

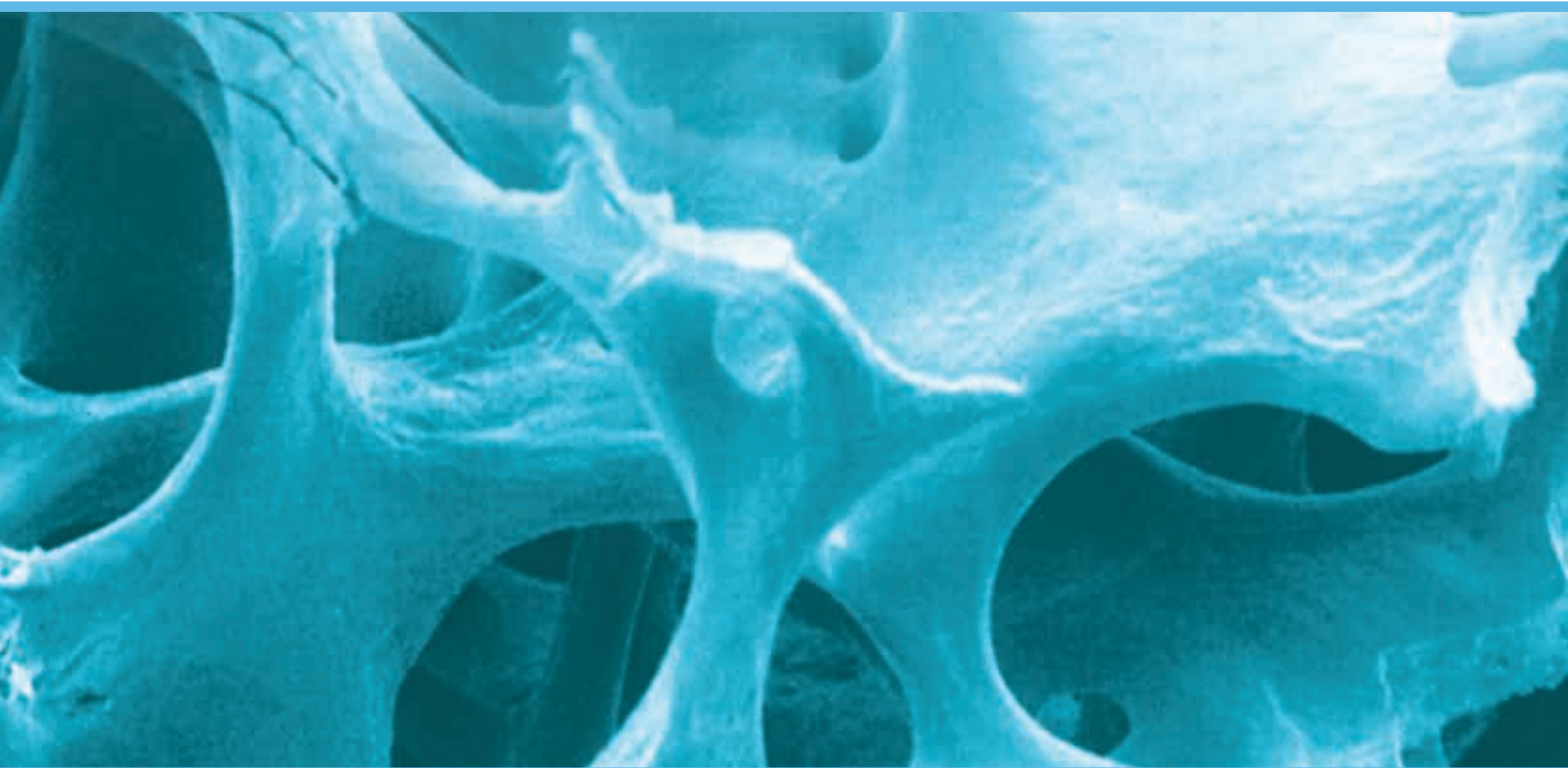


A Case
Book



Clinical Cases

for Regenerative Materials



 **ZimVie**

ZimVie DENTAL SOLUTIONS

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Case 1

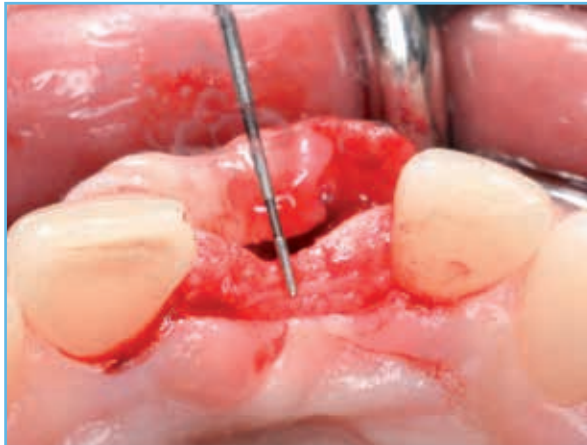
Lateral Onlay Graft Site [21]

Practitioner

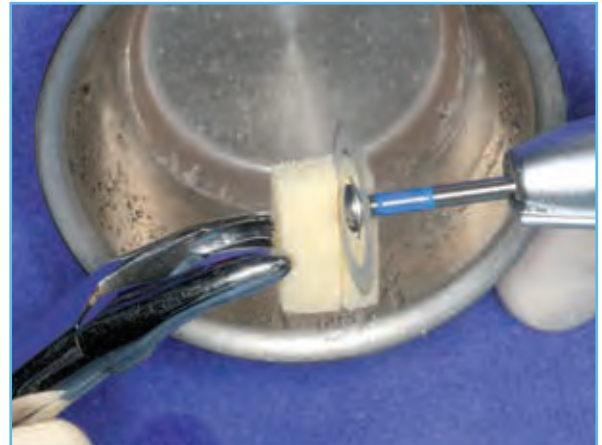
Dr. O. Richter
Hamburg (Germany)

Material

- Puros Allograft Block 15 x 10 x 9 mm
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc
- CopiOs Pericardium Membrane 30 x 40 mm



1 Residual ridge width 3 mm.



2 Shaping the Puros Allograft Block under saline solution using a circular saw.



3 Puros Allograft Block in place.



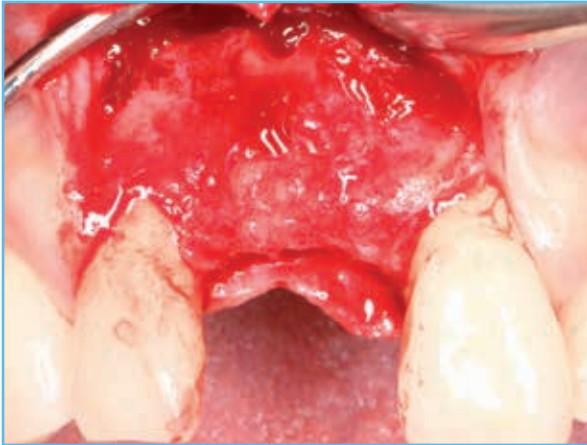
4 Filling inconsistencies in shape with Puros Allograft Cancellous Particles.



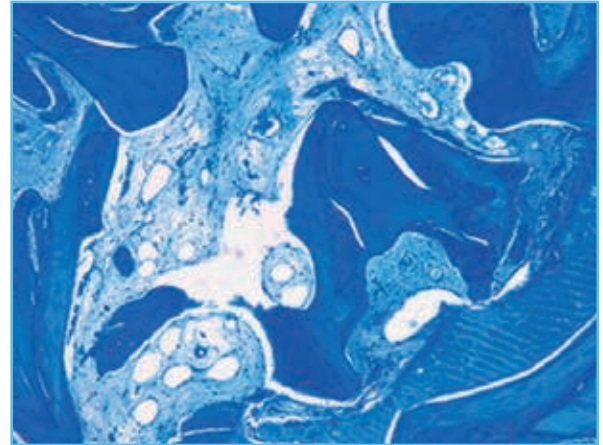
5 CopiOs Pericardium Membrane draped over bone graft prior to closure.



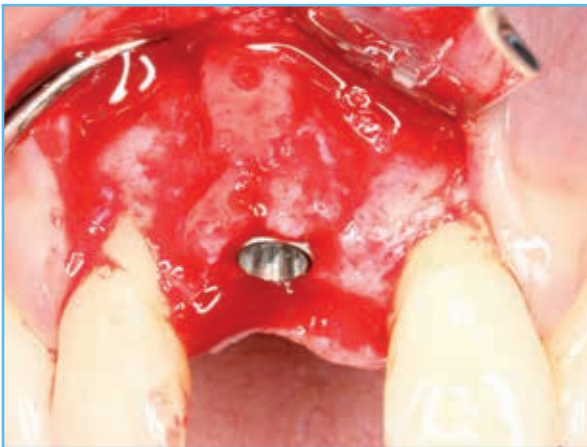
6 6-month post-op re-entry, minimal crestal resorption.



7 Situation following removal of osteosynthesis screws.



8 Histology, toluidine blue.



9 Implant in place.

Case 2

Lateral Onlay Graft Site [21-22]

Practitioners

PD Dr. Dr. K. K. Würzler,
Dr. F. Will
Würzburg (Germany)

Material

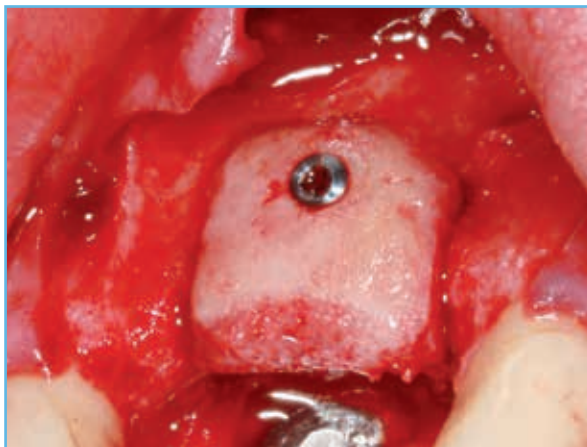
- Puros Allograft Block 15 x 15 x 9 mm
- Puros Allograft Cancellous Particles 0.25–1 mm, 1 cc
- CopiOs Pericardium Membrane 30 x 40 mm



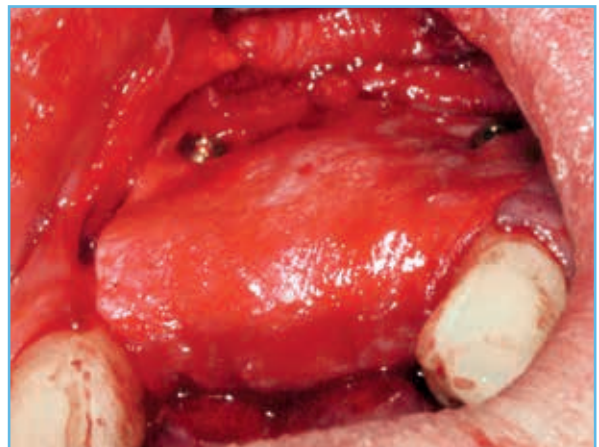
1 Defect situation, lateral view.



2 Defect situation, occlusal view.



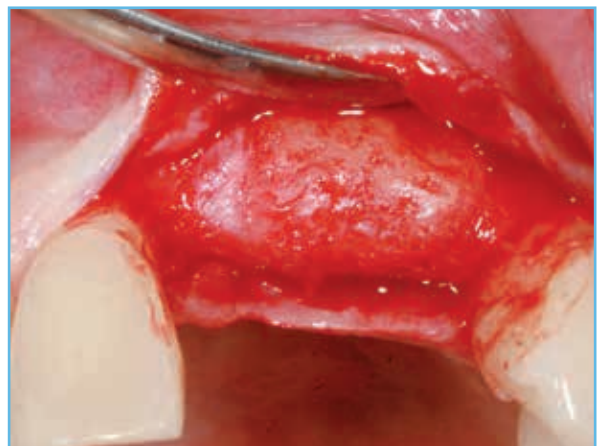
3 Puros Allograft Block in place.



4 CopiOs Pericardium Membrane draped over bone graft prior to closure.

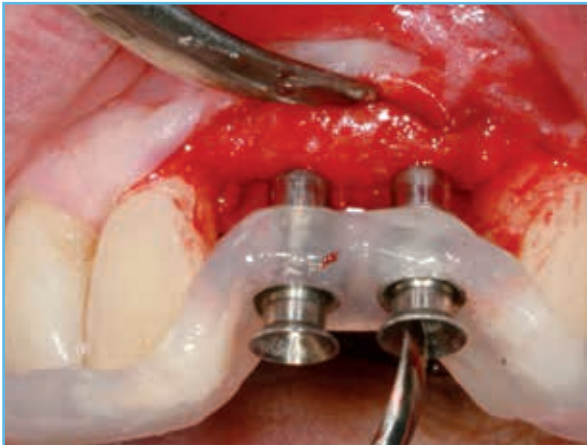


5 Soft tissue, 9 months post-operative.

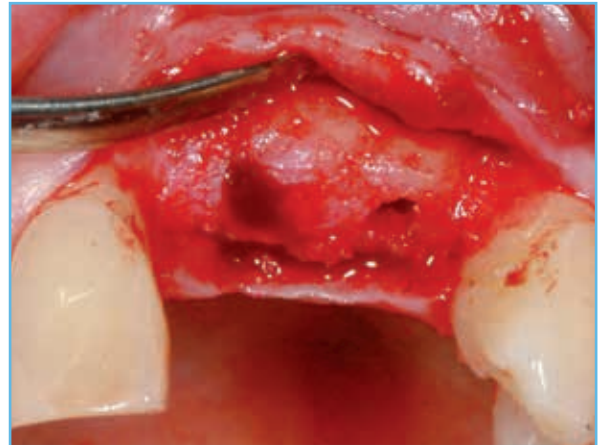


6 9-month post-op re-entry, no visible resorption.

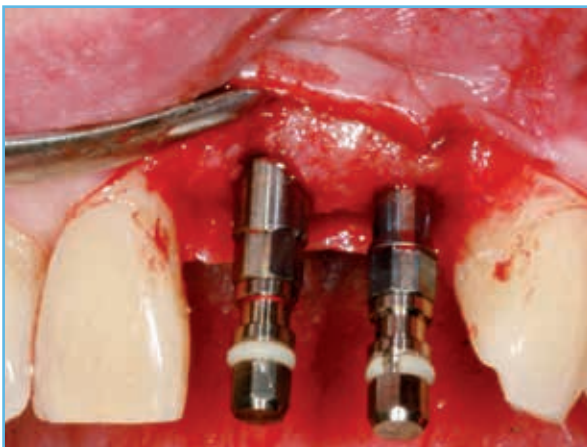
4 Year follow-up



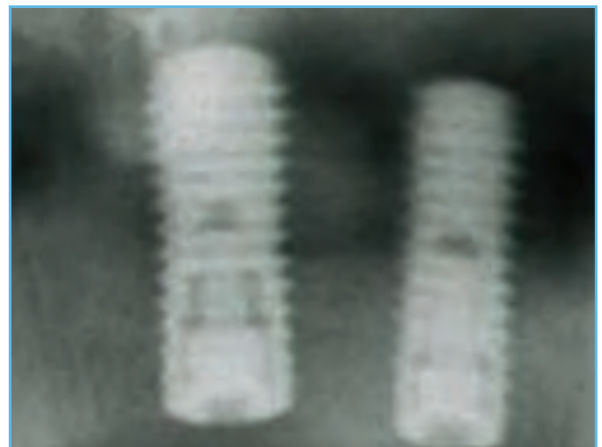
7 Surgical guide in place.



8 Final osteotomies.



9 Implants in place.



10 Post-placement radiograph.



11 4-years follow-up radiograph. Note the stable bone conditions.

Case 3

Lateral Onlay Graft Site [34-37]

R. Stutzki
Magdeburg (Germany)

Material

- Puros Allograft Cancellous Block 10 x 10 x 20 mm
- Puros Allograft Cancellous Particles 1–2 mm, 1 cc
- CopiOs Pericardium Membrane 30 x 40 mm
- Tapered Screw-Vent® Implants



1 Initial situation, narrow ridge left mandible.



2 Puros Allograft Cancellous Block in place, occlusal view.



3 Puros Allograft Cancellous Block in place, lateral view.



4 Puros Allograft Cancellous Particles placed around the block graft and covering with a CopiOs Pericardium Membrane.

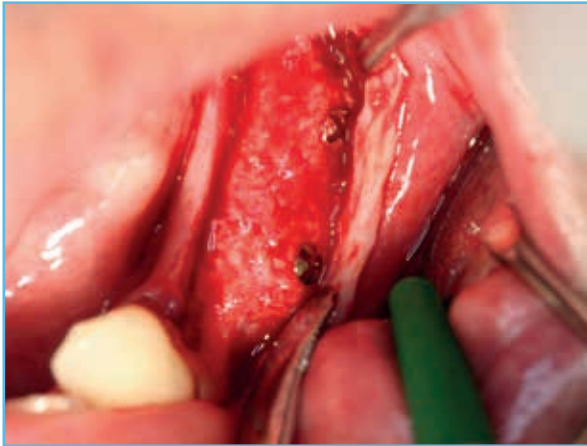


5 Wound closure.

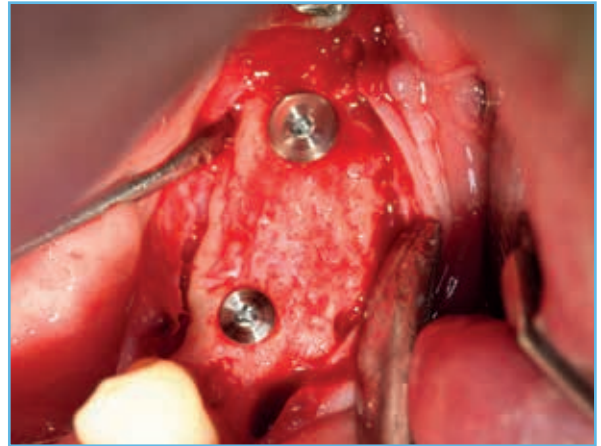


6 Soft tissue, 14 days post-operative.

3 Year follow-up



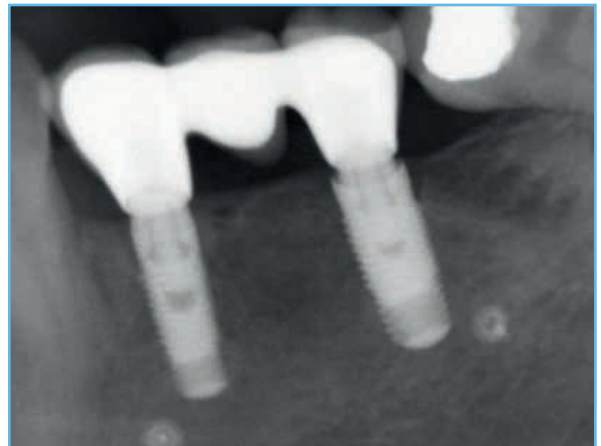
7 6-month post-op re-entry, no resorption.



8 Tapered Screw-Vent Implants in place, occlusal view.



9 Final radiograph.



10 Radiograph taken 3 years post-placement. Note the stable bone conditions.

Case 4

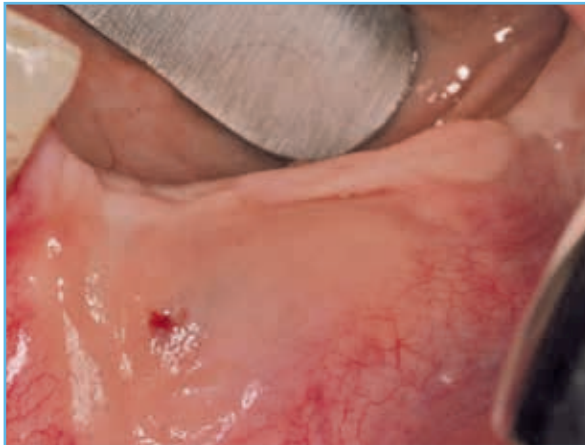
Lateral Onlay Graft Site [33-36], Histological Analysis

Practitioner

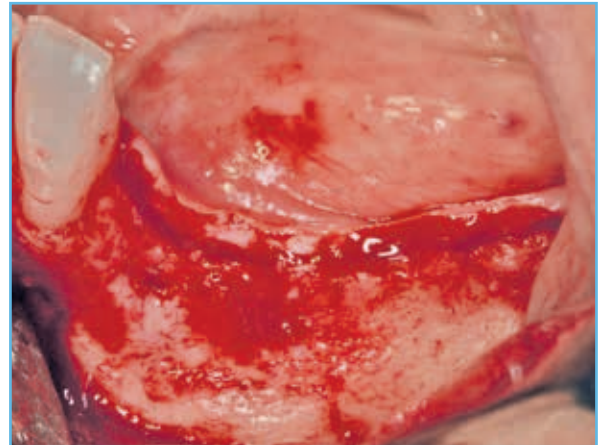
Dr. W. Gutwerk
Aschaffenburg (Germany)

Material

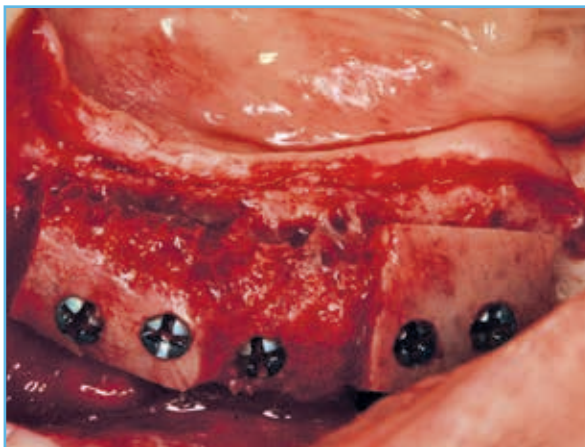
- Puros Allograft Block 15 x 15 x 9 mm
- Puros Allograft Cancellous Particles 0.25–1 mm, 1 cc



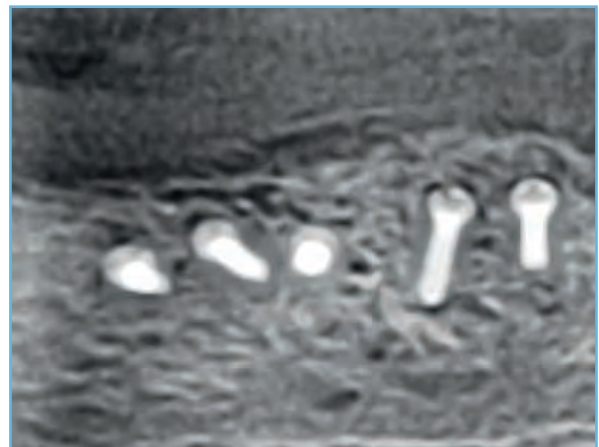
1 Initial situation, narrow ridge left mandible.



2 Elevated flap, revealing reduced ridge width.



3 Puros Allograft Block in place.*



4 6-month post-operative radiograph.

