CLINICAL ORAL IMPLANTS RESEARCH

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Novel 3D polycaprolactone scaffold for ridge preservation – a pilot randomised controlled clinical trial

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Abstract

Objectives: This pilot randomised controlled clinical trial aimed to evaluate the feasibility and effectiveness of using a polycaprolactone (PCL) scaffold in fresh extraction sockets for ridge preservation. The hypothesis was that the insertion of a 3D bioresorbable PCL scaffold in fresh extraction sockets allowed for normal bone healing and better maintenance of ridge dimensions after 6 months as compared to extraction sockets without the scaffold.

Material and methods: Thirteen patients were randomised to either the test group ($N = 6$) where a PCL scaffold was inserted in the tooth socket after extraction or the control group ($N = 7$) where no space filler was used. Alveolar ridge height and width measurements were made at baseline and 6 months post-extraction, for the evaluation of bone resorption. At 6 months, a core of bone was trephined out from the healed ridge for microcomputed tomographic (micro CT) and histological analyses, immediately before Stage I dental implant surgery. Stage II dental implant surgery was performed 4–6 months later.

Results: There was less vertical ridge resorption in the test group compared to the control group, and the difference was statistically significant in the mesio-buccal aspect ($P = 0.008$). Micro CT and histological observations showed mainly mineralised bone formation in both groups, except for one specimen in the test group.

Conclusions: The insertion of a 3D bioresorbable PCL scaffold in fresh extraction sockets allowed for normal bone healing, and there was better maintenance of ridge height after 6 months as compared to extraction sockets without the scaffold.

Tooth extraction sockets usually heal naturally with bone tissue in 1–2 months following tooth extraction (Amler et al. 1960; Evian et al. 1982; Cardaropoli et al. 2003). However, as the normal post-extraction healing response of alveolar bone around a tooth socket is resorptive in nature, this healing process usually occurs with substantial reduction of the original height and width of the alveolar ridge. In a systematic review, a reduction of 3.87 and 1.67 mm in alveolar bone width and height, respectively, within 3 months after dental extraction in humans was reported (Van der Weijden et al. 2009). Another more recent systematic review reported a vertical dimensional change of 11–22% at 6 months and a horizontal dimensional change of 32% at 3 months and 29–63% at 6–7 months in the post-extraction alveolar ridge in humans (Tan et al. 2012). Most of the dimensional alterations occur in the first 2–3 months after tooth extraction (Johnson 1969; Araujo & Lindhe 2005). Bone resorption is more pronounced on the buccal than the palatal/lingual aspect of the ridge (Pietrokovski & Massler 1967; Lekovic et al. 1997, 1998; Araujo & Lindhe 2005). The resultant effect of this resorption pattern is transportation of the diminished ridge to a more palatal or lingual position. This decrease in ridge volume and deformation of ridge contour may preclude optimum implant placement and restorative aesthetics.

Ridge preservation techniques have been introduced as a possible means to preserve the original ridge dimensions and contours (Lekovic et al. 1997, 1998). Xenografts, allografts, autografts and/or synthetic materials used alone or in conjunction with a membrane have been used to fill the tooth socket immediately following tooth extraction. Among the various materials used are bovine porous bone mineral (Artzi et al. 2000), demineralised freeze-dried bone allograft (DFDBA) (Becker et al. 1994,

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1996; Froum et al. 2002), bioactive glass (Camargo et al. 2000; Froum et al. 2002), synthetic resorbable sponge (Serino et al. 2003) and biphasic ceramic bone substitute consisting of hydroxyapatite and β-tricalcium phosphate (Mardas et al. 2010). While studies have shown these techniques to be effective in preserving ridge dimensions to some extent (Ten Heggeler et al. 2010; Vignoletti et al. 2012), the graft materials often interfered with the normal healing process (Becker et al. 1994, 1996; Froum et al. 2002; Heberer et al. 2008). Sites grafted with Bio-Oss® (Geistlich, Princeton, NJ, USA) material were found to comprise of connective tissue and only 40% of the circumference of the Bio-Oss® (Geistlich) particles was in contact with woven bone (Carmagnola et al. 2003). Another study using DFDBA showed no evidence of bone formation on the surfaces of the non-viable particles (Becker et al. 1994). Several other investigators have also demonstrated the presence of graft particles in alveolar sockets for as long as 6–9 months following insertion (Brugnami et al. 1996; Dies et al. 1996; Artzi et al. 2000; Froum et al. 2002).

