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CLINICAL ORAL IMPLANTS RESEARCH

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An open randomized controlled clinical trial to evaluate ridge preservation and repair using SocketKAP™ and SocketKAGE™: part 1-three-dimensional volumetric soft tissue analysis of study casts

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Key words: alveolar bone grafting, bone substitute, tooth extraction

Abstract

Objectives: The aims of this study were to evaluate (i) the efficacy of ridge preservation and repair involving SocketKAP™ and SocketKAGE™ devices following tooth removal; and (ii) ridge contour changes at 6 months post-extraction in intact sockets and sockets with dehiscence defects.

Material and methods: Thirty-six patients required a total of 61 teeth to be extracted. Five cohorts were established with groups A–C involving intact sockets and groups D and E involving facial dehiscence: (A) Negative Control; (B) SocketKAP™ alone; (C) Anorganic Bovine Bone Mineral (ABBM) + SocketKAP™; (D) Negative Control; and (E) ABBM + SocketKAP™ + SocketKAGE™. Preoperative CBCT and laser-scanned casts were obtained. Teeth segmented from preoperative CBCT were merged with study cast images to allow for digital removal of teeth from the casts. Volumetric measurements of ridge contour were performed. Images of preoperative and 6 months post-operative casts were superimposed to measure ridge contour changes.

Results: Post-extraction contour loss occurred in all sockets primarily in the crestal 3 mm but was also detected up to 6 mm from alveolar crest. For intact sockets, SocketKAP™ or SocketKAP™ + ABBM interventions led to greater percentages of remaining ridge contour when compared to controls. A significant difference favoring SocketKAP™ + SocketKAGE™ + ABBM treatment was observed for sockets with facial dehiscence when compared to controls.

Conclusion: SocketKAP™, with or without ABBM, significantly limited post-extraction ridge contour loss in intact sockets. In the absence of a group treated with only the SocketKAGE™, it is not possible to determine its efficacy, although the combination of SocketKAGE™ + SocketKAP™ + ABBM was effective in limiting post-extraction ridge contour loss in sockets with dehiscence defects.

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Multiple individual studies and systematic reviews have closely examined the dynamics of alveolar crestal bone remodeling following tooth extraction in animal models and in human (Amler et al. 1960; Evian et al. 1982; Kuboki et al. 1988; Devlin et al. 1997; Devlin & Sloan 2002; Cardaropoli et al. 2003; Schropp et al. 2003; Araújo & Lindhe 2005; Trombelli et al. 2008; Van der Weijden et al. 2009; van Kesteren et al. 2010).

In a canine model, Araújo & Lindhe (2005) reported that following extraction, resorptive activity begins rapidly, with the most pronounced changes occurring in the crestal 2.5 mm of the facial alveolar bone. These investigators have proposed that the reason for the more intense loss of facial crest is that it is predominantly composed of bundle bone, which is lost following tooth extraction. Examination of the thickness of the facial and lingual/palatal bone has demonstrated that the facial bone is significantly thinner than the lingual/palatal bone (Huynh-Ba et al. 2010). This helps to explain why the facial bone, which is mostly composed of bundle bone, is more susceptible to resorption (Araújo & Lindhe 2005).

In a consensus report, Hämmerle et al. (2012) reported an average of 3.8 mm of horizontal dimension loss and 1.24 mm vertical dimension loss following tooth extraction in human. Current literature has also examined outcome measures of treatment protocols designed to reduce crestal alveolar bone resorption following tooth removal (Mardas et al. 2010; Ten Heggeler et al. 2010; Hämmerle et al. 2012; Horowitz et al. 2012; Vignoletti et al. 2012). An array of treatment protocols has been utilized to minimize the amount of post-extraction dimension loss, including careful tooth extraction with minimal trauma (Fickl et al. 2008b), immediate implant placement in the extraction socket (Araújo et al. 2006), covering the orifice of the socket with a membrane (Diès et al. 1996), and grafting the socket with biomaterials and a resorbable or non-resorbable membrane (Zitzmann et al. 1997; Cardaropoli et al. 2014) or soft tissue punch (Fickl et al. 2008a; Araújo et al. 2015). Based on systematic reviews, ridge preservation procedures reduce the magnitude of the horizontal dimensional loss by 1.8 mm and the vertical dimensional loss by 1.47 mm, compared to extraction alone (Vignoletti et al. 2012; Morjaria et al. 2014). Prospective controlled clinical trials designed to closely examine overall alveolar ridge surface contour alterations following tooth extraction are lacking. Moreover, there is paucity of data regarding the relationship between alterations in alveolar bone and surface mucosal tissue contour. As sufficient alveolar bone volume is important to provide a stable base to achieve implant stability and surface mucosal contour can positively affect esthetic outcomes of implant therapy, examination of both hard and soft tissue changes is merited.

In a 12-month prospective study, Schropp et al. (2003) examined hard and soft tissue ridge contour changes following single premolar or molar tooth extractions. Multiple methods were used to obtain quantitative linear outcome data, including pre- and post-operative measurements of dental casts, standard periapical digital radiography, and subtraction radiography of pre- and post-operative radiographs. Only slight changes of <1 mm in soft tissue height occurred in both jaws after 12 months of healing. However, significant reductions in crestal bone width were seen, with an approximate 50% width reduction, two-thirds of which occurred during the first 3 months following tooth removal.

In a second study examining post-extraction alveolar ridge contour changes, Iasella et al. (2003) examined both soft and hard tissue outcomes following non-molar tooth extractions, with and without guided bone regenerative (GBR) preservation procedures. Linear measures of socket width, socket wall thickness and overlying soft tissue depth were obtained directly. Results demonstrated alveolar bone width loss for both treatment groups, with greater loss in the group that received extraction alone. Chappuis et al. (2013) showed that the pre-extraction thickness of the buccal plate is the most important determining factor in the horizontal dimension loss. They reported that sockets with thickness of <1 mm show significantly more horizontal and vertical bone loss than sockets with thicker facial bone plate. Interestingly, the data from the interventional studies by Barone et al. (2013) and Cardaropoli et al. (2014) confirmed the negative relationship between alveolar bone thickness and post-extraction remodeling, but demonstrated that in sockets treated by ridge preservation, the initial facial bone thickness had no relationship to alveolar bone loss.

Barone et al. (2013) have reported that ridge preservation could be beneficial in the posterior region and simplify the treatment by minimizing the need for more invasive augmentation surgeries prior to implant placement. Furthermore, sites with ridge preservation allow clinicians to place wider and longer implants.

Traditional techniques of measuring ridge contour have mainly involved physically sectioning the study casts and measuring the width with calipers (Pietrokovski & Massler 1967). The main weakness of such methods is the lack of reliability when comparing pre- and post-operative landmarks. More recent techniques for examining post-extraction surface contour changes have utilized optical scans of study casts. Although this approach has enabled better superimposition of pre- and post-operative study casts, published analyses have tended to use 2-dimensional measurements of ridge contour (Fickl et al. 2008a,b). Recently, Thalmair et al. (2013), in a clinical study using optical scanning of study casts, compared 3-dimensional (3D) volumetric soft tissue changes following ridge preservation procedures and were able to demonstrate the effectiveness of free gingival grafts covering extraction socket orifices in limiting post-extraction external ridge contour shrinkage.

