The objectives of this study were to determine the quantitative changes after different ridge preservation techniques (primary aim) and to assess the possibility of placing a dental implant, the bone quality, and the need for bone augmentation (secondary aim). A total of 35 patients who required extraction of at least one tooth (incisor, canine, or premolar) provided 35 single-gap extraction sites. After minimally invasive tooth removal, the sockets were randomly scheduled for one of four treatment modalities: placement of a deproteinized bovine bone mineral (DBBM; Endobon, Biomet 3i) covered with a soft tissue punch from the palate (T1); placement of DBBM alone (T2); placement of DBBM covered with a resorbable collagen membrane (OsseoGuard, Biomet 3i) (T3); or no additional treatment (T4). Silicone impressions were taken before and 6 months after extraction for quantitative-volumetric evaluation (primary outcome). The possibility of placing an implant, bone quality, and need for further bone augmentation were also noted (secondary outcomes). During the study period, no adverse events were observed. No statistically significant difference was found between the four treatments regarding the primary and secondary outcome parameters (P > .05). However, T4 showed double the buccal contour change, with the highest variance compared to the other three groups (T1 –0.874 ± 0.713; T2 –0.968 ± 0.344; T3 –1.26 ± 0.942; T4 –2.15 ± 1.349). Although no statistically significant difference was found between the four treatment modalities, placement of DBBM resulted in only half the contour change (< 1 mm) compared to control sites (> 2 mm).

Ridge preservation with a DBBM with or without soft tissue punch should be considered in esthetically demanding cases and delayed or late implant placement. Int J Periodontics Restorative Dent 2018;38:549–556. doi: 10.11607/prd.3636

Surgical removal of teeth is usually accompanied by significant changes in the hard and soft tissues of the alveolar ridge. Morphologic changes occurring after tooth extraction have been well documented in multiple preclinical and clinical studies.1–3 Schropp et al4 evaluated 46 extraction sites in the maxillary and mandibular posterior areas and demonstrated a shrinkage in the buccolingual ridge width of 50% after 12 months. Remarkably, two-thirds of this change occurred in the buccal area. Furthermore, the bone height was decreased by 0.8 mm 3 months after extraction. Many subsequent studies have dealt with the reasons for these volumetric alterations.

Araújo and Lindhe5 demonstrated histologically that the structure of the bundle bone (the portion of the alveolar bone with inserting periodontal fibers) is significantly involved in these changes. This complex loses its function after tooth extraction and seems to be resorbed. A buccal bone plate consisting solely of bundle bone may be entirely lost after tooth extraction, especially in thin periodontal biotypes.6 Loss of bony structure might impair the possibility of implant placement and create need for bone augmentation along with or prior to implant insertion. In addition, natural bony contour is crucial for an esthetic implant treatment in

Materials and Methods

This paper was prepared following the CONSORT guidelines.

Study Design

This prospective randomized controlled clinical trial included 40 patients, each with one hopeless single-rooted tooth (incisors to premolars) resulting in one extraction site. After tooth extraction, each site was randomly assigned to one of four different treatment modalities (n = 10 per group).

Participants

Subjects were recruited consecutively by independent examiners at the Julius-Maximilians-University, Würzburg, Germany. Each subject signed an informed consent form after thorough explanation of the nature, risks, and benefits of the clinical investigation and associated procedures. The university’s ethical committee approved the consent form and the research protocol on 31 October, 2011 (183/11).

The following exclusion criteria were applied:

- Subjects aged < 18 years
- Uncontrolled, manifest diabetes mellitus (based on patient’s self-report)
- Radiation, chemotherapy, or intravenous bisphosphonates within the last 5 years (based on patient’s self-report)
- Infectious diseases (HIV, Hepatitis B or C) (based on patient’s self-report)
- Pregnant or lactating (based on patient’s self-report)
- Heavy smoker (> 10 cigarettes/day) (based on patient’s self-report)
- Multiple neighboring extraction sites
- Untreated periodontal disease (probing depths ≥ 4 mm in more than five sites)

Teeth with deficient buccal bone plates after tooth extraction were not excluded in this trial. The investigation was entirely carried out in the Department of Periodontology of the Julius-Maximilians-University.

Study Interventions

All subjects received oral hygiene instructions and, if needed, a dental cleaning to remove plaque and calculus. In addition, participants were instructed to rinse with 0.2% chlorhexidine digluconate three times per day starting 4 days before extraction. No pre- or postoperative antibiotics were prescribed.

