JOURNAL OF MATERIALS SCIENCE: MATERIALS IN MEDICINE 5 (1994) 40–42

Effect of polyglycolic acid membrane on bone regeneration around titanium implants inserted in bone sockets

J. MUHONEN, R. SUURONEN, V. J. OIKARINEN
Department of Oral and Maxillofacial Surgery, Institute of Dentistry, University of Helsinki, Finland

E. SARKIALA
Department of Clinical Sciences, College of Veterinary Medicine, Helsinki, Finland

R. -P. HAPPONEN*
Department of Oral and Maxillofacial Surgery, University of Turku, Finland

An experimental animal model was used to evaluate the value of resorbable, non-permeable polyglycolic acid (PGA) membranes in relation to fixtures implanted into simulated extraction sockets. Brånemark fixtures (length 7.0 mm, diameter 3.75 mm) were implanted into edentulous areas of maxillary bone in six sheep. Five fixtures were covered with 0.15-mm-thick PGA membrane (Biofix®) held in place with a cover screw (PGA group) and five were implanted without membrane (control group). The animals were killed after 4 months and undecalcified mesiodistal sections were prepared from resected jaw specimens. Histomorphometry was used to measure the distance from the shoulder of the fixture to the level of intimate bone contact (SB distance). SB distance was found to be greater in the PGA than in the control group in relation both to the mesial (1.44 ± 0.88 mm versus 0.96 ± 0.47 mm) and distal (1.13 ± 0.80 mm versus 0.77 ± 0.63 mm) aspects of implants. This statistically not significant difference in bone regeneration between the two groups is related to the physical properties of the PGA membrane used.

1. Introduction

A healing period of 8 to 12 months is usually required after extraction of teeth before implantation is possible. This delays permanent prosthetic dental treatment. Whether implantation immediately after removing teeth can be successful is controversial. Some animal [1, 2] and clinical studies [3, 4] suggest that immediate implantation can succeed. Principles of guided tissue regeneration [5–7] have been tried in such situations. Polytetrafluoroethylene (PTFE) membranes have been most commonly applied for this purpose [1–4]. Because PTFE is not absorbed, another operation needs to be done later to remove the material. The latter operation can be avoided if a membrane made of absorbable material, e.g. polyglygolic acid (PGA), is used.

PGA was first used for absorbable sutures [8]. Its behaviour has been thoroughly investigated [9]. PGA degrades via hydrolysis of ester bonds, first to glycolic acid, and then to glyoxylate and glycine, which occur normally during human metabolism. The end products are carbon dioxide and water, which are excreted by the lungs and kidneys. PGA is well tolerated by living tissues [10, 11], and causes only a mild non-specific lymphocyte activation [12]. The purpose of this study was to examine if it were possible to enhance bone formation around the neck of the implant by preventing growth of soft tissue into extraction sockets with an absorbable PGA membrane.

2. Material and methods

Eleven Brånemark fixtures (length 7.0 mm, diameter 3.75 mm) were implanted into a maxillary edentulous area on both sides of the mouth in six sheep under general anaesthesia. The animals were given 1 mg of atropine (Atropin 1 mg ml^{-1}, Orion, Espoo, Finland) subcutaneously, 1 500 000 IU of procaine benzylpenicillin (procapen 300 000 IU/ml, Orion), and 1000 mg of tinidazole (Tricanix 5 mg ml^{-1}, Orion), preoperatively. The sheep were anaesthetized by means of ketamine hydrochloride (Ketalar 50 mg ml^{-1}, Parke-Davis, Barcelona, Spain) 1 mg/kg i.m. and medetomidine (Domitor 1 mg ml^{-1}, Lääkefarmos, Turku, Finland) 0.025 mg/kg i.m. The sheep were incubated and anaesthesia was maintained with 1.5% halothane inhalation (Trothane, ICS, Bristol, UK) and oxygen. Flunixine meglumine (Finadyne 50 mg ml^{-1}, Orion) was used to control postoperative pain.

The operation area was first cleaned with chlorhexidine solution (Hibitane Dental 2 mg ml^{-1}, ICI

* To whom correspondence should be addressed.

