ISSN: 2581-5989
PubMed - National Library of Medicine - ID: 101738774

International Journal of Dental Science and Innovative Research (IJDSIR)

IJDSIR : Dental Publication Service

Available Online at: www.ijdsir.com

Volume – 5, Issue – 6, November - 2022, Page No. : 180 - 189

Comparison of patient satisfaction and clinical outcomes in RT-1 and RT-2 recession defects in cases treated with PPG and collagen membrane- A Randomized controlled trial

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Citation of this Article: Vindeshwari Bhatia, Ajay Mahajan, Kanwarjit S. Asi, Nidhi Chandel, Monika S. Walhe, "Comparison of patient satisfaction and clinical outcomes in RT-1 and RT-2 recession defects in cases treated with PPG and collagen membrane- A Randomized controlled trial", IJDSIR- November - 2022, Vol. – 5, Issue - 6, P. No. 180– 189.

Type of Publication: Original Research Article

Conflicts of Interest: Nil

Introduction

Gingival recession is defined as the location of the gingival margin apical to the cemen to-enamel junction (CEJ).[1] The etiology of the gingival recession is multifactorial which may result in impaired aesthetics, dentin hypersensitivity, root caries, compromised plaque control.[2,3] In recent years the role of aesthetics and patient comfort have become increasingly important in dentistry**.** Paralleling this development, the practice of root coverage procedures to treat gingival recession defects (GRDs) along with patient centred outcomes has gained more attention in periodontics.[4,5] Systematic reviews have been published focusing on the importance of patient centred approach as an important criteria while managing GRD and avoiding the need for second surgical site.[6–8] Therefore, recent techniques have been advocated which promote neo-vacsularisation and regeneration. In addition these techniques do not require a second surgical site to harvest a graft, hence resulting in better patient satisfaction. [9,10,11,12]

A graft having its own blood supply that can be harvested adjacent to the recession defect in sufficient amount which do not require any additional surgical site and has the potential to regenerate the lost periodontium has long been needed.[12] The adult human periosteum fulfils all these necessary qualities and hence can be used as a graft for root coverage. Mahajan A in 2009, for the first time reported the use of autogenous Periosteal Pedicle Graft (PPG) for the management of GRDs.[13] PPG can be used for treating single as well as multiple

GRDs. Clinical studies in the literature comparing PPG with sub-epithelial connective tissue graft (SCTG) [12], acellular dermal matrix allograft (ADMA)[10] and modified coronally advanced flap (MCAF) [14] have been published and have shown promising results.

An alternative approach for the coverage of gingival recession defects is Guided Tissue Regeneration (GTR) using resorbable and non-resorbable barrier membranes. The basis of GTR is to avoid the creation of a second surgical site and to improve the probability of new attachment on the denuded root surface. There is evidence that GTR technique has good predictability regarding clinical attachment gain and root coverage.[15]

To the best of our knowledge clinical trials comparing PPG and GTR utilising collagen membrane for the treatment of gingival recession defects have not been reported till date. Therefore, the present study was done to clinically evaluate and compare PPG with GTR for the treatment of GRDs in terms of root coverage and patient centred outcomes.

Materials and Methods:

The present study was a randomized controlled trial (RCT), performed in the Department of Periodontology in a tertiary care dental institute in India between February 2019 to November 2019. The study protocol was approved by the institutional protocol reviewing committee [No:(HFW(GDC) B (12)44/2019)] and was conducted in accordance with the Helsinki's guidelines, 2013 for RCT. The procedures were explained to the participants who signed a written informed consent.

Patients were randomly divided into test (PPG) and control groups (GTR) using simple randomisation method by flipping a coin. Patients were selected based on the following inclusion and exclusion criteria: -

Inclusion criteria

- Men and women between the 18 and 45 years of age.
- Subjects who consented to participate in the study.
- Systemically healthy patients.
- Miller's Class I, Class II, or Class III recession [RT 1 and RT 2] defects ≥2mm.

Exclusion criteria

- Medically compromised patients.
- Pregnant and lactating females.
- Patients with parafunctional habits.
- Smokers, chewers of tobacco.
- Patients with a history of previous periodontal surgeries on selected sites.

