

Evaluation of Changes in the Palatal Mucosal Thickness Post-augmentation using a Xenogeneic Collagen Matrix- An Interventional Study

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ABSTRACT

Introduction: Palatal augmentation is a unique approach that has been developed to increase the donor mucosal thickness and to procure sufficient dimensions of Connective Tissue Graft (CTG) during soft tissue augmentation around natural teeth and implants.

Aim: To evaluate the relative changes in Palatal Mucosal Thickness (PMT) followed by augmentation with xenogeneic collagen sponge.

Materials and Methods: This was an interventional study conducted on 16 subjects presenting with multiple gingival recession defects and also indicated for root coverage procedures at Department of Periodontology, SRM Dental College, Chennai, Tamil Nadu, India from June 2017 to March 2018. PMT was measured using a customised stent at eight standardised points with respect to Canine (C), first Premolar (PM1), second Premolar (PM2) and first Molar (M1) located at 4 mm and 8 mm from the gingival margin.

Xenogeneic collagen sponge was implanted at the donor site and postoperatively reviewed for two months. Changes in PMT were analysed using Mann-Whitney U test.

Results: A total of 16 patients (12 male and 4 female; mean age 36.81 ± 7.27 years) were recruited in the study. At two months, statistically significant ($p < 0.05$) increase in mean thickness of the palatal mucosa was observed at all the study points (at 4 mm: C- 5.24 ± 0.43 mm to 4.82 ± 0.39 mm, PM1- 5.47 ± 0.71 mm to 4.88 ± 0.48 mm, PM2- 5.71 ± 0.58 mm to 5.06 ± 0.65 mm and M1- 5.71 ± 0.58 mm to 5.24 ± 0.43 mm and at 8 mm C- 5.24 ± 0.43 mm to 4.47 ± 0.51 mm, PM1- 5.47 ± 0.62 mm to 4.41 ± 0.61 mm, PM2- 5.47 ± 0.62 mm to 4.35 ± 0.49 mm and M1- 5.65 ± 0.60 mm to 4.76 ± 0.43 mm).

Conclusion: Xenogeneic collagen sponge implantation resulted in a significant increase in the thickness of palatal mucosa.

Keywords: Connective tissue, Graft, Gingival recession, Root coverage

INTRODUCTION

Gingival recession is a well-known clinical condition that is increasing in occurrence worldwide, independent of age or race [1]. Marginal gingival recession can lead to significant aesthetic and functional issues, thus surgical intervention is frequently considered. Since keratinised gingiva and palatal mucosa have a comparable histological architecture, CTG taken from the palate in combination with advanced flap designs are considered as the most predictable treatment options in the management of gingival recession defects [2]. Individual's tissue phenotype, anatomical traits and other local factors determine the feasibility of procuring graft among the population. Harvesting grafts of appropriate dimensions in the treatment of multiple gingival recessions is technically demanding. Moreover, it reduces the morbidity in patients with thin palatal biotype [3,4].

Carnio J and Hallmon WW were the first to report palatal augmentation concept utilising xenogeneic collagen biomaterial [5]. Later, Bednarz W et al., performed augmentation of the thin palatal masticatory with commercially available xenogenic collagen sponge and achieved substantial thickening of the mucosa prior to CTG harvesting [4]. Collagen is the most abundant component of the extracellular matrix, and its ability to provide a scaffold for cell attachment and migration is the rationale for employing it as a biomaterial [6].

In this study, a biomaterial of fish origin (Biofil Sponge ©- Eucare Pharma, India), composed of type I collagen has been used in palatal augmentation for the first time. This material has been

previously used in dentistry in endodontic surgeries, mucogingival and socket augmentation procedures [7,8]. Hence, this study aimed to investigate the changes in the PMT following augmentation with xenogeneic collagen sponge.

MATERIALS AND METHODS

This interventional study was carried out in the Outpatient Department (OPD) of Periodontology, SRM Dental College, Ramapuram, Chennai, Tamil Nadu, India, extending from June 2017 to March 2018. The research design was approved by the Institutional Ethical Committee and Scientific Review Board (IRB No.:SRMDC/IRB/2016/MDS/No.503). The treatment procedures were carried out in accordance with the revised guidelines put forth by the Helsinki declaration. The details of the research including the purpose, intervention benefits with plausible complications were verbally explained to all the participants in detail and the written informed consent was obtained from the volunteers.

Sample size calculation: The sample size was estimated using the findings of Cardaropoli D et al., 2012 [9]. Based on the proportion set with type II error at 90% and type I error at 5%, fifteen adult subjects were to be included. Given the possibility of 5% dropouts which may occur during the 8 week follow-up, a total of 16 patients were enrolled.

Inclusion criteria: Systemically healthy subjects of age range between 18-65 years diagnosed with multiple gingival recession defects having thin gingival biotype, indicated for surgical management were recruited in the study.

Exclusion criteria: Sites with a probing pocket depth >3 mm and associated with radiographic evidence of bone loss, presence of tori, palatal gingival recession, or any other mucosal abnormalities in the palatal area, individuals with poor dental hygiene, tobacco use, a known allergy history to food items of marine origin, or current systemic condition/disease that precludes periodontal surgery were excluded from the study.