Polycaprolactone (PCL) is regarded as a nontoxic and tissue-compatible material (Pitt et al. 1981) and has been used in medical devices for the last 30 years. It was used in Capronor® (RTI, Research Triangle Park, NC, USA), a subdermal contraceptive device (Darney et al. 1989) and in resorbable Monocryl® (Ethicon, Somerville, NJ, USA) monofilament sutures (Bezwada et al. 1995). Both are Food and Drug Administration (FDA) – approved clinical products. More recently, it has been approved as a bone filler for craniofacial applications (510K FDA K051093; http://www.accessdata.fda.gov/cdrh_docs/pdf5/K051093.pdf). The PCL scaffold is intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects (Schantz et al. 2006). An interdisciplinary group at the National University of Singapore, in collaboration with Temasek Polytechnic, evaluated and patented the parameters used to process PCL by fused deposition modeling (FDM) (Zein et al. 2002). The unique feature of these FDM scaffolds lies in the three-angle layering (0/60/120°) that results in a fully interconnected pore network that provides maximum anchorage for cell attachment (Hutmacher 2000; Zein et al. 2002; Rai et al. 2004). The scaffold has mechanical properties closely similar to bone, exhibits slow degradation kinetics and is osteoconductive.

This pilot randomised controlled clinical trial aimed to evaluate the feasibility and effectiveness of using the PCL scaffold in fresh extraction sockets for ridge preservation. It was postulated that the mechanical stability and slow degradation profile would allow for better maintenance of bone volume and contour. The hypothesis was that the insertion of a 3D bioresorbable PCL scaffold in fresh extraction sockets allowed for normal bone healing and better maintenance of ridge dimensions after 6 months as compared to extraction sockets without the scaffold.

Material and methods

The study protocol was independently reviewed and approved by the SingHealth Centralised Institutional Review Board in Singapore. Patients for the study were recruited from the Departments of Oral & Maxillofacial Surgery and Restorative Dentistry, National Dental Centre of Singapore from May 2007 to May 2011. Patients included in this study were at least 21 years of age, of ASA (American Society of Anesthesiologists) I or II classification, required extraction of a single tooth that was bounded by adjacent teeth and was suitable for replacement with a dental implant. Any pre-existing infection at the site of the intended tooth extraction was treated prior to commencement of the study. Patients with a known allergy to biopolymer materials, smokers and those who had a history of radiotherapy to the head and neck region were excluded. Upper lateral incisors, lower central and lateral incisors were excluded as study sites due to their small socket dimensions. Upper posterior sites that required sinus lift surgery prior to implant placement were also excluded.

Patients who met the above criteria and gave written consent to participating in the study were randomised using sealed envelopes to the following two groups:

Test Group: PCL scaffold as space filler after tooth extraction.

Control Group: no space filler after tooth extraction.

Pre-extraction preparation

Dental models and standardised dental radiographs, including periapical and orthopantomogram, were taken. A customised acrylic dental stent was fabricated as a reference tool for standardised measurement of ridge dimensions. Three markings were made (mesio-buccal, mid-buccal, disto-buccal) on the acrylic stent at the intended extraction site (Fig. 1).

Surgical extraction and socket management

Under local anaesthesia, a trapezoidal buccal mucoperiosteal flap was raised and an atraumatic extraction of the tooth was performed. The tooth socket was thoroughly debrided, and any granulation tissue was curetted out. The acrylic measuring stent was then positioned by fitting it to the adjacent teeth, and the following measurements were taken using a periodontal probe (PCPUNC15; Hu-Friedy, Chicago, IL, USA):

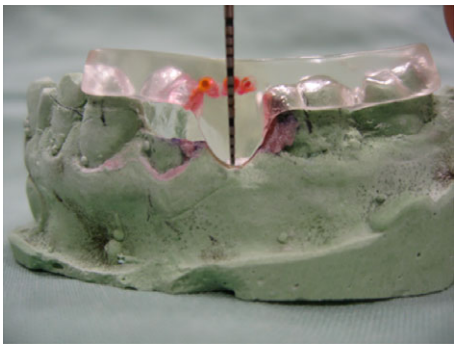

Fig. 1. Customised acrylic dental stent with three gutta-percha markings was used as a reference tool for standardised measurement of ridge height at the mesio-buccal, mid-buccal and disto-buccal aspects.

Ridge height

This was measured indirectly as the vertical distance from each reference marking on the stent to the marginal bone of the tooth socket at the mesio-buccal, mid-buccal and disto-buccal aspects (Fig. 1) and was recorded as RHmeb1, RHmib1 and RHdb1, respectively.

Ridge width

This was the horizontal distance from the buccal aspect to the lingual/palatal aspect of the alveolar crest at the mid-buccal region of the extraction socket (RW1).

