

Evaluation of the efficacy of composite graft (synthetic nanocrystalline hydroxyapatite with collagen – nanograft-C[®]) in the treatment of intrabony defects –A comparative study.

¹Dr. Chandni Gupta, Senior Lecturer, Department of Periodontics, IDST Dental College, Ghaziabad.

²Dr. Vaibhav Joshi, Reader, Department of Periodontics and Oral Implantology, Santosh Dental College and Hospitals, Ghaziabad.

Corresponding author: Dr. Vaibhav Joshi, Reader, Department of Periodontics and Oral Implantology, Santosh Dental College and Hospitals, Ghaziabad.

Citation of this Article: Dr. Chandni Gupta , Dr. Vaibhav Joshi, “A comprehensive review and a proposed classification system for complications encountered with All-On-4[®] dental implant procedure”, IJDSIR- May - 2020, Vol. – 3, Issue -3, P. No. 595 – 600.

Copyright: © 2020, Dr. Vaibhav Joshi, et al. This is an open access journal and article distributed under the terms of the creative commons attribution noncommercial License. Which allows others to remix, tweak, and build upon the work non commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Abstract

Aim: Surgical procedure for periodontitis treatment include open flap debridement and osseous surgery and it could be combined with bone grafting and guided tissue regeneration. The aim of the present study was to clinically and radiographically evaluate the efficacy of composite bone graft, (synthetic nanocrystalline hydroxyapatite with collagen – Nanograft-C[®]) in comparison with open flap debridement alone in the treatment of human intrabony defects.

Materials & Methods: Ten patients aged between 30-60 years with a total of 20 defects in systemically healthy subjects diagnosed with moderate to advanced periodontitis with bilateral clinical and radiographic evidence of angular defects were recruited for the study. Patients selected were divided into 2 groups randomly and treated according to split mouth design. Clinical and

radiographic parameters were recorded at baseline, 3 and 6 months.

Result: The results of the present study demonstrated reduction in the gingival index, plaque index and gingival bleeding index scores along with reduction in PPD, gain in RAL and radiographic area of the defect fill at the end of 3 and 6 months in both the groups (test and control). However, there was a statistically significant difference in the scores when compared between the test and the control groups, from baseline to 6 months, showing increased radiographic resolution of intrabony defects in test group.

Conclusion: An additional benefit with the use of Nanograft-C[®] composite bone graft in intrabony defects was observed and was statistically significant when compared to Open flap debridement alone.

Keywords: intrabony defect, composite graft, nanocrystalline hydroxyapatite, collagen, open flap debridement.

Introduction

The current concept on the etiology of periodontitis includes: a susceptible host, the presence of pathogenic species and the absence or small proportion of 'beneficial bacteria'. In general, small amount of bacterial plaque could be controlled by the body's defense mechanisms without destruction but when the balance between bacterial load and host response is disturbed, periodontal destruction may occur.¹ Certain cell populations within periodontal tissues possess the ability to induce regeneration, provided they have the opportunity to populate the wound or defect.² Various materials such as autogenous grafts, allografts, xenografts, alloplasts have been aimed in the treatment of intrabony defect. Albeit true or false, assuming that their application would potentially manipulate the biological response into a regenerative rather than a predominantly reparative pattern has rendered the use of bone replacement grafts an attractive choice in certain periodontal defect configurations.³ Among the various bone grafts used in the regeneration therapy of intrabony defects, autogenous bone graft was most popularly used for grafting, but the availability of the donor site and the limited quantity of the material caused limitations, therefore alloplastic materials were introduced. These materials are synthetic, biocompatible, inorganic bone graft substitutes which represent a possible alternative for the treatment of intrabony defects. Advantages of these materials are easier availability, eliminating the need of a donor site, and carry no risk for disease transmission.^{4,5}