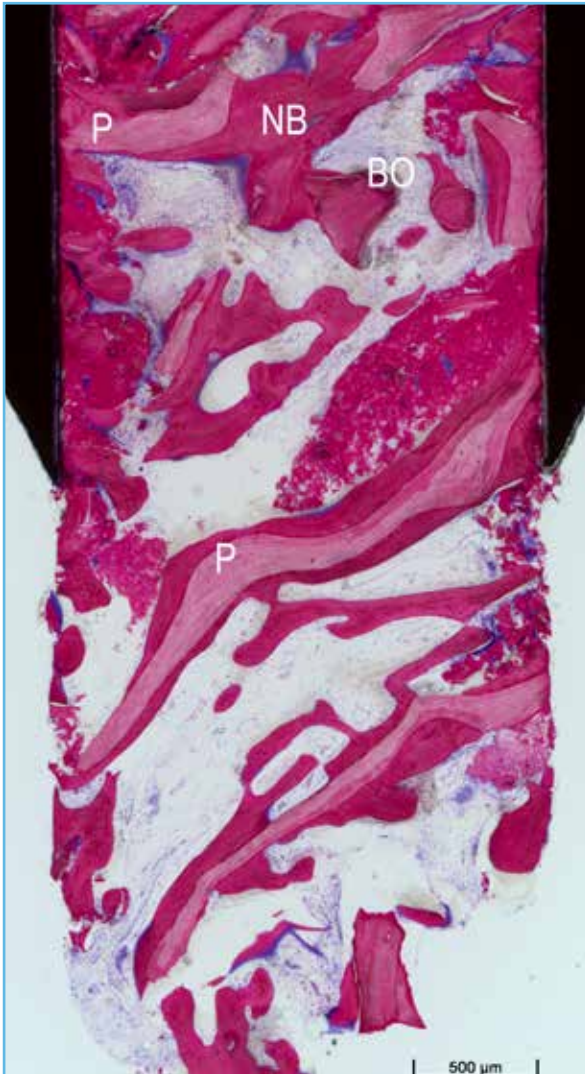


5 6-month post-op re-entry, reconstructed, ridge showing vital bone.

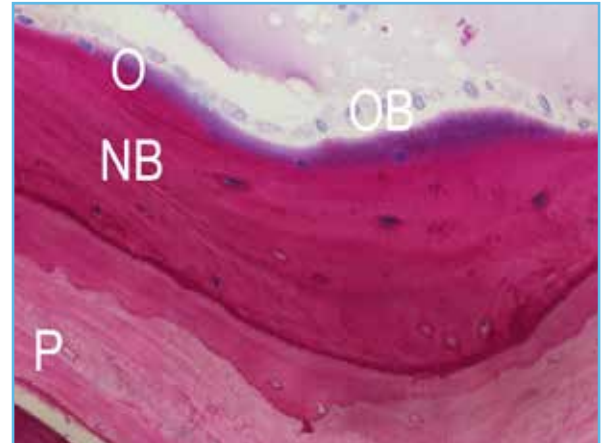


6 Radiograph after implant placement, note the mental foramen distal to site [35].

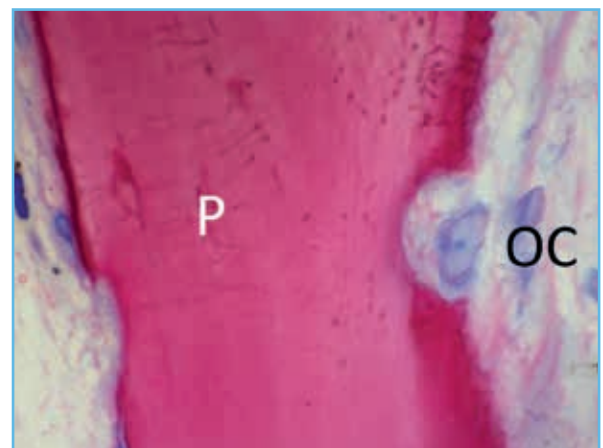
*Gaps grafted with a xenograft and covered with a non-absorbable membrane.



- 7 Histological cross-section (non-decalcified thin section) 50 fold: Healing time 6 months. Formation of vital, new bone (NB, mauve) and remaining Puros Block (P, reddish purple) and Bio-Oss (BO, grey) is clearly discernible.



- 8 Histological cross-section (non-decalcified thin section) 200 fold: Healing time 6 months. Osteoblasts (OB, blue) produce osteoid (O, purple rim). Maturation into newly formed lamellar bone (NB, mauve). Puros Block surface (P, reddish purple).



- 9 Histological cross-section (non-decalcified thin section) 200 fold: Healing time 6 months. Osteoclasts (OC, blue) forming a lacuna on the Puros Block surface (P, reddish purple).

Case 5

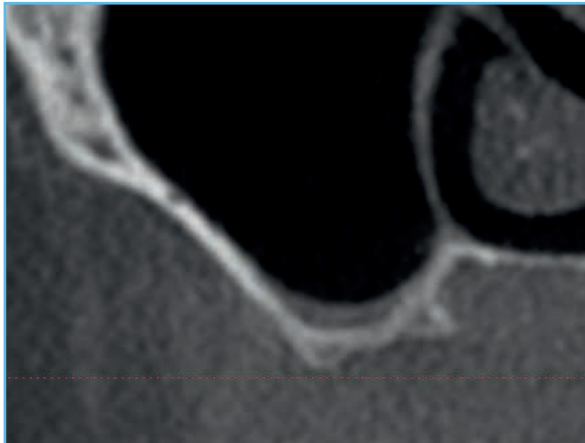
Vertical Onlay Graft with Simultaneous Sinus Lift Site [14-16]

Practitioners

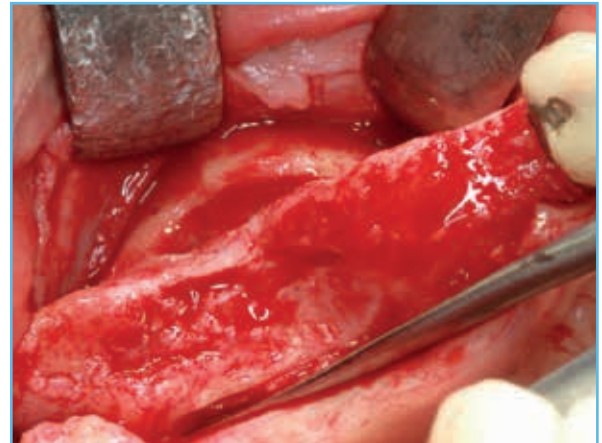
Dr. Dr. Dr. O. Blume, Dr. Dr. T. Müller-Hotop
Dr. M. Back Munich (Germany)

Material

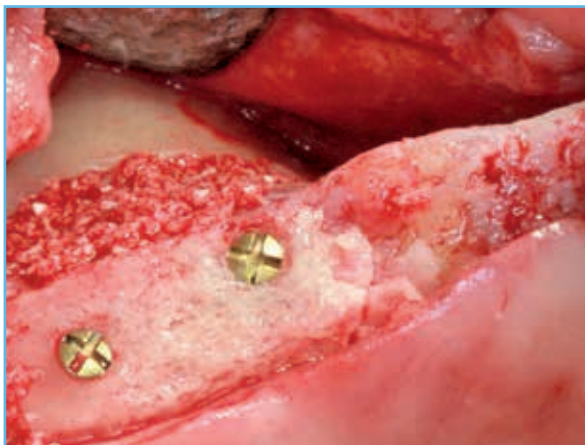
- Puros Allograft Block 15 x 15 x 9 mm
- Puros Allograft Cancellous Particles 0.25–1 mm, 2 cc



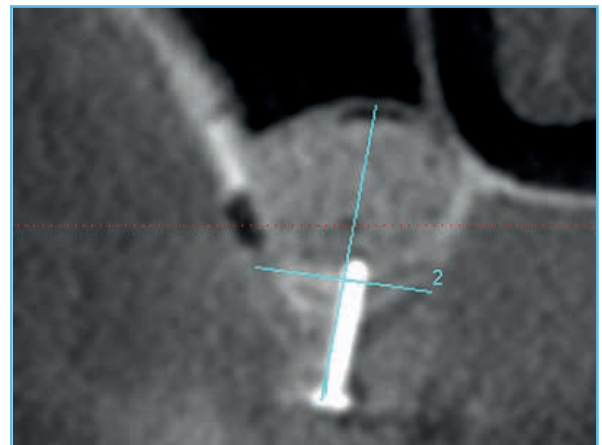
1 Initial situation, CBCT scan showing thin sinus floor.



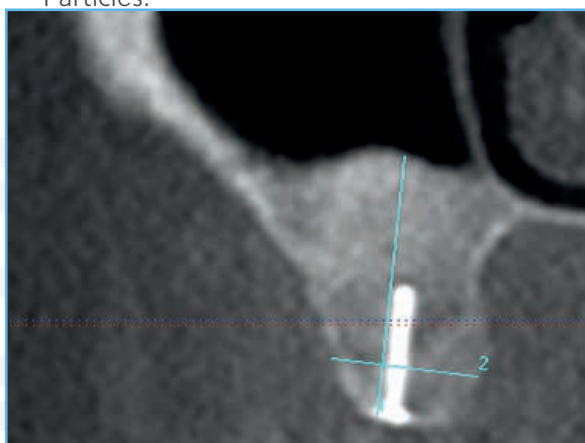
2 Initial situation, occlusal view, lateral window for sinus lift.



3 Puros Allograft Block in place, inconsistencies in shape filled with Puros Allograft Cancellous Particles.



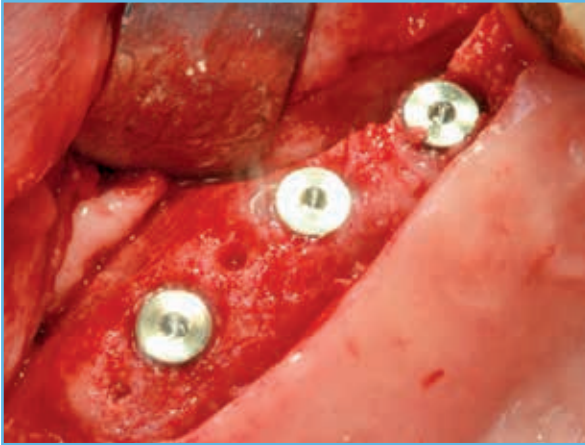
4 Post-augmentation CBCT scan.



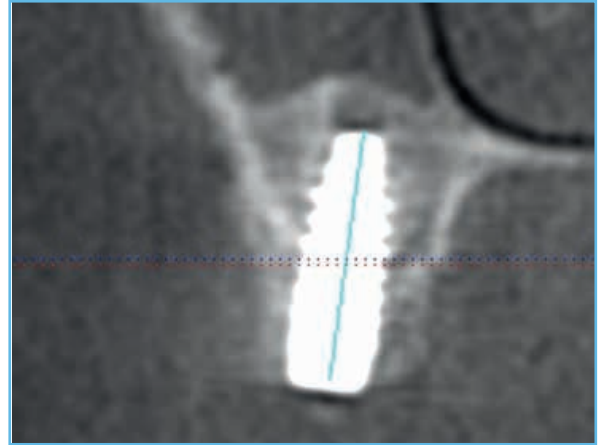
5 CBCT scan 7 months after augmentation.



6 7-month post-op re-entry, no resorption.



7 Implant placement, occlusal view.



8 Final CBCT scan.

Case 6

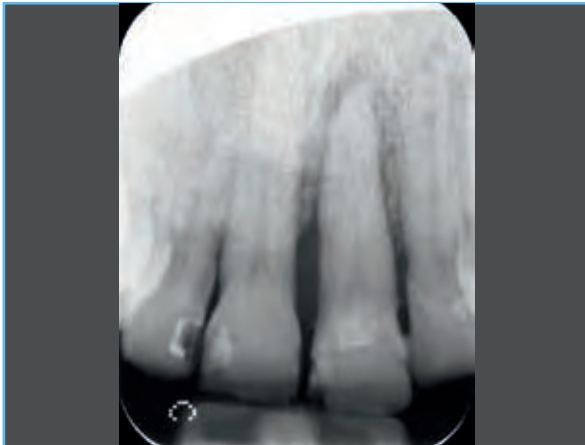
Lateral Onlay Graft Site [21]

Practitioner

Dr. M. Hinze
Gräfelfing (Germany)

Material

- Puros Allograft Cancellous Block 10 x 10 x 20 mm
- CopiOs Pericardium Membrane 20 x 30 mm



1 Initial situation tooth [21] needs to be removed.



2 Volume deficit, facial view.



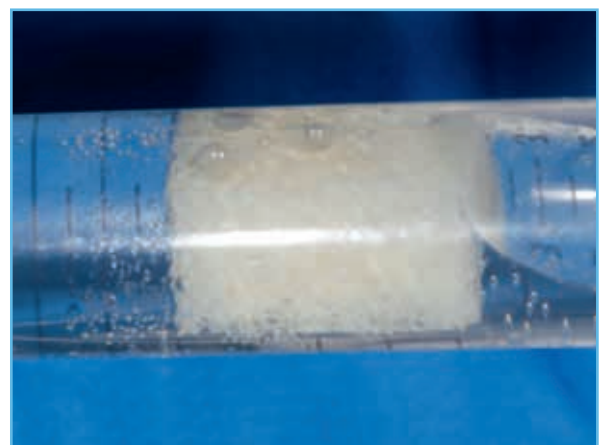
3 Volume deficit, occlusal view.



4 Surgical site, large bony defect.



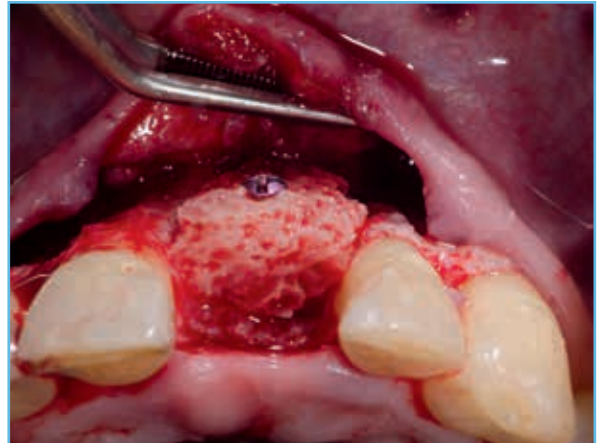
5 Puros Allograft Cancellous Block and CopiOs Pericardium Membrane.



6 Rehydration of Puros Block in a syringe.



7 Puros Allograft Cancellous Block in place, lateral view.



8 Fixed Puros Allograft Cancellous Block in place, occlusal view.



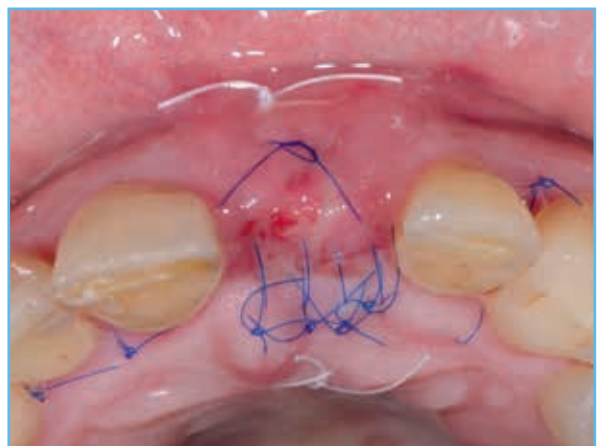
9 Inconsistencies in shape filled with Allograft Particles and covered with a CopiOs Pericardium Membrane.



10 Wound closure and provisional restoration.



11 Post-operative radiograph.



12 Soft tissue, 3 days post-op.

Case 6

Lateral Onlay Graft Site [21]

Practitioner

Dr. M. Hinze
Gräfelfing (Germany)

Material

- Puros Allograft Cancellous Block 10 x 10 x 20 mm
- CopiOs Pericardium Membrane 20 x 30 mm



13 Soft-tissue, 15 days post-op.



14 Soft-tissue, 3 months post-op.



15 Tissue contours, 3 months post-op.



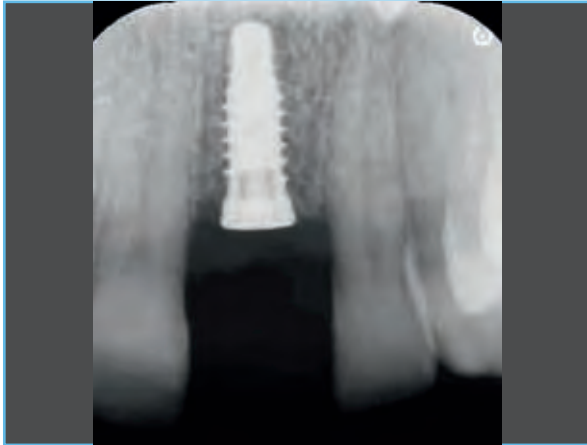
16 3D diagnostics, 7-months post-op, no resorption detected.



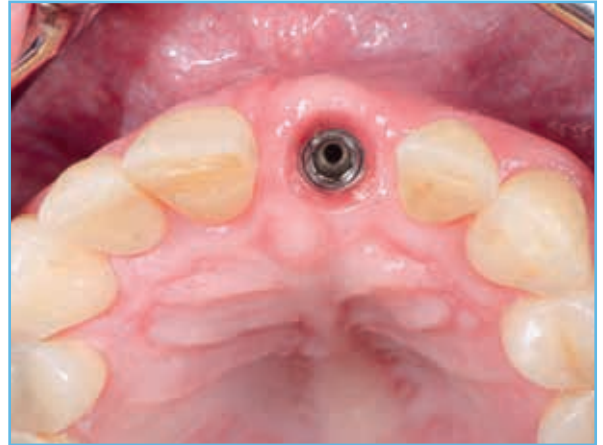
17 Re-entry 7-months post-op, screw head in tight contact with bone.



18 Implant in place.



19 Radiograph taken after implant placement.



20 Well-shaped soft tissue.



21 Single tooth crown.



22 Final aesthetic restoration 15 months after augmentation.



23 Final radiograph.

Prospective trial

Vertical Grafting with Puros Allograft Bone Blocks Compared to Xenogeneic Material

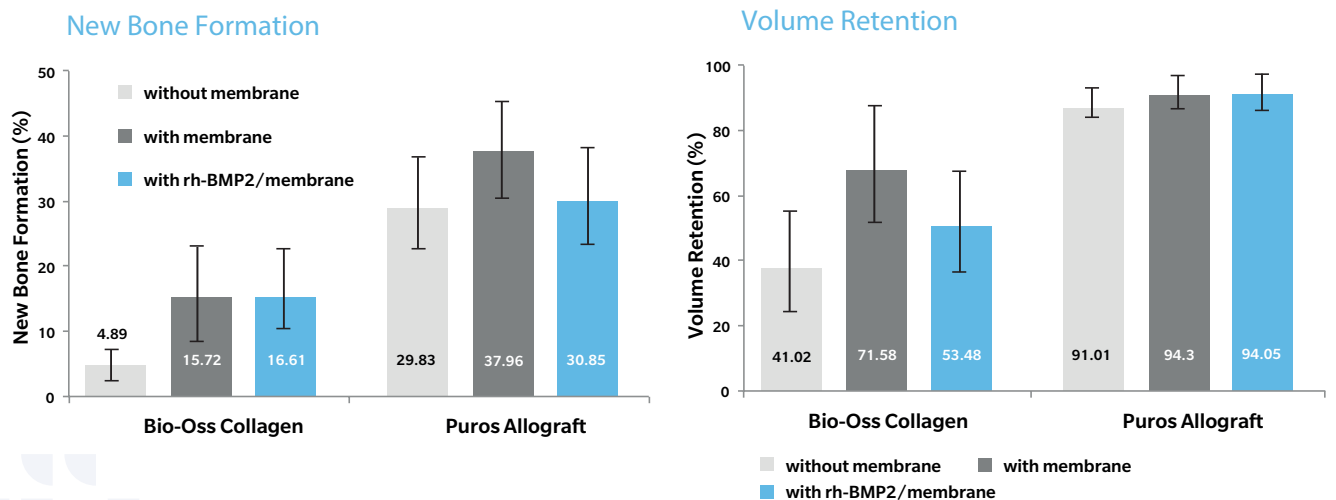
Kim SJ et al. Effect of bone block graft with rh-BMP2 on vertical bone augmentation. *Int J Oral Maxillofac Surg* (2010) 39:883-888

Study Design

Animal experiment on rabbits (white New Zealands), n =15. Formed defect (inlay diameter 6 mm, depth 1 mm) in calvarium and vertical augmentation with bone blocks (diameter 6 mm, height 4 mm) (I) without membrane covering, (II) with membrane covering (PTFE barrier membrane) and (III) after grafting with rh-BMP2 and membrane covering. Histological analysis after healing period of three months.

Results

Compared with the Bio-Oss Collagen groups, new bone formation was significantly higher in the Puros Allograft groups. New bone formation was greater in bone blocks covered with a membrane than blocks without a membrane in both groups. Volume maintainance in the Puros Allograft groups was >90%, with less resorption during healing compared to the Bio-Oss collagen groups. For vertical augmentation no additional benefit is observed either in new bone formation or volume preservation by adding rh-BMP2.



Conclusion

Vertical augmentation with Puros Allograft Blocks has shown excellent results with respect to new bone formation and volume retention.

Case Series

Augmentation Using Puros Allograft Bone Blocks

Keith JD et al. Clinical and histologic evaluation of a mineralized block allograft: Results from the developmental period (2001–2004). *Int J Periodont Rest* (2006) 26:321-327.

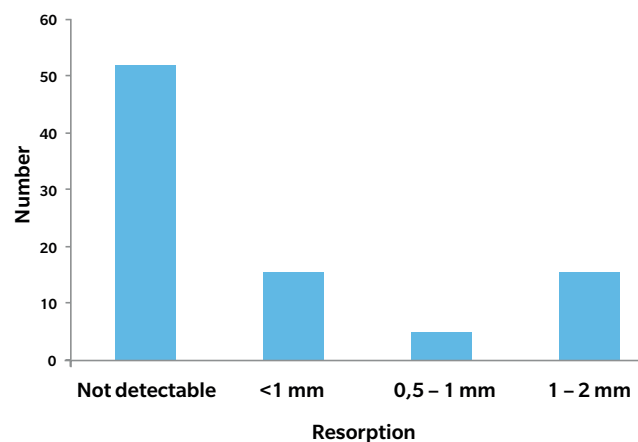
Study Design

73 patients with 82 defects were treated with Puros Allograft Bone Blocks. The allograft blocks were covered with a collagen membrane and the resorption behavior during the healing period has been studied. After a 4–6-month healing period the patients have been treated with Tapered Screw-Vent Implants. There is a three-year follow-up period. Histological analysis of regenerated allograft blocks after a 6-month healing period.

Results

During the 12-month follow-up, 93% of inserted blocks survived. The histological analysis revealed rapid incorporation of the Puros Block Allografts accompanied by active new bone formation on the block surface. In 69% of the blocks NO RESORPTIONS were observed, and in just 31% minor resorptions around the osteosynthesis screws were observed. The implant survival rate was 99% (96/97) at three-year follow-up.

Resorption During Healing Time



Conclusion

Ridge augmentation with Puros Allograft Blocks in combination with a collagen membrane exhibits low resorption rates during the healing period. Further studies are required to investigate long-term outcomes.

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Case 1

Vertical Onlay Graft Site [45-47]

Practitioners

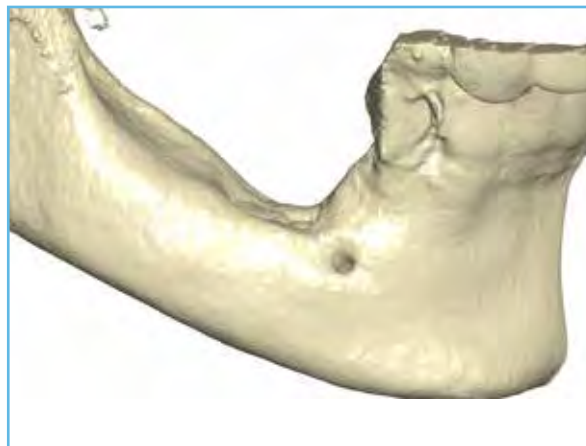
PD Dr. Dr. K. K. Würzler
Dr. F. Will
Würzburg (Germany)

Material

- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc
- CopiOs Pericardium Membrane 30 x 40 mm



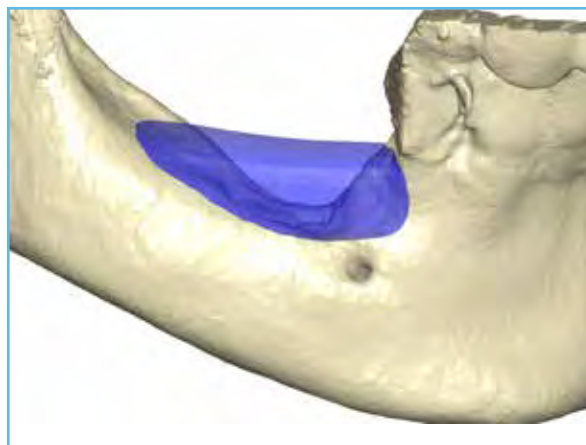
1 Initial situation; failed implants need to be removed.