0957–4530

Pharmaceuticals, Cheshire, UK). After elevating a mucoperiosteal flap, the fixtures were inserted in 7 mm deep and 3.75 mm wide holes (Fig. 1a) prepared with a Brånemark drill kit under continuous saline irrigation. Using a special drill, the cervical diameters of the holes were increased to 6.15 mm to a depth of 4.0 mm before implantation. In the PGA group, six implants were covered with a 0.15 mm thick PGA membrane (15 mm × 15 mm) (Biofix®, Biocon Ltd, Tampere, Finland) held in place with a cover screw (Fig. 1b). In the control group, five implants were inserted similarly but without the membrane (Fig. 1a). The animals were killed after 4 months. Resected jaw specimens were fixed in 4% neutral formalin and embedded in plastic (Technovit, Kulzer GmbH, Wehrheim, Germany). Mesiodistal sections (15 μm) were prepared using a cutting–grinding method (Exakt-Apparetebau, Hamburg, Germany) developed for undecalcified hard tissue specimens [13]. Sections were stained with toluidine blue and evaluated histologically. A computerized analysis system (MicroScale TC, Digithust Ltd, Royston, UK) was used to measure the distance from the shoulder of the fixture to the level of intimate bone contact (SB distance, Fig. 2b), in relation to the mesial and distal aspects of each implant.

3. Results

One fixture was lost in the PGA group, for unknown reasons. No difference was seen between the PGA and control groups with regard to inflammation in the soft tissue around the coronal parts of the fixtures. Small fragments of PGA membrane were detected in connection with all fixtures in the PGA group (Fig. 2a). Only a very mild mononuclear inflammatory reaction was seen around fragments of the membrane in the course of being absorbed.

The mean SB distance in the PGA group was -1.44 ± 0.88 mm (range $+0.40$ to -2.70 mm) in relation to the mesial and -1.13 ± 0.80 mm (range $+0.08$ to -2.23 mm) in relation to the distal aspect of the implants (Fig. 2b, Table I.) The corresponding figures in the control group were -0.96 ± 0.47 mm (range -0.30 to -1.60 mm) and -0.77 ± 0.63 mm (range -0.08 to -1.66 mm), respectively (Fig. 2c). In the PGA group, bone had grown over the shoulder level in relation to the mesial aspect of one fixture and the distal aspect of another fixture. In the calculations presented in Table I, these two SB values were considered zero as if bone had grown to the shoulder level. The differences in SB distance between the PGA and control groups were not statistically significant (Mann–Whitney U-test). No differences were found with regard to the rate of osteointegration in the deeper regions of the implants between the PGA and control groups.

4. Discussion

The polyglycolic acid (PGA) membrane applied in the study has been shown to be biocompatible in experiments in animals and in man [9–12]. The membrane has been used clinically for several years in various surgical indications [14]. The PGA membrane used in the study loses its strength in tissue within 3 to 4 weeks and becomes totally degraded in 6 to 12 months, depending on its size. In our study, small PGA fragments were found 4 months after implantation. Only very minor mononuclear inflammatory cell infiltrates were seen around membrane particles in the course of absorption.

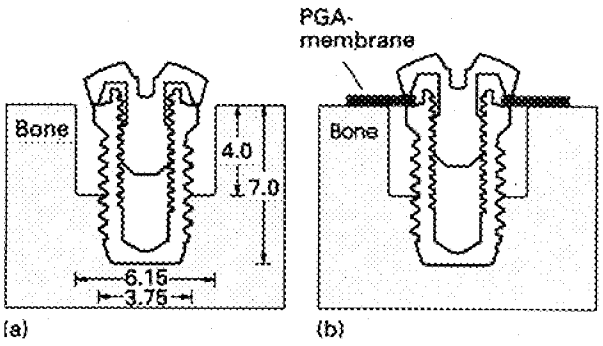

Figure 1 Experimental design. Fixtures were inserted into holes with cervically expanded diameters (a). In the PGA group, implants were covered with PGA membrane (Biofix®) held in place with a cover screw (b) (dimensions in mm).