Collagen, as a natural polymer, is increasingly being used for tissue engineering and repair. Some advantageous properties of collagen over other materials include haemostatic function, allowing an early wound stabilization, chemotactic properties to attract fibroblasts and semipermeability, facilitating nutrient transfer.^{6,7}

However, its mechanical properties are relatively low (E~100 MPa) in comparison to bone [E ~2 50GPa]⁸ and it is therefore highly crosslinked or found in composites, such as collagen-glycoaminoglycans for skin regeneration, or collagen hydroxyapatite for bone remodeling.⁹

Composite grafts can be defined as any combination of materials that includes both an osteoconductive matrix and an osteogenic or osteoinductive material. Such graft combines an osteoconductive matrix with bioactive agents that provide osteoinductive and osteogenic properties, potentially replicating autograft functionality. Hydroxyapatite and type I collagen composite having similar nanostructure and composition could give promising results in periodontal regeneration.⁸ Hence, the purpose of the present study was to clinically and radiographically evaluate the efficacy of composite graft (synthetic nanocrystalline hydroxyapatite with type I collagen – Nanograft-C[®]) in comparison with open flap debridement (OFD) in the treatment of intrabony defects.

Materials & method

Ten patients aged between 30-60 years with a total of 20 defects in systemically healthy patients diagnosed with moderate to advanced periodontitis with bilateral clinical and radiographic evidence of angular defects were recruited for the study, and divided into 2 groups randomly and treated according to split mouth design. 10 Intrabony defects were subjected to open flap debridement only (control group). Another 10 Intrabony defects were subjected to open flap debridement with intrabony defect filled with **Nanograft-C[®]**, composite graft (test group). Patients presenting with chronic periodontitis (moderate to advanced periodontitis) with at least two periodontal osseous defects with bilateral vertical intrabony component in molars, patient free of any systemic disease, patient's age between 30 to 60 years and patients having probing depth of ≥ 5 mm were recruited for the study.

Patients with compromised immune system, patient with any history of recent periodontal surgery in past 6 months, pregnant and lactating patients, smoking, history of antibiotic treatment since past 6 months and uncooperative patients were excluded. Patients selected on the basis of above criteria were then explained about the treatment procedure and the associated risks and benefits. Written consent form was duly signed by the patients. Four weeks following phase I therapy, periodontal re-evaluation was performed to confirm the suitability of the sites for the study. Clinical parameters recorded were : Gingival Index (GI), Plaque Index (PI), Gingival Bleeding Index (GBI), Probing pocket depth (PPD) (in mm) measured by UNC-15 periodontal probe using gingival margin as a reference, Relative attachment level (RAL) (in mm) was recorded using acrylic stent on study cast for each patient and trimmed to height of contour of the teeth and one vertical groove prepared to reproduce the probe angulation and position and Digital radiography to assess the area of the defect. All parameters were recorded post operatively at 3 months and 6 months.

Case management

Local anesthesia (2% lidocaine, epinephrine 1: 100,000) was injected in the site of flap surgery. Crevicular incision with blade no. 12 and an interdental incision with blade no. 15/11 was given and a mucoperiosteal flap was raised. The area was degranulated, curetted and irrigation was done with normal saline solution. Defects were treated by open flap debridement only in control group whereas in test group defects were isolated and pre-suturing was done prior to the placement of graft. After isolation, bone graft **Nanograft - C[®]** (composite graft; synthetic nanocrystalline hydroxyapatite with collagen, 1 mm cube) was wetted with normal saline and placed in small increments and condensed until the defect was filled. The sutures were then tightened over the defect sites and also placed in the