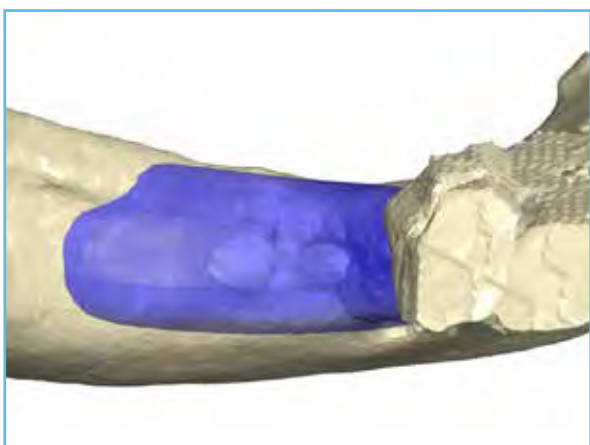
2 Three-dimensional reconstruction of the defect, lateral view.



3 Three-dimensional reconstruction of the defect, occlusal view.



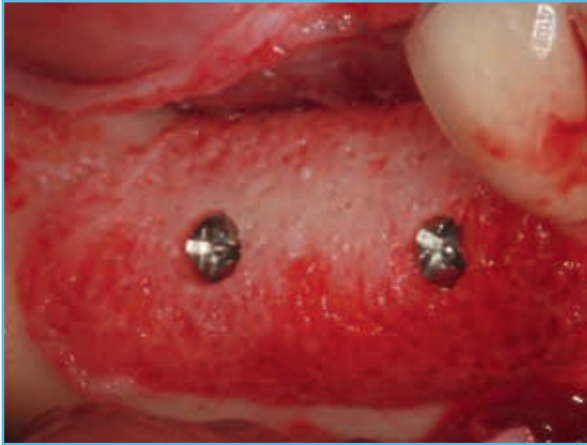
4 Designed bone block, lateral view.



5 Designed bone block, occlusal view.



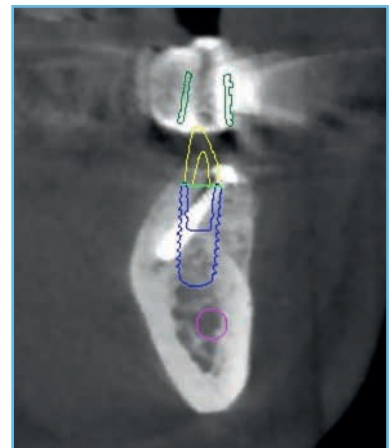
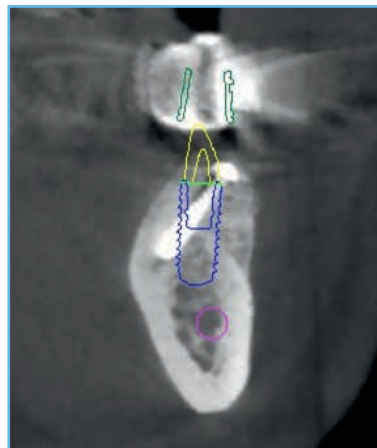
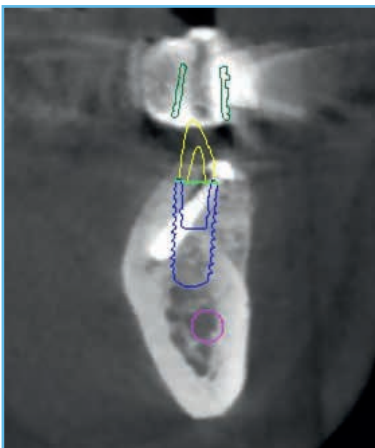
6 Milled Puros Allograft Customized Block.



7 Fixed bone block placed.



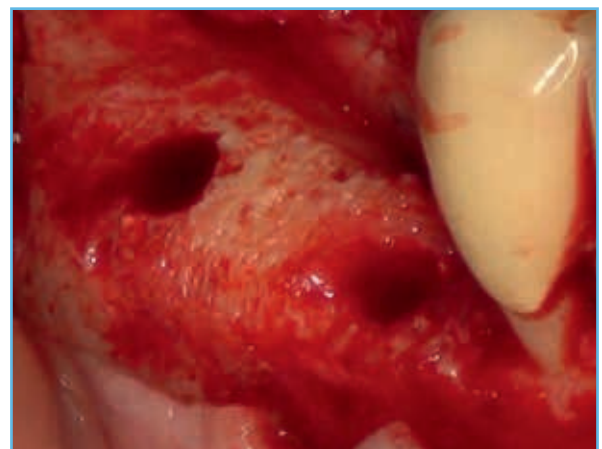
8 Radiograph post-operative.



9 3D diagnostics and implant planning, six months post-op.



10 Re-entry 6-months post-op, screws are in tight contact with bone.



11 Vital bone bed.

Case 1

Vertical Onlay Graft Site [45-47]

Practitioners

PD Dr. Dr. K. K. Würzler
Dr. F. Will
Würzburg (Germany)

Material

- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc
- CopiOs Pericardium Membrane 30 x 40 mm



12 Radiograph after implant placement.



13 Final aesthetic restoration 10 months post-augmentation.



14 1-year follow up.

Case 2

Lateral and Vertical Onlay Graft Site [21-22]

Practitioners

PD Dr. Dr. K. K. Würzler

Dr. F. Will

Würzburg (Germany)

Material

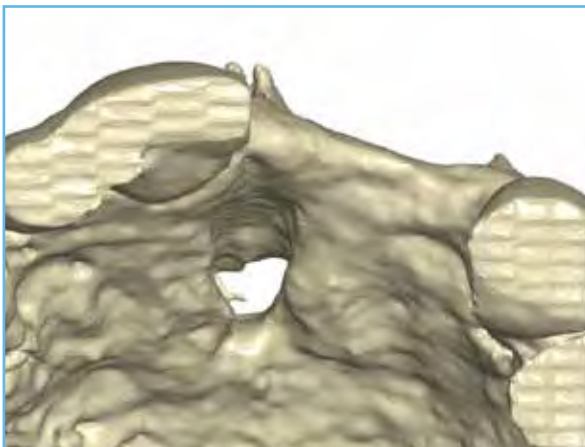
- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc
- CopiOs Pericardium Membrane 30 x 40 mm



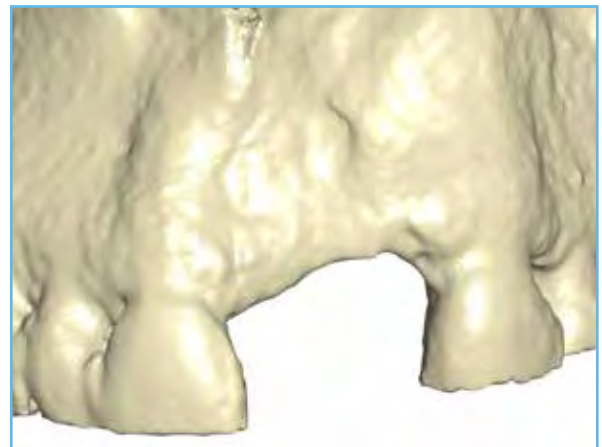
1 Initial situation; narrow ridge, occlusal view.



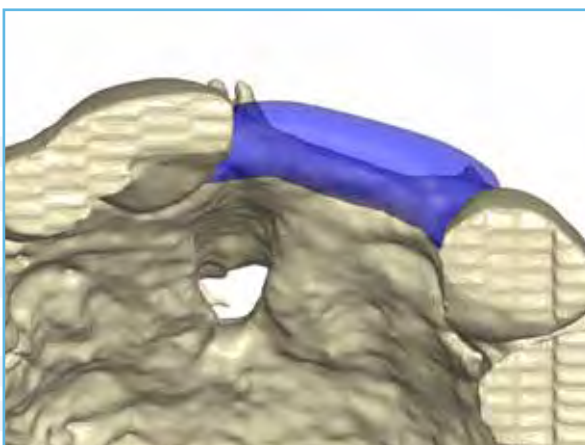
2 Initial situation; vertical deficiency, facial view.



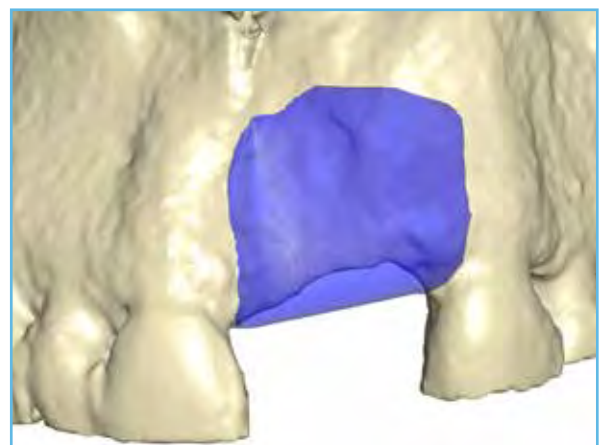
3 Three-dimensional reconstruction of the defect, occlusal view.



4 Three-dimensional reconstruction of the defect, lateral view.



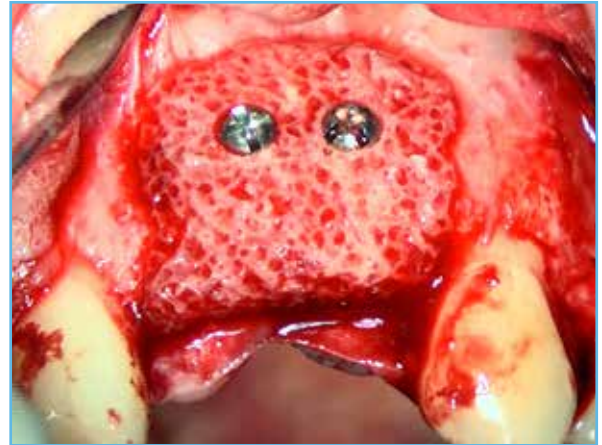
5 Designed bone block, occlusal view.



6 Designed bone block, lateral view.



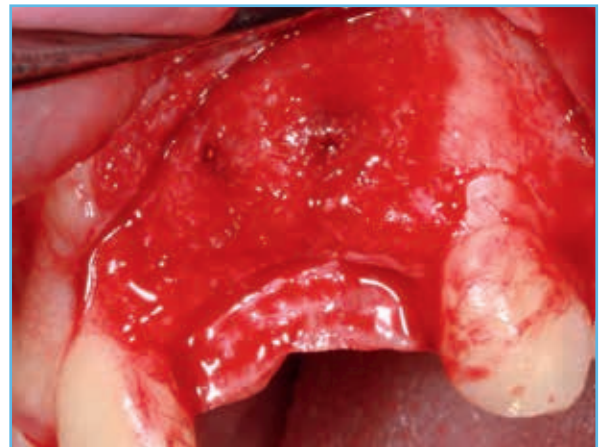
7 Milled Puros Allograft Customized Block.



8 Fixed bone block.



9 Soft tissue, 5-months post-operative.



10 Re-entry 6-months post-op, screw in tight contact with bone.



11 Radiograph taken after implant placement.

Case 2

Lateral and Vertical Onlay Graft Site [12-22]

Practitioner

PD Dr. K. Fischer

University of Witten/ Herdecke (Germany)

Material

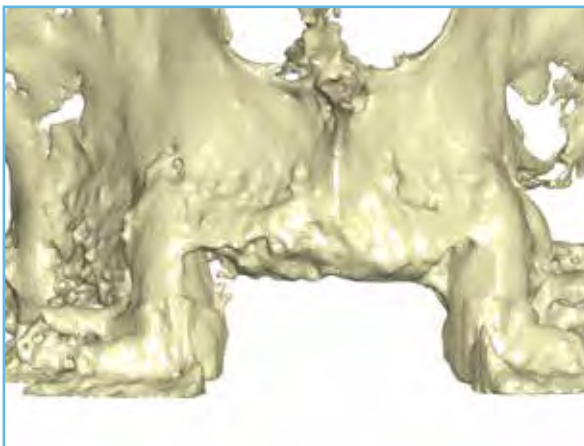
- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc



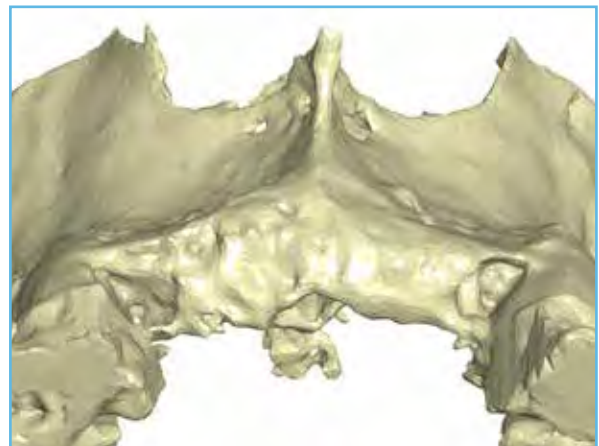
1 Initial situation anterior maxilla, central and lateral incisors are missing.



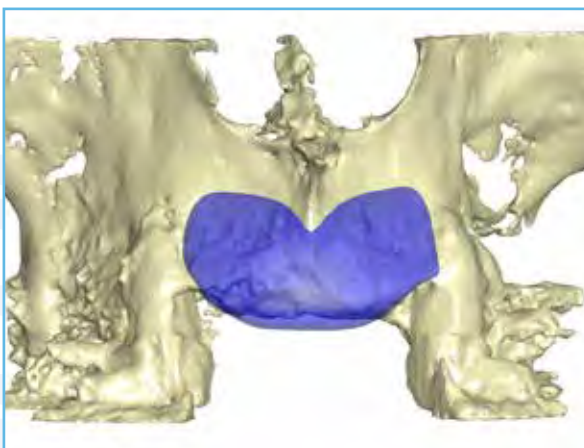
2 Initial situation after removal of the 4-unit fixed partial denture.



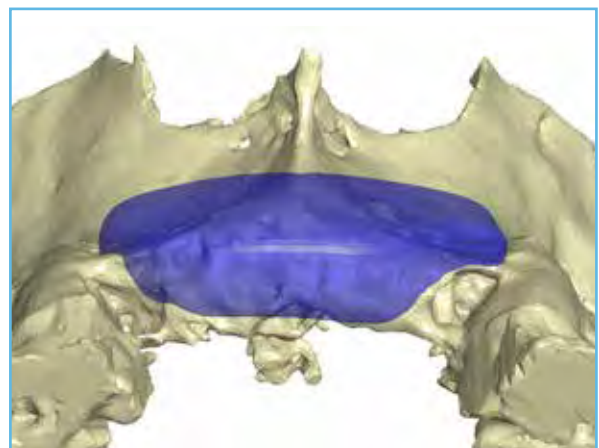
3 Three-dimensional reconstruction of the defect, lateral view.



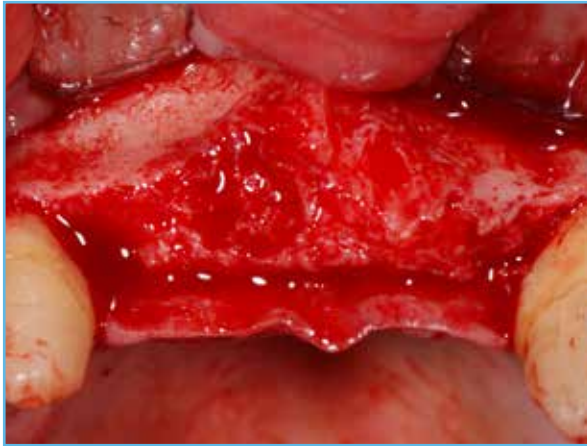
4 Three-dimensional reconstruction of the defect, occlusal view.



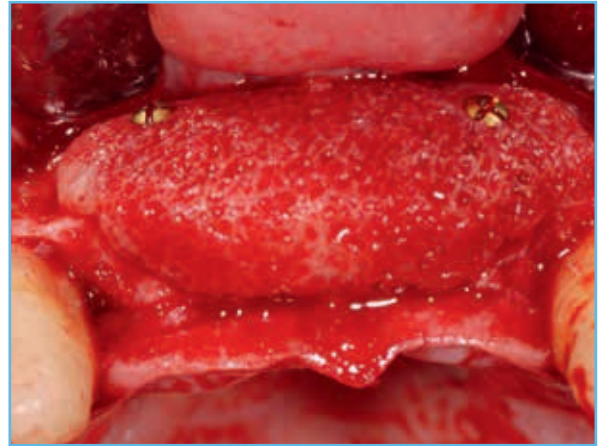
5 Designed bone block, lateral view.



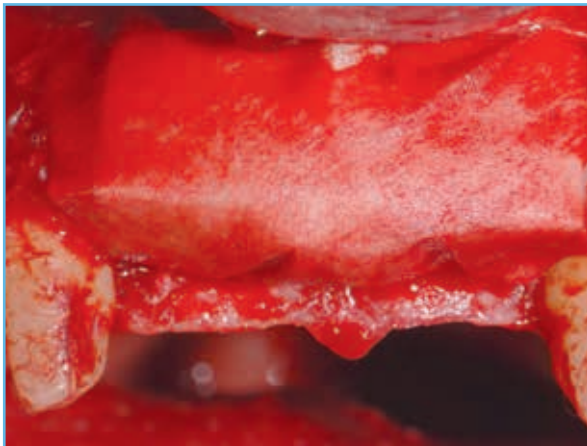
6 Designed bone block, occlusal view.



7 Surgical site.



8 Fixed bone block.



9 Covering with a collagen membrane.*



10 Provisional Restoration.



11 Healing, 14 days post-op.



12 Soft-tissue situation and contour 6-months post-operative, facial view.

*The collagen membrane is not part of the Zim Vie Dental portfolio.

Case 3

Lateral and Vertical Onlay Graft Site [21-22]

Practitioner

PD Dr. K. Fischer
University of Witten/ Herdecke (Germany)

Material

- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc



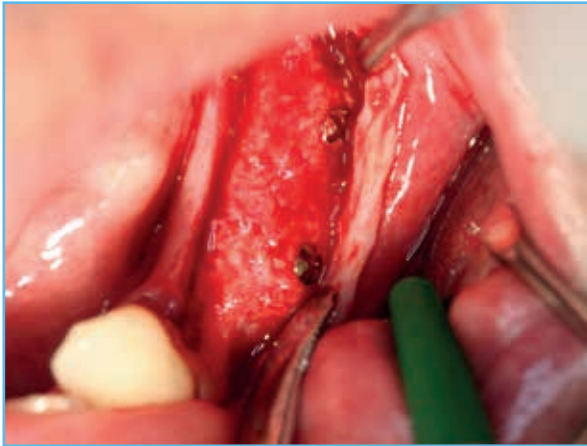
13 Soft-tissue situation and contour 6-months post-operative, occlusal view.



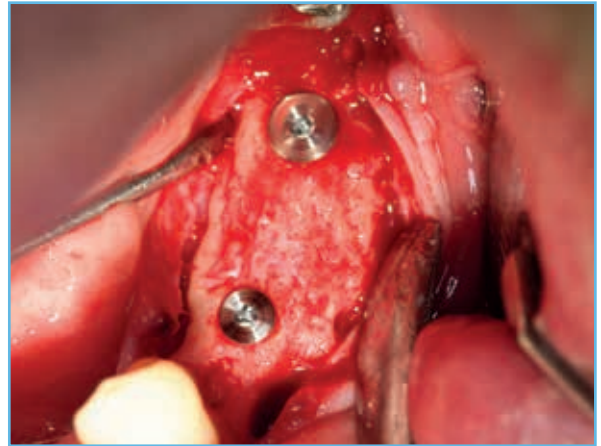
14 Re-entry 6-months post-op, screws in tight contact with bone, residual remnants of membrane visible.



15 Radiograph after implant placement.



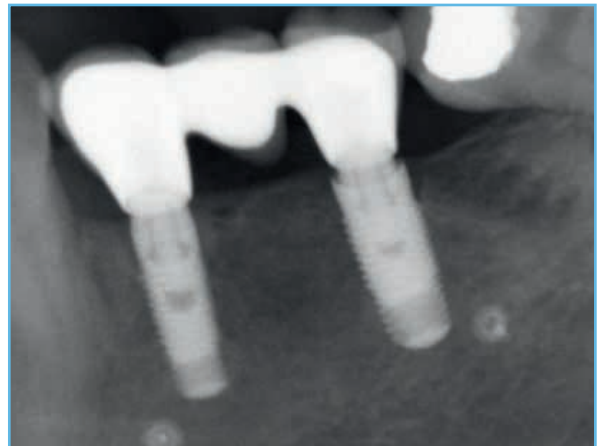
7 6-month post-op re-entry, no resorption.



8 Tapered Screw-Vent Implants in place, occlusal view.



9 Final radiograph.



10 Radiograph taken 3 years post-placement. Note the stable bone conditions.

Case 4

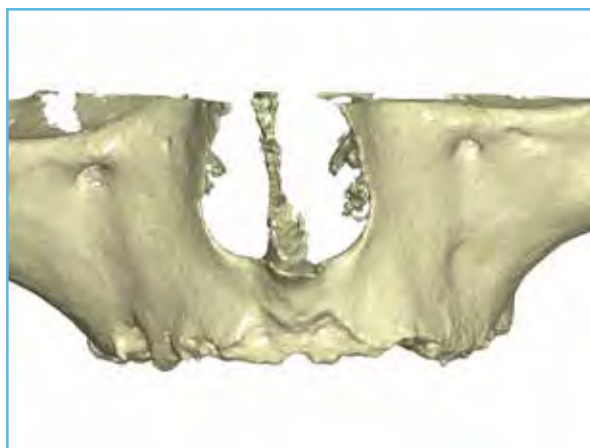
Vertical and Lateral Augmentation Sites [12-16] and [22-26]

Practitioner

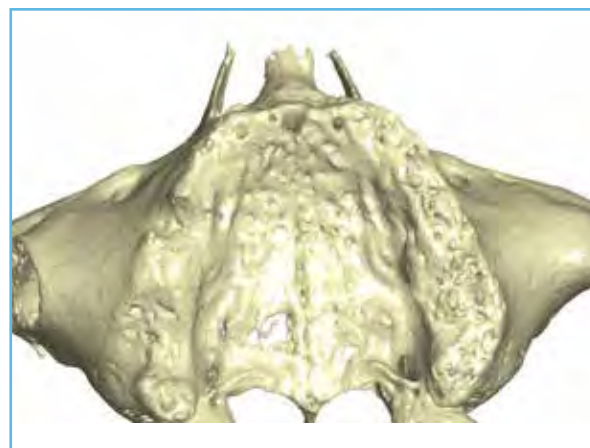
Dr. O. Richter
Hamburg (Germany)

Material

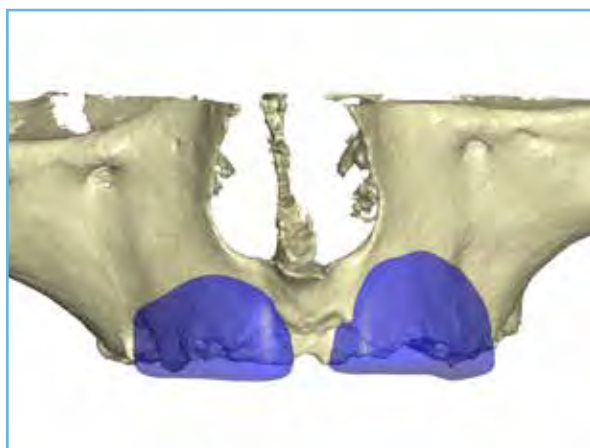
- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc
- CopiOs Pericardium Membrane 30 x 40 mm
- Tapered Screw-Vent Implants



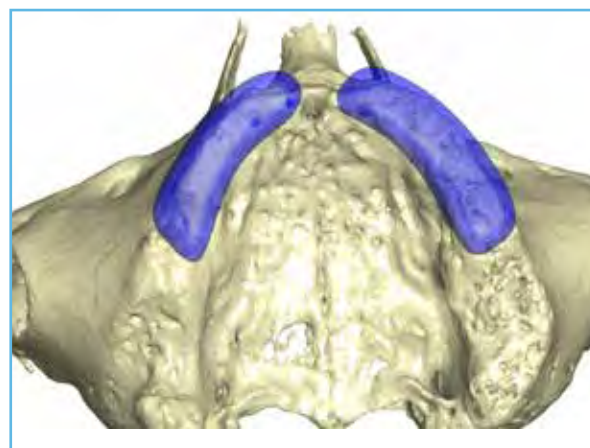
1 Three-dimensional reconstruction of the defect, facial view.