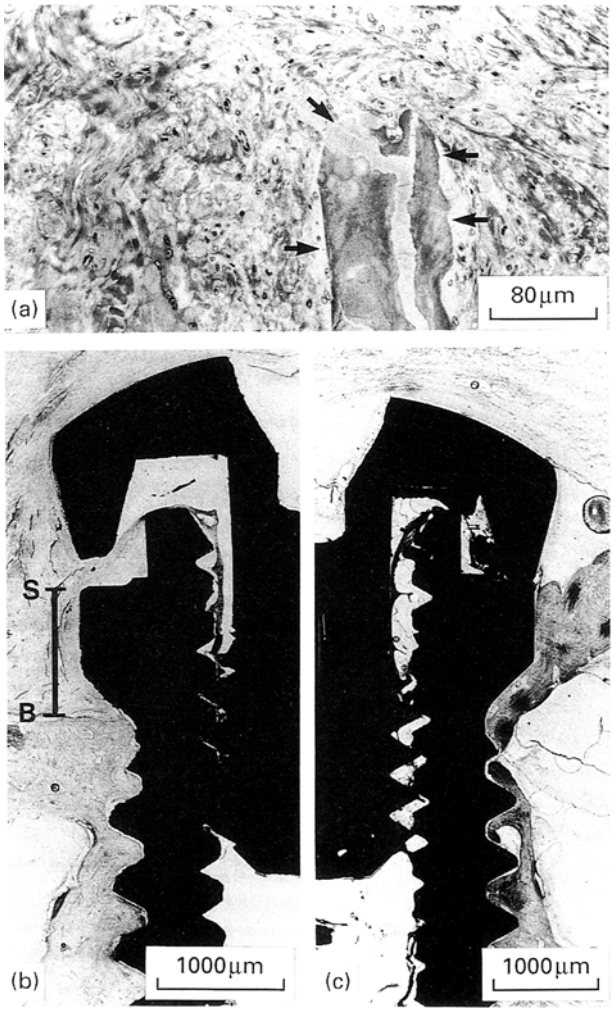

Figure 2 (a) Only a mild chronic inflammatory reaction is seen around fragments of PGA membrane (arrows) in course of absorption between the cover screw and fixture in the PGA group. (b) Micrograph of a fixture with PGA membrane showing the bone level (SB distance) to be 1.18 mm below the shoulder of the implant in relation to the mesial aspect. (c) SB distance in relation to the distal aspect of the fixture implanted without membrane is -0.08 mm. Note good osteointegration in both (b) and (c).

TABLE I Distances (mm) between bone level and shoulders (SB distances) of the fixture in PGA and control groups. Two positive SB values in PGA group were considered as zero in the calculations presented

	PGA Group		Control group	
	Mesial	Distal	Mesial	Distal
	− 1.18	+ 0.08	− 1.60	− 0.72
	− 1.66	− 1.60	− 0.60	− 0.08
	− 2.70	− 2.23	− 0.30	− 0.11
	− 1.68	− 1.35	− 0.95	− 1.66
	+ 0.40	− 0.45	− 1.33	− 1.30
Mean	− 1.44	− 1.13	− 0.96	− 0.77
± SD	± 0.88	± 0.80	± 0.47	± 0.63

Mann-Whitney U-test: Mesial $p = 0.251$
Distal $p = 0.602$

Distances from the shoulder of the fixture to the level of intimate bone contact (the SB distance) were measured in the PGA and control groups. The mean SB distance was greater in relation to both the mesial and distal aspects of the fixtures in the PGA group than in the control group, indicating slightly poorer bone regeneration. One reason for this may be that there has been some hinderance of diffusion of periosteal mediators beneath the non-permeable membrane. Furthermore, the fairly thick and stiff membrane held in place by a cover screw may also have pressed on the tissue around the neck of the fixture, reducing space necessary for bone regeneration [15]. Use of porous, thin membrane could lessen such effects.