One of the challenges in comparing pre- and post-operative study casts is the presence of teeth in the preoperative cast and their absence in post-operative casts. The method described by Thalmair et al. (2013) used landmarks on adjacent structures to serve as post-extraction reference measurement points. In this study, to measure preoperative 3D volumes and contours of the alveolar ridge more accurately, a novel technique was designed to derive data from CBCT examination to subtract out the actual volume of the extracted tooth.

While ridge preservation has been reported to be effective in reducing post-extraction dimension loss, some challenges remain regarding traditional methods used for obturation of the socket orifice. Membranes used in this procedure typically necessitate reflection of a flap, with increased requirement of time, complexity, and morbidity. Moreover, as membranes are flat, the crestal tissue conforms to that flat shape with resultant contour changes. Sockets with facial dehiscence pose an extra challenge, as membranes used for their repair lack the structural integrity to prevent tissue collapse. The primary objective of the present prospective randomized controlled clinical trial was to evaluate the efficacy of ridge preservation and ridge repair procedures in obtaining satisfactory volumetric contour outcomes using 2 pre-fabricated devices, namely SocketKAP™ and SocketKAGE™. SocketKAP™ (Fig. 1a) is a non-resorbable device, composed of polypropylene, designed with a dome-shaped superior surface with suture channels to aid in fixation to the socket orifice. The SocketKAGE™ (Fig. 1b–c) is a resorbable device, composed of poly-L and D-lactide (PLLA) to support the facial soft tissue and prevent its collapse in the extraction sites with facial bone dehiscence. SocketKAGE™ is intended to provide structural support in the portion of the socket with missing alveolar bony wall to maintain the space during healing.

The secondary objective of this study was to compare pre-extraction and 6 months post-extraction digitized study casts of patients undergoing tooth extraction, using quantitative 3D CBCT data in concert with dental laser-scanned casts. By employing 3D volumetric measurement, this study demonstrated that, in the absence of additional intervention, extensive loss of facial alveolar ridge surface contour occurred. The interventions described in this study using SocketKAP™, SocketKAGE™, and ABBM were effective in reducing the magnitude of the contour loss.

Materials and methods

This study has been prepared in accordance with guidelines outlined in the CONSORT statement for reporting of randomized con-

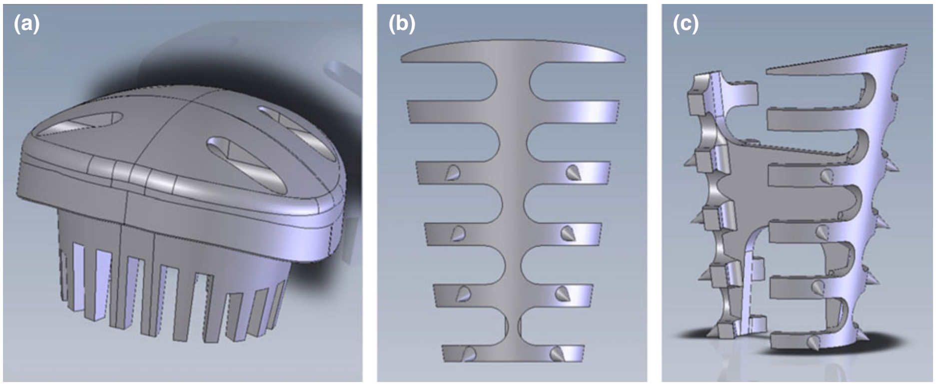

Fig. 1. Ridge preservation devices utilized in the present study. SocketKAP™ is a dome-shaped device composed of polypropylene with channels on the superior surface for the passage of sutures to aid in fixating the device to extraction socket orifice (a). The SocketKAP™ was used for obturation of the extraction socket orifice and protection from the oral environment. Facial (b) and lateral (c) views of the SocketKAGE™ illustrate a device consisting of a rigid series of interconnected ribs composed of poly-L-lactide utilized for support of sockets with facial dehiscence. The conical projections on ribs are intended for stabilization of the device inside the extraction socket, as well as spacers to prevent direct contact with facial and lingual alveolar plates, thereby allowing better blood circulation.

trolled trials (Moher et al. 2010). A copy of the checklist has been included (Appendix S1).

Study participants

The protocol was approved by the Ethics Committee of Qassim University. Thirty-six subjects aged between 21 and 53 years old who met the inclusion and exclusion criteria were included in this study. The enrollment of patients took place between October 2012 and April 2013. The subjects were recruited among patients presenting to the Clinics at Qassim University College of Dentistry, who were treatment planned for tooth extraction by various departments for any clinical indications. All patients filled out a medical questionnaire, followed by interview by study investigator (AA), who ensured fulfillment of inclusion and exclusion criteria. The inclusion criteria were male or female ages 18–75 years old, requiring extraction of a single or multiple adjacent teeth, and willingness to participate in the study and consent to treatment. Teeth with intact alveolar bone walls or facial dehiscence were included. The exclusion criteria were as follows: systemic conditions, which impact wound healing, for example diabetes mellitus, chronic steroid use, autoimmune, or immunoproliferative disorders, bleeding disorders or individuals on anticoagulant therapy, and orthodontic tooth movement into the planned extraction site.

Ridge preservation devices

Ridge preservation devices utilized in this study included SocketKAP™ and SocketKAGE™. SocketKAP™ is a dome-shaped non-resorbable device composed of polypropylene, with channels on the superior surface for the passage of sutures (Fig. 1a). Four sizes of SocketKAP™ are available, allowing the appropriate size to be selected based on the dimensions of the particular socket orifice. The extra small (6 × 8 mm), small (7.5 × 9 mm), medium (9 × 11 mm), and large (10.5 × 13 mm) dimensions of the outer dome were included. The SocketKAP™ also included comb-like projections, which extended 4 mm on the intaglio side of the device. SocketKAGE™ is a resorbable device with rigid interconnected ribs composed of PLLA and was utilized for support of sockets with facial dehiscence (Fig. 1b–c). The degradation profile of PLLA has been reported, and within 6 months, 50% of the weight is degraded (Chen et al. 2003). SocketKAGE™ was available in two different sizes, namely small (13 mm in length, 6 mm in the crestal diameter, and 3 mm in apical diameter) and large (13 mm in length, 7.5 mm in the crestal diameter, and 5 mm in apical diameter). SocketKAGE™ was trimmed, as necessary to conform to the dimensions of the extraction sockets in which it was applied.

Study overview and interventions

Thorough extra- and intra-oral examinations were performed on all patients. Periapical radiographs and preoperative photographs of the proposed extraction sites were obtained at the initial visit.

Patients were enrolled sequentially, and a randomization list was generated. Following tooth extraction, the status of the facial bone plate was evaluated visually and using a periodontal probe. Sockets with intact walls were randomly allocated to groups A, B, or C while sockets with facial dehiscence were allocated to groups D or E. The randomization was performed by the first author (A.A.) using the Random Allocation Software version 1.0 (Isfahan University of Medical Sciences, Isfahan, Iran).