All measurements were taken by the same two investigators (GBT, DT). Measurements that differed by less than or equal to 1 mm were averaged. Those that differed by more than 1 mm were repeated, and a consensus was reached by the investigators. All measurements were approximated to the nearest 0.5 mm.

The extraction sockets were managed differently for the test and control groups:

Test group

The PCL scaffolds were purchased from Osteopore International (Singapore). The scaffolds were fabricated by the latest FDM techniques (FDM 3000; Stratasys, Eden Prairie, MN, USA), in a class 10K clean room environment. Each scaffold had a lay-down pattern of 0°/60°/120°, porosity of 70% and were conical in shape. The scaffolds had a typical

honeycomb structure with interconnected equilateral triangles of regular porous morphology. They were individually packed and sterilised using ethylene oxide (Fig. 2).

During the surgery, the scaffold was shaped by cutting and shaving with a scalpel so as to fit the extraction socket snugly at the crestal half to two-thirds aspect (Fig. 3). The periosteum of the buccal flap was then incised to allow a tension-free primary closure with 4/0 Vicryl® (Ethicon, Somerville, NJ, USA) suture.

Control group

No space filler was inserted in the extraction socket but similar to the test group, the periosteum of the buccal flap was incised to allow a tension-free primary closure with 4/0 Vicryl® Ethicon, Somerville, NJ, USA suture.

A periapical radiograph of the extraction site was taken using standardised settings immediately postoperatively. A 5-day course of Amoxicillin (or Erythromycin if the patient was allergic to Penicillin) was prescribed together with an analgesic and chlorhexidine digluconate 0.2% mouthrinse. The sutures were removed 1 week postoperatively.

Stage I: Dental implant surgery

Surgical placement of a dental implant was performed at 6 months after tooth extraction. Radiographs, including a periapical of the study site, were taken before the surgery. Following local anaesthesia and elevation of a full-thickness mucoperiosteal flap, the site was clinically observed for any signs of inflammation, infection and presence of fibrous or bone tissue ingrowth. The same customised acrylic stent used for the case at the time of the tooth extraction was used for measuring new ridge height dimensions in a manner similar to that described previously. Readings were recorded as RHmeb2, RHmib2 and RHdb2. Ridge width was measured as previously described and recorded as RW2.

The patient in either the test or control group would be taken out of the study at this stage if it was found that the extraction site had undergone extensive bone resorption such as to warrant simultaneous bone grafting with implant placement or pre-implant bone grafting with delayed implant placement.

Prior to implant placement, a core of bone of 2 mm diameter and 6 mm length at the healed extraction site was obtained using a trephine bur (Biomet 3i, Palm Beach Gardens, FL, USA). The core of bone was fixed and stored in 10% neutral buffered formalin and sent for microcomputed tomography (micro CT) scanning and histological preparation.

The implant site was prepared using successive drills, according to the Nobel Biocare® (Nobel Biocare, Goteborg, Sweden) dental implant surgical protocol, at a drilling speed of 1200 rpm. A dental implant (Nobel Biocare® Replace Select) of the appropriate length and diameter was then inserted at an insertion torque of between 20 and 40 Ncm. After placement of the dental implant, Implant Stability Quotient (ISQ) was measured by Resonance Frequency Analysis (RFA) using the Osstell® (Osstell AB, Goteborg, Sweden) machine. A cover screw was placed over the implant. A releasing incision of the periosteum was carried out if necessary, and the surgical wound was closed primarily with 4/0 Vicryl® (Ethicon, Somerville, NJ, USA) (Fig. 4a–d).

A 5-day course of Amoxicillin (or Erythromycin if the patient was allergic to Penicillin) was prescribed postoperatively, together with an analgesic and chlorhexidine digluconate 0.2% mouthrinse. The sutures were removed 1 week postoperatively.

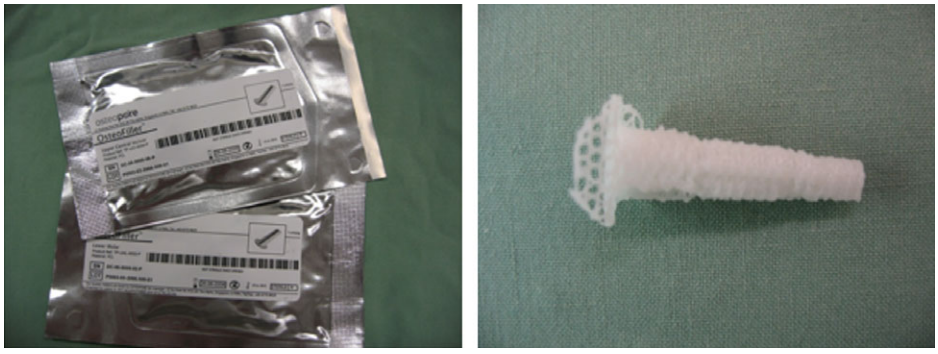

Fig. 2. Prefabricated conical shaped PCL scaffold in sterile packaging.

