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Efficacy of Human Placental Extract Gel as Adjunct to SRP vs. SRP Alone in Stage II Grade B Periodontitis: A Randomized Controlled Trial

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Abstract

Background: Non-surgical periodontal therapy with scaling and root planing (SRP) remains the cornerstone for managing stage II grade B periodontitis, though adjunctive therapies may enhance outcomes in shallow pockets (≤5 mm). This randomized controlled split-mouth trial evaluated human placental extract (HPE) gel as an adjunct to SRP versus SRP alone.

Methods: Fifty bilateral sites in 15 systemically healthy subjects (aged 20-50 years) with stage II grade B periodontitis were randomized: Group A (SRP + HPE gel, n=25 sites) and Group B (SRP alone, n=25 sites). Probing pocket depth (PPD), relative attachment level (RAL), and sulcus bleeding index (SBI) were assessed at baseline, 4 weeks, and 6 weeks using UNC-15 probe and customized acrylic stents. Non-parametric tests (Friedman, Wilcoxon, Mann-Whitney U) analyzed changes ($p<0.05$ significant).

Results: Both groups showed significant intra-group improvements ($p<0.01$). Inter-group comparisons revealed superior outcomes in Group A: PPD reduced by 1.28 mm (vs. 1.08 mm, $p=0.040$ at 6 weeks); RAL gain of 2.08 mm (vs. 1.16 mm, $p<0.001$); SBI dropped to 0.51 (vs. 0.87, $p<0.001$). No adverse effects occurred.

Conclusion: HPE gel significantly augments SRP efficacy in reducing PPD, improving RAL, and minimizing bleeding in stage II grade B periodontitis, likely due to its regenerative (collagen synthesis, growth factors) and anti-inflammatory properties. Longer-term studies are warranted.

Keywords: Human Placental Extract Gel, Scaling and Root Planing, Stage II Grade B Periodontitis, Probing Pocket Depth, Relative Attachment Level, Sulcus Bleeding Index, Split-Mouth Trial

Introduction

The periodontium, comprising gingiva, periodontal ligament, cementum, and alveolar bone [1] forms a symbiotic barrier against microbial invasion to protect periodontal tissues [2]. Periodontitis involves gingival inflammation and loss of connective tissue attachment and alveolar bone, [3] driven by bacterial plaque biofilm that deepens pockets and destroys supporting structures. Non-surgical therapy, primarily scaling and root planing (SRP), remains the cornerstone for initial treatment by removing supra and subgingival biofilm and calculus [4]. Conventional SRP using power-driven/manual instrumentation yields PPD reductions of 1.29-2.16 mm and CAL gains of 0.55-1.19 mm in 4-6 mm pockets, [7] with subgingival debridement plus plaque control achieving 0.64-0.74 mm attachment gains and 1.18 mm PPD reduction [8]. However, limitations persist in deeper pockets, bone defects, and pathogens like *Aggregatibacter actinomycetemcomitans*, [9] necessitating adjuncts and maintenance. Local drug delivery offers targeted, high-concentration therapy with fewer systemic effects than antimicrobials (e.g., tetracycline fibers, chlorhexidine chips), [6] though limited by allergies and biofilm disruption; systemic antibiotics risk resistance [10]. Human placental extract (HPE), rich in proteins, enzymes, hormones, mucopolysaccharides, and polynucleotides, [9, 11] promotes type I collagen production, anti-inflammatory effects, and reduced IL-6/IL-8 in gingival fibroblasts, showing osteogenic/angiogenic potential [12]. Gupta *et al.* (2023) [13] reported superior PPD, CAL, and inflammation improvements with HPE gel adjunct to SRP. Thus, this split-mouth study assessed HPE gel + SRP versus SRP alone on clinical parameters in stage II grade B periodontitis.

Materials and Methods

This study was a split mouth, experimental, randomized controlled trial. Study setting This study was performed on subjects

screened at the outpatient department of periodontology in a tertiary dental care center.It was conducted according to the ADA type II specifications using electrically operated dental chair with proper illumination X-ray unit and autoclaved set of instruments. Source of data Subjects of either sex within the age range of 20-50 years who reported to the Out Patient Department of a tertiary dental care center, with probing pocket depth ≤ 5mm in bilateral sites subjects were selected by convenience sampling technique. Method of selection the subjects for the study were selected based on the following inclusion and exclusion criteria.

Inclusion Criteria

1. Systemically healthy subjects of either sex between 20-50 years.
2. Subjects presenting with bilateral sites with periodontal pockets with probing depth ≤ 5mm.
3. Subjects willing to be a part of the study.