The extraction sockets were randomly divided into one of the following five parallel treatment groups:

Group A: Intact socket unfilled and uncovered (negative control) ($N = 12$)
Group B: Intact socket covered with SocketKAP™ ($N = 11$)
Group C: Intact socket filled with anorganic bovine bone mineral (ABBM; OCS-B particle size of 0.25–1.0 mm, NIBEC Co, Chungcheongbuk-do, South Korea) and covered with SocketKAP™ ($N = 14$)
Group D: Facial dehiscence socket unfilled and uncovered (negative control) ($N = 14$)
Group E: Facial dehiscence socket filled with ABBM and covered with SocketKAP™ + SocketKAGE™ ($N = 10$)

All surgical procedures were performed by the same experienced clinician (H.Z.). All of the analyses were performed by second author (M.O.), who was blind to the randomization and group assignments. For all 36 patients, local anesthesia was administered using lidocaine (2%+epinephrine 1/100,000). Teeth were removed, using a flapless approach with as minimal trauma as possible. To do so, multi-rooted teeth were sectioned using a high-speed hand-piece to remove each root separately to decrease the trauma to the socket. Teeth were extracted using elevators and forceps. Sockets were then thoroughly debrided using a curette, especially in cases with periapical pathosis, to ensure complete removal of granulation tissue. The facial walls were evaluated visually and using a UNC-15 periodontal probe. SocketKAGE™, inserted inside group E sockets, was trimmed to assure stability within the socket and positioned up to the alveolar ridge crest (Fig. 2). In groups C and E, graft material (ABBM) was placed loosely in the extraction socket without apical condensation. SocketKAP™, used for groups B, C, and E to obturate the socket, was secured with 4.0 PTFE sutures (Cytoplast; Osteogenics Biomedical, Lubbock, TX, USA) and removed after four weeks.

Analysis of dimensional alveolar ridge contour changes: patient CBCT & study cast optical laser scan protocols

Accurate quantitative determination of post-extraction alveolar ridge contour changes

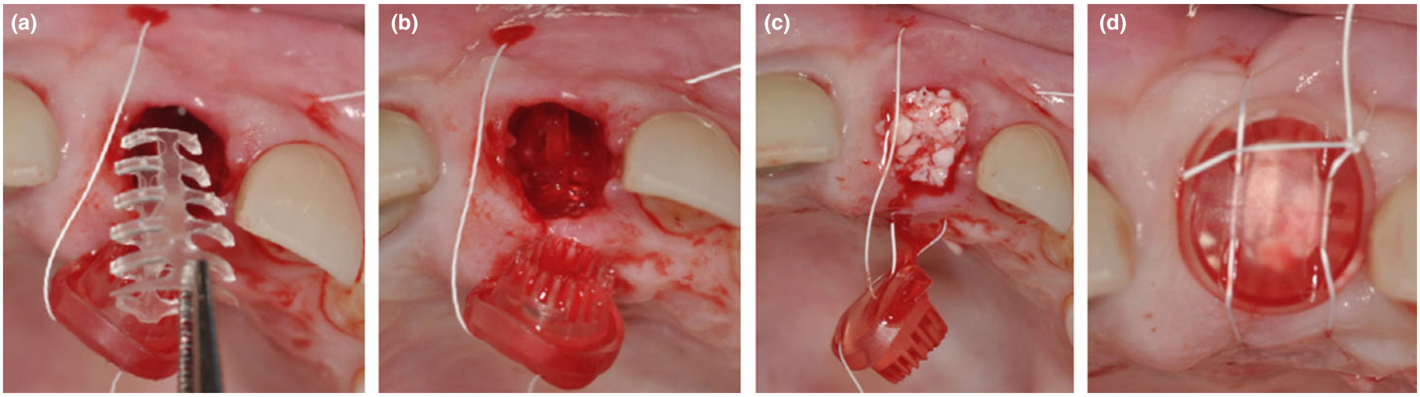

Fig. 2. Group E maxillary lateral incisor. (a) Placement of SocketKAGE™ without flap reflection. (b) SocketKAGE™ stabilized in place. (c) Site filled with ABBM following SocketKAGE™ placement. (d) SocketKAP™ secured in place with PTFE sutures.

required merging two digitally driven protocols: (i) preoperative patient CBCT examinations and preoperative optically laser-scanned casts; and (ii) 6 months post-operative laser-scanned study cast.

Study cast optical laser scan protocol

Alginate impressions for each patient were taken to make preoperative and 6 months post-operative study casts. The impressions were poured in a hard stone using a vacuum machine to avoid air bubble formation. Casts were then optically 3D laser scanned (D-250, 3Shape A/S, Copenhagen, Denmark, Fig. 3a and f). The generated 3D model data were saved as STL files and imported into the reverse engineering software (Geomagic Studio 2012; Cary, NC, USA).

Patient CBCT examination protocol

CBCT scans were obtained preoperatively for all patients (Carestream CS 9300; Carestream Health Inc., Rochester, NY, USA). The following protocol (Materialise Dental; SurgiGuide cook book & scanning protocol for Simplant and SurgiGuide) was uniformly used in the current study: (i) The patient was placed in a fully supine position, with the head in a fixed and stable position on the scanner table; (ii) The axial plane was adjusted parallel to the plane of occlusion, with the gantry tilt at zero degrees for optimum accuracy; (iii) With the patient immobilized and occluding on a disposable wooden stick, CT scanning occurred without inter-arch contact; (iv) Slice thickness was set at 1 mm with a field of view encompassing the entire target arch; (v) An appropriate high-resolution image reconstruction algorithm with a 512 × 512 matrix produced sharp reformatted images.

Following CBCT scanning, all DICOM images were imported into Simplant software (Simplant; Materialise Inc, Leuven, Belgium) and teeth were segmented using a mask creation tool. The 3D models of the teeth, including those intended for extraction, were then generated and exported as STL files. (Fig. 3b)