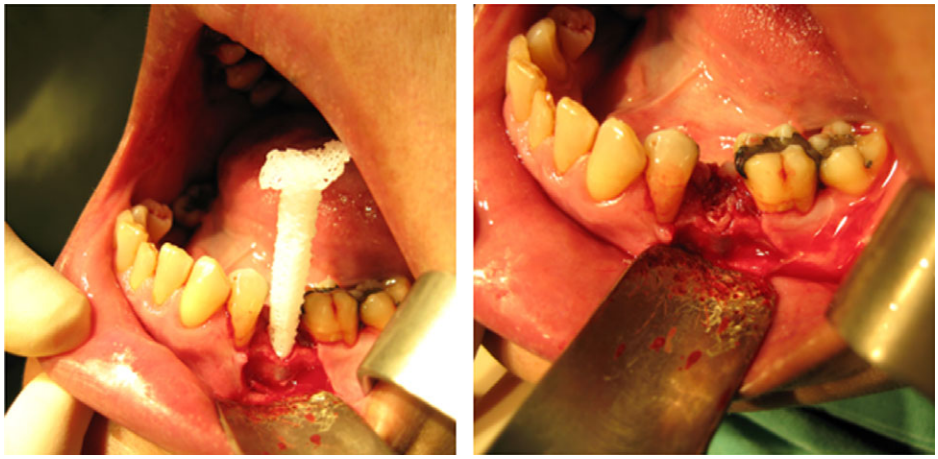

Fig. 3. PCL scaffold was shaped to fit snugly in tooth extraction socket. The excess scaffold had been trimmed off with a scalpel.

Stage II: Dental implant surgery

This was performed 4–6 months after Stage I dental implant surgery. The site was observed for any signs of inflammation, infection as well as clinical stability of the dental implant. ISQ was measured by RFA using the Osstell® machine before attachment of the healing abutment.

Analyses

Clinical analysis of bone resorption

The amount of vertical bone resorption in millimetres (mm) at three aspects was calculated:

Mesio-buccal: RHmeb2 – RHmeb1,
Mid-buccal: RHmib2 – RHmib1,
Disto-buccal: RHdb2 – RHdb1.

The amount of horizontal bone resorption in millimetres at the mid-buccal aspect was calculated:

RW1 – RW2.

Resonance frequency analysis

ISQ at Stage I and II dental implant surgery was measured by RFA for both the test and control groups.