Presurgical Ly, all the patients received oral hygiene instructions with full mouth scaling and root planning. Etiological factors of gingival recessions were eliminated or controlled prior to the surgeries.

Following clinical parameters were included:

- Gingival Recession Depth (RD), recession width (RW) at baseline and after 1 and 6 months post surgically with a periodontal probe (UNC-15, Hu-Friedy)
- Probing Depth (PD), Width of Keratinized Gingiva (WKG), Width of Attached Gingiva (WAG), Gingival Thickness (GT) and percentage of root coverage were taken at baseline till 6 months by using UNC-15 periodontal probe.
- Patient's satisfaction was also assessed using a three-point rating scale[16] and scores were given by the patient as:
- 3-fully satisfied
- 2- satisfied
- 1-unsatisfied

Participants were questioned about their satisfaction with regard to the following patient-centred criteria: Duration, intra-operative pain & discomfort, post-operative pain & discomfort, operator's behavior & handling, cost effectiveness, colour of gums, shape & contour of gums,

relief from dentinal hypersensitivity, root coverage and overall satisfaction.

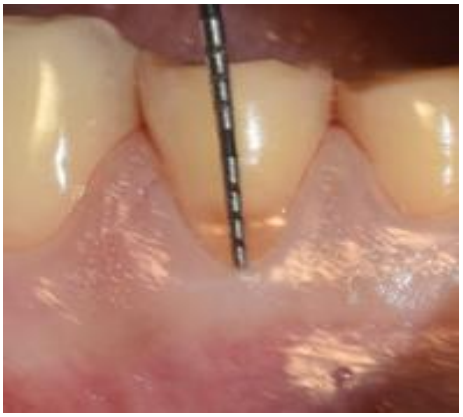
Surgical procedure

All surgical procedures were performed by one operator for the sake of uniformity. Extraoral preparation with 5% Povidone Iodine solution, the patient was asked to rinse with 10 ml of 0.2% chlorhexidine Di gluconate solution for 1 minute.

Test group (PPG) Figure-1 (a-d)

Procedure was performed by following the standard surgical technique (PPG) described by Mahajan A for the treatment of GRDs.[13] All cases were operated under local anaesthesia with a solution of 2% Lignocaine with 1:80,000 adrenaline. After local anaesthesia, an intrasulcular incision was made. Two horizontal incisions were made perpendicular to the adjacent interdental papillae, at the level of the CEJ preserving the gingival margin of the neighbouring teeth. Two oblique vertical incisions were extended beyond the mucogingival junction and a full thickness trapezoidal flap was raised 3–4mm apical to the osseous crest. The flap was then pulled buccally to create tension on the periosteum. An incision was made through the periosteum where the flap was still attached to bone, to create a partial thickness flap. The partial thickness flap was extended to expose a sufficient amount of the periosteum which was then separated from the underlying bone. The process of separating the periosteum was initiated at the apical extent of the periosteum which was then lifted slowly in a coronal direction. The periosteum was not separated completely from the underlying bone, leaving it attached at its coronal most end, maintaininh an active blood supply. The PPG thus obtained was then turned over the exposed root surface. After stabilizing the periosteal graft, the flap was coronally positioned and sutured using a sling suture technique with a non-resorbable 4-0 silk suture. The releasing incisions were closed with interrupted sutures

Figure 1: Test group (PPG)



1a: Pre-operative- GRD with lower left 1st premolar.

1b: Intra-operative- partial thickness flap raised exposing the underlying periosteum.

1c: Intra-operative- periosteum reflected and placed over the defect.

1d: 6-month post-operative.

Control group (GTR) Figure-2 (a-d)

Similar to test group full thickness flap was raised at the recession site. The flap was extended well beyond the Mucobuccal fold so that it exhibited no tension when pulled coronally.

This was followed by tissue debridement, root planning and irrigation with sterile saline solution. A bio resorbable collagen membrane (Colo guide, Colo genesis Healthcare Pvt. Ltd.) was placed on the root surface overextending at least 2 mm over the margin of bone defect.

The flap was then coronally positioned and sutured with 4-0 silk suture with complete closure while avoiding excessive tension on the surgical site.