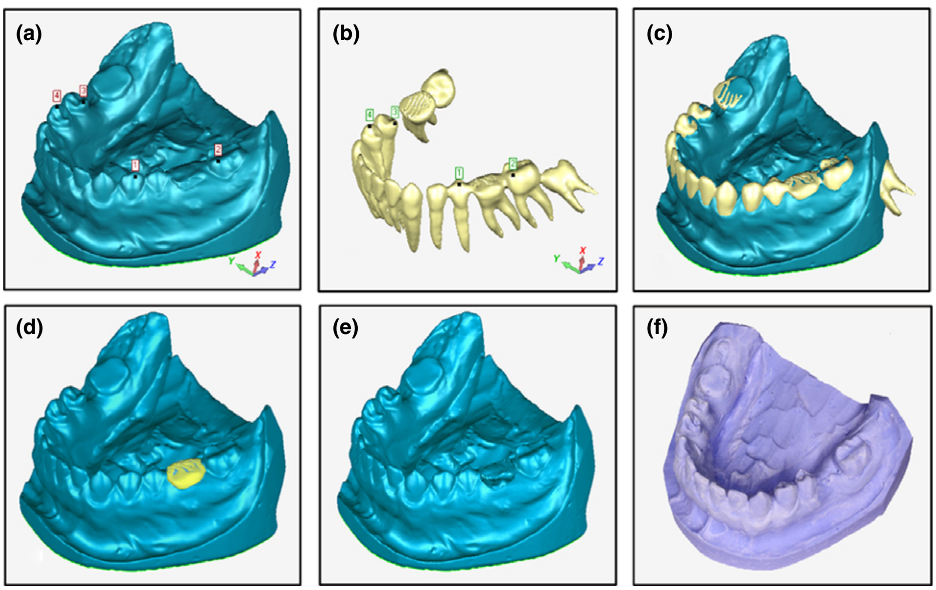

Fig. 3. Protocol for digital manipulation of study casts. (a) Scanned image of preoperative study cast. (b) Segmented images of teeth imported from CBCT. (c) Superimposed image of preoperative study cast and teeth from CBCT. (d) Superimposed image of study cast and the tooth intended for extraction. (e) Image of study cast with the volume corresponding to the treated tooth removed. (f) Post-operative cast.

Determining 6 months post-extraction alveolar ridge contour changes

To accurately quantify changes in alveolar ridge contour at 6 months post-extraction, it was necessary to digitally remove the target teeth from preoperative cast models, allowing those models to be compared to post-operative models. The 3D tooth models from the preoperative CBCT scan were first superimposed on the preoperative digital study cast model using a semi-automatic alignment wizard (Fig. 3c). Digital removal of the target teeth was accomplished using a Boolean subtraction tool, thus providing an image equivalent to the model of the jaw just after tooth extractions (Fig. 3d and e). Another superimposition of the pre- and post-operative casts was performed, followed by digital trimming of the studied sockets using trimming sectional planes mesially and distally.

Quantitating alveolar ridge contour changes

The total preoperative and 6 months post-operative volumes of the sockets were measured, including the volume of overlying soft tissue in three successive zones (0–3, 3–6 and 6–9 mm apical to the alveolar crest), using the highest preoperative socket contour as the point of measurement reference. The volumes of each of the three zones of the sectioned sockets were calculated individually

Table 1. **Demographics and clinical characteristics of the subjects and sites enrolled in this study**

Gender	Male (N = 24)	Female (N = 12)			
Smoking status	Non-smoker (N = 32)	Light smoker ≤10 cig/day (N = 2)	Heavy smoker <10 cig/day (N = 2)		
Reason for extractions	Gross Caries (N = 36)	Severe periodontitis (N = 11)	Peri-apical pathosis (N = 10)	Root resorption (N = 2)	Root fracture (N = 2)
Single/multiple extractions	Single tooth extractions (N = 43)	Multiple adjacent tooth extractions (N = 18)			

in cubic mm using a volumetric analysis tool. The calculated volumes were collected and tabulated for statistical analysis.

Statistical analysis methodology

Statistical analyses were performed using SPSS (version 22, IBM Corp., New York, NY, USA), and quantitative data were expressed as mean and standard deviation (SD). All data were tested for normality and equality of variance using Shapiro–Wilk and Levene tests, respectively. The data were found to show a normal distribution. Therefore, a repeated-measures analysis of variance (ANOVA) was applied to identify any statistically significant differences between the different treatments and zones. As the results of ANOVA showed a statistically significant difference between the treatments and different zones ($P = 0.001$), Tukey's test at significance level of $\alpha = 0.05$ was used as a *post hoc* test comparing the results among multiple intervention means.

Results

Study population

A total of 36 patients were referred to the oral surgery clinic for extraction of non-restorable teeth secondary to gross decay and periodontitis (Table 1). Sixty-one maxillary and mandibular anterior, premolar and molar teeth were included in the study (Table 2).

Table 2. **Information regarding the sites allocated to each intervention group**

	Position					
Group	Max ant, n	Max PM, n	Max molar, n	Mand ant, n	Mand PM, n	Mand molar, n
All teeth	7	11	13	6	8	16
Group A (N = 12)	1	2	2	2	1	4
Group B (N = 11)	1	3	1	1	1	4
Group C (N = 14)	0	3	6	0	3	2
Group D (N = 14)	3	2	3	3	1	2
Group E (N = 10)	2	1	1	0	2	4

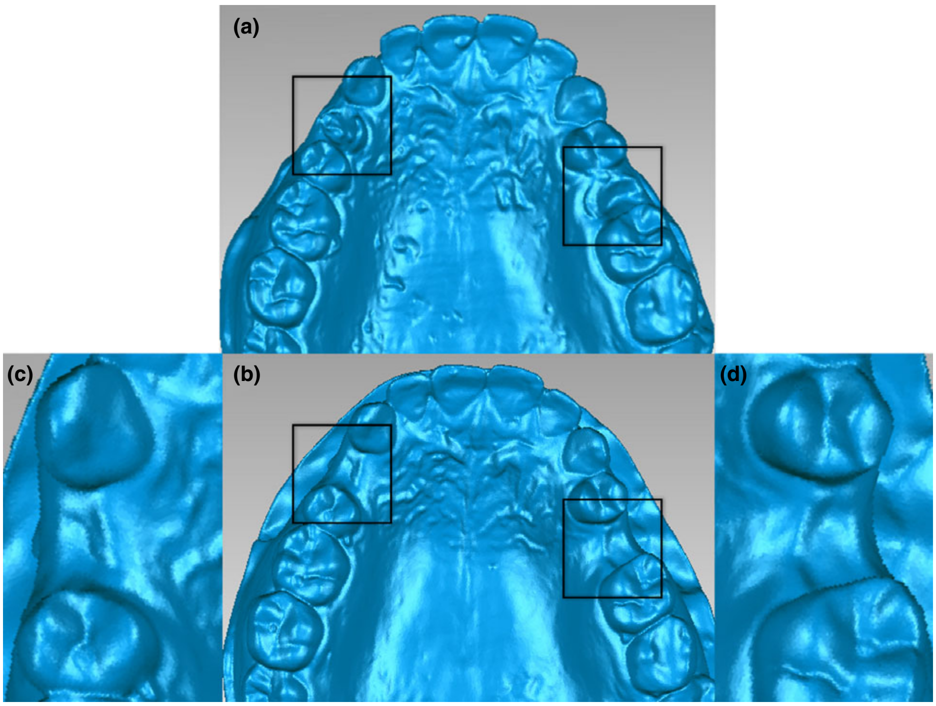

Fig. 4. Study cast model of group A (control site with intact socket) of a Maxillary Left second premolar and group E (dehiscence socket treated with SocketKAP™+ SocketKAGE™ + ABBM) maxillary right first premolar. (a) Pre-extraction. (b) At 6 months post-extraction, significant horizontal width reduction is evident in control group. (c) Higher magnification of group E (dehiscence socket treated with SocketKAP™+ SocketKAGE™ + ABBM) at 6 months post-extraction. (d) Higher magnification of group A (control site with intact socket) at 6 months post-extraction; dental cast shows considerable horizontal atrophy at 6 months post-intervention at the left control site compared to little to none on the right, even though the right treated site presented with a large facial dehiscence defect while the left had intact post-extraction facial bone.