Exclusion criteria

1. Pregnant and lactating mothers.
2. Subjects with habit of smoking, tobacco chewing.
3. Subjects who are not on any medication.
4. Subjects with history of any periodontal treatment in past 6 months.
5. Subjects with any known drug allergy.

Withdrawal Criteria

1. Non-compliant subjects

2. Subjects lost to follow up to match with original sample size fresh subjects were to be recruited for evaluation. But in the present study there was no loss to follow up and all patients were compliant.

Fig 1: Human placental extract (HPE)

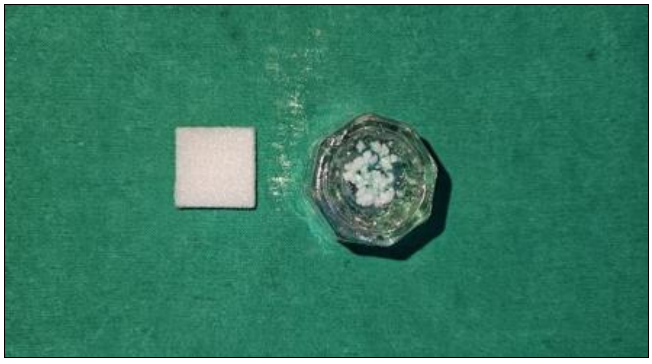


Fig 2: Collagen plug mixed with HPE gel

Fig 3: Post scaling photograph

Fig 4: Intrapocket application of HPE gel

Fig 5: Placement of HPE gel till the pocket is filled completely

Fig 6: Coe pak placement

Group A (SRP+ Human Placental Extract Gel)

Fig 7: At baseline

Fig 8: Follow up at 4 weeks

Fig 13: Follow up at 6 weeks

Group B (SRP)

Fig 14: At Baseline

Fig 15: Follow up at 4 weeks

Fig 16: Follow up at 6 weeks

Results

This study was carried out in the Department of Periodontology to assess the periodontal treatment outcome with Human placental extract gel as an adjunct to scaling and root planning (SRP) as compared to SRP alone in subjects of either sex between 20-50 years of age (mean age of 45 years) with Stage II Grade B periodontitis. Fifty selected bilateral sites in 15 patients (10 males,5 females) with pocket depth ≤ 5mm were randomly divided at Group A (treated with Human placental extract gel + SRP) & Group B (SRP alone). Probing pocket depth, relative attachment level and sulcus bleeding index were recorded at baseline, 4 weeks, 6 weeks **(Table1, Table 2)**.

All the subjects were compliant and there were no dropouts from the study. The changes in the clinical parameters over a period of 6 weeks were recorded. The data obtained was tabulated and subjected to statistical analysis.

Statistical procedures:

All data were entered into a computer by giving coding system, proofed for entry errors. Data obtained was compiled on a MS office Excel Sheet (v 2019, Microsoft Redmond, Washington, United states). Data was subjected to statistical analysis using Statistical package for social sciences (SPSS v 26.0, IBM). Descriptive statistics like frequencies and percentage for categorial data, Mean and SD for numerical data has been depicted.

Normality of numerical data was checked using Shapiro-Wilk test and was found that the data did not follow a normal curve; or for graded data, hence non- parametric

tests have been used for comparisons. Inter Site comparison (Between two sites) was done using Mann Whitney U test. Intra Site comparison was done using Friedman's for (>2 observations) followed by pair wise comparison using Wilcoxon signed rank test.

For all the statistical test,p <0.05 was considered to be statistically significant, keeping α error at 5% and β error at 20%, thus giving a power to the study 80%.

*= statistically significant difference (p<0.05) **= statistically highly significant difference (<0.01).

= Nonsignificant difference (>0.05) for all tables and graphs.

Intra Group Comparison:

The values of PPD for Group A decreased from baseline (4.56±0.50) throughout follow ups at 4weeks (3.68±0.69) and 6 weeks (3.28±0.54). On intra group comparison, there was statistically highly significant difference seen (p<0.01) in PPD between baseline, 4weeks and 6weeks with higher values at baseline **(Table3) (Graph 1)**.

The values of PPD for Group B decreased from baseline (4.68±0.47) throughout follow ups at 4weeks (3.76±0.59) and 6 weeks (3.6±0.5). On intra group comparison, there was statistically highly significant difference seen (p<0.01) in PPD between baseline, 4weeks and 6weeks with higher values at baseline **(Table 4) (Graph 1)**.