Before tooth removal and after 6 months, prior to implant placement, silicone impressions (Identium, Kettenbach) were taken for volumetric measurements. S.F. and K.F. performed all surgeries. Extraction and implant placement were not carried out by
the same clinician. After local anesthesia (4% articaine with 1:100,000 epinephrine) and blinded to treatment group, the surgeon removed the tooth as atraumatically as possible to avoid harming the bony walls with, for example, orovestibular movements, and the extraction socket was carefully cleaned. If necessary, roots were separated with rotating instruments without touching bony structures to allow mobilization of fragments against one another. No flaps were raised, and soft tissue margins were not intentionally approximated. Thereafter, the alveolus was randomly assigned to one of following treatment modalities, as previously described by Fickl et al\textsuperscript{24}:

- **T1**: Demineralized bovine bone mineral (DBBM)/soft tissue punch group. After hydration with sterile saline, DBBM was filled up to the level of bony crest (Endobon, 500- to 1000-µm particle size, Biomet 3i), followed by wound closure with a soft tissue punch harvested from the palate (3 to 4 mm thick, socket orifice + 0.5 mm in diameter) and fixed by microsurgical sutures (Seralene 7-0, Serag Wiesner) according to the socket-seal technique by Jung et al\textsuperscript{25}.

- **T2**: DBBM-only group. This group received the same treatment as group T1 without application of a soft tissue punch.

- **T3**: DBBM/membrane group. A resorbable collagen membrane (Osseoguard, Zimmer Biomet) was adapted to the interior of the buccal bone wall according to Elian et al\textsuperscript{26} the socket was filled with DBBM, and the membrane was folded to cover the bone substitute and fixed to the lingual soft tissues with resorbable sutures (Serafit 6-0, Serag Wiesner).

- **T4**: Control group. The socket was left to blood clot formation without further treatment.

The patients were instructed to rinse with 0.2% chlorhexidine digluconate three times a day for at least 2 weeks. As an antiphlogistic medication, ibuprofen (600 mg) was prescribed. Sutures were removed 7 days after surgery.

At 6 months after ridge preservation, implant surgery was performed according to the manufacturer’s standardized protocol for the implant system used (Osseotrite Certain Implant, Biomet 3i). Following full-thickness flap reflection, the bone quality was assessed by applying single-use surgical drills and the need for reaugmentation was determined by the surgeon and recorded.

**Dimensional Soft Tissue Analysis**

The pre-extraction and follow-up impressions after 6 months were poured in dental stone (Tewerock, Kettenbach). Thereafter, the master casts were optically scanned with a laboratory optical scanner (Ceramill p400, Amann Girbach), resulting in digital STL files. For each patient, the digital surface models representing the two study time points were imported into the volume analysis software (SMOP Swissmeda). The best-fit algorithm was used to superimpose the digital surface models using unchanged tooth surfaces as reference (Figs 1 to 4). The study-relevant area for the dimensional measurements was defined in the same matter as in previous studies.\textsuperscript{20,27,28} The mesial and distal papillary midline, the mucogingival line, and the crown margin served as anatomical reference structures to define the area of interest. If necessary, the coronal area of interest was shifted 1 to 2 mm apical to avoid nonreadable measurements because of invalid superimposition. Naturally, in each patient the area of interest was of different size. To allow for a direct comparison in volumetric changes between patients, the mean dimensional change per area was calculated, resulting in a linear buccal distance. Therefore, the study sites could be compared irrespective of their size and the size of the area of interest. Before the dimensional analysis, a calibration session was conducted to ensure reproducibility.

**Objectives**

The main objective of this study was to determine the influence of different ridge preservation techniques with a xenogenic bone substitute on postextraction bone remodeling. Additional aims were to assess the influence of these techniques on the possibility of placing an implant, on bone quality, and on the need for further bone augmentation.
to enable implant placement. Bone quality was assessed by the surgeon following initial drilling using the classification system of Lekholm et al. 29

Randomization

Randomization was performed using a computerized randomization scheme (SPSS version 16, IBM) and communicated to the surgeon directly following tooth extraction.

Statistical Analyses

The null-hypothesis was that there would be no difference in volumetric changes and no differences in the possibility of placing an implant, bone quality, or need for further bone augmentation between these groups.