Clinical findings

Following tooth removal, grafting, and device insertion, healing for all patients was uneventful, with minimal swelling and inflammation and no signs of post-operative infection. Representative clinical findings are described in Figs 4–6. Over the duration of the study, the only treatment-related adverse events were prematurely loosened SocketKAP™ devices (group B = 2; group C = 3; group E = 1), none of which required early removal.

Quantitative findings

To assess quantitative changes in alveolar ridge contour at 6 months after treatment, total volumetric ridge measurements, including overlying soft tissue, were derived from scanned study casts after digitally removing the volume corresponding to the later extracted teeth from the preoperative casts, guided by the CBCT data. For sockets with intact bony walls, outcome comparisons were made between treatment groups A (negative control), B (SocketKAP™ alone), and C (SocketKAP™ + ABBM graft). For sockets with labial or buccal dehiscence defects, comparisons were made between group D (negative control) and group E (SocketKAP™ + SocketKAGE™ + ABBM graft).

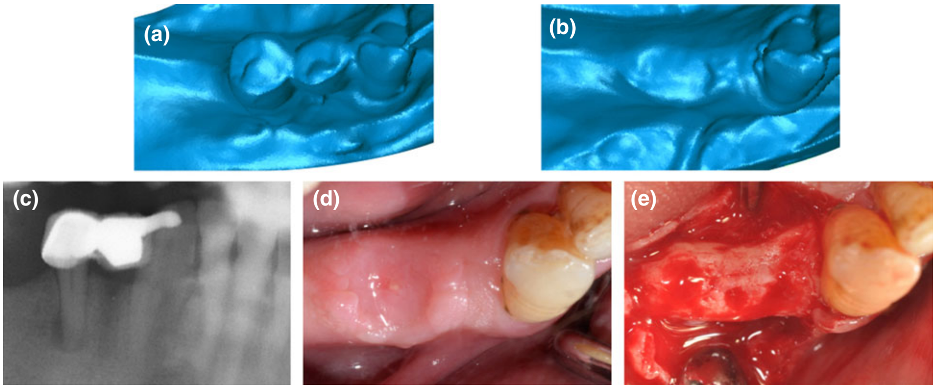

Fig. 5. Group C Intact Mandibular Second Premolar site treated with SocketKAP™ + ABBM (a) Preoperative cast. (b) Six-month cast demonstrates retention of crestal ridge width. (c) Periapical radiograph reveals periapical radiolucency and poor crown-to-root ratio. (d) Images taken 6 months post-grafting and SocketKAP™ placement reveal retained normal crestal ridge width anatomy. (e) Six-month healing of the bone at the time of implant placement.

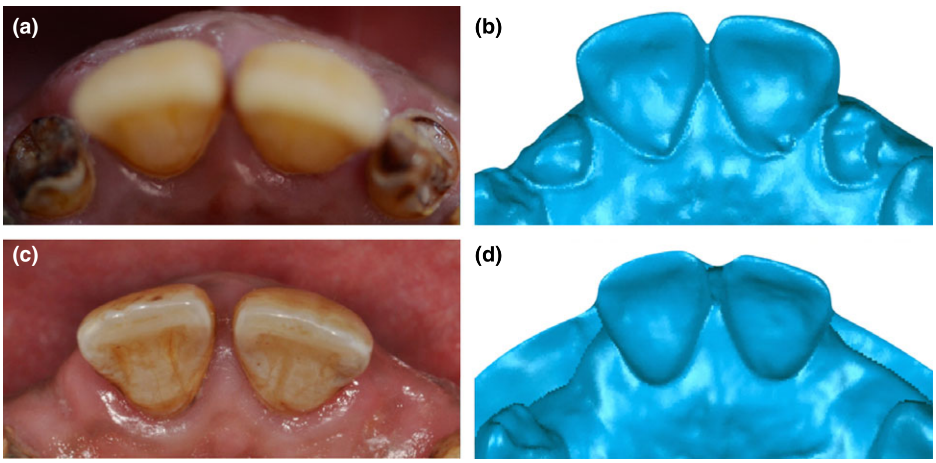

Fig. 6. Group D and group E maxillary lateral incisors. (a) Grossly decayed maxillary right & left lateral incisors. (b) Preoperative cast, right lateral incisor (facial dehiscence group D control site); left lateral incisor (facial dehiscence group E site). (c) Clinical view at 6 months post-extraction revealed narrowed labial–palatal width on the right side (control site) and retained crestal width on the left (group E site grafted with SocketKAP™ + SocketKAGE™ + ABBM). (d) Six-month clinical findings are confirmed with dental cast.

Representative digitized preoperative and 6 months post-operative study cast images, as well as graphs representing mean percentage of remaining ridge contour from each of the intervention groups, are shown in Figs 7a,b and 8a,b.

Figure 7a and b examines the percentage of ridge contour remaining in each of the intact socket groups. In group A, following healing of the extraction socket without additional treatment, 90.4% of the ridge contour in the crestal 3 mm was lost within 6 months. By comparison, obturation of the socket orifice with SocketKAP™ alone (group B) was associated with statistically significant greater ridge preservation (62.9% ridge contour lost) of the crestal 3 mm ($P < 0.05$). Of those intact extraction sockets filled with ABBM and covered with SocketKAP™ (group C), 49.1% of the crestal 3 mm ridge contour was lost, a highly statistically significant difference compared to group A, the negative control ($P < 0.001$). No statistically significant difference was observed within the crestal 3 mm zone between groups B and C. In the next segment of the examined ridge (3–6 mm from the crest), 77.4% of the ridge contour remained in group C, compared to 57.1% and 68.9% of the ridge in groups A and B, respectively ($P = 0.13$). In the more apical zone (6–9 mm from the crest) 84.4%, 80.3%, and 90.7% of the contour remained in groups A, B, and C, respectively, with a statistically significant difference between groups B and C ($P < 0.05$, Fig. 7b, Table 3).

Figure 8a and b examines the percentage of ridge contour remaining in each of the groups with facial wall dehiscence defects. At 6 months, the negative control group D lost 87.6% of the ridge contour within the crestal 3 mm zone, as opposed to a 60.3% contour loss experienced by the group E treated with SocketKAP™ + SocketKAGE™ + ABBM, a highly statistically significant difference ($P < 0.01$). In the zones 3–6 mm and 6–9 mm apical to the ridge crest, no statistically significant differences were seen between groups D and E (Fig. 8b, Table 4).

To better understand individual variability in remodeling patterns within the experimental and control groups, the data for all individual sites were charted in a scatter plot (Fig. 9). The data clearly illustrate that in the absence of intervention, intact extraction sockets underwent extensive ridge contour remodeling, such that in most sites over 90% of the crestal 3 mm of the ridge resorbed. On the other hand, in the group treated with SocketKAP™ alone (group B), 40% of sites exhibited preservation of more than 50% of the crestal 3 mm of the alveolar ridge contour. In the group treated with ABBM + SocketKAP™ (group C), 64% of sites exhibited preservation of more than 50% of the crestal 3 mm of the alveolar ridge contour. Analysis of the 3–6 mm segment of the alveolar ridge revealed that in the negative control group (group A), as well as group B, one-third of the sites underwent resorption of more than 50% of the alveolar ridge. In contrast, aside from one site, sockets treated with ABBM+SocketKAP™ (group C) retained most of the alveolar ridge contour in the 3–6 mm segment. The 6–9 mm segment of the alveolar ridge remained stable in all treatment groups.