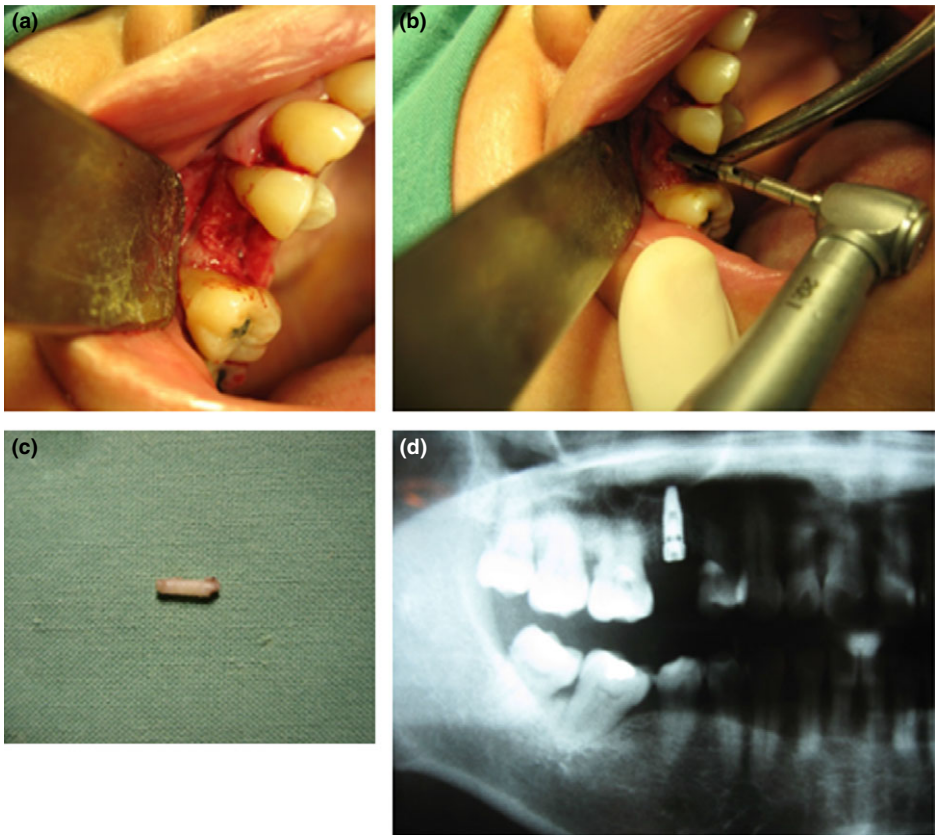

Fig. 4. (a) Healed tooth extraction site with PCL scaffold after 6 months, (b) core of bone removed with a trephine bur, (c) 2 mm × 6 mm core of bone removed for micro CT and histology and (d) orthopantomogram taken after Stage I dental implant surgery at a test site.

Radiopacity grading scale

The degree of radiopacity of the tooth socket observed on the periapical radiograph taken at 6 months post-extraction in both the test and control groups was graded according to the following scale.

1 = Radiolucent similar to tooth socket (compared with baseline periapical taken of tooth socket immediately after surgical extraction);
2 = Increased radiopacity but less than surrounding bone;
3 = Increased radiopacity similar to surrounding bone;
4 = Increased radiopacity more than surrounding bone.

The investigator (GBT) who performed the grading was blinded to the grouping of the radiographs.

Micro CT analysis

Quantitative analysis of bone regeneration was performed using the micro CT (SkyScan 1076, Kontich, Belgium) on three test samples (T1, T2 and T3) and two control samples (C1 and C2). The specimens, consisting of 2 mm diameter by 6 mm length core of bone, were placed in a sample holder and scanned through 180° at a spatial resolution of 30 μm. The image data from the scanned planes were subsequently thresholded, reconstructed to create 3D images and analysed using VGStudio Max 1.1 and CT Analyzer software (Volume Graphics GmbH, Heidelberg, Germany). The region of interest (ROI) was defined by the boundaries of the specimen of each slice. The ROI was interpolated through the entire length of the specimen to form the volume of interest (VOI). To select the area for bone, a bone-defining threshold was set manually and kept constant for all the images. The percentage bone volume (BV%) was obtained from the ratio of bone volume (BV) to total volume (TV):

$$BV\% = BV/TV.$$

Histological analysis

After micro CT scanning, the specimens were dehydrated in a graded series of ethanol, embedded in glycol methacrylate resin and polymerised. The block was trimmed to remove excess plastic with an industrial vertical band saw and cut along its long axis with a diamond band saw (EXAKT standard saw). Ground polished sections of 10 μm thickness were made using the EXAKT micro grinder system (EXAKT Technologies, Inc., Oklahoma City, OK, USA) and were subsequently stained with Haematoxylin and Eosin (H&E), Goldner's trichrome and von Kossa for descriptive histology.

Statistical analysis

Data were entered in Excel spreadsheet and analysed using the SAS Version 9 statistical software (SAS Inc., Cary, NC, USA). Variables were expressed as mean and SD as well as median and interquartile range (IQR). Comparisons between the test and control groups of the change in ridge height and width from baseline to 6 months post-extraction, RFA at Stage I and II implant surgery and radiopacity grading scale were performed using Mann–Whitney *U* test, given the small sample size.

Results

A total of 14 patients were recruited. Seven were randomised to the test group and the remaining 7 to the control group (mean age: 46.8 years, range 29–60 years; seven males, seven females). One patient from the test group who defaulted treatment and was not contactable after the surgical tooth extraction, and PCL scaffold insertion was excluded from the study. The remaining 13 patients completed the study. Patient- and site-related characteristics of the test and control groups are presented in Table 1.

Throughout the study duration, there was no case of infection at the test or control sites. There were, however, two patients (T2 and T3) that presented with partial exposure of the PCL scaffold at 1 week and 3 months, respectively, after insertion. These cases were managed clinically by trimming off the exposed parts of the scaffold with a scalpel. The surrounding oral mucosa subsequently healed over the exposed areas with no further complications.

