<u>Study topic:</u> Lateral Ridge Augmentation Using Allograft Blocks and Guided Bone Regeneration for Implant Sites

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Study Summary

Background:
Clinicians are increasingly faced with the challenge of reconstructing the alveolar ridge as more patients desire fixed implant-supported restorations. Reconstruction of large horizontal alveolar defects still remains a challenge in implantology. Although autogenous blocks from intraoral sites are proven effective for such defects, donor site morbidity and limited graft availability are major limitations. Allogenic bone blocks have been proposed to overcome these limitations, however, the outcomes reported in the literature are inconclusive. Several case series (Acceturi 2002, Petrungaro 2005, Nissan 2008) claim successful ridge augmentation with allogenic bone, whereas others revealed higher failure rates due to bone exposure and graft resorption (Chiapasco 2013, Lumetti 2014, Spin-Neto 2013). In addition, allogenic bone blocks exhibit a higher degree of resorption (Spin-Neto 2013, Lumetti 2014), whereas Novell (2012), showed that resorption of allografts was comparable to autogenous bone blocks. Randomized clinical trials state that bone resorption occurs but does not deter successful placement of implants in augmented sites (Deluiz 2016, Amorfini 2014). This case series aims to evaluate the efficacy of allogenic blocks for lateral augmentation of atrophic ridges for implant sites, over a three-year period.
Materials and methods: In nineteen edentulous sites, cortico-cancellous allogenic blocks (PHOENIX, TBF, France) were shaped to the defect and screw-fixated. A double-layer of autogenous chips and demineralized bovine bone (Bio-Oss, Geistlich Pharma AG, Switzerland) was used to fill the voids. The augmented site was covered by non-cross-linked collagen membrane (Bio-Gide, Geistlich Pharma AG, Switzerland). After a healing period of 9 months, implants were placed and CBCT analysis was performed post-implantation. Following a period of 34 months of function, patients were clinically and radiographically re-examined. The primary outcome measure is the graft stability that is measured by change in lateral ridge width over time. Secondary outcome measures are various soft tissue parameters around the implant.

Study Protocol

***Technique*:**

The present study design is a mono-center three-year follow-up case series study to examine the safety and effectiveness of allograft bone blocks combined with guided bone regeneration (GBR). The study is in accordance to the principles of the Declaration of Helsinki and will obtain approval by the standing ethical committee of the state of Bern, Switzerland.

The preoperative analysis includes a complete medical history, clinical examination of the dentition and a thorough analysis of the implant recipient using 3D cone beam computed tomography (3D Accuitomo 170, Morita, Kyoto, Japan).

Surgical Procedure:

The surgical procedures wil be done in two stages. In the first stage surgery, a full-thickness mucoperiosteal flap will be raised on both the facial and palatal aspects. Ridge augmentation will be done using a mineralized, cortico-cancellous, delipidized, lyophilized allogenic block (ALB; PHOENIX allograft, TBF Mions, France). Following hydration of the ALB, the cortico-cancellous part of the block will be shaped to fit the recipient site and fixated by two fixation screws (Medartis, Modus, Mediartis Holding AG, Basel, Switzerland). Voids around the ALB will be filled with autogenous bone chips (AGB) harvested locally from the

recipient site. The augmented site will be covered by a first layer of deproteinized bovine bone mineral mixed (DBBM; Bio- Oss, Geistlich Pharma, Wolhusen, Switzerland and a non-crosslinked collagen membrane (BG; Bio- Gide, Geistlich AG, Wolhusen, Switzerland) as described previously (Chappuis 2017). A periosteal-releasing incision will be used to provide tension-free flap closure. The wound margins will be approximated using non-resorbable poly- amide suture (Seralon, Serag-Wiessner GmbH, Naila, Germany) to obtain primary wound closure. All patients will be prescribed an antibiotic regimen with 2g of amoxicillin with clavulanic acid 1 hour preoperatively to be continued as 1g twice daily for 3 days post-surgery. Patients will be also prescribed analgesics and chlorhexidine digluconate (0.2%) for chemical plaque control. In patients with post-surgical complications the antibiotic regimen will be prolonged. Sutures will be removed around 14 days postoperatively. Removable provisionals will be adapted, but patients will be instructed to not to wear them unless unavoidable during the initial healing phase.

The second stage surgery will be performed after a minimal healing period of six months. A paracrestal incision will be given to elevate a full thickness mucoperiosteal. The fixation screws from the previous surgery will be removed and the implant bed will be prepared based on the specific requirements of the site. All implants placed will have chemically modified, sandblasted, and acid-etched surface and will have either, a tissue level implant (TL) or a bone level implant (BL) design (SLActive, Straumann AG, Basel, Switzerland). Simultaneous re-grafting will be performed as required using autogenous bone chips, DBBM and a non-cross-linked collagen membrane. A tension-free wound closure will be obtained by non-resorbable sutures. The antibiotic and analgesic regimen and post-surgical care will be the same as in the first-stage surgery. Sutures will be removed after 14 days. Patients will be instructed to wear the provisional with caution. After a healing period of 4-6 months the healing abutments will be placed for the future prosthetics. The implants will be restored with either different prosthetic solutions as required. Patient will be given oral hygiene instructions and directed to enroll onto a supportive periodontal therapy to monitor oral health.

Clinical and radiographic follow-up examination after 3 years:

Clinical parameters - Updates on medical conditions, smoking, oral hygiene and enrollment in a maintenance care program will be collected from the patients. Clinical examinations will be made by the same examiner throughout the three-year follow-up period. The clinical parameters will be assessed as previously described (Chappuis 2017): peri-implant suppuration, modified plaque index (mPLI), modified sulcus bleeding index (mBLI), probing depth, DIM (distance from the implant shoulder to the mucosal margin), width of the KM, mobility and full mouth plaque scores.

Radiographic analysis using 2D radiographs and 3D CBCT - The peri-implant bone loss will be measured on periapical 2D radiographs analyzing the proximal DIB values as the vertical distance from the implant shoulder to the first bone-to-implant contact as described earlier (DIB; mm) (Weber HP et al 1992). The mean DIB value per implant considered will the average of the mesial and distal values.

The horizontal bone gain of the atrophic sites will be assessed by with the smallest field of view (3D Accuitomo 170, Morita, Kyoto, Japan). The image analysis will be performed by a high-resolution screen, using a specialized software (i-Dixel, Morita, Kyoto, Japan). The 3D analysis included a preoperative analysis of the proposed implant site. A standard reference point, 4mm crestal to the shoulder of the future implant will be used for all measurements (Chappuis 2017). CBCT measurements will be repeated prior to implant placement, using

the same reference point and repeated again at the 2-3year follow-up appointment. The radiographic measurements will be done by one examiner.

Assessment of biological, technical complications and patient reported outcome measures (PROMS) - All events of complications, intra-operative and post-operative at each surgical phase (graft surgery and implant surgery), prior to prosthetic treatment and post prosthetic rehabilitation both operator-assessed and self-reported will be recorded.

Patient reported outcome measures will be assessed by the Oral Health Impact Profile (OHIP) scores and patient satisfaction scores based on a visual analog scale (VAS) will be recorded for each patient after the entire treatment is completed and the patients receive the prosthetic replacements.

References

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