There was a statistically highly significant difference seen for the PPD values of at all pairs of time intervals (p<0.01) in Group A **(Table 5).** In Group B, there was a statistically highly significant difference seen for the PPD values between baseline and 4 weeks and there was no significant difference from 4 weeks to 6 weeks (p<0.01) **(Table 6)**.

Inter Group Comparison:

PPD values at baseline between Group A (4.56±0.5) and Group B (4.68±0.47) showed no statistically significant (p<0.05) difference.

At 4 weeks follow up, no statistically significant difference(p<0.01) was observed between both groups, Group A (3.68±0.69) and Group B (3.76±0.59). There was a statistically significant difference seen (p<0.05) for PPD at 6weeks between the Group A (3.28±0.54) and B, with higher values in Group B (3.60±0.50) (Table 7) (Table 12) (Graph 4).

Intragroup Comparison:

The values of RAL for sites in Group A decreased from baseline (7.04±1.30) throughout follow ups at 4 weeks (5.56±1.71) and 6 weeks (4.9±1.48) On intragroup comparison there was statistically significant difference seen (p<0.01) in RAL between baseline, 4weeks and 6weeks with higher values at baseline. **(Table 8) (Graph 2)**.

The values of RAL for Group B decreased from Baseline (8.56±0.82) throughout follow up at 4 weeks (7.48±0.87) and 6 weeks (7.4±0.9) There was statistically highly significant difference seen (p<0.01) in RAL between baseline, 4weeks and 6weeks with higher values at Baseline. **(Table 9) (Graph 2).** There was a highly statistical difference seen for the RAL values between baseline to 4 weeks and there was no significant difference between 4 weeks to 6 weeks of time interval (p<0.01,0.05) at Group B (**Table 6**).

Intergroup Comparison:

There was a statistically highly significant difference seen (p<0.01) for RAL at baseline between the Group A(7.04±1.30) and Group B(8.56±0.8, there is statistical significant difference for RAL at 4 weeks Group A (5.56±1.7), Group B(7.48±1.4), For RAL at 6 weeks group A (4.9±1.48) and Group B (7.4±0.9)there was statistically highly significant difference with higher values in Group B (**Table 7) (Table 12) (graph 5)**.

Sulcus Bleeding Index:

SBI was measured using Periodontal probe at baseline, 4 weeks, 6 weeks.

Intragroup Comparison:

The values of SBI for Group A decreased from baseline (2.55±0.54) throughout follow up at 4 weeks (1.20±0.51) and 6 weeks (0.51±0.99) on intra group comparison There was statistically highly significant difference seen (p<0.01) in SBI between baseline, 4weeks and 6weeks with higher values at Baseline**. (Table 10) (Graph 3)**.

The values of SBI for Group B decreased from baseline (2.8±0.45) throughout follow up at 4 weeks (1.74±0.54) and 6 weeks (0.87±0.38) on intra group comparison, there was statistical significance difference (p<0.01) seen from baseline to 4 weeks and 6 weeks. (**Table 11) (Graph 3)** There was statistically highly significant difference seen (p<0.01) in SBI between Baseline, 4weeks and 6weeks with higher values at baseline.

Intergroup Comparison:

There was statistically significant difference (p<0.01) seen between Group A (2.55±0.54) and Group B (2.8±0.45) at baseline. At 4 weeks follow up, highly statistically significant difference between Group A (1.20±0.51) showed greater reduction in SBI value as compared to Group B (1.74±0.54). At follow up of 6 weeks, highly statistically significant difference (p<0.01) between both groups i.e. Group A (0.51±0.99) with higher values in Group B (0.87±0.38) **(Table7) (Table 12)**.

Tables & Graphs

Table 1: Age wise distribution of subjects

Age (Years)	N
20-35 Years	2
36-40 years	4
41-45 years	5
46-50years	4
Total	**15**

Table 2: Gender wise distribution of subjects

Gender	Group A(N)	Group B(N)
Male	10	10
Female	5	5

Table 3: Intra Group Comparison of PPD at Group A (SRP + human placental extract gel)

	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi- Square value	p value of Friedman Test
PPD BL	25	4.56	0.507	4	5	5.00	2.88	39.325	0.000**
PPD (4w)	25	3.68	0.690	2	5	4.00	1.78		
PPD (6w)	25	3.28	0.542	2	4	3.00	1.34		

Table 4: Intra Group Comparison of PPD at Group B (SRP)

