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EVALUATION OF EFFICACY OF CHITOSAN BASED HAEMOSTATIC AGENT FOR ACHIEVING HAEMOSTASIS IN VARIOUS PERIODONTAL SURGERIES -A PILOT STUDY.

Periodontology

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ABSTRACT

Periodontal surgical procedures like excision of overgrowth and harvesting graft from palate in free gingival graft procedures can cause excessive intraoperative bleeding. Uncontrolled bleeding obscures the visibility of the site for optimal debridement thus increasing the risk for recurrence. It also affects healing of the site, extends the duration of surgery and increases stress for the patient. Aim: To evaluate efficacy of a chitosan based hemostatic agent in achieving hemostasis in various periodontal surgeries. Material and Method: 13 patients indicated for periodontal surgery were selected. Intraoperative bleeding was controlled with chitosan sponge. Duration of hemostasis was recorded. Each patient was evaluated for all the parameters at 24 hrs. and on 7th day post-surgery. Results: The surgical sites treated with chitosan sponge showed mean hemostasis time of 3min 04 +/-15 seconds. Soft tissue healing showed a mean score of 3.61 +/-3 with no patient discomfort. Conclusions: Chitosan sponge reduces intra-operative bleeding time, thus emerging as a novel hemostat.

KEYWORDS

Chitosan, Hemostasis, Periodontal surgeries

INTRODUCTION

Periodontal surgeries are invasive dental procedures that restores what is lost structurally and functionally. These include wide range of procedures like excision of gingival overgrowth, mucogingival surgeries for inadequate width of attached gingiva and surgical debridement. A clinician may witness excessive bleeding during these surgeries. Intraoperative bleeding if not controlled, can lead to serious complications and may have an adverse effect on the surgical outcome. Uncontrolled bleeding obscures the visibility of the site for proper debridement thus increasing the risk for recurrence. It also affects healing of the site, extends the duration of surgery thus leading to increased stress for the patient.

Hemostasis is routinely achieved by application of gauze pieces with adequate pressure until the bleeding stops [1]. However, this conventional method requires a considerable amount of time for complete stoppage of bleeding. An ideal hemostatic agent should be safe, well tolerated, sterile, available in customized form, bacteriostatic and convenient to use [1].

Various studies have evaluated effectiveness of hemostatic agent in oral surgical and periodontal procedures. Olson et al, studied polylactic acid, absorbable gelatin sponge, oxy-generated regenerated cellulose in healing extraction sockets in dogs and concluded that the materials were well tolerated but did not show any osseous regeneration [2]. EK Pang evaluated effect on chitosan on periodontal ligament fibroblasts and on bone formation in rat calvarial defects [3]. Though chitosan has been used as an anti-bacterial agent in various regenerative surgeries, their role as a hemostatic material is not well established.

Hemostatic agents vary in cost and effectiveness [4,5]. However as no single material suffices all these properties, this study aims to clinically assess a new material for achieving hemostasis. It is of utmost importance to achieve hemostasis in shortest duration of time for successful completion of a surgical procedure to prevent occurrence of any untoward event. Lastly no study has evaluated chitosan sponge in periodontal surgeries. This pilot study was proposed to test the hemostatic effect of chitosan sponge in periodontal surgical site. The primary objective of the study was to evaluate time required for hemostasis, patient comfort and wound healing.

SUBJECTS AND METHODS:

The prospective clinical study included 13 patients, according to inclusion and exclusion criteria. All the information about the study were told to the patients in his/her language that he/she understand, for recording informed consent. The patients included in the study were in the age group of 25 to 65 years with no underlying systemic disease and with appropriate indications for surgeries which included aberrant frenum, gingival overgrowth and inadequate width of attached gingiva. Any patient with underlying systemic diseases, allergic to seafoods, pregnant and lactating females were excluded.

On the initial visit, a detailed case history was taken for all patients, followed by clinical examination. Each patient underwent an assessment of general medical status and hematological investigations including hemoglobin count, bleeding time, clotting time, HbsAg and Elisa. Axiostat® hemostatic agent of N-22 size (sponsored by Axiostat BioSolutions, Gujarat) used in the study (Figure 1A). The rest of the armamentarium included surgical instruments, saline, syringe and a stop watch.

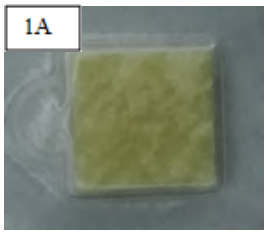

Figure 1A: Chitosan hemostatic sponge2BFigure 1B: Pre-operative. Gingival overgrowth seen in relation to 33 and 34.