Figure 2: Control group (Collagen membrane).

2a: Pre-operative- GRD with lower right canine.

2 b: Intra-operative- Partial thickness flap raised.

2c: Intra-operative- GTR membrane placed and stabilized over the defect.

2d: 6-month post-operative

Postsurgical care

Postoperative instructions were given to the patient and analgesic (tablet Aceclofenac 100 mg) was prescribed twice daily for 3 days. Patients were instructed not to brush the operated site till the sutures are removed and advised to rinse the oral cavity with chlorhexidine 0.12% mouthwash till suture removal is done. After 10 days sutures were removed instructions were given to avoid

excessive pulling. Patients were recalled 1 month, 3 months and 6 months after surgery and clinical recordings were taken.

Data collection and evaluation

The entire data was collected and statistically analyzed by using statistical software and comparative evaluation of both the techniques was done.

Statistical analysis

Mean and standard deviation were calculated in both test and control sites for all the clinical parameters.

For intragroup variation 'Paired t test' and for intergroup comparison 'Unpaired t test' were performed. Assessment of patient centred outcomes was done by using 'Fisher square test'.

All values of $P < 0.05$ were considered as significant and <0.001 were considered highly significant.

Results

At the end of the study period a total of 7 test and 7 control sites were treated using PPG and GTR, respectively.

Healing was uneventful in all the treated sites and the patients were satisfied with the treatment outcomes.

Out of total patients, 78% were males and 22% were females. Patients had a mean age of 31 years (SD-7.45). Data analysis showed that PPG-treated sites had a mean defect coverage of 85 % while GTR- treated sites had a mean defect coverage of 72%.The results of intragroup analysis are summarized in Table 1. Table 2 shows intergroup comparison between the PPG and GTR groups with regard to change in various clinical parameters after 6 months.

At baseline, there were no statistically significant differences between the two groups for any of the parameters evaluated. Statistically significant intragroup differences were found for GRD, WKG, WAG, RW and GT for both test and control groups.

There was no significant difference in the mean PD from baseline to 6 months in both the test and control sites ($P > 0.05$) (Table 1). On intergroup comparison, test group (PPG) had a statistically better root coverage ($P = 0.006$) and resulted in marked increase in width of attached gingiva ($P = 0.0001$), width of keratinized gingiva ($P = 0.0040$) and gingival thickness ($P = 0.0001$) when compared with the GTR group (Table 2).

Table 1: Intragroup comparison of clinical parameters at Baseline and at 6 months for the test and the control sites.

Clinical parameter	PPG Group (n=7)				GTR group (n=7)			
	Initial examination (mean±SD (mm))	Final Examination (mean±SD (mm))	Change from baseline to 6 months (mean±SD (mm)	P Value	Initial examination (mean±SD (mm))	Final Examination (mean±SD (mm))	Change from baseline to 6 months (mean±SD (mm))	P Value
Recession depth	3.14±1.21	0.43±0.53	2.71±0.68	0.0037	3.14±1.07	0.40±0.47	2.74±0.6	0.0037
Recession width	3.86±0.69	2.29±0.49	1.57±0.20	0.0403	3.57±0.79	2.29±1.25	1.28±0.46	0.0403
Width of keratinized gingiva	2.85±0.80	3.62±0.54	0.77±0.26	0.3694	2.11±0.57	2.38±0.51	0.27±0.06	0.3694
Width of attached gingiva	1.28±0.48	2.07±0.34	0.79±0.14	0.0882	0.68±0.24	0.91±0.21	0.23±0.03	0.0882
Gingival thickness	0.87±0.18	1.45±0.36	0.58±0.18	0.0479	0.82±0.13	1.00±0.15	0.18±0.02	0.0479
Probing depth	1.57±0.53	1.71±0.49	0.14±0.04	0.1996	1.43±0.53	1.86±0.38	0.43±0.15	0.1996

Table 2: Intergroup Changes in clinical parameters (mean ± SD) after 6 month for the test and the control sites

Parameter	PPG (n=7)	GTR (n=7)	P value
Recession depth	2.71±0.68	1.86± 0.12	0.006
Recession width	1.57±0.20	1.29±0.46	0.1655
Width of keratinized gingiva	0.77±0.26	0.42±0.02	0.0040
Width of attached gingiva	0.78±0.14	0.27±0.04	0.0001
Gingival thickness	0.27±0.04	0.17±0.02	0.0001
Probing depth	0.14±0.34	0.43±0.15	0.0613

Comparison of Patient centred outcomes

More number of patients in the test group were fully satisfied with the procedure and treatment outcomes as compared to patients treated with GTR (Table 3a).