Sample size calculation was performed on the results of previous studies30,31 and resulted in ten subjects per group. For the primary outcome variable (mean dimensional change), it was assumed that the true difference between groups would amount to 0.75 mm with a SD of 0.5. The Type I error probability was set at 0.05, the statistical power at 90%.

Mean values, SDs, medians, minimums, and maximums were calculated for all groups. Statistical analysis was performed using SPSS 22 (IBM). Nonparametric Kruskal-Wallis and Mann-Whitney U tests were applied for statistical comparison. $P < .05$ was considered statistically significant.

Results

Participant Flow

The study population consisted of 40 patients (24 women and 16 men) aged 18 to 80 years (mean age $55.7 \pm 14.85$ years), each with one or more hopeless teeth with intact neighboring teeth. The 40 patients enrolled in the study either underwent socket preservation (T1, T2, and T3) or comprised the control group (T4). Of these, 35 patients presenting 35 extraction sockets completed the study and complied with all study appointments, and 5 dropouts were recorded due to noncompliance with study protocol (n = 3) or refraining from implant placement (n = 2). No statistically significant difference was found between the
selected and evaluated surface area comparing the four different groups ($P > .05$).

Primary Outcomes

The three socket preservation techniques (T1, T2, and T3) resulted in similar buccal contour changes 6 months after tooth extraction, with the smallest changes in T1. The control group (T4) showed twice the volumetric change compared to socket preservation techniques (Table 1). This difference did not reach statistical significance (Kruskal-Wallis test for comparison of all groups: $P > .05$; Mann-Whitney $U$ test for comparison between single groups: test groups vs control, $P > .05$; Fig 5).

Secondary Outcomes

No difference was recorded for all secondary outcomes (possibility of placing an implant, bone quality, need for bone augmentation), hence these data were not further statistically evaluated.

In all cases, standard-diameter implant placement was possible in relation to tooth position (3.25 mm for maxillary lateral incisors; 4 and 5 mm for all other teeth) and in correct prosthetically driven position; nevertheless, in some cases additional bone augmentation was needed due to bone dehiscence/ fenestration or ridge contour deficiencies (T1: 1; T2: 0; T3: 2; T4: 2; reasons for additional bone augmentation were not differentiated). In 60% of the cases, rather soft bone (type 3) with DBBM partially encapsulated in soft tissue and low drilling resistance was found.

Adverse Events

No adverse events were reported.

Discussion

Key Findings

In this randomized controlled clinical trial, the objective was to determine whether ridge preservation with a bovine xenograft bone substitute reduces alveolar ridge contour changes 6 months after tooth extraction and whether these procedures facilitate implant placement and reduce further need for bone augmentation. No statistically significant difference was found between the four treatment modalities, either for volumetric changes, for possibility of placing an implant, bone quality, or need for bone augmentation. Nevertheless, the three socket preservation techniques resulted in similarly limited buccal contour changes ($< 1$ mm) with the smallest changes occurring in the treatment group in which a soft tissue punch was applied. Leaving the extraction socket solely to blood clot formation (T4) resulted in twice as much contour loss ($> 2$ mm) and the highest variance, and seems to be less predictable. This tissue loss might be clinically relevant, especially in esthetically demanding cases. Bone quality or density was low in most of the sites irrespective of performed treatment, and no difference was noted in need for additional bone augmentation procedures.
Clinical Observations

During implant surgery, different clinical observations were made. First, soft tissue thickness differed between the groups. Placement of a soft tissue punch (T1) resulted in a thick mucosa (3 to 4 mm) over the extraction socket, which enabled soft tissue management during bone augmentation or uncovering surgery. In contrast, rather thin tissues were found above the DBBM especially in T2, which could lead to small soft tissue dehiscence over the implant cover screw. These subjective findings need to be investigated in future studies since soft tissue thickness influences not only esthetics but also bone level stability over time. Recently, it has been shown that a thin biotype (< 2 mm thick) loses significantly more bone, and socket-seal technique with ridge preservation might help change a thin mucosa into a thick one and maintain stable bone levels. Second, DBBM particles were regularly found encapsulated in connective tissue in the coronal first 2 to 3 mm in T1, T2, and T3, although DBBM particles were only filled to the most coronal bony walls. Still, this observation is a matter of debate, since the influence of DBBM on peri-implant soft tissue health and hard tissue stability is unclear. Regarding bone density or drilling resistance, no difference was noted during implant osteotomy.