2 Three-dimensional reconstruction of the defect, occlusal view.



3 Designed bone block, facial view.



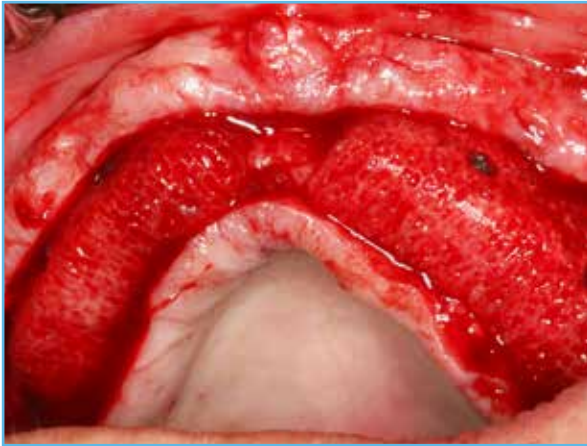
4 Designed bone block, occlusal view.



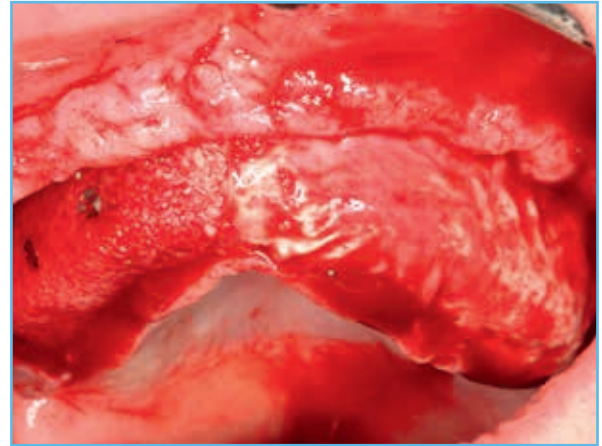
5 Milled Puros Allograft Customized Block.



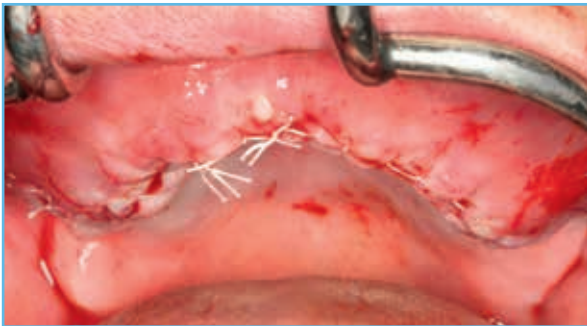
6 Fixed bone block, maxillary right.



7 Fixed bone blocks.



8 Covered with a CopiOs Pericardium Membrane.



9 Wound closure.



10 CBCT scan after augmentation showing, well fitting block, site [13].



11 CBCT scan after augmentation showing well fitting block, site [15].



12 Re-entry 6-months post-op, screw heads in tight contact with bone.

Case 4

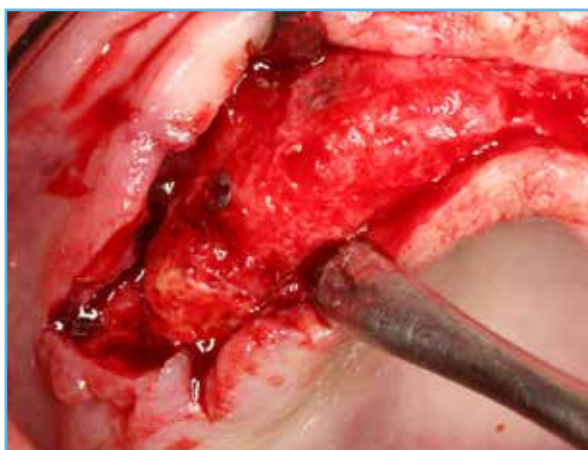
Vertical and Lateral Augmentation Sites [12-16] and [22-26]

Practitioner

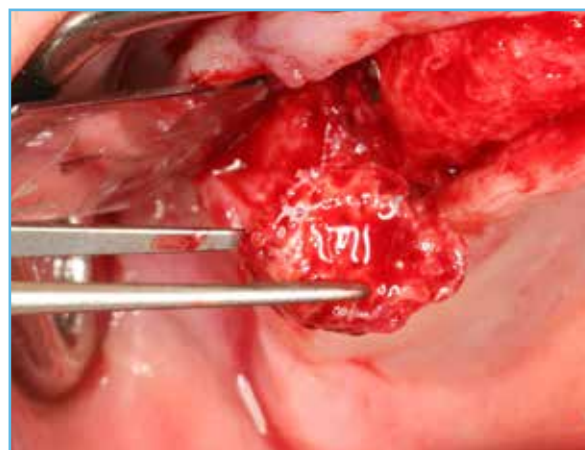
Dr. O. Richter
Hamburg (Germany)

Material

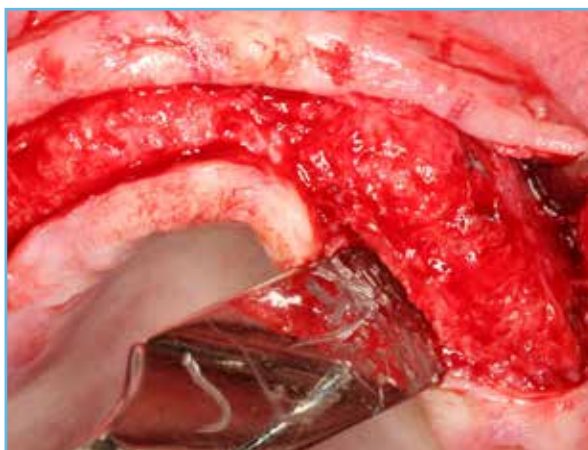
- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc
- CopiOs Pericardium Membrane 30 x 40 mm
- Tapered Screw-Vent Implants



13 Upper right maxilla 1, 6 months post-op, partial sequestrum, site [16].



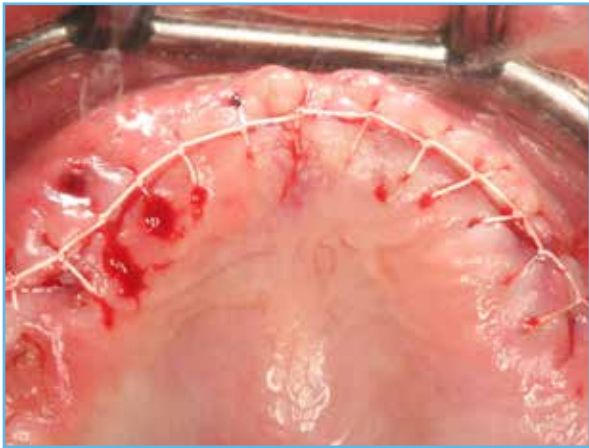
14 Sequestrum removed, site [16].



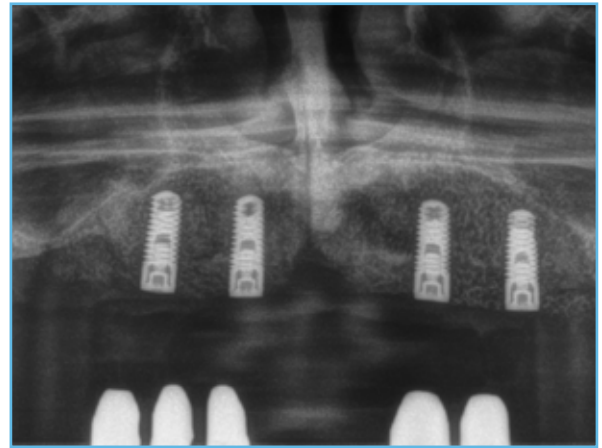
15 Maxillary left, 6 months post-op.



16 Tapered Screw-Vent Implants in place.



17 Wound closure.



18 Radiograph after implant placement.

Case 5

Vertical and Lateral Augmentation Sites [12-16] and [22-26]

Practitioner

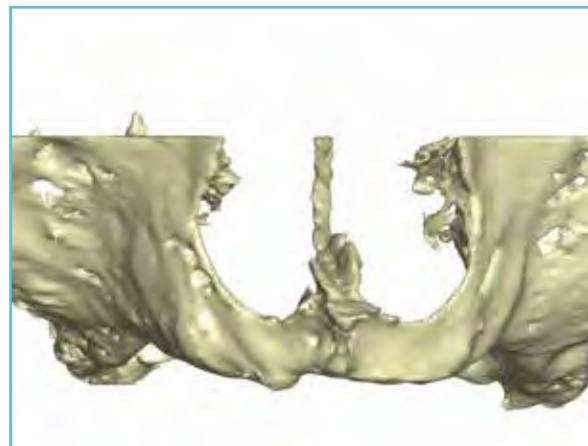
Dr. M. Hinze
Gräfelfing (Germany)

Material

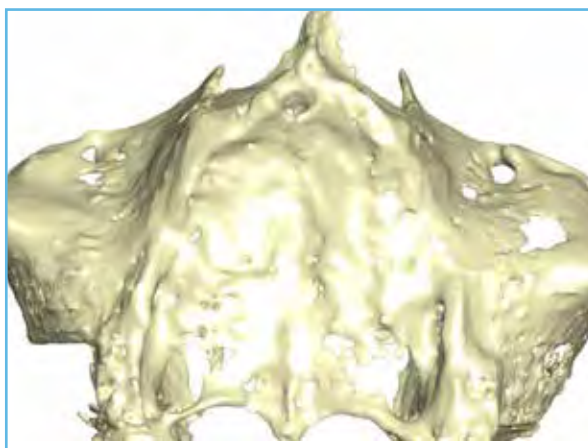
- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc
- CopiOs Pericardium Membrane 30 x 40 mm



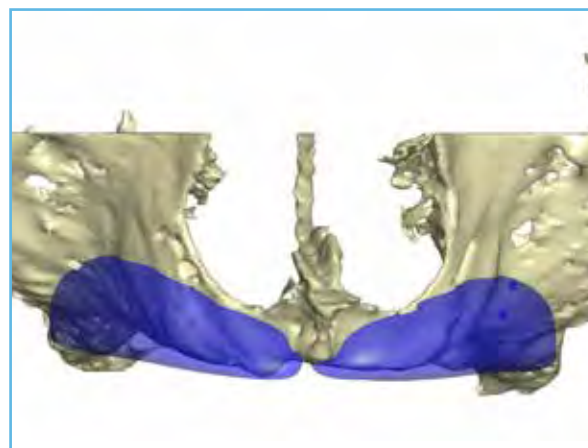
1 Initial situation is showing edentulous maxilla with severe horizontal and vertical bone deficiency.



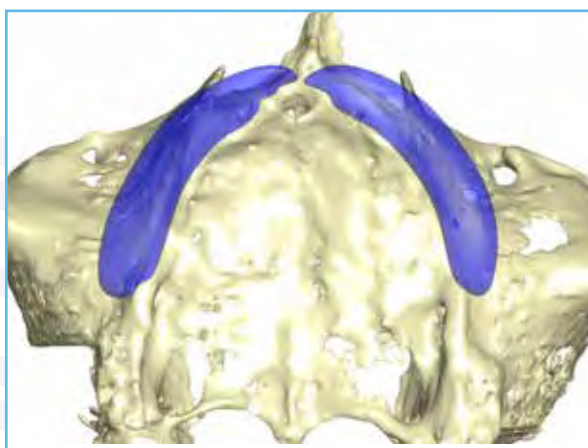
2 Three-dimensional reconstruction of the defect, facial view.



3 Three-dimensional reconstruction of the defect, occlusal view.



4 Designed bone block, facial view.



5 Designed bone block, occlusal view.



6 Milled Puros Allograft.



7 Fixed bone block maxillary right.



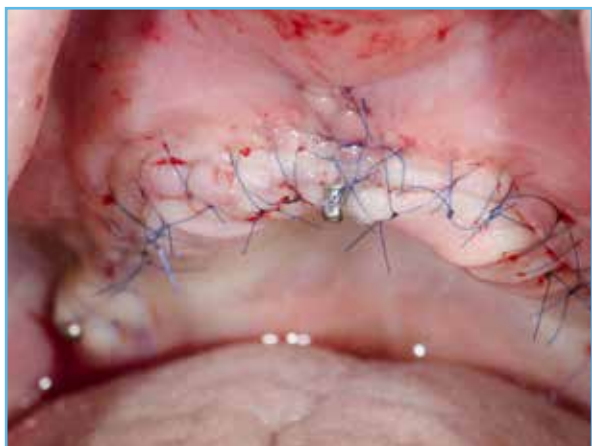
8 Fixed bone block maxillary left.



9 Fixed bone blocks.



10 Covered with CopiOs Pericardium Membranes.



11 Wound closure, temporary implants placed to support provisional restoration.



12 Provisional restoration without pressure on graft.

Case 5

Vertical and Lateral Augmentation Sites [12-16] and [22-26]

Practitioner

Dr. M. Hinze
Gräfelfing (Germany)

Material

- Puros Allograft Customized Block
- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc
- CopiOs Pericardium Membrane 30 x 40 mm



13 Post-op CT scan, showing a well fitting block, site [14].



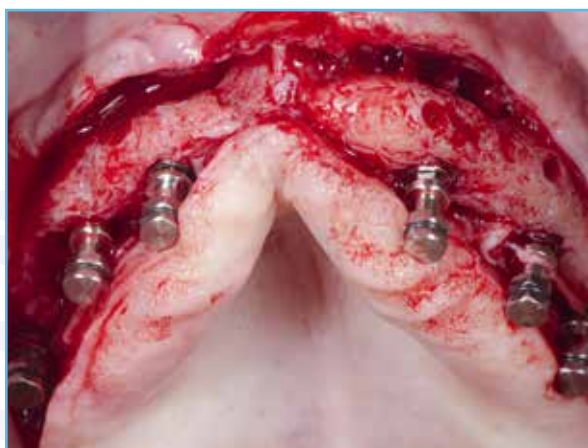
14 CBCT scan after augmentation showing well-fitting block, site [24].



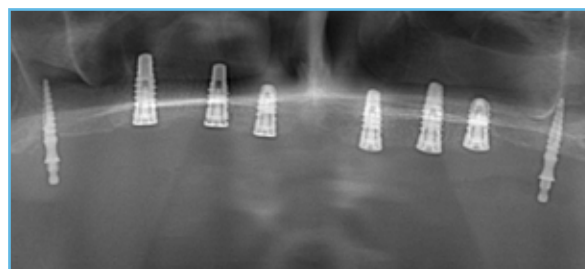
15 Soft tissue, 5-months post-operative.



16 Re-entry 5-months post-op, screw heads in tight contact with bone.



17 Six implants in place.



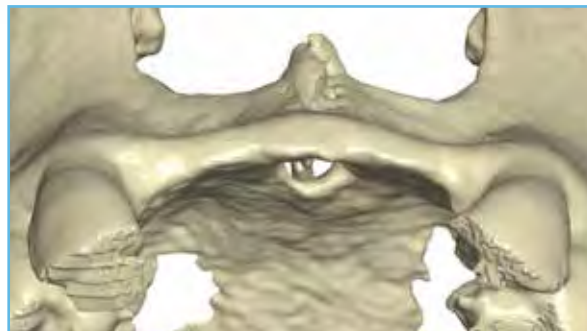
18 Radiograph taken after implant placement.

Design and Milling of A Puros Allograft Customized Block

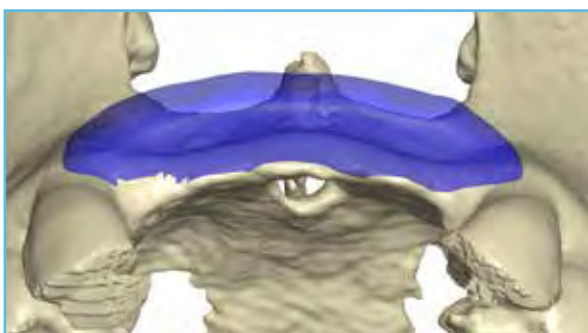
Step by Step



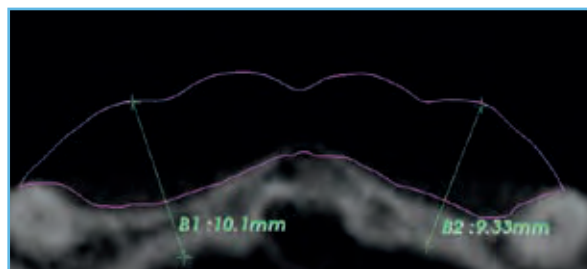
1 Imaging
CT or CBCT, DICOM data, cross-section thickness between 0.2–0.6 mm, high contrast image.



2 Modeling/segmentation



3 Block design
Determination of bony defect, shaping of block geometry.



4 Design control
Review and release by clinician.



5 Manufacture of block
Milling.

References

Literature Regarding Puros Allograft Customized Block

1. Schlee M, Rothamel D. Ridge augmentation using customized allogenic bone blocks: proof of concept and histological findings. *Implant Dent* (2013) 22:304-8.
2. Würzler KK, Will F, Berger S. Herstellung und Anwendung CAD/CAM-gefräster, patientenspezifischer Knochenblöcke. *Implantologie Journal* (2015) 5:30-36.

General Literature Regarding CAD/CAM Techniques for Hard-Tissue Reconstruction

1. Eufinger H, Wehmoller M, Machtens E, Heuser L, Harders A, Kruse D. Reconstruction of craniofacial bone defects with individual alloplastic implants based on CAD/CAM manipulated CT-Data. *J. Craniomaxillofac. Surg.* (1995) 23:175-181.
2. Peters F, Groisman D, Davids R, Hanel T, Durr H, Klein M. Comparative study of patient individual implants from beta-tricalcium phosphate made by different techniques based on CT data. *Materialwiss. Werkstofftech.* (2006) 37:457-461.
3. Blume O, Back M, Born T, Smeets R, Jung O, Barbeck M. Treatment of a bilaterally severely resorbed posterior mandible due to early tooth loss by Guided Bone Regeneration using customized allogeneic bone blocks: A case report with 24 months follow-up data. *J Esthet Restor Dent* (2018), doi:10.1111/jerd.12388-
4. Klein M, Glatzer C. Individual CAD/CAM fabricated glass-bioceramic implants in reconstructive surgery of the bony orbital floor. *Plast Reconstr Surg* (2006) 117:565-570.
5. Hallermann W, Olsen S, Bardyn T, Taghizadeh F, Banic A, Iizuka T. A new method for computer-aided operation planning for extensive mandibular reconstruction. *Plast Reconstr Surg* (2006) 117:2431-7.
6. Khalyfa A, Vogt S, Weisser J, Grimm G, Rechtenbach A, Meyer W, Schnabelrauch M. Development of a new calcium phosphate powder-binder system for the 3D printing of patient specific implants. *J Mater Sci Mater Med* (2007) 18:909-16.
7. Binder WJ. Custom-designed facial implants. *Facial plastic surgery clinics of North America* (2008) 16:133-46, vii.
8. Cohen A, Laviv A, Berman P, Nashef R, Abu-Tair J. Mandibular reconstruction using stereolithographic 3-dimensional printing modeling technology. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod* (2009) 108:661-6.
9. Guo LJ, Tian WD, Feng F, Long J, Li PF, Tang W. Reconstruction of orbital floor fractures comparison of individual prefabricated titanium implants and calvarial bone grafts. *Ann Plas Surg* (2009) 63:624-631.
10. Zhou L-B, Shang H-T, He L-S, Bo B, Liu G-C, Liu Y-P, Zhao J-L. Accurate reconstruction of discontinuous mandible using a reverse engineering/computer-aided design/rapid prototyping technique: a preliminary clinical study. *J Oral Maxillofac Surg* (2010) 68:2115-2121.
11. Lethaus B, Kessler P, Boeckman R, Poort LJ, Tolba R. Reconstruction of a maxillary defect with a fibula graft and titanium mesh using CAD/CAM techniques. *Head Face Med* (2010) 6:16.
12. Saldarriaga JFI, Vélez SC, Posada MDaC, Henao IEBB, Valencia MECaT. Design and manufacturing of a custom skull implant. *American Journal of Engineering & Applied Sciences* (2011) 4:169-174.
13. Brune JC, Hesselbarth U, Seifert P, Nowack D, Von Versen R, Smith MD, Seifert D. CT lesion model-based structural allografts: custom fabrication and clinical experience. *Transfusion Medicine and Hemotherapy* (2012) 39:395-404.
14. Ciocca L, Donati D, Fantini M, Landi E, Piattelli A, Iezzi G, Tampieri A, Spadari A, Romagnoli N, Scotti R. CAD-CAM-generated hydroxyapatite scaffold to replace the mandibular condyle in sheep: Preliminary results. *J Biomater Appl* (2013) 28:207-218.

Case 1

Flapless Procedure with Free Gingival Graft Site [21]

Practitioner

Prof. S. Fickl

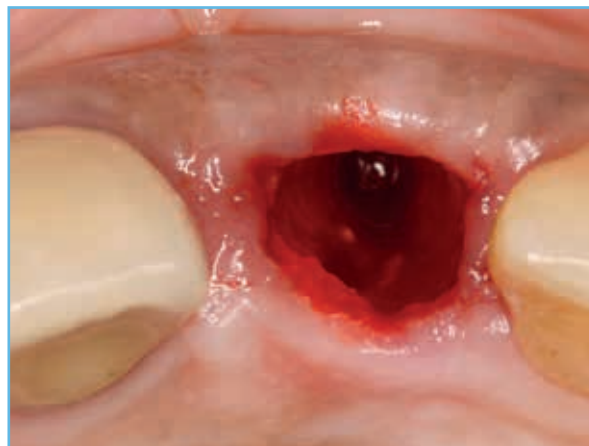
University of Würzburg (Germany)

Material

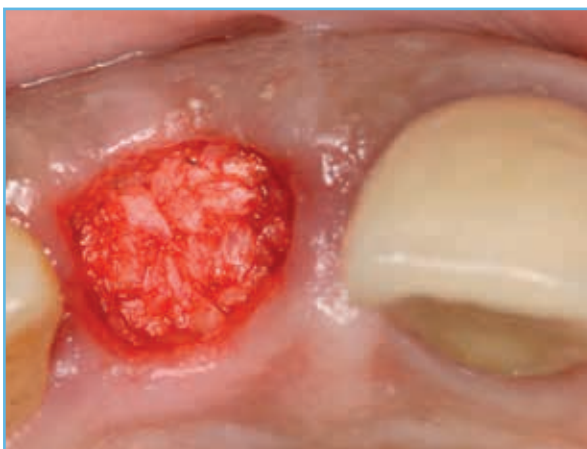
- Puros Allograft Cancellous Particles 1–2 mm, 1 cc



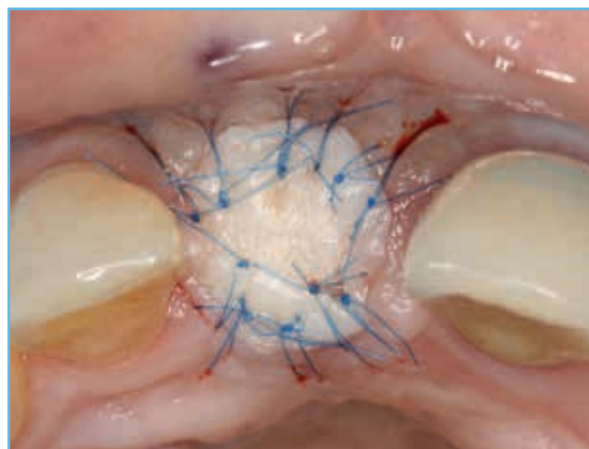
1 Initial situation, fractured central incisor needs to be extracted.



