. Las biopsias recogidas de los lugares de prueba, revelaron que el hueso neoformado a los 6 meses estaba mineralizado, maduro y bien estructurado. No se pudieron identificar partículas del material de injerto en ninguna de las 10 biopsias. El hueso formado en los lugares de control estaba también maduro y bien estructurado.

Conclusión: Los resultados de este estudio indican que la reabsorción del hueso alveolar tras la extracción dentaria puede ser prevenida o reducida por el uso de una esponja sintética biorreabsorbible de ácido poliáctido-póliglicólido. La calidad del hueso formado parece ser óptima para la inserción de implantes dentales.

要旨

背景：異なる移植材料の埋入及び/あるいは抜歯窩を被覆する閉塞性メンブレンの使用は、歯槽堤吸収を予防/軽減するための術式である。しかしながら新鮮抜歯窩における移植材料の使用は、移植材料粒子が埋入6–9ヶ月後に歯槽骨抜歯窩で見つかっており、疑いがもたれている。

目的：本研究の目的は、1) 生体吸収性 poly lactide-poly glycolide スポンジをスペース充填材として使用すると、血餅形成による自然治癒に比べて、抜歯後の歯槽堤吸収が予防あるいは軽減できるかどうかを評価すること、2) 抜歯窩に形成される骨組織の量と質を、生体吸収性材料使用後6ヶ月後に組織学的に評価することであった。

材料と方法：歯周治療を受ける患者36名が本研究に参加した。全ての患者に、1本以上の罹患歯を抜去する予定があった。全層フラップを挙上し抜歯をした後に、個別に製作したステント上の3つのランドマーク（近心頬側面、頬側面中央、遠心頬側面）と歯槽頂の間の距離を測定、評価した。歯槽骨抜歯窩（対照）2箇所は、充填材なしに治癒させた。フラップを縫合し、術創の一次治癒の獲得を意図することなく縫合した。インプラント埋入の手術は、抜歯後6ヶ月後に行った。インプラントの埋入予定部位13箇所（試験部位10、対照部位3）から、生検標本を採取した。

結果：6ヶ月後の臨床的測定では、近心頬側面において骨高径の喪失は、試験部位で 0.2 mm (1.4 SD)、対照部位で 0.6 mm (1.1 SD)であった。頬側面中央では、試験部位で 1.3 mm (1.9 SD)の獲得、対照部位では 0.8 mm (1.6 SD)の喪失が記録され、遠心頬側面では試験部位で 0.1 mm (1.1 SD)の喪失、対照部位で 0.8 mm (1.5 SD)の喪失が記録された。試験部位から採取した生検標本は、6ヶ月後に新生骨は石灰化しており、成熟した良好な構造であることを示した。移植材料粒子は、10箇所の試験部位からの生検標本のいずれにもみとめられなかった。対照部位で形成された骨も成熟し、良好な構造であった。

結論：本研究の結果は、抜歯後の歯槽骨吸収は poly lactide-poly glycolide acid 製の生体吸収性合成スポンジの使用により予防ないし軽減できることを示唆している。形成された骨の質は、インプラント埋入にとって最適であると思われる。