At the re-entry surgery for Stage I dental implant placement, the PCL scaffolds in the test group were noted to be largely intact and no significant degradation was observed. Additionally, all the PCL scaffolds were noted to be firm, that is clinically immobile within the tooth sockets, with ingrowth of relatively hard mature bone, except for 1 case (T1). In T1, the PCL scaffold seemed to be infiltrated by fibrous tissue. A dental implant was inserted in all test and control sites about 6 months after extraction, without the

need for additional bone grafting. The dental implants inserted were all able to achieve primary stability.

Clinical analysis of bone resorption, RFA and radiopacity grading scale

Results of change in ridge height and width from baseline to 6 months post-extraction, RFA at Stage I and II implant surgery and radiopacity grading scale in the test and control groups are presented in Table 2. There was less change in ridge height, that is less vertical resorption in all three aspects (mesio-buccal, mid-buccal and disto-buccal) in the test group compared to the control group, and the difference was statistically significant in the mesio-buccal aspect ($P = 0.008$). There was more change in ridge width, that is more horizontal resorption, lower ISQ at Stage I and II implant surgery and lower radiopacity score at 6 months in the test group compared to the control group, although none of these differences were statistically significant.

Micro CT analysis

BV% of three test samples (T1, T2 and T3) and two control samples (C1 and C2) is presented in a box and whisker plot. T1 was an outlier with BV% of 0.0001. (Fig. 5a,b).

Histological analysis

In the test samples, the PCL scaffold was dissolved during histological preparation and appeared in the sections as empty spaces. Sections from T2 and T3 consisted mainly of mineralised lamellar bone within the porosities of the PCL scaffold, which directly apposed to the struts of the scaffold. A network of bony trabeculae could be seen separated by a labyrinth of spaces containing connective tissue and bone marrow, which is typical of cancellous bone. Blood vessels were observed, interspersed within the bone tissue. There were few inflammatory cells and no sign of fibrous encapsulation of the PCL scaffold struts (Fig. 6a–c). Sections from T1 consisted only of fibrous tissue with no bone formation, a histological observation that corroborated with the clinical and micro CT findings. Interestingly, there were also few inflammatory cells in this specimen.

Sections of the control specimens C1 and C2 also showed cancellous bone formation, consisting of mineralised bony trabeculae with intervening bone marrow (Fig. 7a–c).

Discussion

Although all six test patients who received the PCL scaffold for ridge preservation were able to continue to the next phase of the study for dental implant insertion, three of them (T1, T2 and T3) had presented with complications after the ridge preservation procedure. T2 and T3 presented with wound dehiscence that resulted in exposure of the scaffold. A possible explanation for this complication is that the PCL scaffold was supracrestal when inserted and it subsequently penetrated through the overlying mucosa. Fitting the PCL scaffold 0.5–1 mm below the tooth socket margin may help minimise this complication. This problem, however, was quite easily managed in T2 and T3 by trimming off the exposed PCL scaffold.

The PCL scaffold used in this study was prefabricated in a few standardised sizes. To friction fit it snugly within a tooth socket, it had to be shaped by the surgeon using a scalpel. It can be expected, however, that precise manual shaping might not have been achieved in all cases, and a poor fit could result in micromotion of the scaffold during healing. It is postulated that micromotion was the reason for the fibrous invasion of the PCL scaffold in T1. The dental implant eventually failed in this patient 2 years and 6 months after Stage I Implant Surgery. The use of a fixation device, for example microscrews or bone tacks may help to stabilise the scaffold in the early bone healing period. These may be removed just before a dental implant is inserted.

Histological changes in the alveolar ridge after tooth extraction were previously demonstrated in an experimental study in dogs (Cardaropoli et al. 2003). During the first 3 days of healing, the tooth socket was occupied by a blood clot, composed mainly of erythrocytes and platelets trapped in a fibrous matrix. Immediately, lateral to the hard tissue wall was the bundle bone consisting of severed periodontal ligament or Sharpey's fibres. After 14 days of healing, the periodontal ligament was no longer observed and the bundle bone had largely disappeared. Instead, there were large amounts of new woven bone formation that extended from the old bony walls towards the centre of the socket. At 30 days, the process of remodeling of the woven bone had begun by osteoclastic resorption. After 60 days, the woven bone was gradually replaced by lamellar bone and bone marrow. Thus, following tooth extraction, as the periodontal ligaments are no longer functional, the bundle bone undergoes disuse atrophy resulting in alveolar ridge resorption.