Procedure

Pre surgical phase: Initial preparatory phase consisted of scaling, root planning and measurement of clinical parameters i.e., PMT. A non invasive method was employed to indirectly measure the changes in PMT. Acrylic stents were prepared and bur holes were created facilitating the consistent placement of periodontal probe. PMT was measured by using a periodontal probe (UNC 15) guided by a customised stent at 8 selected points. (i.e., two predetermined regions with respect to each tooth at 4 mm (PMT1) and 8mm (PMT2) away from the palatal gingival margin of Canine (C), first Premolar (PM1), second Premolar (PM2) and first Molar (M1), respectively). The periodontal probe was passed through the stent in the selected regions and allowed gently to contact palatal mucosa. The same procedure was repeated at two months after implantation. The difference in depths of penetrations of the probe before (PMT1) and after therapy (PMT2) were calculated and considered as relative change in the PMT for statistical analysis [10].

Intervention: All the surgical procedures were carried out by a single experienced Periodontist. Following local anaesthesia (2% Lignocaine, 1:80,000 adrenaline), crevicular incisions were given and a full thickness mucoperiosteal flap was elevated extending from the palatal marginal gingiva of canine till the second molar. Flap was undermined apically approximately for 8-10 mm and a xenogeneic collagen sponge (Biofil Sponge®- EucarePharma, India) was placed [Table/Fig-1]. Flap margins were approximated by interdental sutures using 3-0 silk material (Ethicon Mersilk

3-0) and surgical sites were covered with a non eugenol based periodontal dressing (Coe-Pack GC America Inc.). Patients were advised to take tab. paracetamol eight hourly for three days. Patients were instructed to refrain from brushing in the surgical site for one week and 0.12% chlorhexidine mouthwash was recommended as an adjunct to oral hygiene maintenance twice a day for four weeks. The periodontal dressing and sutures were removed at the end of one week. Patients were monitored for a period of two months and PMT was re-evaluated at the end of eight weeks.

STATISTICAL ANALYSIS

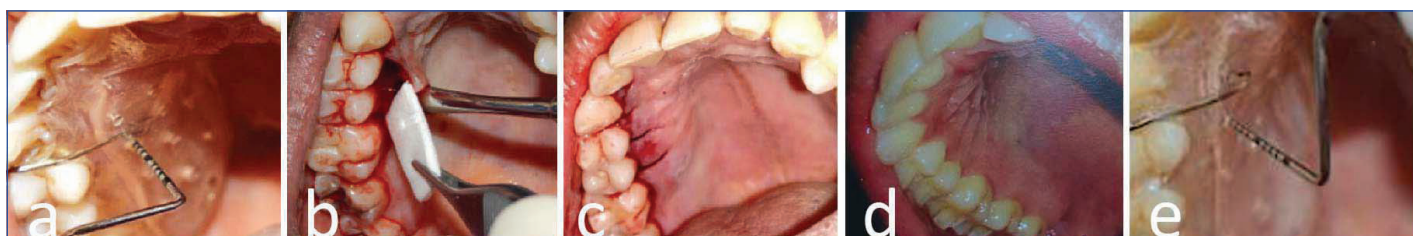
The collected data were analysed with International Business Management (IBM) Statistical Package for the Social Sciences (SPSS) software version 23.0. Descriptive statistics were expressed in terms of mean and standard deviation. To find the significant difference between the repeated measures Friedman test followed by Wilcoxon signed rank test was used. The probability value p≤0.05 is considered as a significant level.

RESULTS

Xenogeneic collagen sponge was implanted with intent to improve the PMT in 12 male and 4 female subjects with the mean age of 36.81±7.27years. [Table/Fig-2] showed the indirect measurements of mean PMT at 4 mm and 8 mm from marginal gingiva with respect to canine, first premolar, second premolar and first molar at various time points. Significant changes in mean PMT were noted from baseline to eight weeks at all study sites (p<0.05).

DISCUSSION

The objective of this intervention was to assess the relative changes in palatal mucosa post-augmentation with xenogeneic collagen sponge. A total of 96 predetermined sites in 16 systemically healthy adults were examined and all the investigated sites had a significant gain in mean PMT at the end of two months (p<0.05).



[Table/Fig-1]: a) Baseline Palatal Mucosal Measurement; b) Xenogenic Collagen Sponge Insertion; c) Flap Approximation; d) Review at two months; e) Palatal mucosal measurement at two months.