All the periodontal surgeries were executed under 2% local anesthesia. Chitosan sponge was immediately placed after bleeding from surgical site was evident clinically (Figure 1B, 2A & 2B). A gentle pressure was given to the site at the time of bleeding until clinically no bleeding was seen. In cases where the surgical site resulted in excessive bleeding, blood-soaked sponge was replaced with a new sponge. The sponge was removed when complete hemostasis was achieved (Figure 3A). Time was calculated from the moment the sponge was placed and until no bleeding was visible clinically with the help of a stop watch. On arrest of bleeding, the sponge was irrigated with saline and removed with a tweezer. Surgery was completed by giving interrupted sutures. (Figure 3B)

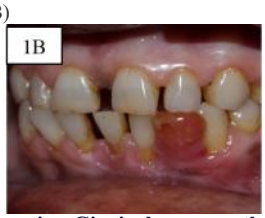

Figure 1B: Pre-operative. Gingival overgrowth seen in relation to 33 and 34.

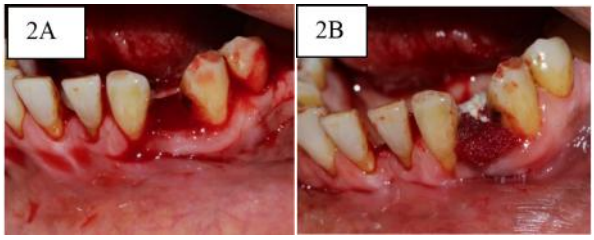

Figure 2A: Excision of overgrowth and bleeding from surgical site seen.

Figure 2B: Chitosan sponge placed in the excision site.

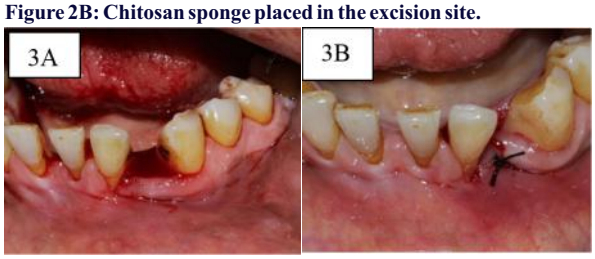

Figure 3A: Hemostasis achieved with clean surgical site
Figure 3B: Interrupted Sutures given.

Figure 4: Post-operative after 7 days.

Patient comfort was assessed, immediately after surgery was completed, by questionnaire method which included following questions: Did the material result in any discomfort. Whether the material was palliative. Whether it resulted in any kind of irritation. Patients were recalled after 24 hours and 7 days for evaluation of soft-tissues and for record of any untoward event. (Figure 4)

Wound healing was assessed by soft tissue healing index by Landry et al [6]. It assessed tissue colour, bleeding on palpation, granulation tissue, incision margin, suppuration.

TABLE 1 Healing index by Landry, Turnbull and Howley [6].

Healing index	Tissue color	Bleeding on palpation	Granulation tissue	Incision margin	Suppuration
1 - Very Poor: 2 or more signs are present	≥ 50% of red gingiva	yes	yes	not epithelialized, with loss of epithelium beyond incision margin	yes
2 - Poor	≥ 50% of red gingiva	yes	yes	not epithelialized, with exposed connective tissue	no
3 - Good	25 - 50% of red gingiva	no	no	no exposed connective tissue	no
4 - Very Good	< 25% of red gingiva	no	no	no exposed connective tissue	no
5 - Excellent	all pink tissues	no	no	no exposed connective tissue	no

RESULTS:

Out of 13 patients, 9 patients underwent surgical excision, 3 were treated with free gingival graft procedure and 1 frenectomy was performed. The parameters evaluated were time taken by the chitosan sponge for hemostasis, patient comfort and effect on wound healing.

Mean time recorded for all the patients was 3.04 +/15 seconds. Further, mean time recorded was 2.79 mins for excisional procedure, 4.13 mins for free gingival graft procedures and 2 mins for frenectomy. Overall the minimum time recorded was 1.30 mins and maximum time required for hemostasis was 4.30 mins.

Questionnaire asked immediately after surgery yielded a negative response, which implied that the chitosan product did not cause any discomfort or irritation when applied.

Wound healing assessed with soft tissue healing index given by Landry et al, showed 25-50% of the patients with the reddish gingiva, no bleeding on palpation and no granulation tissue. The incision margin was epithelialized with no exposure of connective tissue. And suppuration was not present. The mean soft tissue healing score for all the surgeries was 3.61. However wound healing score showed a mean of 3.5 for excisional procedure, 4 for free gingival graft, and 3 for frenectomy.