2 Atraumatic extraction, socket intact.



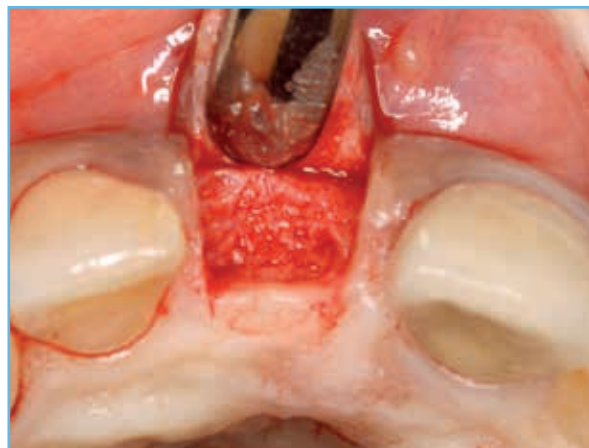
3 Socket augmentation using Puros Allograft Cancellous Particles.



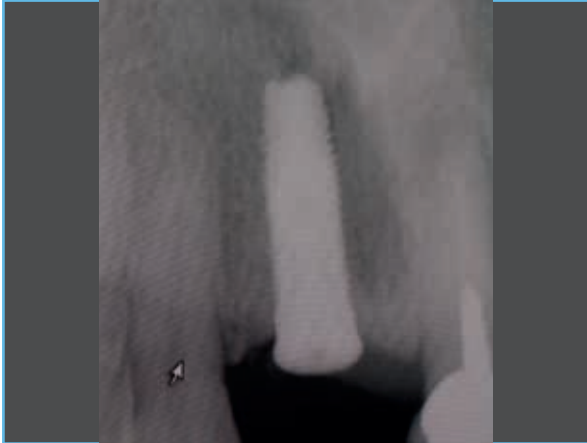
4 Covered with a free gingival graft.



5 Soft tissue, 6 months post-op.



6 Bone situation, 6 months post-op.



- 7 Radiograph taken after implant placement, showing implant placed in healed bone.

Case 1

Ridge Preservation After Multiple Extraction, Site [11-12]

Practitioner

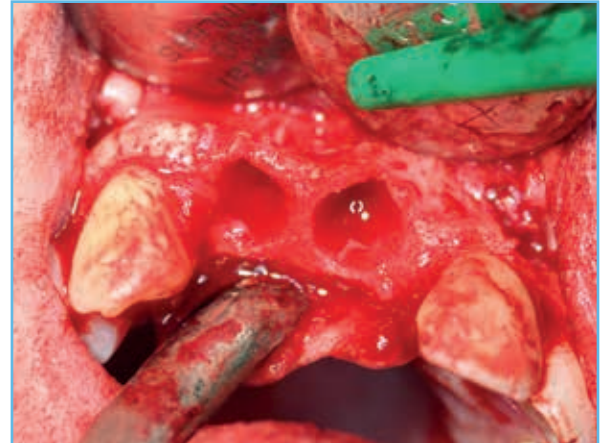
R. Stutzki
Magdeburg (Germany)

Material

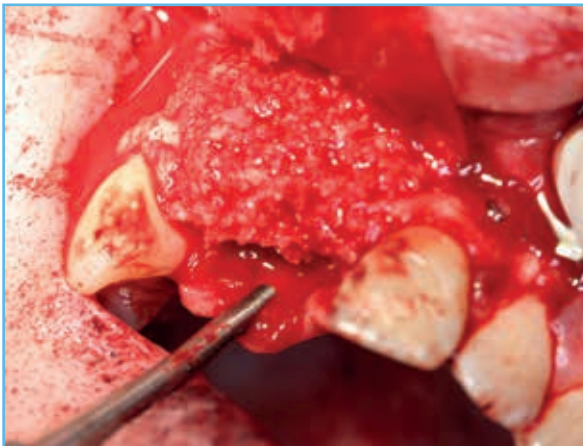
- Puros Allograft Cancellous Particles 0.25–1 mm, 2 cc
- CopiOs Pericardium Membrane 30 x 40 mm
- Tapered Screw-Vent Implants



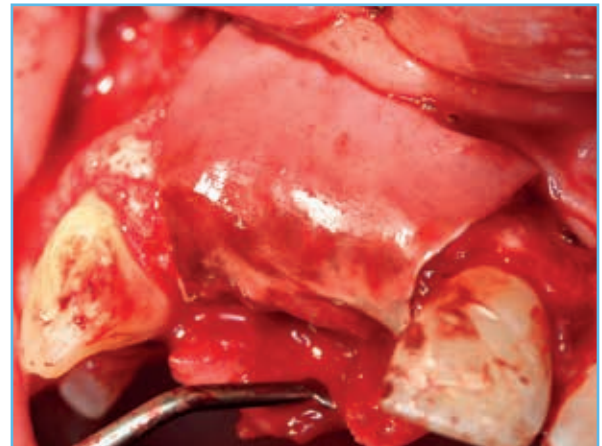
1 Initial situation, healed soft tissue after extraction of tooth [11] and [12].



2 Horizontal bone deficiency after flap elevation.



3 Augmentation with Puros Allograft Cancellous Particles.



4 Covering with a CopiOs Pericardium Membrane.

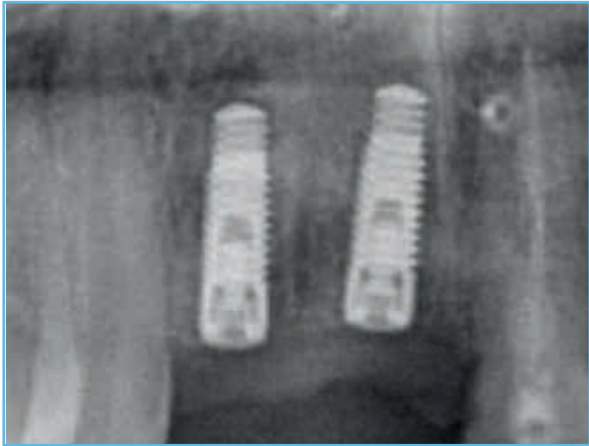


5 Bone situation at re-entry 6 months post-op.

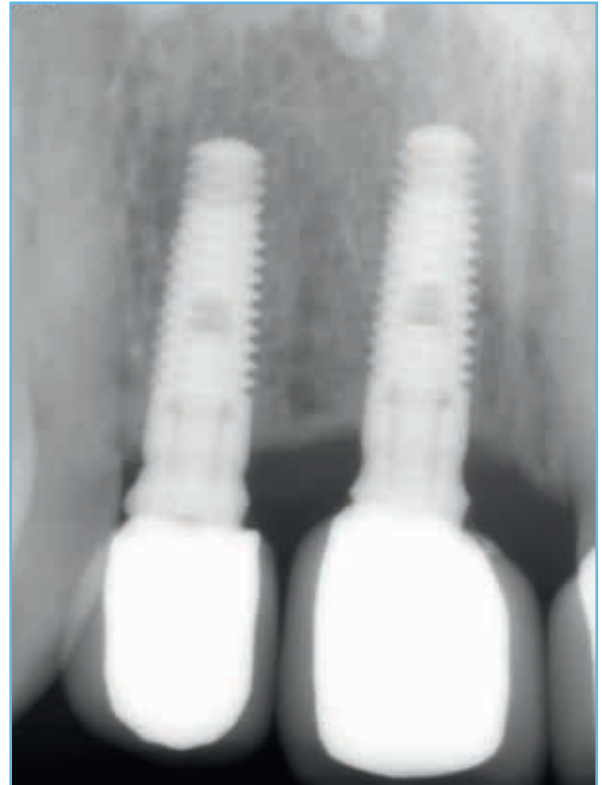


6 Placement of Tapered Screw-Vent Implants, occlusal view.

4 Year follow-up



7 Final radiograph.



8 Radiograph taken 3.5 years after implantation. Note the stable bone conditions.

Literature Review

Prospective Trial

Grafting of Extraction Sites with Puros Allograft Cancellous Particles Compared to Non-Grafted Sites

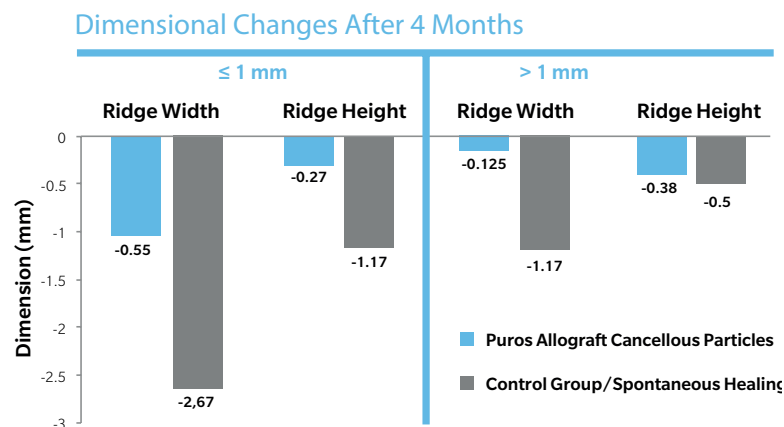
Spinato S. et al. Is socket healing conditioned by buccal plate thickness? A clinical and histologic study 4 months after mineralized human bone allografting. *Clin Oral Implants Res* (2014) 25:e120-6.

Study Design

After 31 extraction (flapless procedure) in 31 patients, the sockets were divided into 2 groups (I) thick buccal bone plate (> 1 mm); (II) thin buccal bone plate (≤ 1 mm). 19 sockets were grafted with Puros Allograft Cancellous Particles 0.25–1 mm (test group) and covered with a resorbable wound dressing (CollaPlug®, Zimmer Dental). 12 patients did not receive a graft (spontaneous healing, control group). After four months, changes to socket dimensions were measured and biopsies taken.

Results

Grafting with Puros Allograft Cancellous Particles reduces height and width loss in sockets with both thin (≤ 1 mm) and thick buccal lamellae (> 1 mm) compared to spontaneous healing. The thickness of the buccal bone plate appears to affect the dimensional changes. Histomorphometry of test group (Puros): Total mineral content 41.48 vs. 45.78%; soft tissue/bone marrow 58.52 vs. 54.21% (≤ 1 mm vs. > 1 mm).



Conclusion

Spontaneous healing of extraction sites leads to significant dimensional losses, which may affect a subsequent implant placement. Grafting with Puros Allograft can reduce the dimensional changes.

Prospective Comparison

Grafting of Extraction Sites with Puros Allograft Cancellous Particles Healing Period 3.5 Months vs. Six Months

Beck TM et al. Histologic analysis of healing after tooth extraction with ridge preservation using mineralized human bone allograft. J Periodontol (2010) 81:1765-1772.

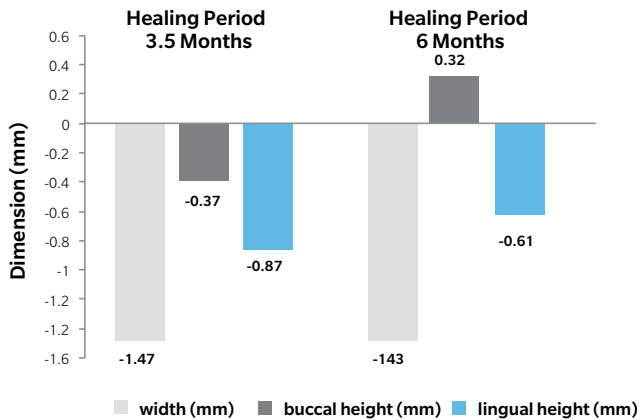
Study Design

After 38 extractions in 33 patients (flapless procedure), the sockets were grafted with Puros Allograft Cancellous Particles (particle size 0.25–1 mm) and covered with a resorbable wound dressing (CollaTape®) or Zimmer Socket Repair Membrane. Re-entry was performed after a healing period of 3.5 (Group 1)/6 months (Group 2), with dimensional changes to the sockets measured and biopsies taken.

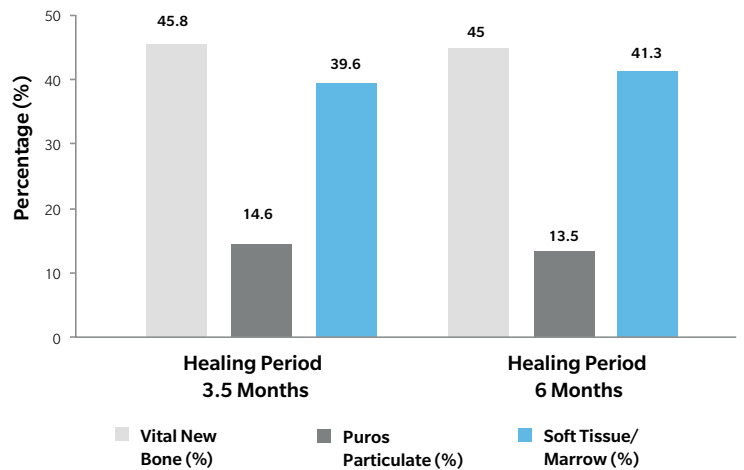
Results

All biopsies showing a high proportion of new bone with some residual Puros particles, which were almost completely surrounded by newly formed bone. No statistically significant differences were detected with respect to the dimensional changes to the sockets and bone formation.

Dimensional Changes



Histomorphometry



Conclusion

A healing period of 6 months after tooth extraction and grafting with Puros Allograft Cancellous Particles does not increase new bone formation or alter dimensional changes in comparison with a 3.5-month healing period. Implants placed after a 3.5-month healing period may have the same long-term results as implants placed after a longer healing period.

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10. Beck TM, Mealey BL. Histologic analysis of healing after tooth extraction with ridge preservation using mineralized human bone allograft. *J Periodontol* (2010) 81:1765-72.
11. El Char ES. Soft tissue closure of grafted extraction sockets in the posterior maxilla: the rotated pedicle palatal connective tissue flap technique. *Implant Dent* (2010) 19:370-7.
12. Fickl S. Socket Preservation zum Zeitpunkt der Zahnextraktion. *Parodontologie Nachrichten* (2010) 1:14.
13. Kistler S. Praxisgerechte Techniken der Alveolar Ridge Preservation. *dentalspiegel* (2011) 5:22-26.
14. Tolstunov L, Chi J. Alveolar ridge augmentation: comparison of two socket graft materials in implant cases. *Compendium of Continuing Education in Dentistry* (2011) 32:E16-E124.
15. Fischer K, Jockel-Schneider Y, Bechtold M, Fickl S, Schlagenhauf U. „Socket preservation“ nach Zahnextraktion. *Der Freie Zahnarzt* (2011) 55:62-68.
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19. Spinato S, Galindo-Moreno P, Zaffe D, Bernardello F, Soardi CM. Is socket healing conditioned by buccal plate thickness? A clinical and histologic study 4 months after mineralized human bone allografting. *Clin Oral Implants Res* (2014) 25:e120-6.
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Case 1

Lateral Augmentation Prior to Implantation Site [21]

Practitioners

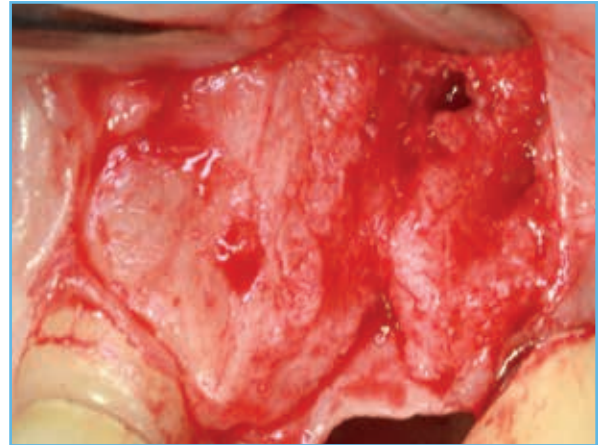
Dr. Dr. Dr. O. Blume, Dr. Dr. T. Müller-Hotop
Dr. M. Back
Munich (Germany)

Material

- Puros Allograft Cancellous Particles 1–2 mm, 1 cc
- CopiOs Pericardium Membrane 20 x 30 mm



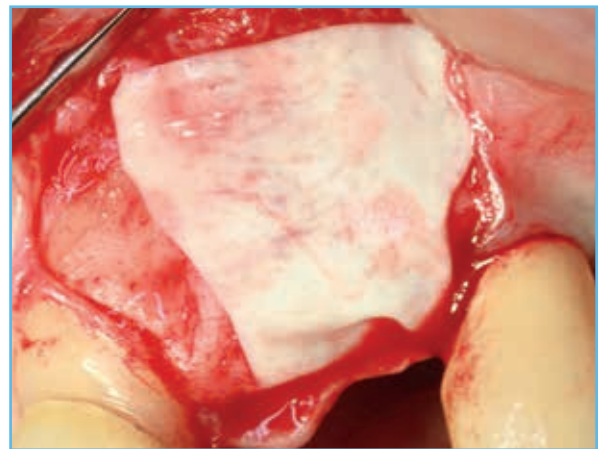
1 Initial situation; horizontal deficiency site [21].



2 Lateral/vertical defect, initial situation, lateral view.



3 Grafting with Puros Allograft Cancellous Particles.



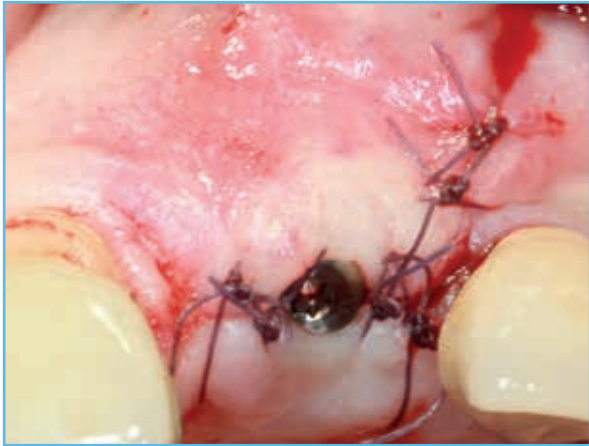
4 Covering with a CopiOs Pericardium Membrane.



5 Bone situation at re-entry 4 months post-op.



6 Final osteotomy.



7 Wound closure.



8 Radiograph taken after implant placement.

Case 2

Lateral Augmentation Prior to Implantation Site [44-47], Histomorphometric Analysis

Practitioner

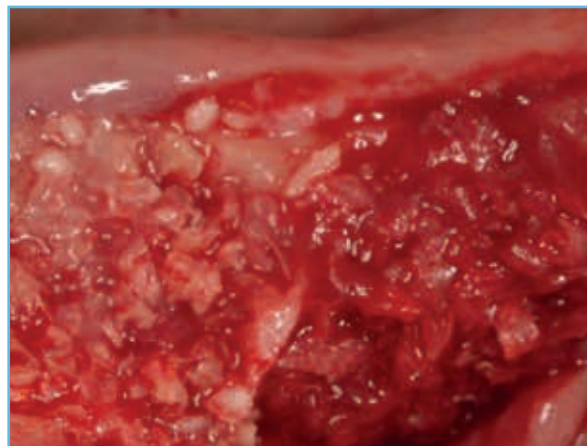
Dr. Ö. Solakoglu
Hamburg (Germany)

Material

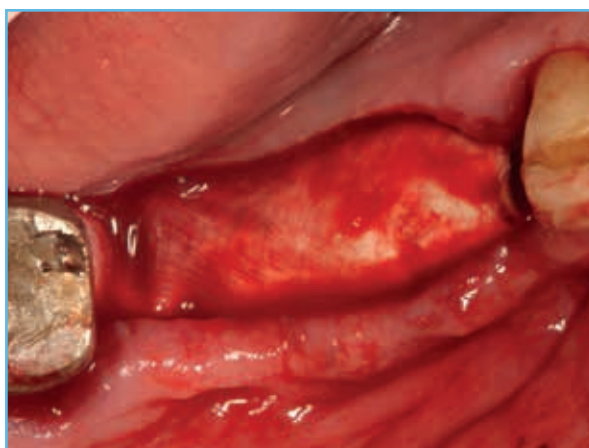
- Puros Allograft Cancellous Particles 1–2 mm, 1 cc
- CopiOs Pericardium Membrane 20 x 30 mm



1 Bony defect, reduced crestal width.



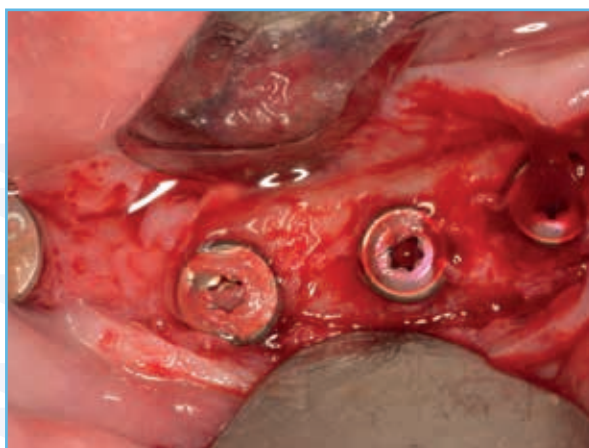
2 Augmentation with Puros Allograft Cancellous Particles, site [44] to [47].



3 Covering with a CopiOs Pericardium Membrane.



4 Bone situation at re-entry 4 months post-op. Visually vital bone with well integrated graft material.



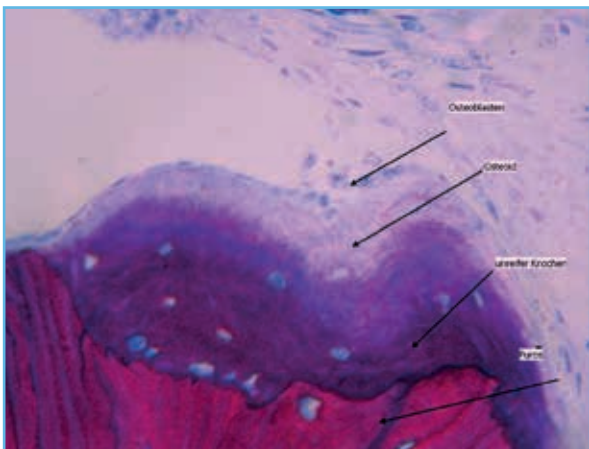
5 Exposure of implant after 4-months healing period.



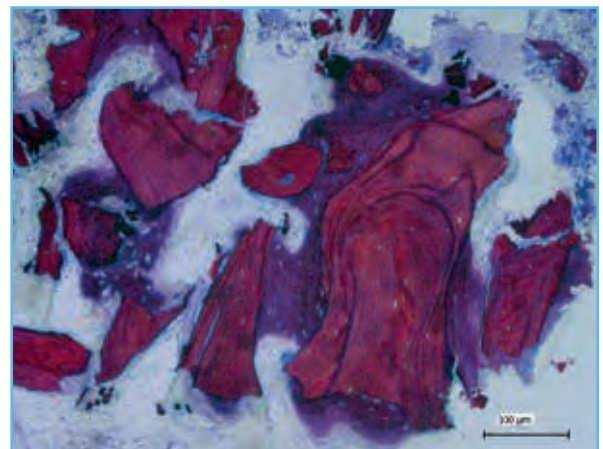
6 Final prosthetic restoration 9 months post-op, lateral view.



