PREDICTABLE BONE AUGMENTATION, PERI-IMPLANTITIS TREATMENT, AND LONG-TERM CRESTAL BONE STABILITY USING PUROS® PARTICULATE ALLOGRAFTS

Author

Jenny Park, PhD

Marie Pollard, DPhil

Hai Bo Wen, PhD

ZimVie

Background

Reconstruction of bone defects is one of the frequent challenges in oral implantology as adequate bone volume is required for the primary stability of dental implants and long-term success in function. Various aspects need to be considered for the selection of suitable grafting materials and surgical techniques. Grafting materials must provide mechanical stability for space maintenance of the recipient site while also supporting bone regeneration for osseointegration of implants. Also, a balance between resorption of the remaining residual materials and replacement with newly formed bone tissues is a desirable feature for achieving predictable long-term clinical outcomes.[1-6] Grafting materials with slow resorption rates can limit spaces for vascularization and vital bone regeneration. Sufficient vascularization and vital bone formation result in continuous metabolic activity that is required to support the long-term clinical stability of bone tissues in restored sites.[1,3,5-7] Autografts have a long-standing position as the gold standard for use in grafting applications. The preference has been mainly attributable to biocompatibility and inclusion of osteogenic cells as well as osetoinductive and osteoconductive properties. However, clinicians often seek alternatives due to several inherent limitations of autografts, such as availability, potential morbidity of the harvest site, and increased chair time.[1,3,8] The closest available alternative based on structure and congenital properties are allografts, which can circumvent some of the limitations associated with autografts.

Approach

Puros Particulate Allografts has become the bone allograft choice for many clinicians, as the proprietary Tutoplast® Tissue Sterilization Process which preserves the natural structure of the collagen matrix and bone-tissue integrity. In comparison to other alternative grafts, the osteoconductive scaffold of Puros Particulate Allografts provides a higher surface area for osteogenic progenitor cells to adhere, differentiate and form new vital bone tissues.* [9-11] Effective bone regeneration follows a general progression similar to the resorption profile of Puros Particulate Allografts thus, allowing for clinical stability of the recipient sites and predictable long-term survival of implants. Long-term clinical outcomes following the use of Puros Particulate Allografts were identified from recent publications of clinical studies. The data are summarized along with supportive clinical studies that attest to years of clinical experience in the use of Puros Particulate Allografts in procedures such as post-extractive ridge preservation, sinus lift, and peri-implantitis treatment.

Post-Extractive Sites

Grafting of a post-extractive site is a common approach to preserve alveolar ridge dimensions for implant placement. Baldi et al. (2019) showed clinical effectiveness of the Puros Cancellous Particulate Allograft in reconstruction of post-extractive atrophic sites before implant placement.[12] Puros Cancellous Particulate Allograft was placed with a resorbable pericardium membrane seven days after tooth extraction. After a 5-month healing period, samples of the 10 regenerated sites in nine patients were obtained for histological and histomorphometrical analysis before implant placement. Also, clinical data were analyzed from 10 implants at a 6-year follow-up period. The mean vertical bone augmentation was 4.1 mm and 3.35 mm in the lower jaw and maxilla, respectively. The mean horizontal bone augmentation in the lower jaw was 2.02 mm and 2.15 mm in the maxilla. Histological analysis showed intense bone metabolic activity with active osteoblasts and osteoid production in the recipient sites, including new vessel formation indicative of angiogenesis. None of the samples showed histological signs of inflammation and two resulted in complete replacement of Puros Particulate Allografts with newly formed bone. Histomorphometric analysis resulted in a mean total bone area of 60.01%, with 98.41% of that comprising mineralized mature bone tissue. At the 6-year follow-up, all implants were stable in function without any complications and the peri-implant bone resorption was minimal (0.14 mm mesial and 0.21 mm distal). Excellent outcomes were observed in terms of quantity and quality of bone regenerated in post-extractive sites where Puros Cancellous Particulate was used. As a result, dental implants placed in post-extractive sites were able to achieve long-term clinical performance at a 6-year follow-up period.

Sinus Lifts

The maxillary sinus floor region is often associated with thin and insufficient amount of bone for implant placement. Implant placement in such sites that have less than 3 mm of remaining crestal bone is challenging as it may result in a higher incidence of peri-implant bone resorption. Soardi et al. (2020) performed sinus lifting procedures to treat extremely atrophic maxillary sinuses (< 2 mm bone height).[13] These sinus lift procedures included the use of a mixture of Puros Particulate Allografts (20% cancellous and 80% cortical mixture) and a resorbable collagen membrane. The Puros Particulate Allografts mixture was inserted through the crestal access window of the sinus lift followed by primary closure with a resorbable collagen membrane. A 6- to 9-month healing period preceded the placement of 140 implants in 93 healed maxillary sites of 69 patients. A high implant survival rate (98%) with minimal complications were reported at the 5-year follow-up period. Moreover, a mean vertical bone height of 11.73 mm was successfully achieved by the use of Puros Particulate Allografts.