Analysis of the scatter plot of sites with existing facial bone dehiscence demonstrated that the majority of the sites in the control group (group D) exhibited loss of 80–90% of the crestal 3 mm alveolar ridge contour. Sites repaired with SocketKAGE™ + ABBM + SocketKAP™ (group E), however, preserved significant portions of the alveolar ridge 60% of the time, while 40% of the sites continued to have resorption patterns similar to the control group. In the more apical 3–6 mm zone, 80% of the sites showed at least 60% of the ridge remaining in both groups.

Discussion

Obtaining accurate quantitative parameter assessments is critical in determining valid outcome measures following ridge preservation and augmentation procedures. Multiple measurement methodologies, frequently summarized in published systematic reviews, are currently used for outcome assessments.

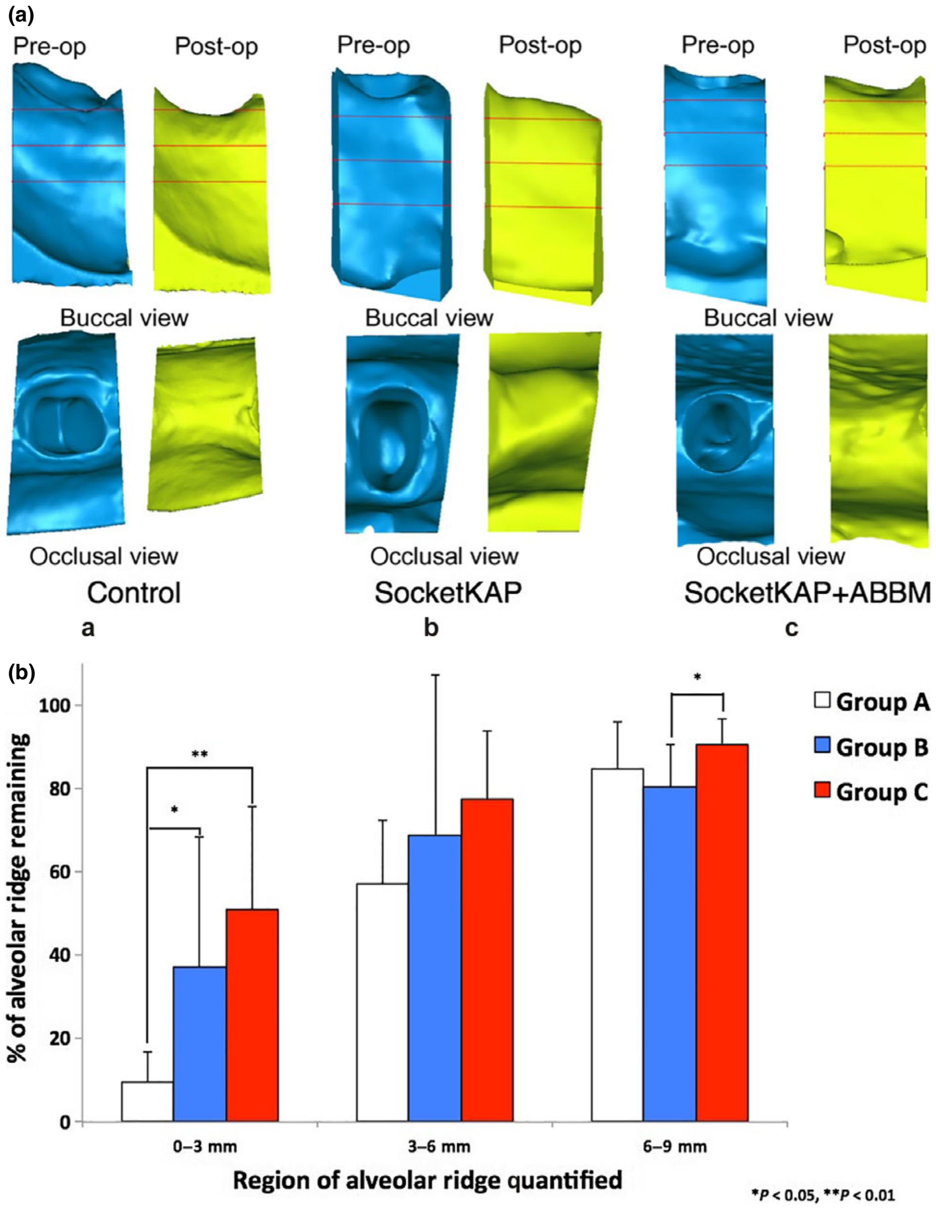

Fig. 7. (a) Representative facial and occlusal images of digitized study casts from extraction sites with intact socket walls preoperatively and at 6 months post-operative. Group A negative control demonstrates significant contour loss within the 0–3 mm zone apical to the ridge crest in both ridge width and height. Group B (SocketKAP™) alone shows milder post-operative contour changes at 6 months compared to group A within the 0–3 mm zone. Group C SocketKAP™ + ABBM retains clinically greater surface contour volume at 6 months compared to groups A and B. (b) Percentage of alveolar ridge contour remaining 6 months after intervention in groups A, B, and C sites, all with intact socket bony walls.

The most frequent assessment methodologies include the following: (i) comparisons of direct clinical measurements immediately following tooth extraction with future reentry assessments, often using an acrylic stent to allow for reproducible measurements; (ii) radiographic assessments of outcome changes over time using periapical radiographs, panoramic radiographs, and computerized tomographic scans (CT scans); and (iii) comparison of directly measured pre- and post-operative dental study cast ridge dimensional values (Van der Weijden et al. 2009; Ten Heggeler et al. 2010; Vignoletti et al. 2012). None of these assessment protocols, however, allow for the 3D ridge contour volumetric analysis used in the current study.

A number of studies reference placement of a free gingival graft at the socket orifice following tooth removal as beneficial in limiting alveolar ridge resorption and helping to maintain critical ridge contour (Fickl et al. 2008a,b; Thalmair et al. 2013). Of particular relevance to the current study, Thalmair et al. (2013) examined volumetric alveolar ridge contour changes following tooth extraction and placement of a free gingival graft at the socket orifice. Using an outcome assessment approximating what was used in the present study, Thalmair et al. (2013) optically scanned, digitized, and superimposed baseline and 4-month follow-up dental cast models using the facial surfaces of adjacent teeth for accurate superimposition of scanned images. Dimensional contour changes pre-extraction and 4 months post-extraction were then calculated using specific computer software (SMOP, Swissmeda, Zurich, Switzerland), demonstrating the effectiveness of free gingival grafts covering extraction socket orifices in limiting, but not eliminating, post-extraction external ridge contour shrinkage. The use of SocketKAP™ in this study similarly limited the dimensional loss following tooth extraction. We hypothesize that SocketKAP™ supported the collar of the soft tissue and prevented the collapse of marginal gingiva following extraction, thereby reducing the resorption of the alveolar crest and helping to maintain the alveolar ridge contour. Moreover, by stabilizing the soft tissue, SocketKAP™ increased the zone of keratinized tissue over the extraction socket, which further improved the site for future implant placement. SocketKAP™ also decreased the possibility of contamination of the biomaterial by minimizing the amount of time that the materials were exposed to the oral cavity. With the specific design of the SocketKAP™ and the suture channel on the dome, sutures can be placed prior to placement of the graft biomaterial and therefore the sockets were sealed shortly after ABBM placement.