There are differences between our experimental model and clinical situations in human patients. In patients the alveolar bone around the implant rarely reaches the level of the shoulders of the fixture. This being so, the healing results in both groups may be considered good. Measurement of SB distance in relation to healing could, conversely, be criticized. The SB distance was measured because the shoulder of the implant served as an exact reference point. The period of our study was 4 months, although a healing period of 6 months is recommended in relation to implants in the maxilla. However, better bone healing with regard to SB distance cannot be anticipated even if the experiment time had been longer. The function of the membrane was to keep the periosteum elevated over the bone sockets thus enhancing bone formation around the neck of the implant. The membrane was almost totally absorbed within 4 months and it was no more effective for the assumed task.

In our study, no advantage with regard to bone regeneration was achieved by the use of PGA membrane as compared with implants without membrane. Warrer *et. al.* [2] have reported that a PTFE membrane can secure complete osteointegration of implants inserted immediately into extraction sockets. However, in their study the membrane became exposed in half of the experiment animals leading to poor bone regeneration. This kind of problem was not encountered with PGA membrane. Bone healing found in the case of implants without membrane was good enough to support the opinion that fixtures may be inserted immediately into non-infected extraction sockets. It is important, however, that the upper diameter of the extraction wound is small enough to hinder growth of soft tissue into the socket. Slightly poorer bone regeneration in the PGA group than in the control group is due to technical aspects which are related to the physical properties of the PGA membrane used but not its biological effects within tissue. More experimental work is needed if an absorbable membrane for oral implantology is to be optimized.

References

1. W. BECKER, B. E. BECKER, M. HANDELSMAN, C. OCHSENBEIN and T. ALBREKTSSON, *J. Periodontol.* **62** (1991) 703.
2. K. WARRER, K. GOTFREDSEN, E. HJÖRTING-HANSEN and T. KARRING, *Clin. Oral Impl. Res.* **2** (1991) 166.
3. R. J. LAZZARRA, *Int. J. Periodont. Rest. Dent.* **5** (1989) 333.
4. S. NYMAN, N. P. LANG, D. BUSER and U. BRAGGER, *Int. J. Oral. Maxillofac. Implants* **5** (1990) 9.
5. C. DAHLIN, L. SENNERBY, U. LEKHOLM, A. LINDE and S. NYMAN, *ibid.* **4** (1989) 19.
6. C. DAHLIN, J. GOTTLOW, A. LINDE and S. NYMAN, *Scand. J. Plast. Reconstr. Surg. Hand. Surg.* **24** (1990) 13.
7. S. NYMAN, *J. Clin. Periodontol.* **18** (1991) 494.
8. E. J. FRAZZA and E. SCHMITT, *J. Biomed. Mater. Res.* **1** (1971) 43.
9. P. TÖRMÄLÄ, T. POHJONEN, P. HELEVIRTA, R. TAURIO, H. M. MIKKOLA, S. VAINONPÄÄ, O. BÖSTMAN and P. ROKKANEN, in "Biomedical applications of composites", edited by C. Migliaresi and J. L. Kardos (CRC Press, Boca Raton) in Press.
10. H. DARDIK, I. DARDIK and H. LAUFMAN, *Amer. J. Surg.* **121** (1971) 656.
11. P. H. CRAIG, J. A. WILLIAMS, K. W. DAVIS, A. D. MAGOUN, A. J. LEVY, S. BOGDANSKY and J. P. JONES, *Surg. Gynecol. Obstet.* **1** (1975) 1.
12. S. SANTAVIRTA, Y. T. KONTTINEN, T. SAITO, M. GRÖNBLAD, E. PARTIO, P. KEMPPINEN and P. ROKKANEN, *J. Bone Joint Surg.* [Br] **72B** (1990) 597.
13. K. DONATH and G. BREUNER, *J. Oral. Pathol.* **11** (1982) 318.
14. C. SASSERATH, J. VAN RECK and J. GITANI, *Acta stomatol. Belg.* **88** (1991) 5.
15. W. BECKER, B. E. BECKER, M. HANDLESMAN, R. CELLETTI, C. OCHSENBEIN, R. HARDWICK and B. LANGER, *Int. J. Periodont. Rest. Dent.* **10** (1990) 93.

Received 5 January
and accepted 10 May 1993