The mixture with Puros Cortical and Puros Cancellous Particulates allowed for a slower resorption rate to maintain adequate bone volume during new bone turnover in sites with severe bone atrophy.[13] A similar previous study reported successful long-term clinical stability of maxillary sinus floors regenerated with a mixture of Puros Particulate Allografts (50% cancellous and 50% cortical particulates).[14] The Puros Particulate Allografts mixture was inserted into 11 sinuses in seven patients through the lateral access window followed by a mean healing period of 8.1 months before placement of 25 implants. The regenerated bone sites were clinically stable and resulted in a 100% implant survival rate after an approximate 5-year mean follow-up. Radiographic analysis showed that all implants were surrounded by dense bone after a 4-month healing period and no measurable loss in bone volume occurred after an approximate 5-year mean follow-up period. Histological and histomorphometric analysis demonstrated that almost all residual materials were surrounded by bone, suggesting good integration of the grafting materials with the host bone. While cortical particulates with a slower resorption profile provided mechanical stability, increased resorption rate via cancellous particulates allowed for

new vital bone formation via earlier osteoclastic activities and faster revascularization. Therefore the above referenced studies show how a combination of Puros Cortical and Cancellous Particulate Allografts supported the patient's ability to regenerate bone resulting in long-term clinical stability. Further investigation is needed to determine the ideal cortical-cancellous particulate ratios for different surgical procedures.

Peri-implantitis Regenerative Treatments

The consensus report of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions defines peri-implantitis as a plaque-associated pathological condition occurring in tissues around dental implants that is characterized by inflammation in the peri-implant mucosa and subsequent progressive loss of supporting bone.[15] Various therapeutic approaches have been proposed for peri-implantitis treatment in attempts to decontaminate infected sites for restoration of implant function as well as aesthetics and some cases may involve bone regeneration via grafting materials.[16]

Solakoglu et al. (2019)[17] demonstrated a modified Cumulative Interceptive Supportive Therapy (CIST) for peri-implantitis that employed methods to reduce the surrounding inflammation followed by regenerative treatment. This therapy included the use of a mixture of a Puros Cancellous Particulate Allograft (70%) and autogenous bone (30%) as well as a resorbable pericardium membrane. The modified CIST option was chosen according to diagnostic criteria involving radiological assessment together with periodontal measures, which indicated bone loss, detachment, and/or probing depth (PD) and peri-implant inflammation or bleeding on probing (BOP). Sixty-four implants in 16 patients with advanced peri-implant bone loss were treated with a series of decontamination procedures followed by filling of the peri-implant bony defects with the Puros Particulate Allografts mixture. The grafted sites were then each covered with a pericardium membrane and clinical data were obtained after a 5-year follow-up period.

Before treatments, the mean crestal bone level was 4.72 mm, the mean PD was 6.48 mm and 34.84% of the sites presented BOP. Significant improvements were observed in all clinical and radiologic parameters after treatment (Figure 1). The mean depth of the crestal bone level was reduced to 0.95 mm (3.77 mm mean bone gain), the mean PD improved to 3.25 mm (3.23 mm mean reduction), and BOP was reduced to 14.79% of sites (20.05% mean reduction). The clinical measures (Table 1) and 100% implant survival rate at a 5-year follow-up period represent the long-term benefit of using Puros Particulate Allografts as part of the regenerative bone treatment within peri-implantitis sites.[17] The osteoconductive properties of the Puros Particulate Allograft may complement the autograft by allowing osteogenic progenitor cells from the autogenous bone to attach and differentiate on a biologically equivalent scaffold.[18] Another recent study reported successful clinical outcomes following regenerative treatment of peri-implantitis sites that included Puros Particulate Allograft without mixing with autogenous bone.[16] Clinical and radiographic assessments were obtained from 34 implants in 34 patients during a mean follow-up period of 50.62 months. Results consisted of 100% implants survival rate with 78% having a marginal peri-implant bone loss of less than 1.0 mm.[16]