7 Prosthetic restoration, radiograph taken 9 months post-op, osseointegrated implants.



8 Histological cross-section (non-decalcified thin section) 10 fold: Healing period 4 months. Formation of vital, new bone (mauve) and residual graft material (reddish purple) is clearly discernible.



9 Histological cross-section (non-decalcified thin section) 40 fold: Healing period 4 months. Osteoblast activity, apposition of osteoid and conversion into immature bone (mauve) on the surface of the graft material (reddish purple).

Comments: Histological and histomorphometric analysis by M. Hasper, HIK Hannover.

The complete case series has been published: Solakoglu Ö. Präimplantologische laterale Kieferkammaugmentation mit allogenem Knochenersatzmaterial: Eine Fallserie mit histologischer und histomorphometrischer Dokumentation.

Zeitschrift für Zahnärztliche Implantologie (2012) 27:24-32.

Histomorphometric Analysis of Biopsy

Newly formed bone [%]	Connective tissue/ bone marrow [%]	Residual graft material [%]
27.3	65.2	7.5

Case 3

Lateral Augmentation Prior to Implantation Site [21]

Practitioners

Dr. K. Fischer
University of Witten/
Herdecke (Germany)

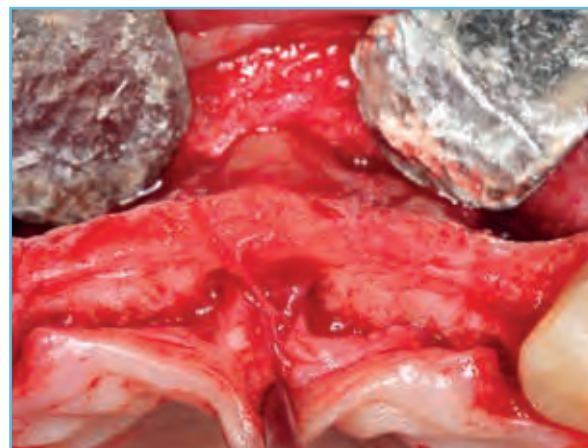
Prof. S. Fickl
University of Würzburg
(Germany)

Material

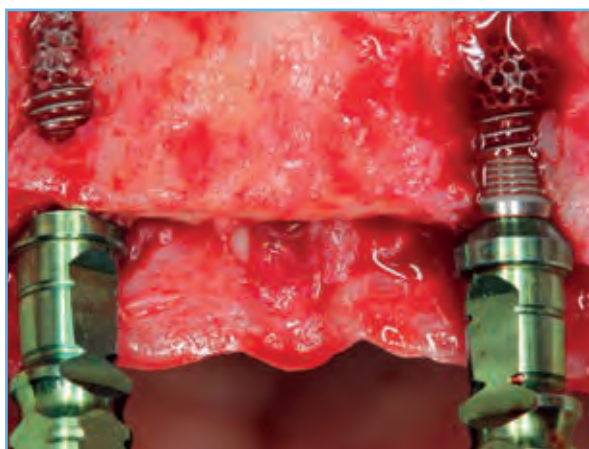
- Puros Allograft Cancellous Particles 1–2 mm, 1 cc
- CopiOs Pericardium Membrane 20 x 30 mm
- Trabecular Metal™ Implants 4.1 x 11.5 mm



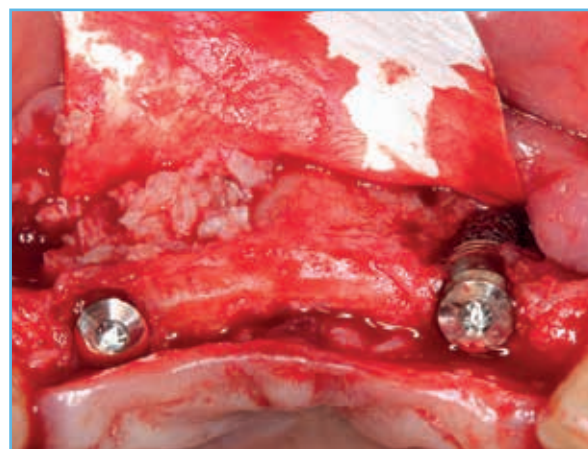
1 Initial situation, four incisors are missing.



2 Bony situation after flap elevation.



3 Trabecular Metal Implants in place, lateral fenestrations.



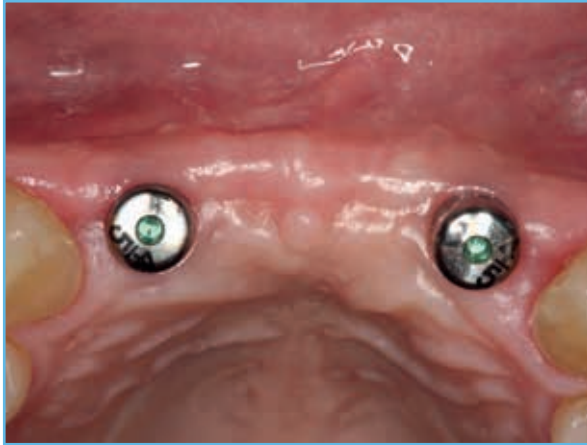
4 Augmentation with Puros Allograft Cancellous Particles and covering with a CopiOs Pericardium Membrane.



5 Wound closure.



6 Radiograph taken after implant placement.



7 4 months post-op during making of impression, occlusal view.



8 Screw-retained ceramic bridge restoration.



9 Radiograph taken after prosthetic restoration.

Case 4

Implantation and Lateral Augmentation Site [12-22]

Practitioner

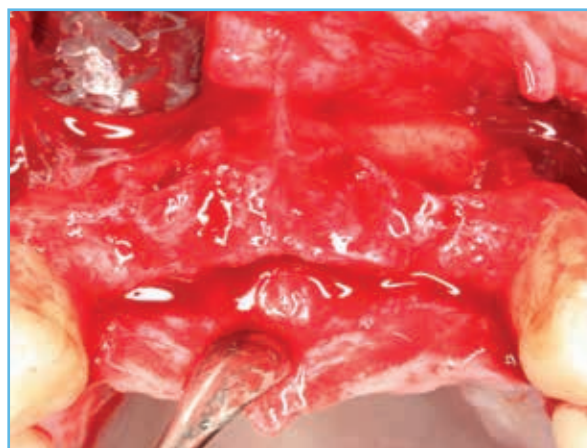
Dr. O. Richter
Hamburg (Germany)

Material

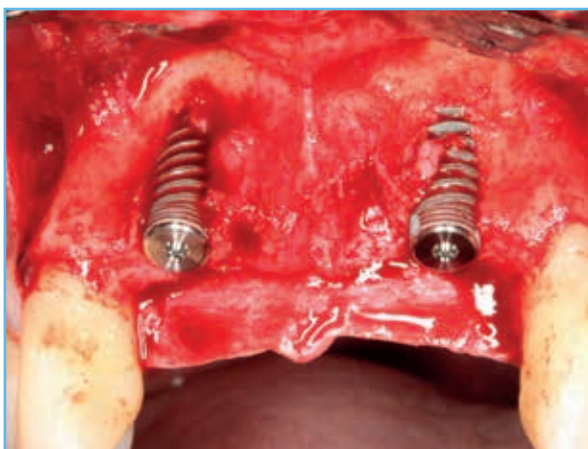
- Puros Allograft Cancellous Particles 1–2 mm, 1 cc
- CopiOs Pericardium Membrane 15 x 20 mm



1 Initial situation, four incisors are missing.



2 Elevated flap showing reduced ridge width.



3 Implants placed resulting in lateral fenestrations.



4 Sites grafted with Puros Allograft Cancellous Particles and covered with a CopiOs Pericardium Membrane.



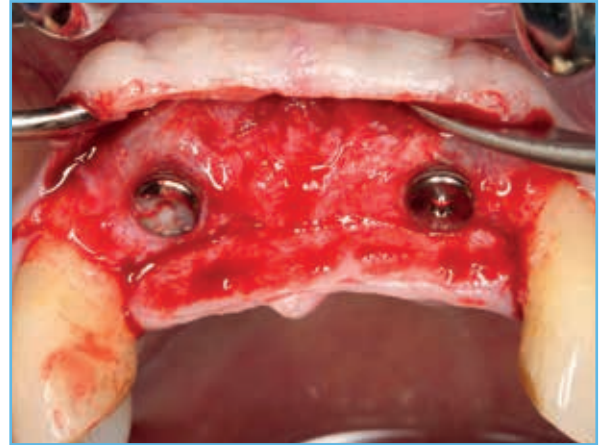
5 Wound closure.



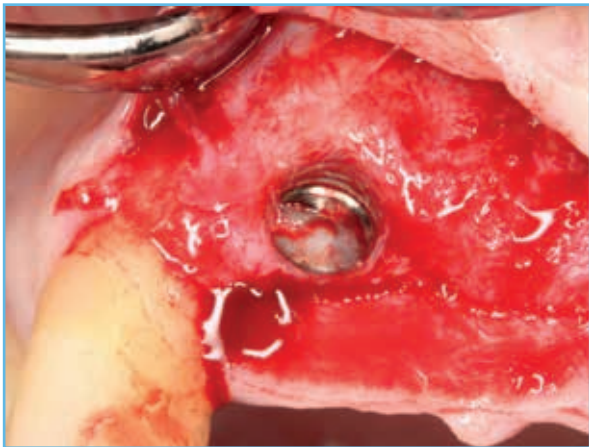
6 Radiograph taken after implant placement.



7 Soft tissue, 4 months post-op.



8 Re-entry 4 months post-op, newly formed bone on implants.



9 Implant site [12], newly formed bone covering the implant.



10 Screw-retained fixed partial denture.

Case 5

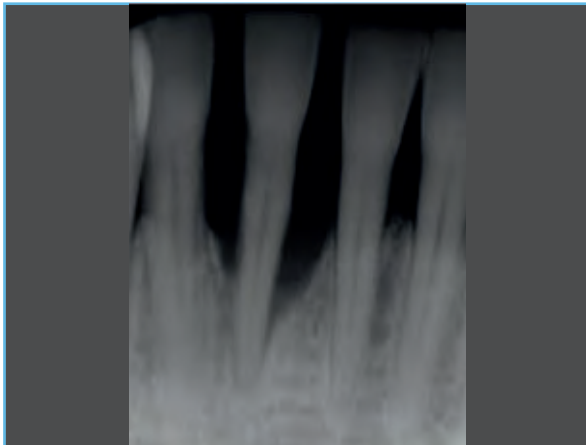
Delayed Implant Placement and Vertical Augmentation, Site [43]

Practitioner

Dr. O. Richter
Hamburg (Germany)

Material

- Puros Allograft Cancellous Particles 1–2 mm, 1 cc
- CopiOs Pericardium Membrane 15 x 20 mm



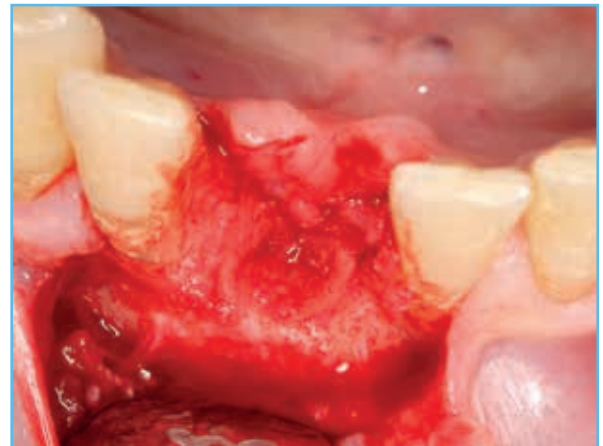
1 Radiograph of initial situation showing vertical bone loss site [43].



2 Healed soft-tissue situation after extraction.



3 Elevated flap revealing one wall, vertical bone defect.



4 Hard-tissue situation, occlusal view.



5 Implant placed and gaps filled with Puros Allograft Cancellous Particles.



6 Covered with a CopiOs Pericardium Membrane.

4 Year follow-up



7 Soft-tissue, 4 months post-op.



8 Re-entry 4-months post-op.



9 Radiograph taken 4 months after implant placement.



10 Definitive prosthetic restoration.



11 Radiograph taken 8 months after implant placement.



12 Radiograph taken 12 months after implant placement.



13 Radiograph taken 24 months after implant placement.



14 Radiograph taken 48 months after implant placement, stable bone conditions.

Case 6

Lateral Augmentation Prior to Implantation Site [16] with Xenogeneic Bone Substitute, Histomorphometric Analysis

Practitioner

PD Dr. K. Fischer
University of Witten/Herdecke (Germany)

Material

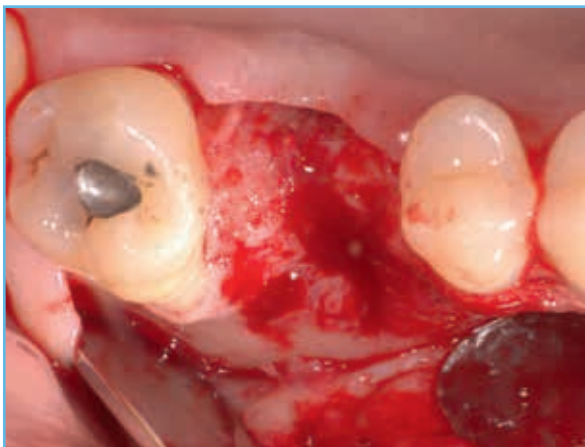
- CopiOs Xenograft Cancellous Particles 0.25–1 mm, 2 cc
- CopiOs Pericardium Membrane 20 x 30 mm



1 Initial situation showing horizontal deficiency, occlusal view.



2 Initial situation showing vertical deficiency, lateral view.



3 Bony defect after flap elevation.



4 Augmentation with CopiOs Xenograft Cancellous Particles, lateral view.



5 CopiOs Xenograft Cancellous Particles in place, occlusal view.



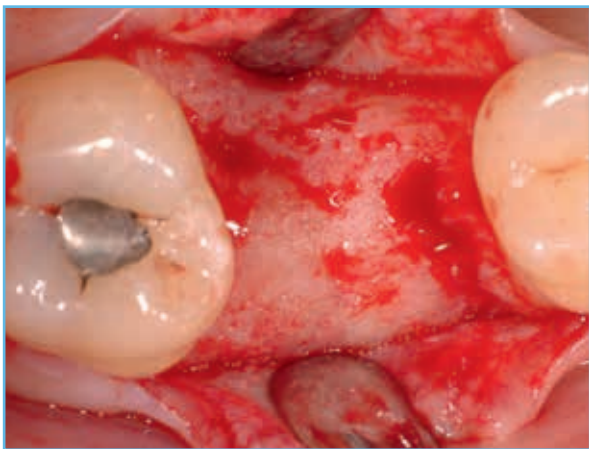
6 Covered with a CopiOs Pericardium Membrane.



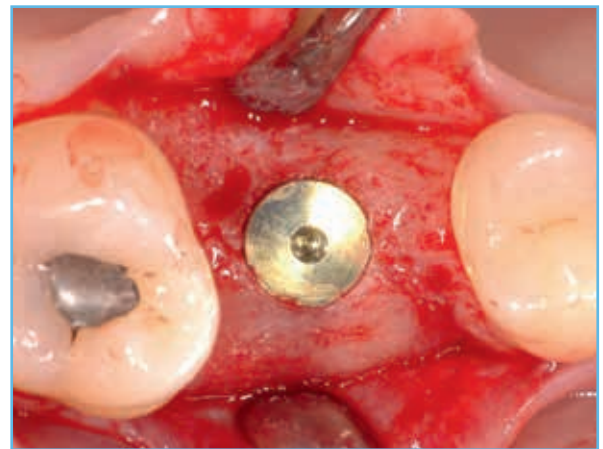
7 Wound closure.



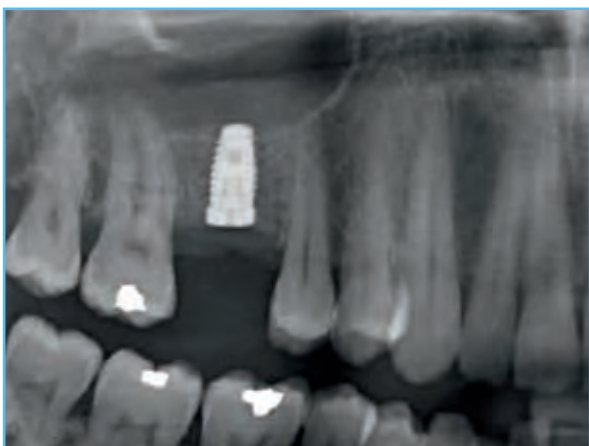
8 Soft-tissue situation and contour 6-months post-operative.



9 Bony situation at re-entry 6 months post-op. Visually vital bone with well integrated graft material.



10 Implant in place.



11 Radiograph taken after implant placement.

Case 6

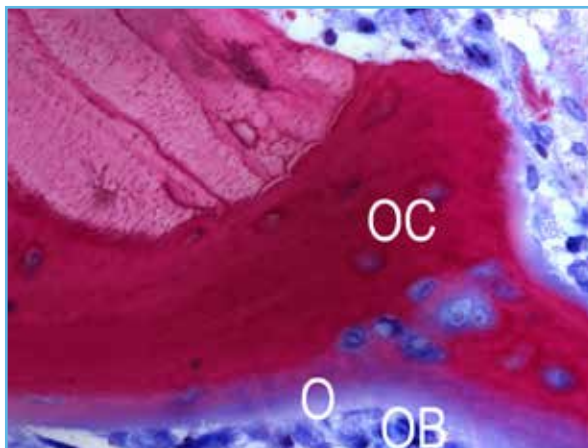
Lateral Augmentation Prior to Implantation Site [16] with Xenogeneic Bone Substitute, Histomorphometric Analysis

Practitioner

PD Dr. K. Fischer
University of Witten/Herdecke (Germany)

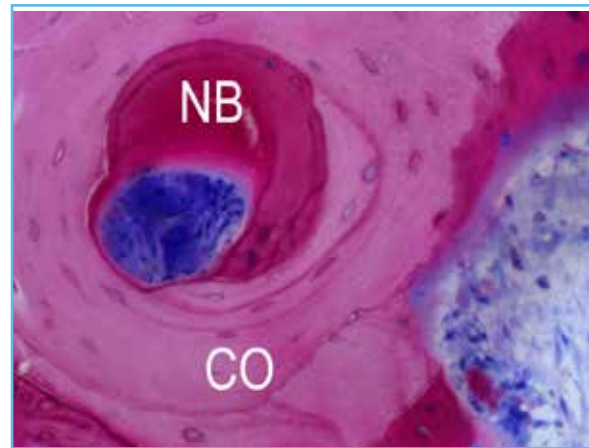
Material

- CopiOs Xenograft Cancellous Particles 0.25–1 mm, 2 cc
- CopiOs Pericardium Membrane 20 x 30 mm



HISTOLOGICAL CROSS-SECTION

(non-decalcified thin section), 400-fold: healing time 6 months; osteoblasts (OB, blue) produce osteoid (O, purple rim) and osteocytes (OC) immured in new bone (purple); residual CopiOs Xenograft Cancellous Particles (reddish purple).



HISTOLOGICAL CROSS-SECTION

(non-decalcified thin section), 200-fold: healing time 6 months; new osteon formation within CopiOs Xenograft Cancellous Particles (CO) and new bone formation (NB).

NOTE:

*Histological analysis by Dr H. Nagursky,
University of Freiburg.*



Case 7

Lateral Augmentation Prior Implantation Site [34-37] with Xenogeneic Bone Substitute

Practitioner

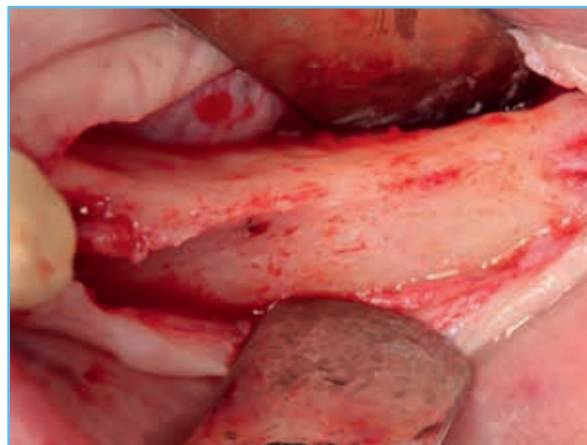
Prof. S. Fickl,
University of Würzburg (Germany)

Material

- CopiOs Xenograft Cancellous Particles 0.25–1 mm, 2 cc
- Cytoplast Ti-250, 25 x 30 mm dPTFE membrane



1 Initial situation, narrow ridge left mandible, occlusal view.



2 Narrow ridge.



3 Perforated cortical bone to induce bleeding.



4 Augmentation with CopiOs Xenograft Cancellous Particles and stabilization with a dPTFE membrane.



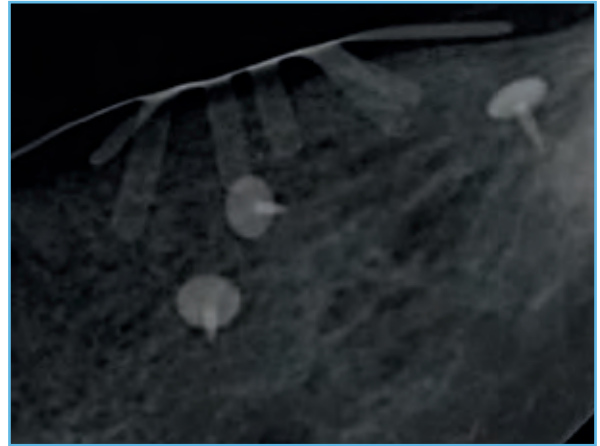
5 Titanium-reinforced dPTFE membrane in place.



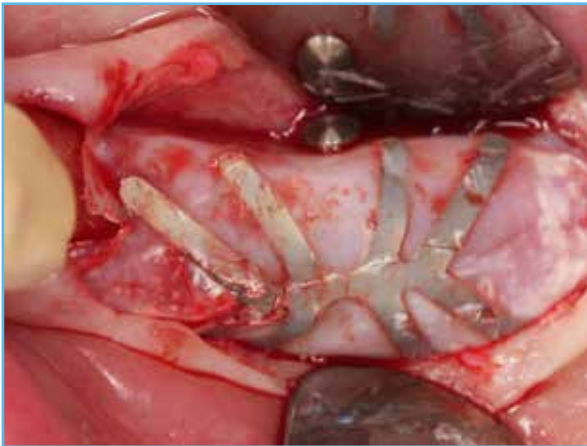
6 Wound closure.



7 Soft tissue, 5-months post-operative.



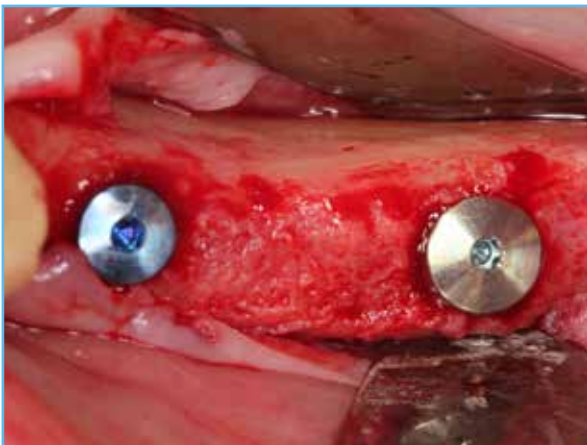
8 5 months post-op.