References

- Adriaens, P.A. (1999) Preservation of bony sites. In: Lang, N.P., Karring, T. & Lindhe, J., eds. *Proceedings of the Third European Workshop on Periodontology: Implant Dentistry*, 266–280. Chicago: Quintessence Publishing Co. Inc.
- Amler, M.H., Johnson, P.L. & Salman, I. (1960) Histological and histochemical investigation of human alveolar socket healing in undisturbed extraction wound. *Journal of the American Dental Association* **61**: 46–48.
- Artzi, Z., Tal, H. & Dayan, D. (2000) Porous bovine bone mineral in healing of human extraction socket. Part 1. Histometric evaluation at 9 months. *Journal of Periodontology* **71**: 1015–1023.
- Becker, W., Becker, B.E. & Caffesse, R. (1994) A comparison of demineralized freeze-dried bone and autologous bone to induce bone formation in human extraction socket. *Journal of Periodontology* **65**: 1128–1133.
- Becker, W., Urist, M., Vincenzi, G., De Georges, D. & Niederwanger, M. (1996) Clinical and histological observation of sites implanted with intraoral autologous bone graft or allograft. 15 Human case reports. *Journal of Periodontology* **67**: 1025–1033.
- Becker, W., Clokie, C., Sennerby, L., Urist, M. R. & Becker, B. E. (1998) Histological findings after implantation and evaluation of different grafting materials and titanium micro screws into extraction sockets: case reports. *Journal of Periodontology* **69**: 414–421.
- Boyne, P.J. (1997) *Osseus reconstruction of the maxilla and mandible*. Chicago: Quintessence Publishing Co, Inc.
- Brugnam, F., Then, P.R., Moroi, H. & Leone, C.W. (1996) Histologic evaluation of human extraction socket treated with demineralized freeze-dried bone allograft (DFDBA) and cell occlusive membrane. *Journal of Periodontology* **67**: 821–825.
- Buser, D., Hoffmann, B., Bernard, J.P., Lussi, A., Mettler, D. & Schenk, R.K. (1998) Evaluation of filling materials in membrane-protected defect. *Clinical Oral Implants Research* **3**: 137–150.
- Carmagnola, D., Adriaens, P. & Berglundh, T. (2001) Healing of human extraction sockets filled with Bio-Oss. In: *Bone Tissue Reaction at Sites Grafted with Bio-Oss*, Thesis, Göteborg, Sweden: Göteborg University.
- Dies, F., Etienne, D., Bou Abboud, J. & Ouhayoun, J.P. (1996) Bone regeneration in extraction sites after immediate placement of an e-PTFE membrane with or without a biomaterial. A report of 12 consecutive cases. *Clinical Oral Implants Research* **7**: 277–285.
- Evian, C.I., Rosenberg, E.S., Coslet, J.G. & Corn, H. (1981) The osteogenic activity of bone removed from healing extraction sockets in humans. *Journal of Periodontology* **53**: 81–85.
- Froum, S., Cho, S.-C., Rosenberg, E., Rohrer, M. & Tarnow, D. (2002) Histological comparison of healing extraction socket implanted with bioactive glass or demineralized freeze-dried bone allograft: a pilot study. *Journal of Periodontology* **73**: 94–102.
- Holland, S.J., Tighe, B.J. & Gould, P.L. (1986) Polymers for biodegradable medical device. I. The potential of polyesters as controlled macromolecular release system. *Journal of Controlled Release* **4**: 155–180.
- Howell, T.H., Fiorellini, J., Jones, A., Alder, M., Nummikoski, P., Lazaro, M., Lilly, L. & Cochran, D. (1997) A feasibility study evaluating rhBMP-2/absorbable collagen sponge device for local alveolar ridge preservation or augmentation. *International Journal of Periodontology & Restorative Dentistry* **17**: 125–139.
- Laurencin, C.T. & Lane, J.M. (1999) Poly-lactide acid and poly-glycolide acid: orthopedic and surgery applications. In: *Tissue Engineering: Application in Maxillofacial Surgery and Periodontics*, 325–339. Chicago: Quintessence Publishing Co. Inc.
- Lekovic, V., Camargo, P.M., Klokkevold, P.R., Weinlaender, M. & Nedic, M. (1998) Preservation of alveolar bone in extraction sockets using bioabsorbable membrane. *Journal of Periodontology* **69**: 1044–1049.
- Lekovic, V., Kenney, E.B., Weinlaender, M., Han, T., Klakkevold, P., Nedic, M. & Orsini, M. (1997) A bone regenerative approach to alveolar ridge maintenance following tooth extraction. Report of 10 cases. *Journal of Periodontology* **68**: 563–570.
- McCall, P.A. & Rosenfeld, A.L. (1991) Influence of residual ridge resorption patterns on implant fixture placement and tooth position. 1. *International Journal of Periodontics & Restorative Dentistry* **11**: 8–23.
- Nowzari, H., Matian, F. & Slots, J. (1995) Periodontal pathogens on polytetrafluoroethylene membrane for guided tissue regeneration inhibit healing. *Journal of Clinical Periodontology* **22**: 469–474.
- Pinholt, E.M., Bang, G. & Haanaes, H.R. (1991) Alveolar ridge augmentation in rats by Bio-Oss. *Scandinavian Journal of Dental Research* **99**: 154–161.
- Selvig, K., Nilveus, R.E., Fitzmorris, L., Kersten, B. & Khorsadi, S.S. (1990) Scanning electron microscopic observation of cell population and bacterial contamination of membrane used for guided periodontal tissue regeneration in human. *Journal of Periodontology* **61**: 515–520.
- Simion, M., Boldoni, M., Rossi, P. & Zaffe, D. (1994a) A comparative study of the effectiveness of e-PTFE membrane with or without early exposure during the healing period. *International Journal of Periodontics & Restorative Dentistry* **14**: 167–180.
- Simion, M., Dahlin, C., Trisi, P. & Piattelli, A. (1994b) Qualitative and quantitative comparative study on different filling materials used in bone tissue regeneration: a controlled clinical study. *International Journal of Periodontics & Restorative Dentistry* **14**: 198–215.