TABLE 2 Data showing Mean values of parameters recorded.

Procedure performed	No of patients	Mean hemostasis time	Wound healing (mean score).
1] Excision	9	2.79 mins	3.5
2] Free gingival graft	3	4.13 mins	4
3]Frenectomy	1	2 mins	3

DISCUSSION:

Chitosan as a hemostatic agent has not been evaluated in periodontal surgeries so far. So, this pilot study was an attempt to establish its efficacy and performance in various periodontal surgeries. FDA approved Chitosan dressing is available in various sizes, thus facilitating its use in customized form in surgeries.

Chitosan is a polycationic polymer containing 5000 glucosamine units [7,8]. It is obtained from shrimps, crab shell chitin by alkaline deacetylation [9,10]. It has been evaluated in periodontal surgeries as scaffold for regenerative material, antibacterial and for release of growth factors [11]. Chitosan sponge was evaluated in oral surgeries as a hemostatic agent [12]. Sharma et al investigated it's use in achieving hemostasis and healing of extraction wounds in patients on oral antiplatelet drugs. And concluded that, arrest of bleeding was seen in a mean time of 1 min 13 seconds compared to 14 mins 1 sec in control group with minimal postoperative pain and better healing [13].

A similar study was carried out by Malmquist J P et al where HemCon dental dressing containing chitosan was evaluated in patients on anticoagulant therapy for extraction site wounds. Hemostasis was achieved in less than a minute than in the control site with 9.53 minutes. The study also assessed healing, pain scores and alveolar osteitis. Improved healing with no negative sequelae was seen. The pain scores and the incidence of alveolar osteitis was less in Haemcon group [14].

Chitosan acts as a scaffold for RBCs to bind and aggregate under electrostatic attraction. Chitosan being positively charged attracts negatively charged platelets leading to platelet adhesion and aggregation [15]. It's hemostatic action is not dependent on the clotting cascade, but it acts as a scaffold and provides primary seal, allowing the body to initiate its coagulation pathway effectively [16].

In this study, the mean hemostasis time achieved was in the range of 3 to 4 mins. Individually mean hemostasis time for free gingival graft surgeries was 4.13 minutes which is far less than the mean time of 9.90 mins as recorded by conventional method in a study by Jeffery et al [17]. Thus, the early hemostasis property could be attributed to its cell adhesion properties shown by Cunha-Reis et al wherein, the effect of porosity and diameter of fibers on cell adhesion and degradation of chitosan scaffolds was demonstrated [18].

The soft tissue healing scores obtained for the study showed an average of score 3 to 4 on 7th day indicating faster wound healing. Particularly in soft tissue procedures, after harvesting of the graft, approximately 2 to 4 weeks are required for open wound to heal, thus causing discomfort to the patient in healing period [19,20]. However, the soft tissue healing scores obtained for free gingival graft procedures showed an average of score 4 on 7th day itself, thus implying faster and better wound healing. Also the wound site was epithelialized with no granulation tissue or connective tissue exposure.

The wound healing property of chitosan is attributed to release of growth factors from platelets and the differentiation of osteoprogenitor cells, promoting bone formation [21,22].

Chitosan provides a barrier against wide range of bacterias which was also stated as the reason for superior healing in sites treated with chitosan than that in the control group [22,23].

The handling of the material was moderately easy. It did not cause any

irritation or unpleasant taste to the subjects. Postoperative records did not show any cases of allergy. There was only one excisional surgery recorded where hemostasis time exceeded beyond the mean time obtained for the study. This may be owing to factors like excessive inflammation, poor oral hygiene and presence of habits like chronic smoking.

However, the study has to be extended for larger number of sample and its application should be evaluated separately for each category of the surgery, so as to reduce the bias obtained by unequal size of wound. Also, the findings of the study should be established as statistically significant by comparing it with a control site. Further comparisons with various other hemostatic material is needed to assess its efficacy over others.

CONCLUSION:

Chitosan sponge proved effective in immediate control of bleeding and providing a clean field for execution of surgery. Considering chitosan's role in platelet adhesion, aggregation and as an antimicrobial agent, Chitosan sponge will prove to be a promising material in achieving hemostasis, preventing infections and thus aiding in wound healing.