adjacent sites so as to ensure complete approximation of the flaps. Interrupted sutures were given. Following this a non-eugenol periodontal pack was applied over the site. Postoperative instructions were given, medications (500 mg amoxicillin, three times daily for 5 days as antibiotic coverage, and 400 mg ibuprofen, twice daily for 3 days as an anti-inflammatory drug) were prescribed, and the patients were instructed to rinse with chlorhexidine gluconate (0.2%) twice daily for 1 minute for 2 weeks. Sutures were removed after 10 days. Patients were recalled after 1 month for re-evaluation of oral hygiene and oral prophylaxis. The clinical and radiographic parameters were recorded at baseline, and post-operatively at 3 and 6 months respectively (Fig 1). Also, patients were reinforced with oral hygiene instructions at every visit. Data were expressed as the mean – SD. Differences in the clinical parameters at baseline, 3 months, and 6 months were analysed with the paired Student ‘t’ test for intragroup comparisons and unpaired Student ‘t’ test for intergroup comparisons. p-value < 0.05 indicated significant difference between the group means at 5% level of significance

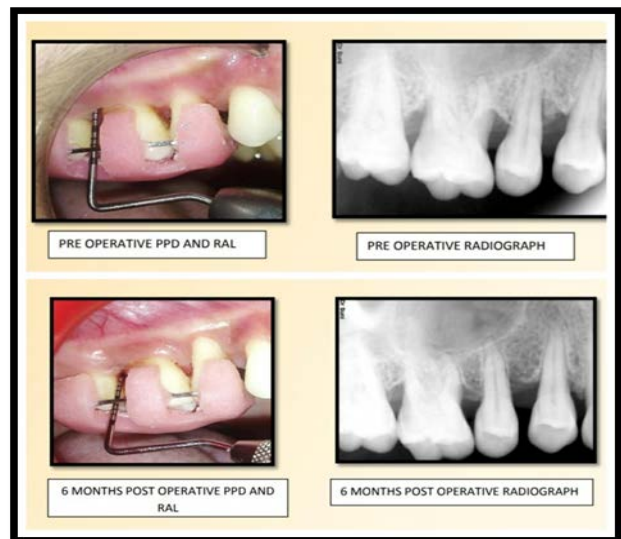


Fig.1: Clinical and radiographic parameters at baseline and 6 months

Result

On comparison between the control and test groups at 6 months, difference was statistically not significant ($p < 0.05$) in GI, PI and GBI. However, the improvement in scores from baseline to 6 months showed significant improvement in both test and control groups which could be attributed to the rigorous oral hygiene maintenance regime, regular follow-up visits and reinforcement of oral hygiene instructions throughout the study period. At the end of 6 months, a statistically significant difference was found in PPD, RAL and radiographic area of the defect from baseline to 3 and 6 months in both groups. However, the mean difference in PPD values between control and test group at the end of 3 and 6 months was 1.50 and 1.90, respectively, which was statistically significant ($P < 0.05$). Statistically significant differences were found in RAL between control and test group at 3 months ($P = 0.02$), and 6 months ($P = 0.04$). At the 6-month re-evaluation, the reduction in the radiolucency of the area of the defect from baseline to 6 months postoperatively was 93% for test group and 73% for control group (Fig-2). Therefore, there was a significant difference between the two groups in intrabony defect fill values at the end of 6 months.

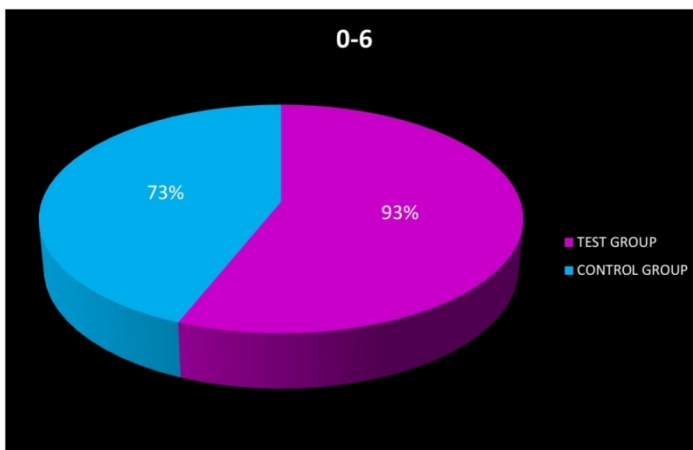


Fig.2: The circular/pie diagram of % improvement for radio graphic assessment from base line – 3 months in test & control group