Parameters measured (N=16)		Canine (C)	First premolar (PM1)	Second premolar (PM2)	First molar (M1)
Palatal Mucosal Thickness at 4 mm from gingival margin (PMT1)					
Baseline (mm)		5.24±0.43	5.47±0.71	5.71±0.58	5.71±0.58
2 months (mm)		4.82±0.39	4.88±0.48	5.06±0.65	5.24±0.43
Friedman analysis	Chi-square (χ²)	45.24	51.66	53.26	50.62
	p-value	0.0007*	0.0009*	0.0005*	0.0003*
Wilcoxon signed rank test	z value	-2.33	-3.16	-3.31	-2.82
	p-value	0.020*	0.002*	0.001*	0.005*
Palatal Mucosal Thickness at 8 mm from gingival margin (PMT2)					
Baseline (mm)		5.24±0.43	5.47±0.62	5.47±0.62	5.65±0.60
2 months (mm)		4.47±0.51	4.41±0.61	4.35±0.49	4.76±0.43
Friedman analysis	Chi-square (χ²)	54.87	68.20	65.37	55.30
	p-value	0.0008*	0.0005*	0.0006*	0.0008*
Wilcoxon signed rank test	z value	-3.35	-4.02	-3.95	-3.41
	p-value	0.0011*	0.0002*	0.00017*	0.0016*

[Table/Fig-2]: Mean Palatal Mucosal Thickness (PMT) in the study points across the time points. (*p-value ≤0.05 considered significant)

S. No.	Study	Type of study and number of cases	Material used	Parameters assessed	Outcome
1.	Carnio J and Hallmon WW, 2005 [5]	Clinical case report (n=1)	Lyophilised bovine collagen sponge	Palatal mucosal thickness	Increase in palatal mucosal thickness post-augmentation.
2.	Carnio J and Koutouzis T, 2015 [17]	Consecutive case series (71 sites in 26 patients)	Lyophilised bovine collagen sponge	Assessment of palatal thickness	Significant improvement in palatal thickness.
3.	Rocha AL et al., 2012 [16]	Clinical case series (n=10 cases)	Lyophilised collagen sponge	Palatal mucosal thickness and histological evaluation	Significant increase in palatal mucosal thickness in clinical and histological assessment.
4.	Bednarz W et al., 2016 [4]	Comparative case series with split mouth design (n=10 patients)	BIOKOL Collagen sponge and Gel O sponge on contralateral sites of same patient	Palatal mucosal thickness and histological assessment	Increase in palatal mucosal thickness in BIOKOL group with significant amount of mature fibrous connective tissue.
5.	Present study	Interventional study (N=16 patients) with multiple gingival recession defects and planned to undergo root coverage and palatal mucosal augmentation procedure, were included.	Xenogeneic collagen sponge insertion done for palatal mucosal thickness and augmentation	Palate Mucosal Thickness (PMT) was assessed by periodontal probe guided by customised stent	There was significant increase in mean palatal mucosal thickness (PMT) noted from baseline to two months at all study sites.

[Table/Fig-3]: Literature reports investigating palatal augmentation.

The main source of CTG for periodontal plastic surgery is the palatal masticatory mucosa between the canine and first molar. Anatomic parameters influencing the dimensions of the CTG were highlighted by Reiser GM et al., in 1996 [11] and Harris RJ in 2003 [3]. Literature reports suggested that CTG thickness of 1.5 to 2 mm is required for optimum root coverage [12-14]. Khatri M et al., in 2017 reported that the average thickness of the palatal mucosa in an Indian population was 2.68 ± 0.36 mm and 2.63 ± 0.61 mm for males and female subjects, respectively [15]. Inadequate PMT in donor site may arise complications such as insufficient dimensions of procured grafts and also increased postoperative morbidity with delayed healing in donor sites [3].

To improve the palate mucosal thickness, the concept of palatal augmentation was introduced. Collagen matrices employed for soft tissue augmentations had shown adequate volume stability in order to allow enough time for cells to invade into the collagen matrix and to build new soft tissue. Xenogeneic resorbable collagen sponge that is being employed in this case series enhances wound healing and formation of granulation tissue, acts as a scaffold for regeneration and soft tissue augmentation [7,8].

Literature reports employing palatal augmentation techniques with various xenogenic matrices quoted a mean gain in PMT ranging from 1-1.54 mm, which was in accordance with the present study [5,16,17]. The comparative findings and results obtained for PMT from previous studies along with present study are shown in [Table/Fig-3] [4,5,16,17]. Variations in the outcomes could be attributed to the differences in the biomaterials being used i.e., composition, extent of crosslinking, resorption time and also to the variation in methodologies in measurement of PMT. Xenogenic type I collagen, employed in current study, predominantly composed of minimally crosslinked type I collagen and has a resorption time of three to four weeks [8]. In a recent clinical evaluation by Bednarz W et al., the author observed that the CTG harvested from augmented palatal sites yielded superior results in terms of root coverage [4].

Limitation(s)

Inclusion of smaller sample population and lack of a comparative group were the limitations of the current study.

CONCLUSION(S)

The observations from this study indicated that palatal augmentation with fish derived collagen matrix had resulted in significant gain

in mucosal thickness. Concept of palatal augmentation can be extended to individuals presenting with thin gingival phenotype requiring voluminous soft tissue autografts in treatment of multiple gingival recession and also for soft tissue augmentation in deficient alveolar ridges, around dental implant supported prosthesis. Future studies with larger sample size with longer follow-up are desired for significant conclusions.

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