Original Article

Evaluation of the efficacy of 100% Type-I collagen membrane of bovine origin in the treatment of human gingival recession: A clinical study

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Abstract

Background: Various treatment modalities have been devised for gingival recession, which is one of the most common signs of periodontal disease. The present study evaluates the efficacy of bioresorbable 100% type I collagen membrane of bovine origin in the treatment of human gingival recession. **Materials and Methods:** Twenty cases of Miller's class I or class II localized gingival recession defects on the facial surface were treated with 100% type I collagen membrane of bovine origin in conjunction with coronally positioned flap. Pre-operative and post-operative assessments were performed with respect to probing pocket depth, clinical attachment level and clinical recession at 12, 24 and 36 weeks. The data thus collected were analyzed statistically. **Results:** Statistically significant improvement based on Student's "t" test was found in all the three clinical parameters. **Conclusion:** Bioresorbable 100% type I collagen membrane of bovine origin has given inspiring results in the treatment of human gingival recession defects, thereby justifying the use of this material wherever indicated.

Key words: Clinical attachment loss, guided tissue regeneration, marginal tissue recession, mucoperiosteal flap, periodontitis

INTRODUCTION

Gingival recession or marginal tissue recession is one of the common clinical findings of periodontal disease in which the gingiva occupies a position apical to the cementoenamel junction thus exposing the root surface.[1] Various anatomical and pathological factors are responsible for the same. The principal cause of concern to a periodontist is the loss of tooth support, leading to compromised esthetics and other associated problems like plaque retention, gingival bleeding, abrasion, pain due to cervical dentin hypersensitivity, root caries and fear of tooth loss[2] for the patient. These problems led the clinicians to devise new methods for obtaining root coverage aiming at periodontal regeneration, the most coveted goal of periodontal therapy. Guided tissue regeneration (GTR) has emerged as an important pillar in the entire scheme of periodontal regeneration. There are various non-resorbable and resorbable barrier membranes available for GTR. The resorbable membranes include collagen membranes, cargile membrane, polylactic acid, vicryl (polyglactin 910), synthetic skin (biobrane) and freeze-dried duramater. Collagen has been demonstrated to be a weak immunogen,[3] and its mechanical properties of malleability, adaptability and ease of manipulation fulfill a number of criteria for an optimal barrier material. Collagen also possesses a number of biologic qualities that may enhance the type of wound healing desired following GTR therapy.[3] Type-I collagen is the most dominant protein in human connective tissue, including periodontal tissues.

BioMend® is one of the purest forms of type I collagen that is commercially available. It is derived from bovine deep flexor (Achilles) tendon. It is a white, compressed non-friable resorbable matrix and has an effective pore

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size of 0.004 microns, which will retard epithelial downgrowth during the early phases of healing. Being semi-occlusive, it allows essential nutrients to pass through the membrane. It incorporates into the surrounding tissues and is completely absorbed within 4-8 weeks.[4]

In this study, an attempt has been made to evaluate the efficacy of 100% type I bioresorbable collagen membrane of bovine origin in the treatment of gingival recession defects on the facial surface in humans.

MATERIALS AND METHODS

Selection of the patients

Twenty patients having localized visible gingival recession (Miller's class I and class II) on the facial surfaces of the maxillary and mandibular anterior teeth were selected among the patients visiting the Department of Periodontics, Punjab Government Dental College and Hospital, Amritsar, India. Patients giving a history of current alcohol intake, smoking, medically compromised status and allergy were excluded from the study.

Materials used

100% type-I resorbable collagen membrane of bovine origin (BioMend®, Sulzer Calcitek, Carlsbad, CA, USA) was used [Figure 1].

Method

For every patient, routine laboratory investigations for blood and urine were carried out. Oral prophylaxis and occlusal equilibration, if required, was performed and the patients were put on strict plaque control measures.