	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi- Square value	p value of Friedman Test
PPD BL	25	4.68	0.476	4	5	5.00	2.92	40.582	0.000**
PPD (4w)	25	3.76	0.597	3	5	4.00	1.62		
PPD (6w)	25	3.60	0.500	3	4	4.00	1.46		

Table 5: Pair wise Comparison using Wilcoxon Signed Ranks Test at Group A (SRP + Human Placental Extract Gel)

Pairs	Z value	p value of Wilcoxon Signed Ranks Test
PPD 4w - PPD BL	-4.147	0.000**
PPD 6w - PPD BL	-4.463	0.000**
PPD 6w - PPD 4w	-2.887	0.004**
RAL 4w - RAL BL	-4.239	0.000**
RAL 6w - RAL BL	-4.458	0.000**
RAL 6w - RAL 4w	-3.419	0.001**
SBI 4w - SBI BL	-4.387	0.000**
SBI 6w - SBI BL	-3.897	0.000**
SBI 6w - SBI 4w	-3.717	0.000**

Table 6: Pair wise Comparison using Wilcoxon Signed Ranks Tests at Group B

Pairs	Z value	p value of Wilcoxon Signed Ranks Test
PPD 4w - PPD BL	-4.796	0.000**
PPD 6w - PPD BL	-4.508	0.000**
PPD 6w - PPD 4w	-1.414	0.157#
RAL 4w - RAL BL	-4.838	0.000**
RAL 6w - RAL BL	-4.420	0.000**
RAL 6w - RAL 4w	-0.816	0.414#
SBI 4w - SBI BL	-4.385	0.000**
SBI 6w - SBI BL	-4.384	0.000**
SBI 6w - SBI 4w	-4.400	0.000**

Table 7: Intergroup Comparison of Variables at Group A (SRP + Human Placental Extract Gel) and Group B (SRP)

Group		N	Mean	Std Deviation		Mann Whitney U value			Z value	P value of Mann Whitney U Test
PPD BL	A	25	4.56	0.507	24	600	5	275.000	-0.865	0.387#
	B	25	4.68	0.476	27	675	5			
PPD 4w	A	25	3.68	0.690	24.88	622	4	297.000	-0.342	0.732#
	B	25	3.76	0.597	26.12	653	4			
PPD 6w	A	25	3.28	0.542	21.8	545	3	220.000	-2.056	0.040*
	B	25	3.60	0.500	29.2	730	4			
RAL BL	A	25	7.04	1.306	17.36	434	7	109.000	-4.12	0.000**
	B	25	8.56	0.821	33.64	841	9			
RAL 4w	A	25	5.56	1.710	17.64	441	5	116.000	-3.921	0.000**
	B	25	7.48	0.872	33.36	834	7			
RAL 6w	A	25	4.96	1.485	15.28	382	5	57.000	-5.067	0.000**
	B	25	7.40	0.913	35.72	893	7			
SBI BL	A	25	2.55000	0.549621	21.5	537.5	2.5	212.500	-1.994	0.046*
	B	25	2.83000	0.454835	29.5	737.5	3			
SBI 4w	A	25	1.20000	0.515388	17.96	449	1	124.000	-3.737	0.000**
	B	25	1.74000	0.547152	33.04	826	1.5			
SBI 6w	A	25	0.51000	0.998645	17.46	436.5	0.25	111.500	-3.951	0.000**
	B	25	0.87000	0.389444	33.54	838.5	0.75			

Table 8: Intragroup Comparison of RAL Group A (SRP + Human Placental Extract Gel)

	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi- Square value	p value of Friedman Test
RAL BL	25	7.04	1.306	5	9	7.00	2.94	43.929	0.000**
RAL (4w)	25	5.56	1.710	3	9	5.00	1.82		
RAL (6w)	25	4.96	1.485	3	7	5.00	1.24		

Table 9: Intragroup Comparison of RAL at Group B (SRP)

	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi-Square value	p value of Friedman Test
RAL BL	25	8.56	0.821	7	10	9.00	2.96	43.772	0.000**
RAL (4w)	25	7.48	0.872	6	9	7.00	1.54		
RAL (6w)	25	7.40	0.913	6	9	7.00	1.50		

Table 10: Intragroup Comparison of SBI at Group A (SRP + Human Placental Extract Gel)