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REFERENCES:

[1] Newman, Michael G., Henry H. Takei, and Fermin A. Carranza. 2002. Carranza's clinical periodontology. Philadelphia: W.B. Saunders Co.
[2] Olson RA, Roberts DL, Osbon DB. A comparative study of polylactic acid, Gel foam and surgical in healing extraction sites. Oral Surg Oral Med Oral Pathol.1982;53:441-449
[3] Pang EK, Paik JW, Kim SK, Jung UW, Kim CS, Cho KS, et al. Effects of Chitosan On human periodontal ligament fibroblasts invitro and on bone formation in rat calvarial defects. J periodontol.2005;76(9):1526-33.
[4] Blinder D, Manor Y, Martinowitz U et al. Dental extractions in patients maintained on continued oral anticoagulant: comparison of local hemostatic modalities. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1999; 88:137.
[5] Valle AD, Sammartino G, et al. prevention of postoperative bleeding in anticoagulated patients undergoing oral surgery: use of platelet rich plasma gel. J Oral Maxillofac Surg. 2003;61:1275.
[6] Landry RG, Turnbull RS, Howley T. Effectiveness of benzydiamine HCL in the treatment of periodontal post-surgical patients. Res clini Forums. 1988;10:105–18
[7] Muzzarelli RAA. Biochemical significance of exogenous chitins and chitosan in animals and patients. Carbohydr Polym. 1993;20:7–16.
[8] Goosen M.F.A. 1997. Applications of chitin and chitosan. Lancaster, PA Technomic Publishing Co.
[9] Kumar R, Muzzarelli R, Muzzarelli C, et al. Chitosan chemistry and pharmaceutical perspectives. Chem Rev.2004;104:6017
[10] Liu XF, Guan YL, Yang DZ, Li Z, Yao KD. Antibacterial action of chitosan and carboxymethylated chitosan. J Appl. Polym. Sci.2001;79(7):1324.
[11] Shin SY, Park HM, Kim KH, Lee MH, Choi YS, Park YJ. Biological evaluation of chitosan nanofiber membrane for guided bone regeneration. J Periodontol 2005; 76:1778-1784.
[12] Sinha N, Mazumdar A, Mitra J, Sinha G, Baunthiyal S, Baunthiyal S. Chitosan based Axiostat Dental Dressing following Extraction in Cardiac Patients under Antiplatelet Therapy. Int J Oral Health Med Res 2017;3(5):65-67.
[13] Sharma s, Kale TP, Balihallimath LJ, Motimath A. Evaluating Effectiveness of Axiostat Hemostatic Material in achieving Hemostasis and Healing of Extraction Wounds in Patients on Oral Antiplatelet Drugs. The Journal of Contemporary Dental Practice, September 2017;18(9):802-806.
[14] Malmquist JP, Clemens SC, Oien HJ, Wilson SL. Hemostasis of oral surgery wounds with HaemCon dental dressing. J Oral Maxillofac Surg 2008; 66:1177-1183.
[15] Savage NW, Daly CG. Gingival enlargements and localized gingival overgrowths. Australian Dental Journal 2010;55:(1 Suppl): 55–60.
[16] Chou TC, FU E, Wu CJ, Yeh JH. Chitosan enhances platelet adhesion and aggregation. Biochem Biophys Res Commun. 2003;302(3):480-3.
[17] Roosmann JA, Rees TD: A comparative evaluation of hemostatic agents in management of soft tissue graft donor site bleeding. J periodontal, 1999;70:1369-1375.
[18] Cunha- Reis C, Tuzlakoglu K, Baas E, et al: influence of porosity and fiber diameter on degradation of chitosan fiber-mesh scaffolds and cell adhesion. J Master Sci Mater Med 2007;18:195.
[19] Farnoush A. Techniques for the protection and coverage of the donor sites in free soft tissue grafts. J Periodontol. 1978;49(8):403-5.
[20] Griffin TJ, Cheung WS, Zavras AI, Damoulis PD. Postoperative complications following gingival augmentation procedures. J Periodontol.2006;77(12):2070-9.
[21] Shen E-C. Chou T-C, Gau C-H, et al. Releasing growth factors from activated human platelets after chitosan stimulation: A possible biomaterial for platelet -rich plasma preparation. Clin Oral Implants Res. 2006; 17:572
[22] Klokkevold PR, Vandemark L, Kenney EB, Bernard GW. Osteogenesis enhanced by chitosan (poly- N- acetyl glucosaminoglycan) in vitro. J periodontal 1996; 67(11):1170-1175.
[23] Burkatovskaya M, Tegos GP, Swietlik E, Demidova TN, P Castano A, Hamblin MR. Use of chitosan bandage to prevent fatal infections developing from highly contaminated wounds in mice. Biomaterials 2006;27(22):4157-4164.