Pre-operative measurements for probing pocket depth, clinical attachment level (CAL) and clinical recession were taken using William's periodontal probe [Figure 2]. Pre-medication in the form of diazepam 10 mg and glycopyrrolate 0.3 mg was given intramuscularly 45 min before the procedure. Surgery was performed under local anesthesia. A full-thickness flap was raised to gain access and clean the designated area [Figures 3 and 4]. With the help of curettes, the exposed root surface of the tooth was planed. To obtain a concave profile, a rotary bur was used [Figure 5]. This concavity may help in the migration of progenitor cells toward and onto the detoxified root surface, where differentiation of cementoblasts and formation of new cementum and periodontal ligament are desired.[5] Following this, the entire surgical area was irrigated profusely with 1% betadine followed by normal saline. BioMend® was placed over the naked root surface/surfaces [Figure 6] extending from the cemento-enamel junction (CEJ) to 2-3 mm beyond the bony margins both laterally and apically and sutured in position with vicryl (3-0) resorbable sutures with the continuous sling suture technique. The flap was coronally repositioned at

Figure 1: The bioresorbable Type-I collagen membrane (Biomend®)

Figure 2: The pre-operative recession of canine in a patient prepared to undergo surgery

Figure 3: The incision being given for exposing the site of recession

the CEJ to cover the membrane completely and the facial and lingual flaps were approximated in the interproximal areas. Sling sutures were placed with the same suture material [Figure 7]. The same post-operative antibiotics and anti-inflammatory drugs (Doxycycline 100 mg once daily for 21 days and ibuprofen 400 mg plus paracetamol 325 mg TDS for 5 days) were given to all the patients. Patients were discharged after giving post-operative instructions.

Post-operative measurements for probing depth, CAL and clinical recession were taken at the end of 12, 24 and 36 weeks [Figures 8-10] after surgery and vigorous plaque control measures were again emphasized. The data thus compiled were put to statistical analysis.

RESULTS

Table 1 shows the probing depth ascertained clinically at baseline and 12, 24 and 36 weeks post-operatively (mm). Probing depth showed a mean reduction of 0.35 ± 0.11 mm each from baseline to 12 weeks, baseline to 24 weeks and baseline to 36 weeks post-operatively, which, when subjected to statistical analysis, proved to be significant at the 1% probability level implying, thereby, that substantial pocket depth reduction had taken place at the three points of time [Table 2].

Table 3 shows the CAL ascertained at baseline and 12, 24 and 36 weeks post-operatively (mm). CAL showed a mean gain of 3.10 ± 0.16 mm, 3.00 ± 0.19 mm and 2.85 ± 0.23 mm at 12, 24 and 36 weeks post-operatively, respectively, which is statistically

Table 1: Probing depth ascertained clinically at baseline, 12 weeks, 24 weeks and 36 weeks postoperatively (mm)

	Pre-operative measurements	Post-operative measurements at		
		12 weeks	24 weeks	36 weeks
Mean±SE_m	1.55±0.15	1.20±0.09	1.20±0.09	1.20±0.09
C.V. (%)	44.28	34.20	34.20	34.20
C.I. (95%)	1.25-1.85	1.02-1.38	1.02-1.38	1.02-1.38
C.I. (99%)	1.15-1.95	0.96-1.44	0.96-1.44	0.96-1.44

C.V.: Coefficient of variation, C.I.: Confidence interval

Figure 4: The mucoperiosteal flap being raised

Figure 5: The planing and flattening of the root surface being performed with rotary instruments

Figure 6: The recession defect with placement of Type-I collagen membrane

Figure 7: The operated area sutured after coronal repositioning of the flap

significant at the 1% probability level implying, thereby, that a substantial gain in attachment was obtained during these three time intervals [Table 4].

Table 5 shows the clinical recession ascertained at baseline and 12, 24 and 36 weeks post-operatively (mm). Clinical recession showed a reduction of 2.80 ± 0.19 mm, 2.70 ± 0.22 mm and 2.55 ± 0.26 mm at 12, 24 and 36 weeks post-operative, respectively, which, when subjected to statistical analysis, proved to be significant even at the 1% probability level [Table 6].

Figure 8: The operated area 12 weeks after surgery

Figure 9: The operated area 24 weeks after surgery

Figure 10: The operated area 36 weeks after surgery

DISCUSSION

Most of the reports in the literature describing various ways of root coverage have shown healing with long junctional epithelium,[5-9] which, in spite of giving satisfactory clinical results, do not meet the requirements of periodontal regeneration.[1,10-12]

Table 2: Reduction in probing depth (mm)

	Pre-operative to post-operative		
	12 weeks	24 weeks	36 weeks
Mean±SE$_m$	0.35±0.11	0.35±0.11	0.35±0.11
$t^{\$}$	3.199**	3.199**	3.199**