There was a statistically significant difference between the two groups when overall patient satisfaction scores were compared (P = 0.001) (Table 3b and 3c).

When the two groups were compared in terms of individual satisfaction criteria, statistically significant differences (P= 0.0003) were noticed only in parameters measuring patient satisfaction relating to cost effectiveness of the procedure, post-operative pain and discomfort and aesthetic outcomes (Table 3c).

Table 3(a): Patient satisfaction ratings

	PPG (n=7)			GTR (n=7)			
Patient-Centered Outcomes	Fully Satisfied	Satisfied	Unsatisfied	Fully Satisfied	Satisfied	Unsatisfied	'P' Value
Duration	6	1	0	5	2	0	0.51
Intra-operative Pain & Discomfort	6	1	0	4	3	0	0.236
Post-operative Pain & Discomfort	4	3	0	1	6	0	0.0943
Operator's Behavior &Handling	7	0	0	4	3	0	0.057
Cost Effectiveness	7	0	0	0	1	6	0.0003*
Colour of Gums	6	1	0	3	4	0	0.0943
Shape & Contour of Gums	1	6	0	0	7	0	0.299
Relief from Dentinal Hyper sensitivity	6	1	0	4	2	1	0.41
Root Coverage	4	3	0	3	4	0	0.593

Table 3(b): Changes in clinical parameters (mean±SD) after 6 months.

Patient	Tooth no		duration		Intraoperative pain & discomfort		Post operative pain & discomfort		Operator's behaviour & handling		Cost effectiveness		Colour of gums		Shape and contour of gums		Relief for dentinal hypersensitivity		Root coverage		Overall satisfaction	
	PPG	GTR	PPG	GTR	PPG	GTR	PPG	GTR	PPG	GTR	PPG	GTR	PPG	GTR	PPG	GTR	PPG	GTR	PPG	GTR	PPG	GTR
1	24	34	3	3	3	3	3	2	3	2	3	1	3	3	3	2	3	3	2	3	26	22
2	23	43	3	3	3	3	3	3	3	3	3	1	3	3	2	2	3	3	2	3	25	24
3	43	13	3	3	3	2	2	2	3	3	3	2	3	3	2	2	2	2	3	3	24	22
4	33	14	3	3	3	3	2	2	3	3	3	1	3	2	2	2	3	3	2	2	24	21
5	23	24	3	2	3	2	3	2	3	2	3	1	3	2	2	2	3	2	3	2	25	17
6	33	31	2	2	3	3	3	2	3	3	3	1	2	2	2	2	3	3	3	2	24	20
7	44	41	3	3	3	2	2	2	3	2	3	1	3	2	2	2	3	2	3	2	25	18
																				24±0.76		20.57±2.44

Table 3(c): Intergroup Comparison of Overall Patient Satisfaction.

Patient Satisfaction	PPG Group	CAF Group	'P' Value
Mean ± SD	24±0.76	20.57±2.44	0.0010

Discussion

Till recently, the success of periodontal plastic surgery primarily relied on complete root coverage of exposed roots, however, currently the basis for success criteria has focused not only on percentage of root coverage but also on patient based outcome measures. [10,17,18] .Moreover, recent systematic reviews have also highlighted the patient related outcomes and suggested the need to conduct more studies, related to patient's satisfaction with the procedure, and aesthetics outcomes, comfort, and cost-effectiveness.[8,19] Therefore, new techniques to fulfil these requirements without compromising the patient based measures need to be developed. Considering these facts, the present study was undertaken to clinically evaluate and compare the PPG with GTR in the treatment of gingival recession defects.