Discussion

Periodontal surgery benefits the patient in terms of pocket reduction and microbial shift, especially in cases of intrabony defects and furcation involvement.¹⁰ A wide range of procedures have been proposed for the treatment of periodontal disease to promote bone regeneration over the last decades. Both collagen type I and hydroxyapatite enhance osteoblast differentiation, but combined together, they have shown to accelerate osteogenesis. A composite matrix when embedded with human-like osteoblast cells, showed better osteoconductive properties compared to monolithic HA and produced calcification of identical bone matrix.¹¹

In the present study, the mean reduction of gingival index scores in the test group was 2.42 ± 0.452 at baseline to 0.30 ± 0.106 at 6 months. While in the control group, the mean gingival index observed at baseline was 2.42 ± 0.452 which was decreased to 0.35 ± 0.162 at 6 months. Similarly, mean scores of plaque index in the test group at baseline was 2.15 ± 0.39 which was decreased to 0.60 ± 0.24 at 6 months while in the control group, the mean plaque index observed at baseline was 2.15 ± 0.39 which was decreased to 0.73 ± 0.29 at 6 months. Also, the mean gingival bleeding index scores in the test group at baseline was $79.60\% \pm 19.02\%$ which was decreased to $4.50\% \pm 1.29\%$ at 6 months and in the control group, the observations recorded depict the reduction in gingival bleeding index scores at baseline and 6 months as $79.60\% \pm 19.02\%$ and $5.63\% \pm 2.22\%$ respectively. A statistically significant difference ($p < 0.05$) was observed between different time intervals (e.g. 0-3 months, 3-6 months & 0-6 months) in both test and control groups while no significant difference statistically ($p > 0.05$) was observed at baseline, 3 months and 6 months between test & control group. These results were in accordance to the previous studies conducted by Mistry S et al.¹²

Presence of periodontal pocket marks the active sign of periodontal destruction therefore its reduction following surgery is a key factor for successful periodontal therapy. The results of the present study demonstrated that grafting and OFD treatment modalities provide clinical and statistical significant improvement in PPD measurements compared to baseline value where the test group exhibited additional benefit in terms of PPD reduction compared to OFD group. These results were in accordance with the results of the study done by Cortellini et al¹³ and Aichelmann-Reidy ME et al.¹⁴ Digitized imaging has become an important tool in determining the subtle alterations seen on images of bone defects, not only because of the magnification of the image on the screen but also due to the possibility of adjusting its brilliance and contrast.¹⁵ The results of the radiographic area of the defect fill in the present study confirmed preliminary findings described by Minabe M et al (1998) as implantation of an HAP-collagen complex promoted cementogenesis of the demineralized root surface and could establish a stronger interdigitation between the root surface and the gingival connective tissue fibers.¹⁶ Results of the present study demonstrated clinical and radiographic improvement in the composite bone graft group superior to that of the open flap debridement group. When comparing ceramic scaffolds and ceramic composite scaffolds, it was shown that Col-HA composites performed well compared to single HA or TCP scaffolds (Wang et al., 2003).¹¹ Composite synthetic grafts offer an alternative that could potentially unite the three essential bone-forming properties in more controlled and effective combinations without the disadvantages found with autograft. Till now, numerous animal and human studies have reported the use of ceramic, collagen and their combination in the intrabony defects. To the best of our knowledge, no human study was found in the

course of the current study which evaluated the use of Nanograf - C[®] (synthetic nanocrystalline hydroxyapatite with collagen; composite graft) in the treatment of periodontal defects. Therefore, further studies using more subjects and a longer post treatment observation interval may be needed to confirm the stability of clinical outcome and also clarify the benefits of the new synthetic composite bone grating material.