SocketKAGE™ is utilized in sockets with facial dehiscence. It is hypothesized that SocketKAGE's mechanisms of action include provision of structural support to prevent collapse of soft tissues during healing, and creation of a protected space to allow bone formation within the socket.

Similar to Thalmair et al., the analytic protocol used in the current study introduced several important variations, which may allow for more accurate 3D assessments of volumetric contour changes over time following tooth extraction. In addition to optically scanning the dental casts, preoperative CBCT scans were obtained, superimposed onto the laser-scanned preoperative dental cast image, and followed by accurate digital subtraction of the target tooth from the optically scanned preoperative cast. The net result was a 3D reproducible and measurable image of volumetric surface contour just after tooth extrac-

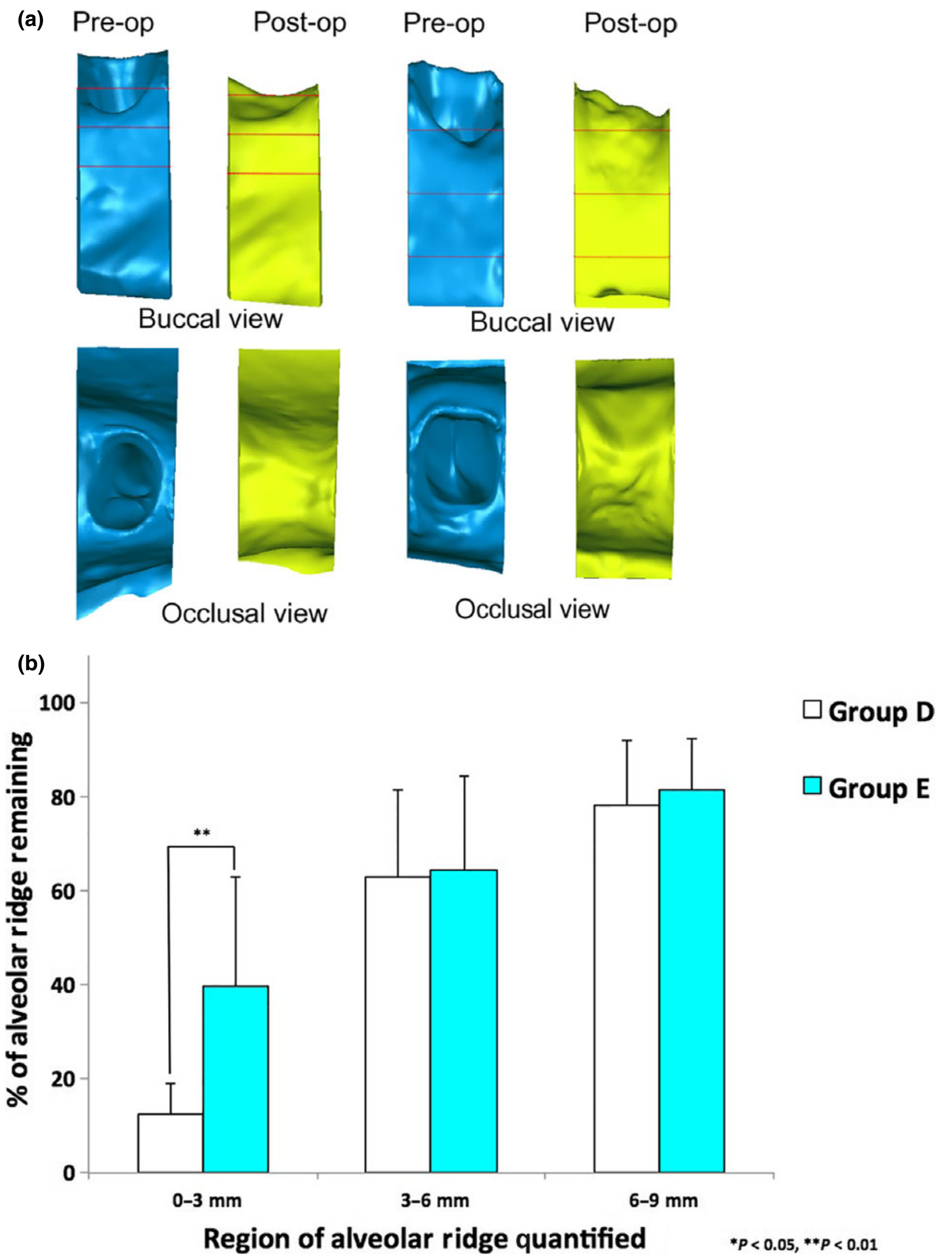

Fig. 8. (a) Representative facial and occlusal images of digitized study casts from extraction sites with facial wall dehiscence defects at baseline and at 6 month post-extraction. Group D (control) demonstrates significant contour loss of both height and width within the 0–3 mm zone apical to the ridge crest. Group E (SocketKAP™ + SocketKAGE™ + ABBM) demonstrates significantly improved height and width contour retention compared to group D at 6 months post-extraction. (b) Percentage of alveolar ridge contour remaining 6 months after intervention in facial wall dehiscence defect sites from groups D and E.

tion, permitting highly accurate pre- and post-operative follow-up comparisons of the laser-scanned models with readily defined, stable reference points for repeated measurements over time.

This study was the first clinical trial to evaluate the efficacy of SocketKAP™ and SocketKAGE™ devices in ridge preservation procedures. The present study had a number of limitations. These include the relatively heterogeneous enrollment of subjects, which included teeth extracted due to periodontitis, severe caries, endodontic failure, etc. Another aspect of the heterogeneity was enrollment of sites in all oral regions, as well as single and multiple extractions. Although such non-selective enrollment is helpful in that the subjects are representative of typical cases encountered in clinical practice, the heterogeneity of sites is likely to have increased the variability of outcomes.

Several important findings were observed in this randomized controlled prospective study.