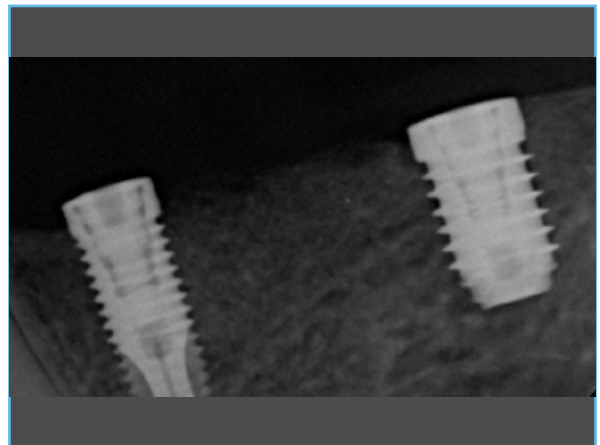
9 Re-entry 5-months post-op.



10 Bony situation at re-entry 5 months post-op. Visually vital bone with well integrated graft material.



11 Implants in place.



12 Radiograph taken after implant placement.

Literature Review

Prospective Randomized Clinical Trial

Augmentation of Facial Dehiscences on Implant Surfaces with Puros Allograft Particles Effect of Covering with a CopiOs Pericardium Membrane

Fu JH et al. A randomized clinical trial evaluating the efficacy of the sandwich bone augmentation technique in increasing buccal bone thickness during implant placement surgery: I. Clinical and radiographic parameters. *Clin Oral Implants Res* (2014) 25:458-67.

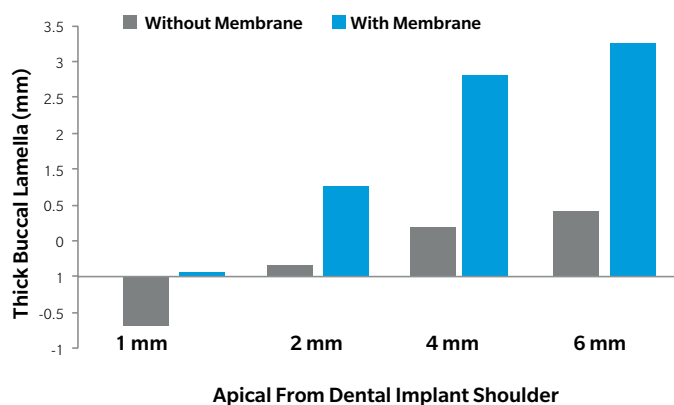
Study Design

Patients (n=26) with an anterior maxillary defect, received implants (TSV® with machined rim). All implants were inserted primary stable (≥ 35 Ncm). Due to missing bone at the buccal lamellae implants threads were not fully covered by bone. These dehiscences were grafted using a defined quantity of Puros Allograft particles 0.25–1 mm and then either covered with a CopiOs Pericardium Membrane (test group, n=13) and closed, or closed without membrane (control group, n=13). At re-entry after 6 months, percentage of defect fill and the thickness of the buccal lamellae have been determined.

Results

Grafting with Puros Allograft Particles in combination with a CopiOs Pericardium Membrane (test group) leads to a significant increase in the width of the buccal lamellae compared to the control group without membrane. Defect fill was 90.6% in the test group and 75.7% in the control group.

Dimensional Changes



Conclusion

Use of a CopiOs Pericardium Membrane reduces resorption of buccal plate compared with defects grafted without a membrane.

Case Series

Lateral Augmentation with Puros Allograft Particles: Histology and Histomorphometry

Solakoglu Ö. Präimplantologische laterale Kieferkammaugmentation mit allogenem Knochenersatzmaterial: A case series with histological and histomorphometric documentation. Zeitschrift für Zahnärztliche Implantologie (2012) 27:24-32.

Study Design

In the case series (n=5) lateral bone defects were grafted with Puros Allograft Cancellous Particles and covered with a CopiOs Pericardium Membrane. After a healing time of four, six or twelve months, biopsies were taken from the graft site prior to implant placement and histological and histomorphometric analysis was performed.

Results

Ridge widenings can be reliably obtained by lateral augmentation with Puros Allograft Cancellous Particles and a CopiOs Pericardium Membrane. All implants achieved primary stability at the time of placement. Histomorphometry results show that the bone graft is fully remodeled after a period of six and twelve months. Active osteoclasts and osteoblastic cells were detected on the surface of the grafting material. The new bone is vital, and depending on the healing period, free of residual graft material.

Patient	Biopsy Sample (Mo)	Bone (%)	Connective Tissue (%)	Residual Graft Material (%)
1	4	3.54	34.68	61.79
2	4	27.28	65.18	7.54
3	6	45.68	47.62	0
4	12	69.00	31.00	0
5	12	94.10	5.90	0

Conclusion

This procedure and materials described above can achieve promising results in lateral ridge augmentation.

Case Series (cont.)

Prospective Study

Defect Fill with CopiOs Xenograft Cancellous Particles Compared to Xenogeneic Materials

Thorwarth M et al. Evaluation of substitutes for bone: comparison of microradiographic and histological assessments. *Br J Oral Max Surg* (2007) 45:41-47.

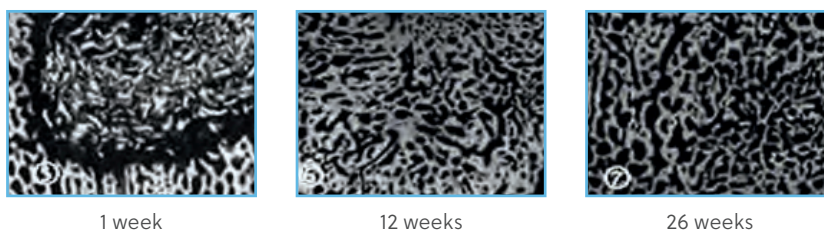
Study Design

Defined defects were created in the calvaria of pigs (diameter 10 mm and depth 10 mm). The defects were grafted with a variety of bone substitutes (Osteograf®/N-300, Dentsply; Bio-Oss, Geistlich Pharma AG; Aligpore™, Dentsply; Navigraft™, Tutogen Medical GmbH) followed by soft-tissue closure. Control groups were one dummy and one defect filled with autogenous bone. Two animals were sacrificed after healing periods of 1, 2, 4, 8, 12 and 26 weeks. Tissue sections from the graft site were evaluated microradiographically and the integration of each material was evaluated and quantified. Histological sections were stained with toluidine blue and quantified.

Results

Defect fill in the dummy group was incomplete after 26 weeks. The second control group (autogenous bone), exhibited full regeneration. Osteograf and Bio-Oss were surrounded by newly formed bone. After a healing period of 26 weeks, residual particles of Bio-Oss and Osteograf were detected. Aligpore was well integrated and 20% of the material was still present after 26 weeks. Navigraft (now CopiOs Xenograft Cancellous Particles) showed signs of initial resorption after a healing period of two weeks. After four weeks Navigraft and new bone were no longer distinguishable by microradiography. After a healing period of 26 weeks the defect had undergone complete regeneration (see illustration).

CopiOs Xenograft Particles

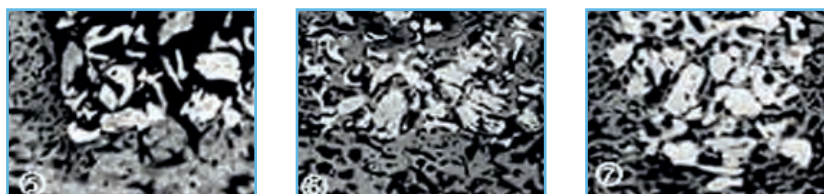


1 week

12 weeks

26 weeks

Bovine Xenograft*



Microradiograph of defects grafted with CopiOs Xenograft Cancellous Particles (top) and Geistlich Bio-Oss (bottom) following various healing periods. Note the complete integration and defect fill after 26 weeks in the CopiOs group. In the Bio-Oss group, incomplete bone regeneration can be seen cranially and centrally.

Conclusion

CopiOs Xenograft Cancellous Particles is largely converted to vital bone within 26 weeks resulting in fully regenerated defects.

* Bio-Oss from Geistlich.

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Case 1

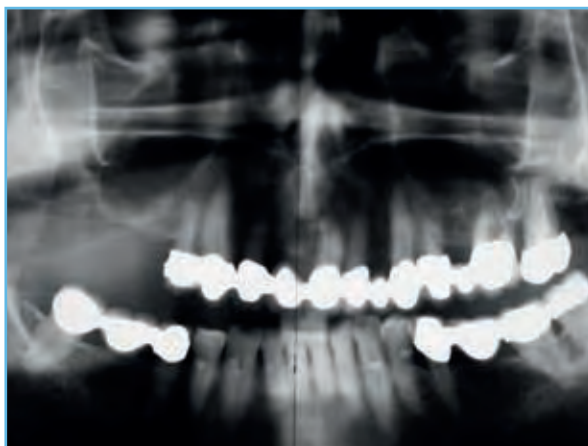
Sinus Lift with Allogenic Bone Graft Site [15-17]

Practitioner

Dr. O. Richter
Hamburg (Germany)

Material

- Puros Allograft Cancellous Particles 0.25–1 mm, 2 cc
- CopiOs Pericardium Membrane 15 x 20 mm



1 Radiograph of initial situation showing thin sinus floor right maxilla.



2 Lateral sinus wall after raising full-thickness flap.



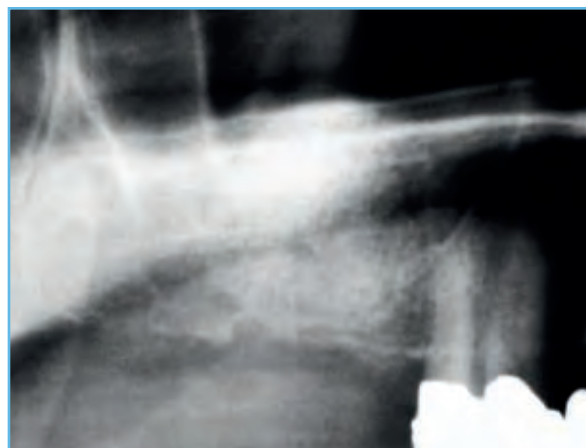
3 Sinus lift using Puros Allograft Cancellous Particles.



4 CopiOs Pericardium Membrane draped over lateral window.

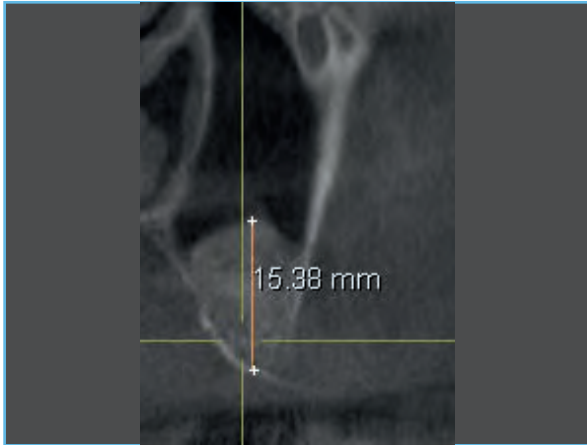


5 Wound closure.

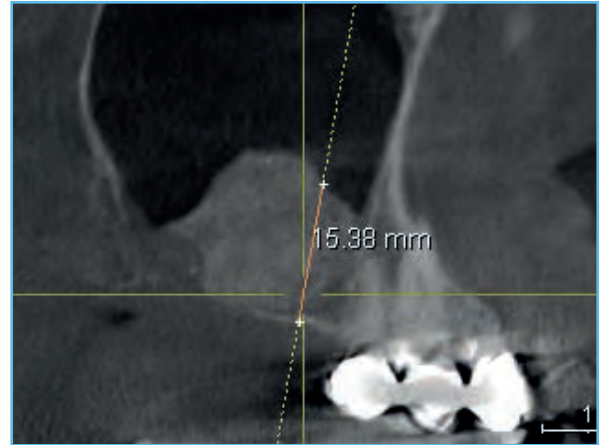


6 Post-operative radiograph.

Clinical photographs courtesy of Dr O. Richter. Individual results may vary.



7 4-months post-operative CBCT scan. sagittal cross-section, oral left, labial right.



8 4-months post-operative CBCT scan.

Case 2

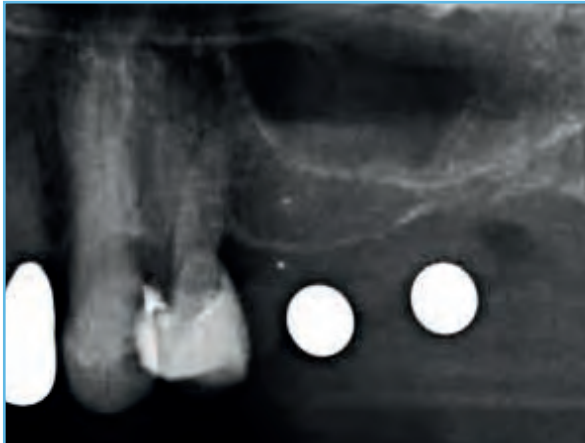
Histological and Histomorphometric Analysis Following Sinus Lift with Allogenic Bone Graft Site [25-26]

Practitioner

Dr. F. Conradi
Bremen (Germany)

Material

- Puros Allograft Cancellous Particles 1–2 mm, 2 cc
- CopiOs Pericardium Membrane 20 x 30 mm



1 Radiograph of initial situation, showing thin sinus floor maxilla left.



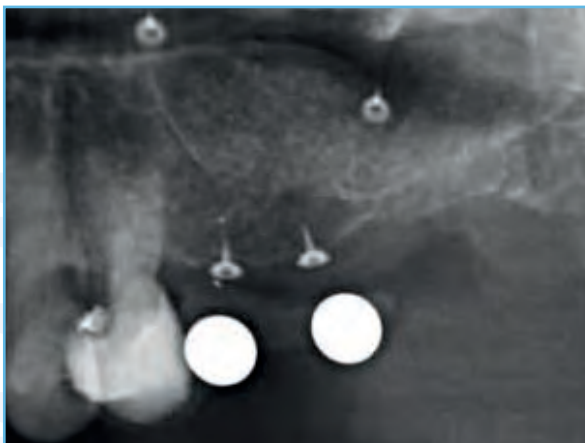
2 Lateral approach was used to elevate the Schneiderian membrane.



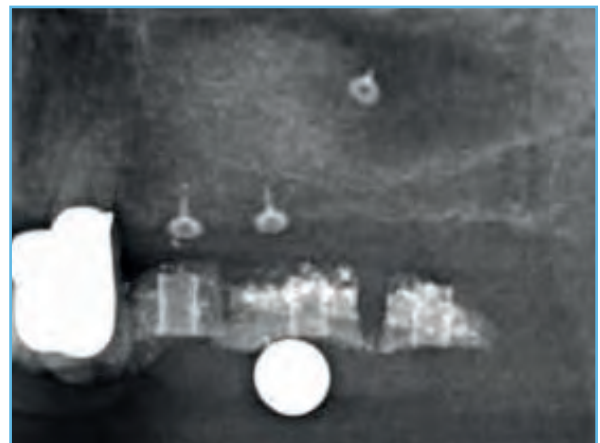
3 Puros Allograft Cancellous Particles in place.



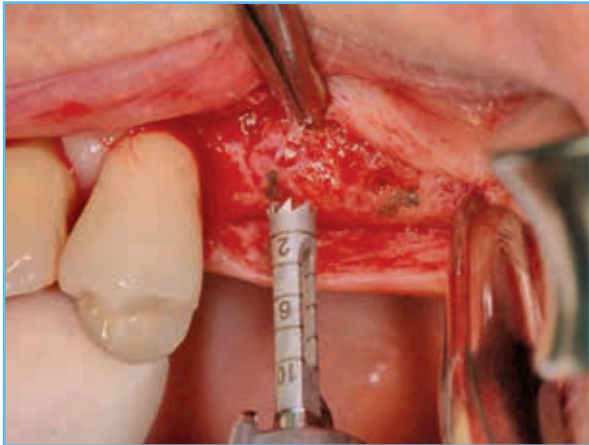
4 CopiOs Pericardium Membrane fixed with pins.



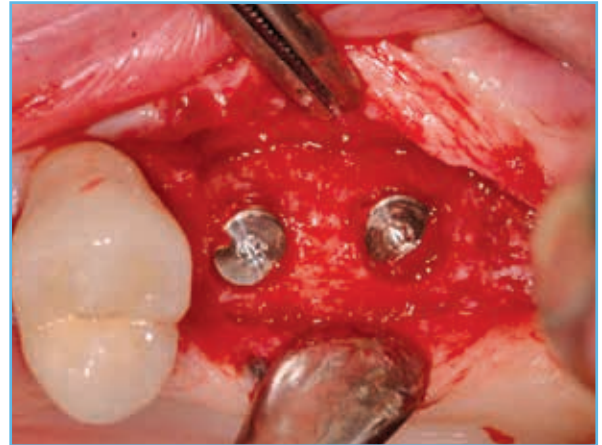
5 Post-operative radiograph.



6 5-months post-operative radiograph with surgical guide.



7 Re-entry 5-months post-op, collection of biopsy.



8 Implants placed in grafted sites.



9 Post-placement radiograph.



10 Radiograph taken after prosthetic restoration.

Case 2

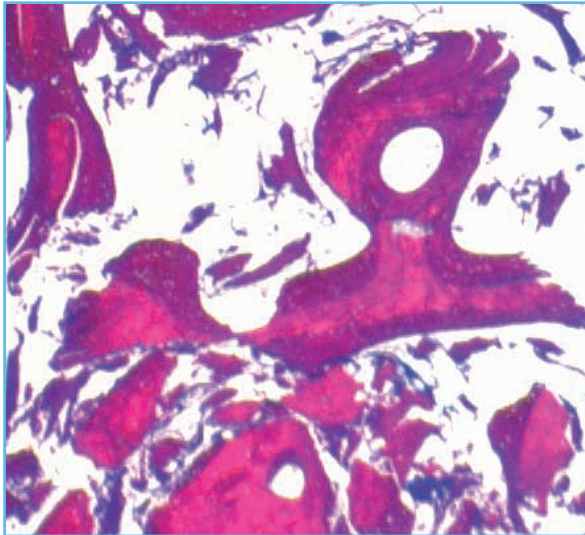
Histological and Histomorphometric Analysis Following Sinus Lift with Allogenic Bone Graft Site [25-26]

Practitioner

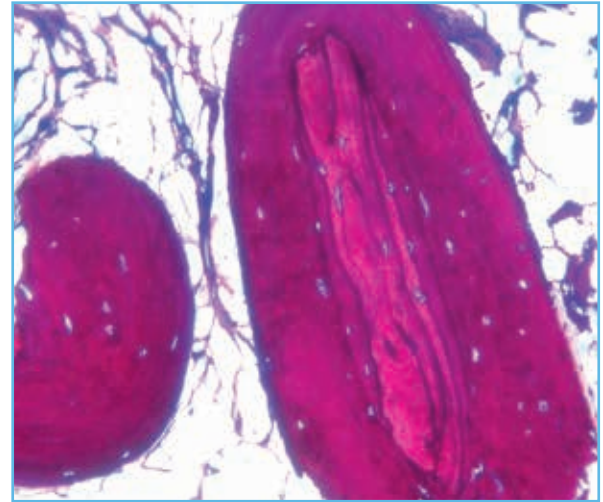
Dr. F. Conradi
Bremen (Germany)

Material

- Puros Allograft Cancellous Particles 1–2 mm, 2 cc
- CopiOs Pericardium Membrane 20 x 30 mm



11 Histological cross-section (non-decalcified thin section) 50 times: Healing period 5 months. Production of vital, newly formed bone (mauve) and residual Puros Particles (reddish purple) are clearly discernible.



12 Histological cross-section (non-decalcified thin section) 200 fold: Healing period 5 months. Newly formed bone (mauve) encloses Puros Cancellous Particle (reddish purple).

Histomorphometric Analysis Of Biopsy

New Bone Formation [%]	Connective Tissue/ Bone Marrow [%]	Residual Graft Material [%]
34.42	62.10	3.48



Case 3

Histological Analysis Following Sinus Lift with Xenogeneic Bone Substitute, Site [26-27]

Practitioner

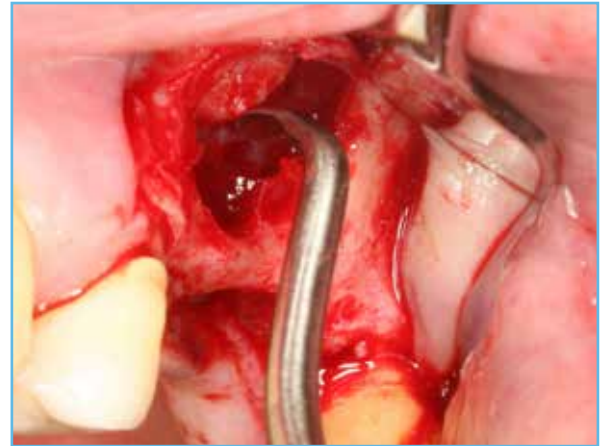
Dr. O. Richter
Hamburg (Germany)

Material

- CopiOs Xenograft Cancellous Particles 1–2 mm, 2 cc
- CopiOs Pericardium Membrane 20 x 30 mm



1 Radiograph of severely pneumatized sinus membrane and lack of ridge.



2 Window created lateral approach to sinus elevation.



3 Rehydrated CopiOs Xenograft Cancellous Particles.



4 CopiOs Xenograft Cancellous Particles in place.



5 Post-operative radiograph.



6 4-month post-operative radiograph, healing with good volume stability.



7 Re-entry 4-months post-op, adequate supply of bucco/ oral bone.



8 Biopsy taken at re-entry.



9 TSV-T Implant 4.1x10 mm.



10 TSV-T Implants in place.



11 Implants in place, occlusal view.



12 Post-placement radiograph.

Case 3

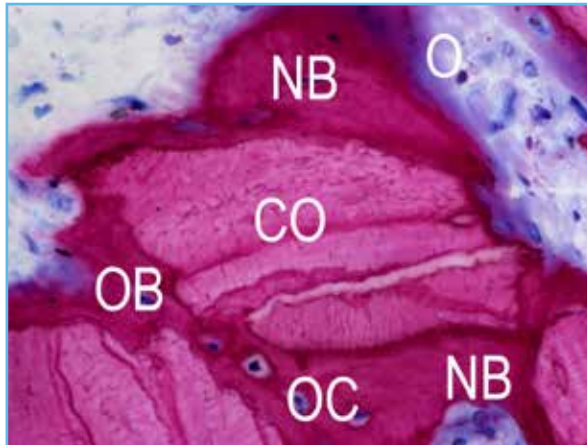
Histological Analysis Following Sinus Lift with Xenogeneic Bone Substitute, Site [26-27]

Practitioner

Dr. O. Richter
Hamburg (Germany)

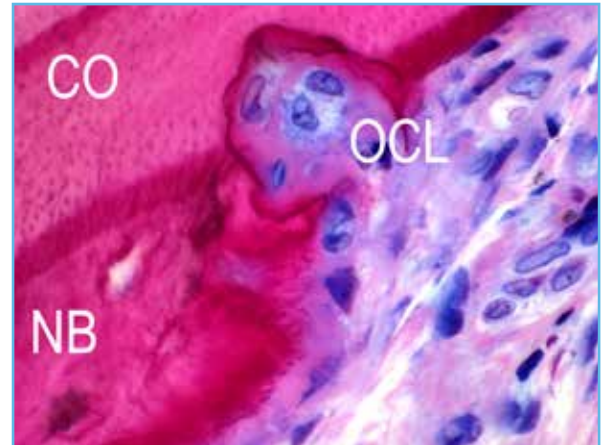
Material

- CopiOs Xenograft Cancellous Particles 1–2 mm, 2 cc
- CopiOs Pericardium Membrane 20 x 30 mm



Histological cross-section

(non-decalcified thin section), 400-fold : healing period 4 months; osteoblasts (OB, blue) produce osteoid (O, purple rim); Newly formed bone (NB, mauve) and osteocytes (OC) immured in new bone; residual CopiOs Xenograft Cancellous Particles (CO, reddish purple).