Practical implications

1. Composite synthetic grafts offer an alternative that could potentially unite the three essential bone-forming properties in more controlled and effective combinations without the disadvantages found with autograft.
2. Also, the addition of collagen to a ceramic structure could provide many advantages to surgical applications: shape control, spatial adaptation, increased particle and defect wall adhesion and the capability to favour clot formation and stabilization.

What is unique - To the best of our knowledge, no human study was found in the course of the current study which evaluated the use of Nanograf - C[®] (synthetic nanocrystalline hydroxyapatite with collagen; composite graft) in the treatment of periodontal defects.

References

1. Newman MG, Takei HH, Klokkevold PR, Carranza FA. Classification of diseases and conditions affecting the periodontium. Clinical Periodontology. 12th Edition, Saunders; Elsevier India Pvt Ltd; 2014: p 150-63.
2. Sheikh, Z., Qureshi, J., Alshahrani, A.M. et al. Collagen based barrier membranes for periodontal guided bone regeneration applications. *Odontology* 2017;105:1-12.
3. Shukla S, Chug A, Mahesh L, Singh S, Singh K. Optimal management of intrabony defects: current insights. *Clin Cosmet Investig Dent*. 2019;11:19-25.

4. Rita Singh R, Mahesh L, Shukla S, Mahesh L. Infections resulting from bone grafting biomaterials. *International Journal of Oral Implantology & Clinical Research*. 2013;4:68–71.
5. Wahl DA, Czernuszka JT. Collagen-hydroxyapatite composites for hard tissue repair. *Eur Cell Mater* 2006;11:43-56.
6. Yaffe A, Ehrlich J, Shoshan S. Restoration of periodontal attachment employing enriched collagen solution in the dog. *J Periodontol* 1984;55:623-28.
7. Clarke KI, Graves SE, Wong ATC, Triffitt JT, Francis MJO, Czernuszka JT. Investigation into the formation and mechanical-properties of a bioactive material based on collagen and calcium-phosphate. *J Mater Sci Mater Med* 1993;4:107-10.
8. Graziani F, Karapetsa D, Mardas N, Leow N, Donos N. Surgical treatment of the residual periodontal pocket. *Periodontol 2000*. 2018;76(1):150–163.
9. Giannoudis PV, Dinopoulos H, Tsiridis E. Bone substitute: An update. *Int J Care Injure* 2005;36(3):20-27.
10. Kaushick BT, Jayakumar ND, Padmalatha O, Varghese S. Treatment of human periodontal infrabony defects with hydroxyapatite+ β tricalcium phosphate bone graft alone and in combination with platelet rich plasma: A randomized clinical trial. *Indian J Dent Res* 2011;22:505-10.
11. Wang RZ, Cui FZ, Lu HB, Wen HB, Ma CL, Li HD. Synthesis of nanophase hydroxyapatite collagen composite. *J Mater Sci Lett* 1995;14:490-92.
12. Mistry S, Kundu D, Datta S, Basu D. Effects of bioactive glass, hydroxyapatite and bioactive glass - hydroxyapatite composite graft particles in the treatment of infrabony defects. *J Indian Soc Periodontol* 2012;16:241-46
13. Cortellini P, Tonetti MS. Clinical concepts for regenerative therapy in intrabony defects. *Periodontol* 2000. 2015;68(1):282–307.
14. Aichelmann-Reidy ME, Reynolds MA. Predictability of clinical outcomes following regenerative therapy in intrabony defects. *J Periodontol* 2008;79:387-93.
15. Gomes-Filho IS, Sarmento VA, de Castro M, da Costa NP, da Cruz SS, Trindade SC et al. Radiographic features of periodontal bone defects: evaluation of digitized images. *Dentomaxillofacial Radiol* 2007;36:256-62.
16. Minabe M, Sugaya A, Satou H, Tamura T, Ogawa Y, Hori T et al. Histological study of the hydroxyapatite-collagen complex implants in periodontal osseous defects in dogs. *J Periodontol* 1988;59:671-78.