In this present study, bony ridge resorption following tooth extraction was noted in both groups, with or without the PCL scaffold, as evidenced by the ridge width and height reduction (except there was a gain in ridge height at the mesio-buccal aspect of the test group) after 6 months. It seems, therefore, that the use of a PCL scaffold did not prevent

Table 1. **Patient- and site-related characteristics in test and control groups**

Characteristics	Test ($N = 6$)		Control ($N = 7$)	
Age (years): Mean (SD)	46.8 (12.1)		46.9 (9.2)	
Females: *N*	3		3	
Tooth no. (FDI notation)/reason for extraction*	T1	15/A	C1	36/A
	T2	45/A	C2	14/B
	T3	35/B	C3	35/B
	T4	46/B	C4	25/A
	T5	36/B	C5	46/B
	T6	46/D	C6	36/C
			C7	15/D

*A = cracked tooth; B = caries; C = periodontal disease; D = failed root canal treatment.

Table 2. **Results of change in ridge height and width, RFA and radiopacity grading scale**

Variables	Test ($N = 6$)	Control ($N = 7$)	*P*-value
Change in height_meb (baseline-6 months)	0.13 (0.96), 0.13 (1.25)	−2.18 (1.02), −2.25 (1.75)	0.008
Change in height_midb (baseline-6 months)	−0.25 (1.43), −0.25 (2)	−1.11 (2.85), −2 (1.50)	0.25
Change in height_db (baseline-6 months)	−1.46 (1.85), −1.13 (3.25)	−2.25 (1.37), −2.50 (2.75)	0.39
Change in width (baseline-6 months)	2.08 (0.68), 2.13 (0.75)	1.57 (1.81), 0.50 (3.75)	0.28
RFA at Stage I – ISQ (baseline)	67 (11.1), 69 (22)	72.8 (10.1), 68.5 (11)	0.70
RFA at Stage II – ISQ (6 months)	70.5 (13), 73 (19)	74.9 (8.6), 75 (16)	0.78
Radiopacity grading scale (6 months)	2 (1.3), 1.5 (2)	2.4 (0.8), 3 (1)	0.45

Data are expressed as Mean(SD), Median(IQR).

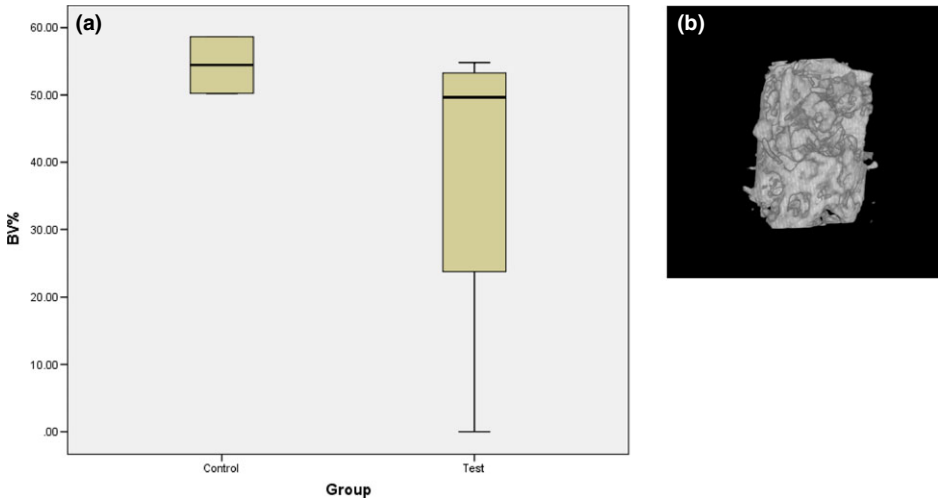

Fig. 5. (a) BV% of three test samples (T1, T2 and T3) and two control samples (C1 and C2) and (b) 3D reconstructed micro CT image of a test specimen.

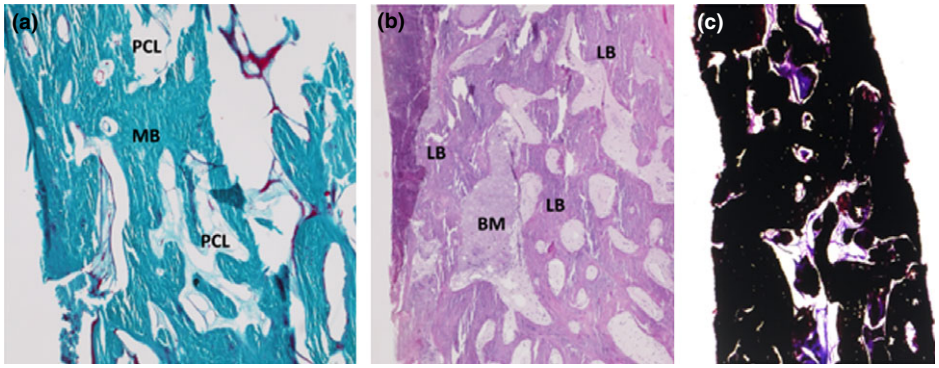

Fig. 6. Test specimen (a) Goldner trichrome stain, (b) H&E stain and c: von Kossa stain. PCL: Dissolved PCL scaffold spaces; MB: mineralised bone; LM: lamellar bone; BM: bone marrow.