Histological cross-section

(non-decalcified thin section), 630-fold: healing period 4 months; production of vital, newly formed bone (NB, mauve) and residual particles from the CopiOs Xenograft Cancellous Particles (CO, reddish purple) and osteoclasts (OCL) are clearly discernible.

NOTE:

*Histological analysis by Dr H. Nagursky,
University of Freiburg.*



Literature Review

Prospective Study

Maxillary Sinus Augmentation With Puros Allograft Cancellous Particles, Bio-Oss, BoneCeramic, and Autologous Bone

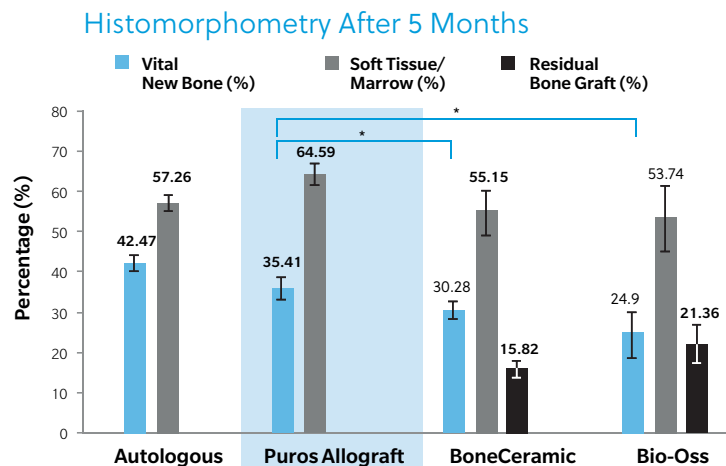
Schmitt CM et al. Histological results after maxillary sinus augmentation with Straumann® BoneCeramic, Bio-Oss, Puros and autologous bone. A randomized controlled clinical trial. Clin Oral Implants Res (2013) 24:576-585.

Study Design

Patients (n=30) with residual bone height ≤ 4 mm in posterior maxilla were divided into four groups and maxillary sinus floor augmentations performed. The augmentations were performed with: (I) autologous bone (intraoral); (II) Puros Allograft Cancellous Particles 0.25–1 mm; (III) Straumann BoneCeramic 0.1–0.5 mm and (IV) Geistlich Bio-Oss 0.25–1 mm. At re-entry after a healing period of 5 months a total of 53 biopsies were taken and 94 implants inserted. The composition of the biopsies were subjected to a histological and histomorphometric analysis.

Results

The volume of newly formed, vital bone in the Puros Allograft group is higher than in the BoneCeramic and Bio-Oss groups. In the Puros Allograft group, after a healing period of 5 months no residual Puros particles were quantified/detected. The percentage of non-vital residual particles found in the Bone Ceramic group was 15.82% and 21.36% in the Bio-Oss group.



Conclusion

Puros Allograft Cancellous Particles have been largely converted to vital bone within 5 months. Placement of primary stable implants can be achieved.

Prospective Study

Maxillary Sinus Augmentation With Puros Allograft Particles, and Bio-Oss

Froum SJ et al. Comparison of mineralized cancellous bone allograft (Puros) and anorganic bovine bone matrix (Bio-Oss) for sinus augmentation: histomorphometry at 26 to 32 weeks after grafting. *Int J Periodont Rest* (2006) 26:543-551.

Study Design

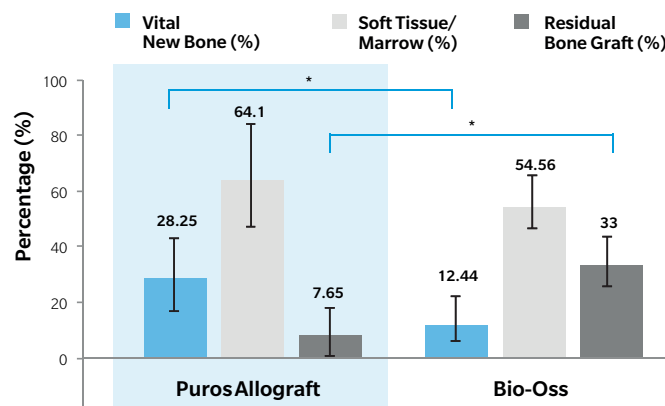
Patients (n=13) with residual bone height ≤ 5 mm in posterior maxilla were divided into two groups and bilateral maxillary sinus floor augmentations performed. The augmentations were performed in the split mouth design with: (I) Puros Allograft Cancellous Particles 50:50 (0.25–1 : 1–2 mm); (II) Bio-Oss 50:50 (0.25–1 : 1–2 mm). At re-entry (after a healing period of 6 to 7 months) a total of 20 biopsies were taken and a histological and histomorphometric analysis conducted.

Results

The volume of newly formed, vital bone in the Puros Allograft group is higher than in the Bio-Oss group. The proportion of non-vital residual particles is significantly lower in the Puros Allograft group than in the Bio-Oss.

Conclusion

Histomorphometry After 6–7 Months Healing Time



Puros Allograft Cancellous Particles are a suitable alternative to autologous bone or bovine bone substitute in maxillary sinus floor augmentation. New bone formation is significantly higher compared to Bio-Oss.

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Case 1

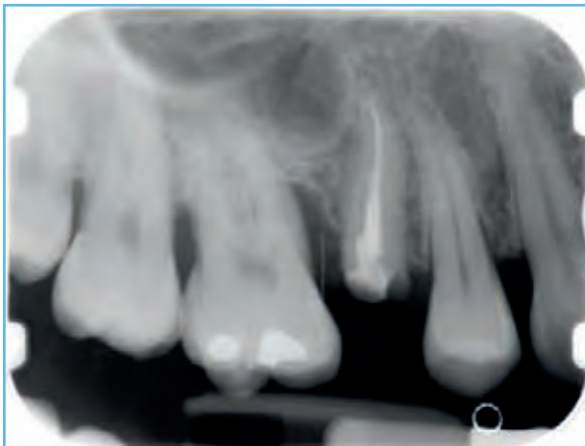
Tooth [14-16]

Practitioner

Dr. D. Engler-Hamm
Munich (Germany)

Material

- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc*



1 Bony defect mesially, tooth [16].



2 Intraoperative bony defect, probing depth 7 mm following Phase I treatment.



3 Augmentation with Puros Allograft Cancellous Particles.*



4 Re-entry 9 months post-op due to need for surgical crown extension mesial of tooth [15].



5 Occlusal view following odontoplasty (mesial) tooth [15], osteotomy and osteoplasty.



6 Lateral view following surgical crown extension.

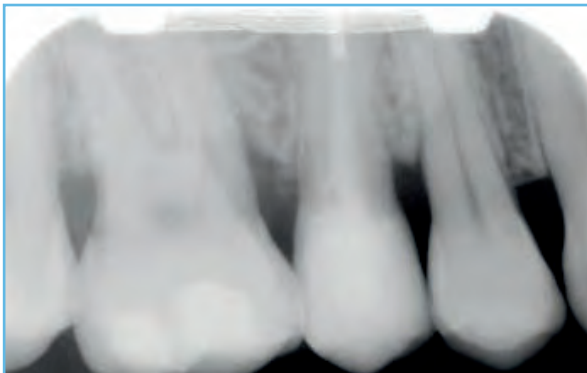
5 Year follow-up



7 Radiograph taken 12 months after regenerative procedure.



8 5-year follow up. Lateral view.



9 Periapical radiograph taken 5 years after regenerative procedure.

Scientifically Proven:

International Literature Review

Case Series:

Treatment of periodontal defects using Puros Allograft Cancellous Particles

Browning ES et al. Evaluation of a mineralized cancellous bone allograft for the treatment of periodontal osseous defects: 6-month surgical reentry. *Int J Periodont Rest Dent* (2009) 29:41-47.

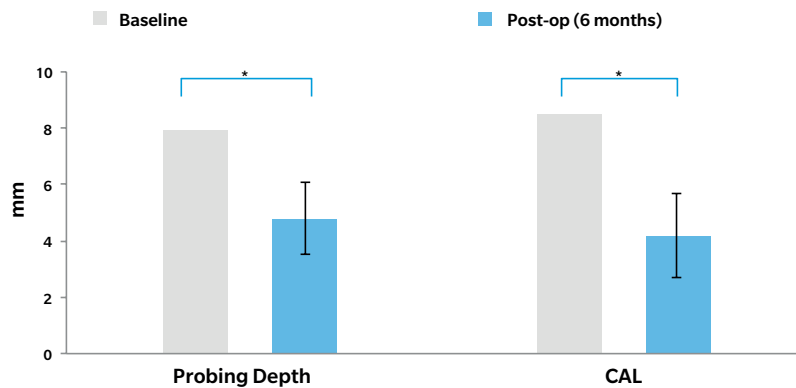
Study Design

In patients (n=20, av. 55 years) with chronic periodontitis and at least one intrabony defect (radiological bone defect ≥ 4 mm, probing depth ≥ 7 mm) the study evaluated the effectiveness of Puros Allograft Cancellous Particles for the treatment of periodontal osseous defects. A full flap procedure was followed by debridement of the defect, root planning, placement of bone graft, and then flap closure. Clinical and surgical measurements were taken at baseline and at 6-month re-entry.

Results

Following grafting and healing, average probing depth reduction was 4.8 ± 1.3 mm. Average gain in clinical attachment (CAL) was 4.2 ± 1.5 mm. Both changes were statistically significant. Bone fill was $66.8\% \pm 26.2\%$ and average percent defect resolution was $71.5\% \pm 25.5\%$.

Clinical Measurements After 6 Months



Conclusion

Puros Allograft Cancellous Particles are a promising and effective material for the treatment of osseous defects in patients with chronic periodontitis.

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Case 1

Site [14-16]

Practitioner

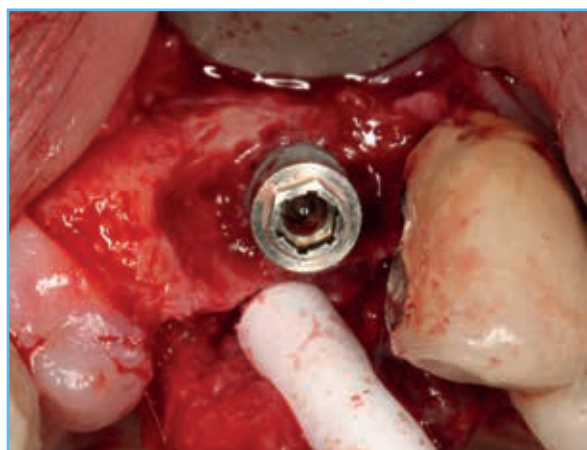
Dr. Ö. Solakoglu
Hamburg (Germany)

Material

- Puros Allograft Cancellous Particles 0.25–1 mm, 0.5 cc*
- CopiOs Pericardium Membrane 15 x 20 mm



1 Peri-implant bone defect in site [22] on a Brånemark System® Mk IV Implant, 12 years in place.



2 Bone defect after flap formation.*



3 Augmentation with Puros Allograft Cancellous Particles** and draping with CopiOs Pericardium Membrane.



4 Wound closure.



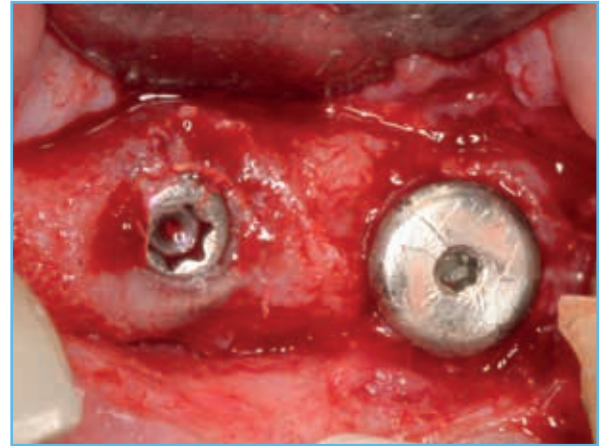
5 Radiograph site [22] after peri-implantitis treatment.



6 4-month post-op re-entry, regenerated vital bone around implant.



7 Post-implant radiograph of site [21].



8 Reentry, site [21], healing period 4 months.



9 Definitive prosthetic restoration with PFM crowns
9 months post-augmentation, lateral view.



10 Radiograph taken after 9 months post-augmentation with prosthetics.

The procedure is published:

Solakoglu Ö. Therapie der Periimplantitis – ein Protokoll für klinischen Erfolg.
Zahnarzt & Praxis (2011) 14:306-315.

* Decontamination of implant surface: Details of the decontamination of the implant surface are presented in detail in the published article.

** Puros Allograft Cancellous Particles were mixed with PRGF before delivery (third phase).

Clinical photographs courtesy of Dr Ö. Solakoglu. Individual results may vary.

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Puros Allograft – Facts You Should Know

ZimVie's Puros family of hard-tissue grafting products provides an effective and predictable¹ clinical outcome for patients requiring bony enhancement in a timely manner. Puros Cancellous Particulates act as an osteoconductive scaffold, enabling the ingrowth of vascular and cellular connective tissue.²

Leading

Puros Allograft products are used worldwide in clinical practice.

Clinically And Scientifically Proven

Puros Allografts, a leading allograft brand, are distributed in many countries worldwide, and have more than 350+ articles in dental applications supporting their reliability and predictability during bony augmentation procedures. A face-to-face study shows superior bone formation and remodeling compared to freeze-dried allograft particulates.³

Multi-Step Safety System

1. Donor Selection

Donor selection and serological testing comply with EU⁴⁻⁶ and national guidelines.⁷⁻⁹

2. Tissue processing in the Tutoplast Sterilization Process

The Tutoplast process gently removes unwanted components. The process preserved the biomechanical properties and has been validated for inactivation of viruses and pathogens. Virus inactivation by $\leq 12 \log^{10}$ has been validated and confirmed by several different, independent institutions.¹⁰

3. Terminal low-dose gamma irradiation

All Puros Allograft products are sterilized using terminal low-dose gamma irradiation: Sterility assurance level: 10^{-6} .¹¹

Vitality

Puros Allograft products have the structural properties of natural tissue. These properties allow them to produce more new, vital bone in comparison with xenogeneic and synthetic products.¹²

Handling And Strength

The Tutoplast process does not affect the mechanical properties of the products.¹³ This enables comfortable handling and secure fixing of Puros Allograft products (e.g. Puros Allograft Bone Blocks).

Safety, Reliability, Consistency

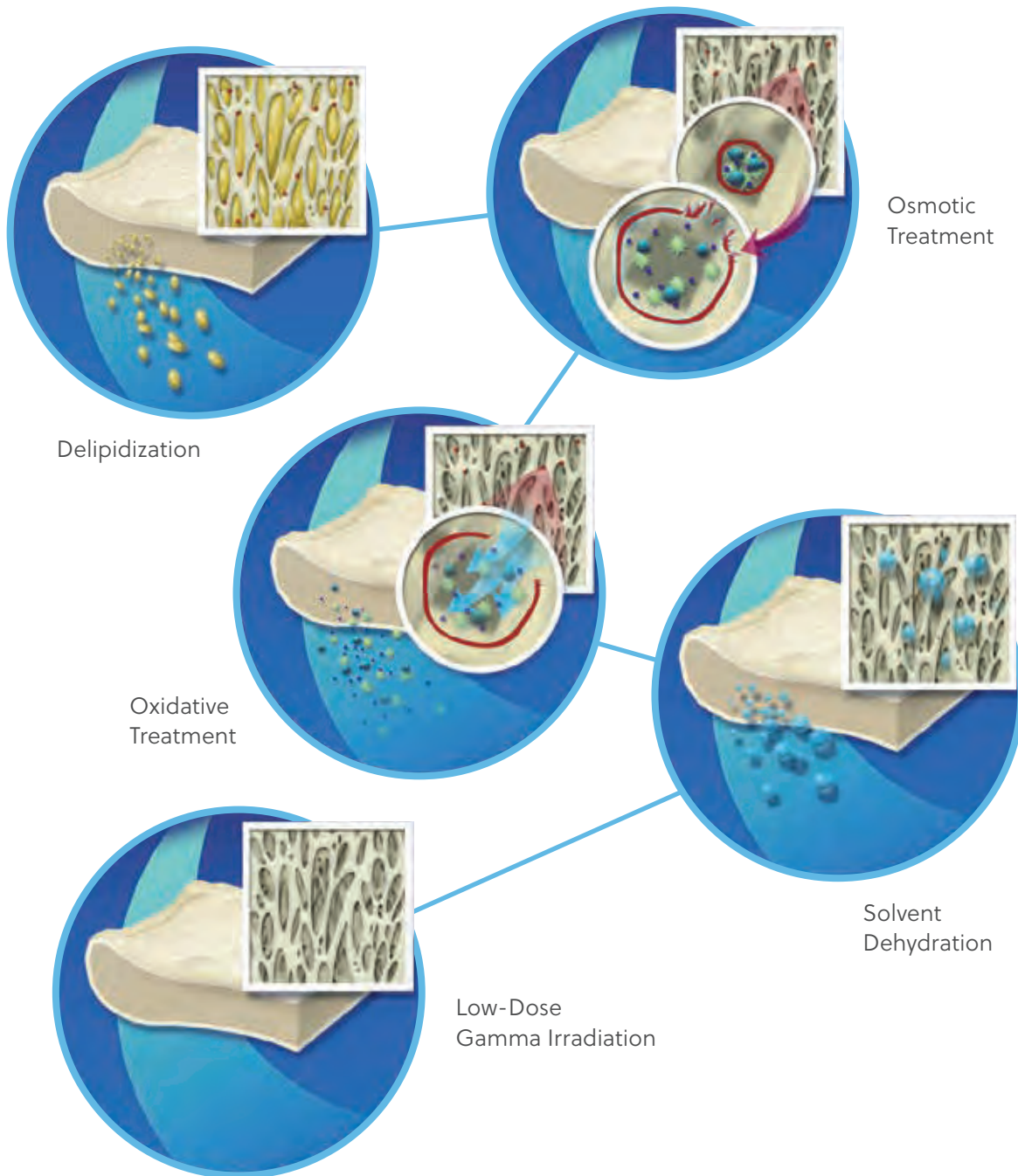
For over 50 years, Tutoplast processed tissues have been safely used in more than 5 million procedures.¹⁰

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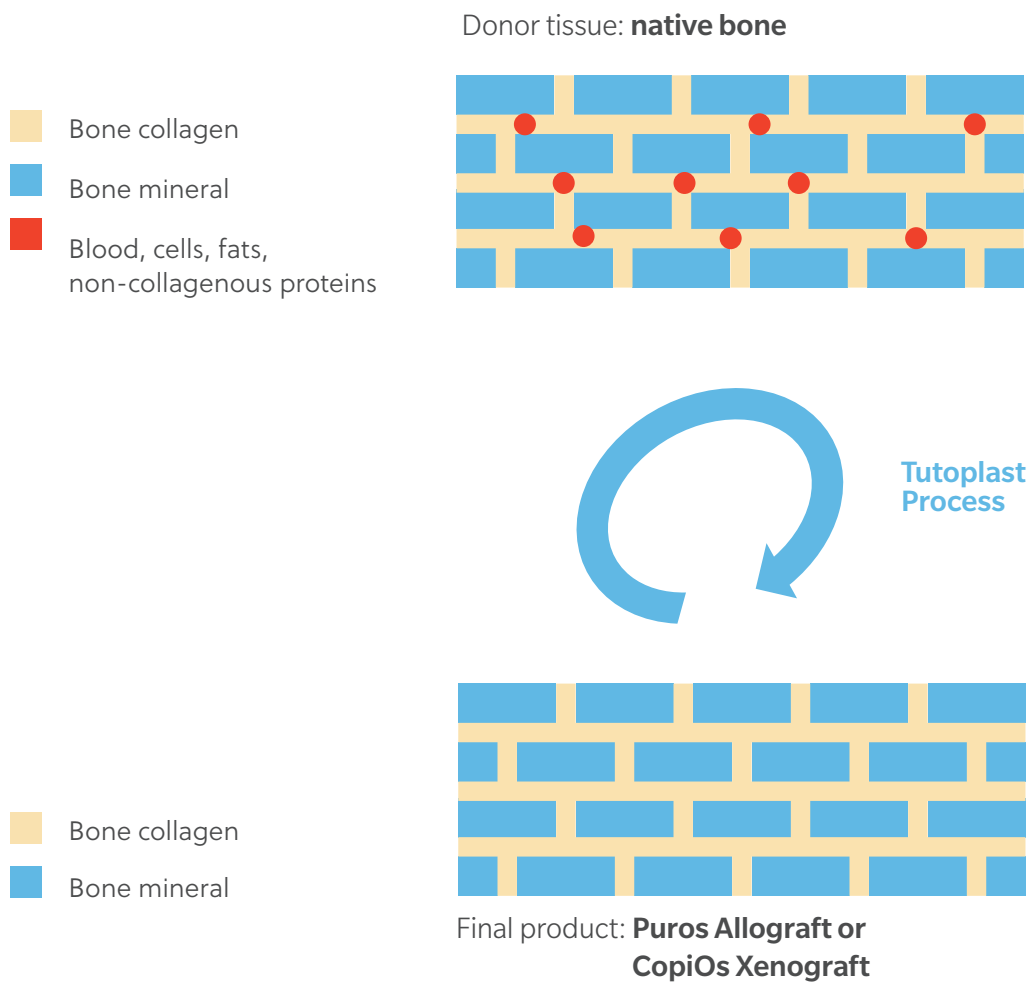
The Proprietary Tutoplast® Process

Processing of Puros Allograft and CopiOs Xenograft Bone Grafts



The Proprietary Tutoplast® Process

Puros Allograft and CopiOs Xenograft products are manufactured using the Multi-Step Tutoplast Sterilization Process. The **process** aims to preserve the natural **collagen and mineral structure** of the hard tissue, providing a scaffold for regeneration and assimilation into the recipient bed. The Tutoplast Process has been scientifically validated for **preservation** of tissue biomechanical properties, while inactivating pathogens and gently removing unwanted materials, such as cells, antigens, and viruses - resulting in predictable, reliable, sterile, and safe tissue.¹ More than **11 million implants** have been sterilized through the Tutoplast Process with **zero confirmed** incidence of implant associated infection.¹



¹Data on file at RTI Surgical, Inc.



For more information, visit [ZimVie.com](https://www.zimvie.com)

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Name of the product: PUROS® ALLOGRAFT | Composition: Human cancellous tissue (with cortical component in the Puros® Allograft Blend version), preserved using the Tutoplast® Process, sterilised by gamma irradiation. | Therapeutic indications: To cover or fill bone defects or to create bony structures in maxillofacial surgery. Therapeutic indications for which positive experience has been reported include the following: Regeneration of periodontal bone defects; Regeneration of furcation defects; Regeneration following cyst resection and apicoectomy; Regeneration of extraction sockets; Regeneration of gaps between the alveolar wall and dental implants; Regeneration of defects following block removal; Regeneration of gaps around block grafts; Horizontal alveolar ridge augmentation (particles); Sinus augmentation; Three-dimensional (horizontal and/or vertical) alveolar ridge augmentation (block augmentation). Further applications have been described in other surgical specialties. | Contraindications: None known. | Undesirable effects (frequency cannot be estimated from the available data): Graft rejection, implant site reaction, graft failure. As with every surgical procedure, there is the possibility of infection due to the procedure itself. | Warnings: Store dry, sunlight protected and not over 30 °C. Do not freeze. Discard any unused material; do not resterilise! See also instruction for use. Keep out of reach of children. | General classification for supply: Prescription only. | Further information: see package leaflet; | Date of revision of the text: 02.2018 „11“. | Pharmaceutical Entrepreneur: Tutogen Medical GmbH, Industriestraße 6, 91077 Neunkirchen am Brand, Germany | Co-distributor: Zimmer Dental GmbH, Wilhelm-Wagenfeld-Str. 28, D - 80807 München.

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