$: Students t-ratio through paired *t*-test at 19 degrees of freedom. NS: Values are statistically non-significant, as these are smaller than the critical value of 't' even at 5% level of significance. *: Values are significant at 5% probability level (critical value of student's 't' at 5% level of significance and at 19 degrees of freedom is 2.093). **: Values are significant at 1% probability level (critical value of student's 't' at 1% level of significance and at 19 degrees of freedom is 2.861)

Table 3: Clinical attachment loss ascertained at baseline, 12 weeks, 24 weeks and 36 weeks postoperatively (mm)

	Pre-operative measurements	Post-operative measurements at		
		12 weeks	24 weeks	36 weeks
Mean±SE$_m$	5.85±0.22	2.75±0.22	2.85±0.23	3.00±0.27
C.V. (%)	16.89	35.15	36.49	40.47
C.I. (95%)	5.42-6.28	2.33-3.17	2.39-3.31	2.47-3.53
C.I. (99%)	5.28-6.42	2.19-3.31	2.25-3.45	2.30-3.70

C.V.: Coefficient of variation, C.I.: Confidence interval

Table 4: Gain/loss in clinical attachment level (mm)

	Pre-operative to post-operative		
	12 weeks	24 weeks	36 weeks
Mean±SE$_m$	3.10±0.16	3.00±0.19	2.85±0.23
$t^{\$}$	19.304**	15.630**	12.255**

$: Students t-ratio through paired *t*-test at 19 degrees of freedom. NS: Values are statistically non-significant, as these are smaller than the critical value of 't' even at 5% level of significance. *: Values are significant at 5% probability level (critical value of student's 't' at 5% level of significance and at 19 degrees of freedom is 2.093). **: Values are significant at 1% probability level (critical value of student's 't' at 1% level of significance and at 19 degrees of freedom is 2.861)

Table 5: Clinical recession ascertained at baseline, 12 weeks, 24 weeks and 36 weeks postoperatively (mm)

	Pre-operative measurements	Post-operative measurements at		
		12 weeks	24 weeks	36 weeks
Mean±SE$_m$	4.30±0.15	1.50±0.17	1.60±0.18	1.75±0.22
C.V. (%)	15.28	50.73	51.30	55.23
C.I. (95%)	4.01-4.59	1.17-1.83	1.24-1.96	1.33-2.17
C.I. (99%)	3.92-4.68	1.08-1.94	1.13-2.07	1.19-2.31

C.V.: Coefficient of variation, C.I.: Confidence interval

Table 6: Decrease/increase in clinical recession (mm)

	Pre-operative to post-operative		
	12 weeks	24 weeks	36 weeks
Mean±SE$_m$	2.80±0.19	2.70±0.22	2.55±0.26
$t^{\$}$	15.023**	12.337**	9.952**

$^{\$}$: Students *t*-ratio through paired *t*-test at 19 degrees of freedom. NS: Values are statistically non-significant, as these are smaller than the critical value of '*t*' even at 5% level of significance. *: Values are significant at 5% probability level (critical value of student's '*t*' at 5% level of significance and at 19 degrees of freedom is 2.093). **: Values are significant at 1% probability level (critical value of student's '*t*' at 1% level of significance and at 19 degrees of freedom is 2.861)

GTR has emerged as a reliable method to achieve periodontal regeneration. The introduction of resorbable membranes has allowed clinicians to avoid a second surgical procedure and to achieve a predictable, new connective tissue attachment over the exposed root surface.[13,14] The above findings stimulated the research for development of bioresorbable materials, made of collagen and other materials like cargile membrane, polylactic acid, vicryl (polyglactin 910), synthetic skin (biobrane) and freeze-dried duramater, which could eliminate the second surgical procedure.

Collagen is biocompatible and has got a hemostatic function (aggregates platelets) facilitating early clot formation and wound stabilization. It also has a chemotactic function for fibroblasts, which may aid in cellular migration to promote primary wound closure. It provides a collagenous scaffold for tissue repair as well as augmenting the gingival tissue thickness. Being semi-permeable, it permits gaseous exchange and nutrient passage to ensure better flap healing.[15] Type I collagen membrane BioMend® is easy to manipulate and was well tolerated by the patients with no negative response as regard to its post-operative healing as well as signs and symptoms of any other allergic manifestation. These findings are also supported by Wang *et al.* (1994).[16]