1. In the negative control groups (groups A and D), significant 3D volumetric contour loss rapidly occurred following tooth extraction in both intact sockets and sockets with facial dehiscence defects, a finding consistent with multiple systematic reviews (Van der Weijden et al. 2009; Ten Heggeler et al. 2010; Vignoletti et al. 2012; Morjaria et al. 2014).
2. Previously, it has been shown that following extraction, alveolar ridge loss occurs in the crestal portion of the ridge. However, the present study demonstrated that not only did significant resorption occur in the crestal 3 mm of the ridge, but also one-third of sites with intact facial bone lost more than 50% of the alveolar ridge contour in the 3–6 mm zone. The methodology used in the present study enabled us to perform very accurate 3D comparison of pre- and post-operative volumes, which could explain this finding. Nonetheless, as the technique is different than what was previously reported in the literature, direct comparison of the results is not feasible.
3. In both intact sockets and those with facial dehiscence defects, tooth extraction and device insertion were performed without flap elevation to minimize the trauma to the extraction site. Fickl et al. (2008b) reported that flap elevation increased the amount of bone resorption following extraction both with and without ridge preservation. Nonetheless, other studies have reported that flap elevation does not have any effect on the amount of bone resorption following extraction (Araújo & Lindhe 2009). Given the current protocol design, it is impossible to determine, from this study, the impact of flap reflection on post-extraction crestal ridge contour loss.
4. For intact sockets, treatment with SocketKAP™ alone or SocketKAP™ + ABBM led to statistically greater percentages of remaining ridge contour when compared to the negative control group. No statistically significant contour differences for intact sockets were seen, however, between the groups treated with SocketKAP™ alone and SocketKAP™ + ABBM, although the clinical trend, especially noted in the scatter plot data, favored the latter treatment group. The lack of statistical significance between these two groups may be a function of the low number of enrolled subjects rather than a valid study finding. In addition, the lack of a group with post-

Table 3. **The significance level (*p*) for the comparison of alveolar ridge contour loss between untreated control (group A), socketKAP™ (B), and ABBM+SocketKAP™ (C) groups in sites with intact socket walls in different zones, measured in mm from the crest**

	Intact sockets (Groups A, B, and C)	
	ABBM + SocketKAP™ (C)	SocketKAP™ (B)
0–3 mm		
Control (A)	0.0001	0.02
SocketKAP™ (B)	0.322	–
3–6 mm		
Control (A)	0.109	0.496
SocketKAP™ (B)	0.675	–
6–9 mm		
Control (A)	0.252	0.468
SocketKAP™ (B)	0.022	–

Table 4. **The significance level (*P*) for the comparison of alveolar ridge contour loss between untreated control (D) and ABBM+SocketKAP™+SocketKAGE™ (E) groups for sites with facial dehiscence defects in different zones, measured in mm from the crest**

Dehiscence sockets (Groups D and E)	
0–3 mm	0.005
3–6 mm	0.846
6–9 mm	0.519

extraction facial dehiscence defects treated with SocketKAP™ + SocketKAGE™ alone prevents the determination of whether the addition of a bone graft substitute is required for effective restoration and maintenance of alveolar ridge contour.

5. Comparison of the outcomes of single tooth extractions with multiple adjacent extractions revealed numerically more loss of ridge contour in the latter group, although differences between these subsets were not statistically significant (data not shown). It is possible that the inability to demonstrate statistically significant difference between single and multiple adjacent extractions is due to the small sample size in the present study. Future larger scale studies will be required to determine the influence of multiple adjacent tooth extractions. It is important to note that although previous studies have demonstrated significantly more bone remodeling in multiple adjacent tooth extractions (Al-Askar et al. 2013), soft tissue contour differences between single and multiple tooth extractions have not been investigated.

Other aims of the present clinical trial were to evaluate changes to the alveolar bone and the effects of interventions involving SocketKAP™ and SocketKAGE™ following extraction. Quantitative assessment of pre- and post-extraction CBCT data enabled determination of volumetric changes to the alveolar bone following extraction with and without additional interventions, which are reported in the second part of this study. Post-extraction alveolar bone volumetric loss occurred in all sockets primarily in the 0–3 mm zone. For intact sockets, SocketKAP™ + ABBM interventions led to greater percentages of remaining alveolar bone when compared to negative control. A significant difference favoring SocketKAP™ + SocketKAGE™ + ABBM treatment was observed for sockets with facial dehiscence when compared to controls. Documentation and quantitative measurements of alveolar bone have important implications on the ability to restore sites with implant-supported restoration.

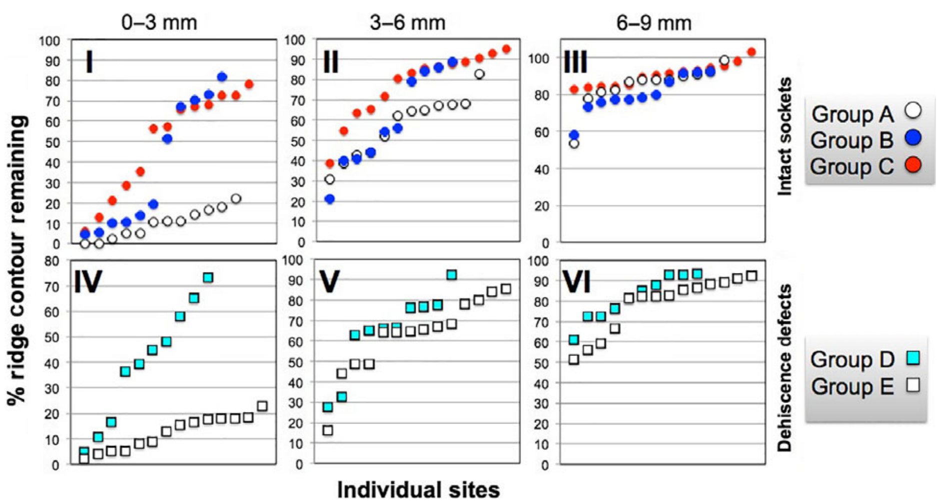

Fig. 9. Percentage of alveolar ridge contour remaining 6 months after intervention in individual sites. The outcomes of intact sockets (I to III) and dehiscence sockets (IV to VI) at 0–3 mm (I and IV), 3–6 mm (II and V), and 6–9 mm (III and VI) relative to the alveolar ridge crest are shown.

Recommendation and future directions

Of importance is the histologic analysis of the healed extraction sites following treatment with SocketKAP™ and SocketKAGE™. As a continuation of this study, dental implants were placed at the extraction sites and during this procedure, core samples were collected for histological and histomorphometric analysis. The results have demonstrated favorable histologic outcome for each of the intervention groups examined (manuscript in preparation).

In view of the limited number of subjected included in this study, a larger multi-center randomized controlled clinical trial with more subjects in each group and additional treatment groups for sockets with facial bone dehiscence (SocketKAP™, SocketKAGE™, or SocketKAP™+SocketKAGE™ without the use of graft material) would be beneficial. The additive effect of the graft material to the treatment protocol is still not clear due to limitation in the number of cases in each group. Moreover, comparison of the ridge preservation and augmentation protocol using SocketKAP™ and SocketKAGE™ device with traditional membranes is merited.

In conclusion, results from the current study suggest that the SocketKAP™ device, with or without ABBM, may prove clinically effective in limiting post-extraction alveolar ridge contour loss in intact sockets. In the presence of facial dehiscence, the combination of SocketKAP™ + SocketKAGE™ with ABBM appears to significantly reduce post-extraction ridge contour loss when compared to no treatment following tooth removal.

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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.