At the end of the study, patients treated with PPG had a mean root coverage of 85% and predictability of > 80 % root coverage was 71%. In contrast GTR group had mean root coverage of 72 % and predictability of > 80% root coverage was just 42%. The results obtained in test sites (PPG) were in accordance with the earlier studies done by Mahajan et al 2012[12] and Dandu Et al 2016 [20], Sweet Nisha et al (2016) [14], which showed a mean defect coverage of 91.3% ,71% and 85% respectively with 80 % predictability of root coverage. The results obtained in control sites (GTR) were in accordance with the earlier studies done by Wang HL et al 2001[21] ; Trombelli L et al 1998[22] ; Muller H-P et al 1999 [23], which showed a mean defect coverage ranging from 51% to 85% and poor predictability of root coverage.

Wound healing after periodontal surgery is affected by clot stabilization, revascularization and maintenance of blood supply, along with repopulation of connective

tissue cells along the denuded root surface. A graft having its own blood supply has high chances of survival on an avascular root surface compared to a free grafted membrane without an active blood supply.[2] The better predictability and high percentage of root coverage in PPG treated sites may be attributed to the fact that, during the healing period, the cells with potential to regenerate the cementum and periodontal ligament are the first to populate the root surface followed by osteoblasts and their progenitors cells. Therefore, PPG places the proper cells at proper location for regeneration [20,24]. Moreover, periosteum has a rich vascular plexus and cells in the layers of periosteum also releases vascular endothelial growth factor [12].

Poor predictability and low percentage of root coverage in GTR treated sites may be due to membrane exposure in few of the control sites. This resulted in its contamination, early degradation and collapse of membrane leading to partial root coverage only. Early exposure and the inability of the GTR membrane to create and maintain space by itself have been proven to disturb periodontal regeneration. [23,25]

Collagen membrane acts only as a matrix and barrier with no active blood supply during the healing phase. On the other hand, PPG being a vascular graft could have resulted in uncomplicated healing and better regeneration, even if it was exposed during the healing period.

One more reason, for better results in the PPG treated sites, could be the clinically significant increase in the gingival thickness at the test sites. Adequate gingival thickness is considered to be very important clinical parameter for the success of root coverage procedures as it plays an important role in the pathogenesis of gingival recession and also affects the treatment outcomes.[26,27] The possible reason for increased GT in the test group could be due to better tissue integration of the autogenous vascular periosteum with the overlying flap when compared to the avascular xenogenic collagen membrane. Furthermore, gingival thickness also influences the Esthetic results following root coverage surgeries [28], which could be the reason that in our study, the gingival contours and color matching seemed to be more favourable at sites treated with PPG as compared to sites treated with GTR.

Statistically significant differences were observed in the overall patient satisfaction (P=0.0010) and cost effectiveness (P= 0.0003), both of which were rated better in test group than in control group. Moreover, patients also rated GTR inferior in terms of duration of the procedure and post-operative pain and discomfort. The intraoperative time for performing root coverage in the control group was more as the extra time was taken for stabilizing the collagen membrane when compared to the test group. Also, it is a known fact that the intra-operative time is directly proportional to the post-operative pain and discomfort. Furthermore, PPG treated sites presented better esthetics especially in terms of shape and contour of the gums, when compared with GTR treated sites which could be attributed to the better thickness and healing of the surgical sites treated with PPG. These results were in accordance with the previous study done by Mahajan 2018, Godavarthi et al 2016 [15,19]

Even though the present study was limited to 6 months only, the probability of obtaining more stable and sustainable results utilizing PPG, cannot be overlooked owing to the immense regenerative potential of the periosteum due the presence mesenchymal stem cells. [24] Emerging histological evidence also supports that PPG, when used for treating GRDs, results in complete regeneration of PDL, cementum and bone at treated sites.[29]

Future studies comparing PPG with collagen membrane for multiple gingival recession defects needs to be conducted. Although the results showed statistically significant difference between the two groups, the small study group necessitate future studies with a large sample size and long term follow up.

Conclusion

PPG results in predictable clinical and patient cantered outcomes when used to treat GRDs. An added advantage of PPG when used to treat GRDs could be the possibility of regeneration and long-term sustainable results.

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