Barrier membrane BioMend® mechanically prevents the epithelial cell migration[3] during the initial stages of healing, which may allow the repopulation of the treated root surface by connective tissue cells, leading to the development of a new connective tissue attachment. The cross-linked structure slows the degradation rate so that the membrane stays for a sufficient period of time underneath the flap and prevents the apical migration of epithelial cells in later stages of healing thus discouraging the formation of long junctional epithelial attachment and favoring development of connective tissue attachment.[17,18] BioMend® is rigid enough to create and maintain space.[3] This space is necessary to provide a channel for migration of progenitor cells toward and onto the detoxified root surface, where differentiation of cementoblasts and formation of new cementum and periodontal ligament are desired.[19]

The present study showed a statistically significant gain in CAL and reduction in clinical recession [Tables 4 and 6]. Similar findings were observed by Kimble *et al.,* (2004)[5] who used a collagen membrane in GTR-based root coverage and reported a statistically significant ($P < 0.05$) reduction in recession depth (2.1 ± 0.9 mm) and a gain in CAL (2.1 ± 1.0 mm). Shieh *et al.* (1997)[20] used a bioresorbable collagen membrane as a barrier device in root coverage treatment of recession defects and reported a statistically significant ($P < 0.01$) reduction in recession depth (-1.66 ± 0.25 mm) and a mean gain of 1.34 ± 0.47 mm in CAL at 6 months after surgery. Zahedi *et al.* (1998)[21] used a diphenylphosphorylazide (DPPA) cross-linked collagen membrane in the treatment of gingival recession and observed a mean reduction of recession from 3.7 mm at baseline to 0.8 mm at 2 years post-surgery, corresponding to a mean root coverage of 82.2% ($P < 0.0001$) and an average gain in CAL of 3.5 mm ($P < 0.0001$).

In the present study, another observation made was that recession defects treated in the maxilla yielded better results as compared with mandibular recession defects. Favorable gravitational forces, better blood supply and a wider dimension of pre-operative keratinized tissue in the maxilla may have favored more root coverage in the maxilla as compared with the mandible. Of the 14 maxillary recession defects, seven were in relation to incisors and six in relation to canines and pre-molars. It was further observed that the mean reduction in clinical recession noted in six of the maxillary canines and pre-molars at the end of the study (3.5 mm) was slightly more than that in the seven maxillary incisors (2.85). The difference may be due to the anatomy of the incisor area, which makes stable coronal repositioning more difficult due to labial movements and muscle insertions.[12] Moreover, the present study included only six mandibular defects as compared to 14 in the maxilla hence showing less than expected gain in various parameters. It was also observed that inadequate zone of attached gingiva, associated frenal pull found especially in the mandibular arch and heavier functional mechanical forces in mandible[22] posed a stumbling block in the way of achieving complete root coverage. To overcome these problems, deepening of the vestibule was done prior to GTR surgery.

Another observation at the end of 36 weeks showed that in 18 of the 20 cases, there was a further

1-3 mm recession from the CEJ at which the flap was placed and in five of 20 cases, clinical recession increased during the post-operative course of the study [Table 5]. Such observations may be the cumulated outcome of one or more of the following factors acting in conjunction or individually:

- Thin and delicate marginal tissue phenotype pre-operatively and placement of the barrier membrane underneath may have contributed additional tension in the thin and delicate flap[9]
- Chronic trauma from injuries during undirected tooth brushing or inflammatory reactions at the surgical site[14]
- Coronal repositioning of the flap may contribute to tension in the flap, thus jeopardizing the healing due to strangulation of the blood vessels.[23,24] Sites with deeper recession often have compromised vestibular depth, thereby complicating the tension-free coronal repositioning of the flap[25]
- The flap may not be of sufficient thickness to cover the barrier membrane to achieve optimal tissue regeneration. Similar findings were observed by Harris (1997),[26] who achieved 95.9% root coverage with GTR-based procedures when the tissue was ≥0.5 mm thick as compared with 26.7% root coverage when the tissue was <0.5 mm thick.

The use of collagen is capable of providing an increase in gingival thickness when associated with coronally advanced flap.[27] The collagen matrix provides a tissue substrate or scaffold capable of thickening tissues, which may be a desirable attribute when treating thin tissue biotypes.[28]

SUMMARY AND CONCLUSIONS

Within the limits of this study, it can be concluded that bioresorbable 100% type-I collagen membrane of bovine origin exhibited promising results in the treatment of human gingival recession defects, warranting the routine clinical use of this material wherever required.

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