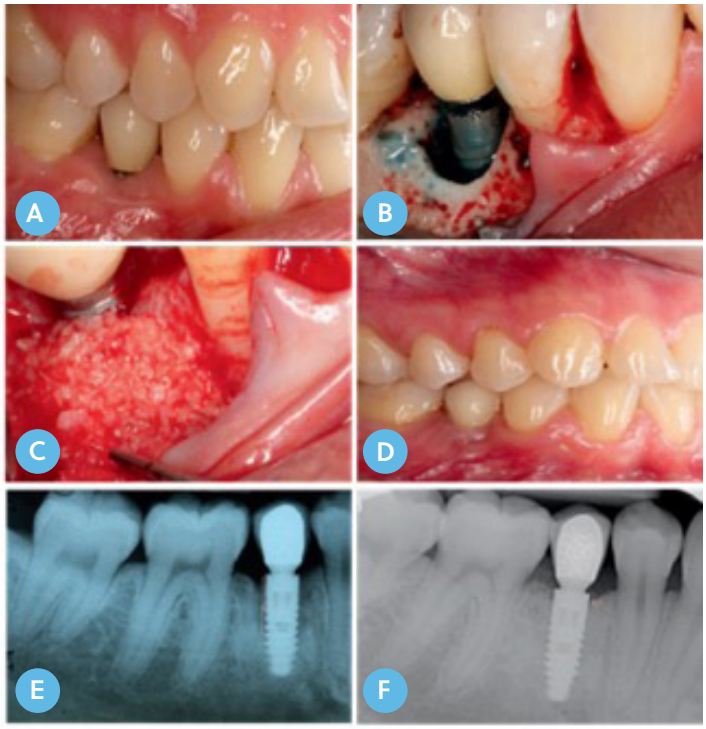

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Figure 1: A) Initial view of the diseased peri-implant area. B) Intraoperative view of the bone defect after surface decontamination procedures. C) Application of a mixture of autologous bone and the Puros Particulate Allograft. D) Post-treatment view after 5 years. E) Radiographic measurement of the peri-implant defect before treatment. F) Radiographic measurement of the peri-implant defect after treatment at the 5-year follow-up.

Table 1

Mean values of crestal bone level (CBL), bleeding on probing (BOP), and probing depth (PD) before therapy and after a mean follow-up of 36.1 months

Parameter	CBL Baseline, mm	CBL Follow-Up, mm	BOP Baseline, %	BOP Follow-Up, %	PD Baseline, mm	PD Follow-Up, mm
Mean	4.72	0.95	34.84	14.79	6.48	3.25
SD	0.90	0.70	18.44	8.50	1.82	0.44
Min	3.25	0.00	9.00	5.00	4.17	2.33
Max	6.50	2.50	70.00	35.00	10.50	4.00

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Rehabilitation of Failed Implant Sites

A case study which included the use of Puros Cancellous Particulate Allograft shows the rehabilitation of previously failed implants.[18] After removing the failing implants from a severe anterior maxillary defect in a female patient, successful vertical bone regeneration of approximately 10 mm was achieved using a mixture of Puros Particulate Allografts and autogenous bone in combination with a nonresorbable membrane. After a 9-month healing period, a satisfactory functional and aesthetic restoration was achieved. Also, stability of the regenerated bone and restored implants was maintained during the 14-year follow-up period.[18]

Conclusions

Predictable long-term clinical performance with excellent bone quantity and quality were achieved through various surgical procedures which included the use of Puros Particulate Allografts to fill bone voids in post-extractive ridge preservation, sinus lift, and peri-implantitis treatment. The various treatments represented a range from mild to severe bone defects and the use of different surgical techniques. The broad applicability of Puros Particulate Allografts was consistent with the ability to customize mixtures of the slower versus faster resorption rate of cortical and cancellous bone, respectively. As an alternative to the gold standard, procedures that used Puros Particulate Allografts resulted in excellent long-term outcomes in the presence or absence of an autograft. Therefore, Puros Particulate Allografts is not only a viable alternative to autografts but can facilitate the latter attributes in conditions where availability and morbidity of the harvest site are limiting factors.