Comparison with Previous Studies

Placement of different bone substitutes has been shown to partially preserve the alveolar ridge after tooth extraction. For example, Perelman-Karmon et al reported a higher percentage of new bone formation after DBBM/collagen membrane compared to DBBM alone, increasing from apical to coronal (47% vs 36.3% and 35.2% vs 22.8%, respectively). Mardas et al detected new bone formation and reduced bone loss after the application of a biphasic synthetic biomaterial or a bovine DBBM with a barrier membrane after 8 months. On the other side, they found biomaterial particles encapsulated in soft tissue in both groups, as also reported from Carmagnola et al or Fickl et al.

Preclinical and clinical studies have evaluated the effects of different ridge preservation techniques on soft tissue level. Additional soft tissue augmentation or socket-seal surgery seems to reduce ridge contour changes or soft tissue collapse. A recent consensus statement, however, was indecisive concerning this additional procedure, and that a second surgical site is created at the palate with higher postoperative morbidity has to be weighed against the expected advantage. Nevertheless, Thalmair et al reported the lowest volumetric changes after the application of a palatal punch with or without bone grafting. After 4 months of healing, they found significantly less volumetric shrinkage compared to untreated control sites (–0.79/–0.85 vs –2.29). These data are similar to those is presented in this study (–0.87 vs –2.2). In addition, thinner mucosal tissues were encountered in the present study when no soft tissue punch was placed. In some cases, this lead to early implant exposure due to small tissue dehiscence over the implant cover screw.

Darby et al reviewed 37 human studies and concluded that ridge preservation reduces horizontal and vertical bone loss after tooth extraction. However, data is inconclusive regarding whether these procedures improve the ability to place implants, questioning their helpfulness if further bone augmentation is needed. A more recent consensus study came to similar conclusions, stating that less need for bone augmentation might be anticipated but that the effect on implant success or future bone loss is uncertain.

After soft tissue closure, on the other hand, early implant placement with guided bone regeneration (GBR) seems to be a reliable approach with esthetically demanding cases. Buser et al demonstrated stable peri-implant hard and soft tissues and satisfactory esthetic outcomes after 5 to 9 years after early implant placement with GBR. In addition, Araújo et al have shown that socket grafting interferes with bone regeneration and might delay bone healing.

Strengths and Limitations of the Study

In this randomized controlled clinical trial, surgeons were unaware of the treatment group before extraction or during implant placement and blinded examiners performed data collection and analysis to avoid bias. The presented volumetric evaluation is a well-established method
and allows three-dimensional measurements. The presented study population was also evaluated two-dimensionally to test a more clinically orientated assessment method, such as that presented by Schropp et al. Using linear measurements in the bucco-oral direction on stone casts, significant differences were found between test and control groups. The conflicting results between these two methods might be explained by the higher accuracy of three-dimensional methods and by the difference in the selected area of interest.

Although varying contour changes were noted, no statistically significant differences were found between the test and control groups. Nevertheless, the results and findings are clinical relevant. The relatively small number of included extractions sites and the four different treatment modalities might explain this, although sample size calculation was carried out before study initiation. Future studies might include larger numbers of patients or focus on only one test group and a control group. Another explanation might be the efficacy of ridge preservation itself. In cases with deficient socket walls, which were not excluded from this study, a flapless approach might not be capable of preserving the ridge contour, and the treatment would be ineffective. Raising a flap, however, seems to increase bone loss and has no beneficial effect with regard to bone formation within the socket. This study primarily focused on dimensional changes in relation to ridge volume based on impressions over the soft tissues. Hence, no conclusions can be drawn regarding the underlying bone tissue, either volumetrically or histologically. No difference in need for further bone augmentation was found; however, additional differentiation was not made esthetic and functional reasons for augmentations. This factor should be included in future research.

Conclusions

Although no statistically significant difference was found between the four treatment modalities, placement of a DBBM (in groups T1, T2, and T3) resulted in half the contour change with less variance compared to control sites (T4). This difference can be clinically significant, especially in esthetically demanding cases. Combined hard and soft tissue augmentation (T1) appears to be the most predictable approach to maintaining ridge contour.

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The authors reported no conflicts of interest related to this study.

References