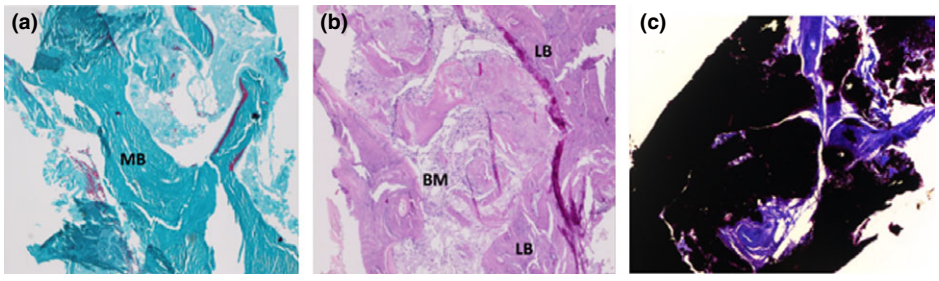

Fig. 7. Control specimen (a) Goldner trichrome stain, (b) H&E stain and c: von Kossa stain. MB: mineralised bone; LM: lamellar bone; BM: bone marrow.

resorptive remodeling of the alveolar bone after tooth extraction. Better maintenance of the ridge height in the test group compared to the control group, however, could be explained by the fact that the PCL scaffold remained largely intact structurally after 6 months. The PCL scaffold thus maintained its vertical dimension even as the surrounding bony ridge resorbed vertically to below the level of the PCL scaffold, over time.

In principle, when implanted in the body, a bioresorbable scaffold degrades over time, and the space occupied by the scaffold is gradually replaced by newly formed bone (Alsberg et al. 2003). For ridge preservation, if the scaffold degrades too early, it fails its function as a space maintainer before sufficient bone ingrowth and consolidation can occur. Conversely, if the scaffold takes too long to degrade, it will act as a barrier and hinder new bone formation within the tooth socket. PCL, like other members of the aliphatic polyesters, undergoes a 2-step degradation process. The first step occurs by autocatalysis with non-enzymatic random hydrolytic chain scission of ester linkages. The second step occurs, as the mechanical strength and weight are lost, thereby increasing the surface area for bio-erosion. The final breakdown products of PCL are CO_2 and H_2O (Pitt et al. 1981). PCL scaffolds degrade at a slow rate due to its high molecular weight and hydrophobicity. In this study, the presence of a relatively large amount of PCL in the tooth socket even after 6 months had blocked new bone ingrowth. This probably accounted for the lower mean radiopacity score and ISQ of the dental implants in the test group compared to the control group, although these differences were not statistically significant. For dentoalveolar reconstruction, a scaffold that degrades in about 5–6 months is considered ideal for bone regeneration and remodeling (Yeo et al. 2008). Despite the presence of PCL in the peri-implant region, however, the mean ISQ of the dental implants in the test group was >65 at both Stage I and II dental implant surgery, indicating that the implants were relatively stable (Sennerby & Meredith 2008).

The histological sections of the test specimens (T2 and T3) showed mineralised bone growth that infiltrated the porosities of the PCL scaffold. The new bone directly adapted to the surface of the scaffold, without a fibrous interface or signs of an inflammatory reaction. This showed that the PCL material used was inert, biocompatible and osteoconductive.

In conclusion, within the limitations of the small sample size, the study confirmed the hypothesis that the insertion of a 3D bioresorbable PCL scaffold in fresh extraction sockets allowed for normal bone healing and that there was better maintenance of ridge height after 6 months as compared to extraction sockets without the scaffold. In future, the use of a composite scaffold comprising of PCL and tricalcium phosphate (PCL-TCP) shall be investigated in a clinical trial for ridge preservation. PCL-TCP was shown to have improved mechanical and biochemical properties as well as more favourable degradation and resorption kinetics than PCL (Hutmacher et al. 2007; Lei et al. 2007; Yeo et al. 2008). Strategies to prevent micromotion of the scaffold during bone healing shall also be considered in future studies.

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Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. CONSORT 2010 checklist of information to include when reporting a randomised trial