References

1. McAllister, B. S. & Haghighat, K. Bone augmentation techniques. J Periodontol 78, 377-396, doi:10.1902/jop.2007.060048 (2007).
2. Mittal, Y., Jindal, G. & Garg, S. Bone manipulation procedures in dental implants. Indian J Dent 7, 86-94, doi:10.4103/0975-962X.184650 (2016).
3. Titsinides, S., Agrogiannis, G. & Karatzas, T. Bone grafting materials in dentoalveolar reconstruction: A comprehensive review. Jpn Dent Sci Rev 55, 26-32, doi:10.1016/j.jdsr.2018.09.003 (2019).
4. Sheikh, Z., Sima, C. & Glogauer, M. Bone Replacement Materials and Techniques Used for Achieving Vertical Alveolar Bone Augmentation. Materials 8, 2953-2993, https://doi.org/10.3390/ma8062953 (2015).
5. Henkel, J. et al. Bone Regeneration Based on Tissue Engineering Conceptions - A 21st Century Perspective. Bone Res 1, 216-248, doi:10.4248/BR201303002 (2013).
6. Rolvien, T., Barbeck, M., Wenisch, S., Amling, M. & Krause, M. Cellular Mechanisms Responsible for Success and Failure of Bone Substitute Materials. Int J Mol Sci 19, doi:10.3390/ijms19102893 (2018).
7. Tonelli P, Duvina M, Barbato L, et al. Bone regeneration in dentistry. Clin Cases Miner Bone Metab. 8(3):24-28. (2011).
8. Sakkas, A., Wilde, F., Heufelder, M., Winter, K. & Schramm, A. Autogenous bone grafts in oral implantology-is it still a"gold standard"? A consecutive review of 279 patients with 456 clinical procedures. Int J Implant Dent 3, 23, doi:10.1186/s40729-017-0084-4 (2017).
9. Park, S. J. et al. Effects of Allograft Surface Properties on Behavior of Osteogenic Cells. 97th General Session & Exhibition of the International Association for Dental Research Vancouver, BC, Canada (2019).
10. Rasch, A., Naujokat, H., Wang, F., Seekamp, A., Fuchs, S., Klüter, T. Evaluation of bone allograft processing methods: Impact on decellularization efficacy, biocompatibility and mesenchymal stem cell functionality. PLoS One. 2019;14(6):e0218404. doi:10.1371/journal.pone.0218404 (2019).
11. Seebach, C., Schultheiss, J., Wilhelm, K., Frank, J. & Henrich, D. Comparison of six bone-graft substitutes regarding to cell seeding efficiency, metabolism and growth behaviour of human mesenchymal stem cells (MSC) in vitro. Injury 41, 731-738, doi:10.1016/j.injury.2010.02.017 (2010).
12. Baldi, D., Pesce, P., Musante, B., Pera, F., Fulcheri, E., Romano, F., Menini, M., Radiological and Histomorphometric Outcomes of Homologous Bone Graft in Postextractive Implant Sites: A 6-Year Retrospective Analysis. Implant Dent. 28(5):472-477. doi: 10.1097/ID.0000000000000920. (2019).
13. Soardi, C. M., Soardi, B. & Wang, H. L. Crestal Window Sinus Lift and Its Long-Term Clinical Outcomes. Int J Periodontics Restorative Dent, doi:10.11607/prd.4292 (2020).
14. Annibali, S. et al. Human maxillary sinuses augmented with mineralized, solvent-dehydrated bone allograft: a longitudinal case series. Implant Dent 20, 445-454, doi:10.1097/ID.0b013e31823420a4 (2011).
15. Berglundh, T., Armitage, G., Araujo, M.G., Avila-Ortiz, G., Blanco, J., Camargo, P.M., Chen, S,, Cochran, D., Derks, J., Figuero, E., Hämmerle, C.H.F., Heitz-Mayfield, L.J.A., Huynh-Ba, G., Iacono, V., Koo, K.T., Lambert, F., McCauley, L., Quirynen, M., Renvert, S., Salvi, G.E., Schwarz, F., Tarnow, D., Tomasi, C., Wang, H.L., Zitzmann, N. Peri-implant diseases and conditions: Consensus report of workgroup 4 of the 2017 World Workshop on the Classification of Periodontal and Peri-Implant Diseases and Conditions. J Periodontol. 89 Suppl 1:S313-S318. doi: 10.1002/JPER.17-0739. PMID: 29926955. (2018).
16. La Monaca, G., Pranno, N., Annibali, S., Cristalli, M. P. & Polimeni, A. Clinical and radiographic outcomes of a surgical reconstructive approach in the treatment of peri-implantitis lesions: A 5-year prospective case series. Clin Oral Implants Res 29, 1025-1037, doi:10.1111/clr.13369 (2018).
17. Solakoglu, O. & Filippi, A. Regenerative Therapy of Peri-Implantitis: Clinical and Radiologic Documentation of 16 Consecutive Patients With a Mean Follow-Up of 3 Years. J Oral Implantol 45, 145-153, doi:10.1563/aaid-joi-D-18-00168 (2019).
18. La Monaca, G., Pranno, N., Pompa, G., Annibali, S., Vozza, I., Cristalli, M.P. Vertical Guided Bone Regeneration with Mineralized Cancellous Bone Allograft in a Severe Anterior Maxillary Defect: A Clinical Report with 14-Year Follow-Up. Case Rep Dent. 2019:6725351. doi:10.1155/2019/6725351 (2019).

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