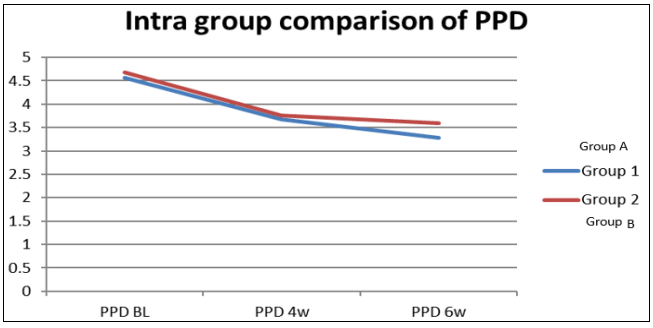
	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi- Square value	p value of Friedman Test
SBI BL	25	2.55000	0.549621	2.000	3.500	2.50000	2.96	44.240	0.000**
SBI (4w)	25	1.20000	0.515388	0.500	3.000	1.00000	1.96		
SBI (6w)	25	0.51000	0.998645	0.000	5.000	.25000	1.08		

Table 11: Intragroup Comparison Of SBI at Group B (SRP)

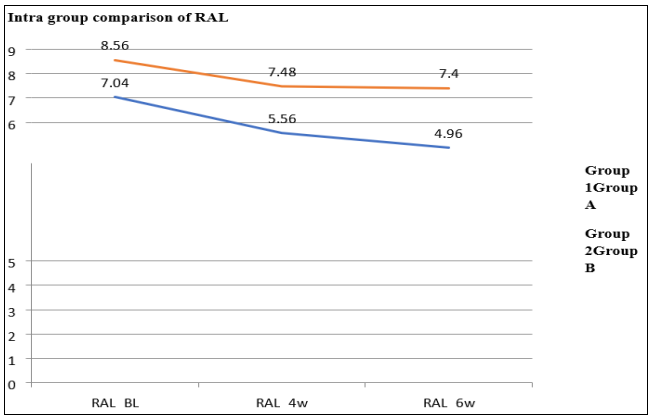
	N	Mean	Std. Deviation	Minimum	Maximum	Median	Mean Rank	Chi-Square value	p value of Friedman Test
SBI BL	25	2.83000	0.454835	1.750	3.500	3.00000	3.00	50.000	0.000**
SBI (4w)	25	1.74000	0.547152	0.500	2.750	1.50000	2.00		
SBI (6w)	25	0.87000	0.389444	0.000	1.750	0.75000	1.00		

Table 12: Inter Group Comparison af Variables at Group A and Group B

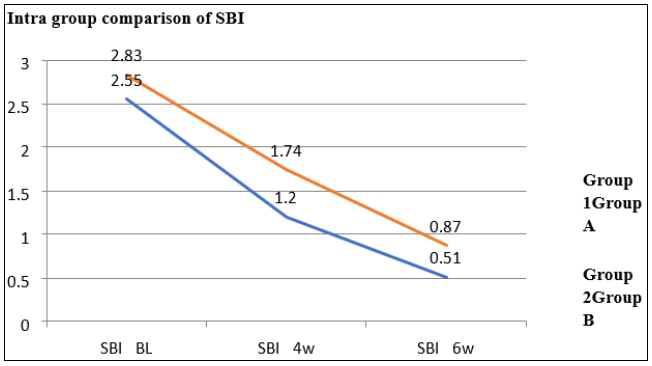
PPD BL	A	25	4.56	0.507	24	600	5	275.000	-0.865	0.387#
	B	25	4.68	0.476	27	675	5			
PPD (4w)	A	25	3.68	0.690	24.88	622	4	297.000	-0.342	0.732#
	B	25	3.76	0.597	26.12	653	4			
PPD (6w)	A	25	3.28	0.542	21.8	545	3	220.000	-2.056	0.040*
	B	25	3.60	0.500	29.2	730	4			
RAL BL	A	25	7.04	1.306	17.36	434	7	109.000	-4.12	0.000**
	B	25	8.56	0.821	33.64	841	9			
RAL (4w)	A	25	5.56	1.710	17.64	441	5	116.000	-3.921	0.000**
	B	25	7.48	0.872	33.36	834	7			
RAL (6w)	A	25	4.96	1.485	15.28	382	5	57.000	-5.067	0.000**
	B	25	7.40	0.913	35.72	893	7			
SBI BL	A	25	2.55000	0.549621	21.5	537.5	2.5	212.500	-1.994	0.046*
	B	25	2.83000	0.454835	29.5	737.5	3			
SBI (4w)	A	25	1.20000	0.515388	17.96	449	1	124.000	-3.737	0.000**
	B	25	1.74000	0.547152	33.04	826	1.5			
SBI (6w)	A	25	0.51000	0.998645	17.46	436.5	0.25	111.500	-3.951	0.000**
	B	25	0.87000	0.389444	33.54	838.5	0.75			



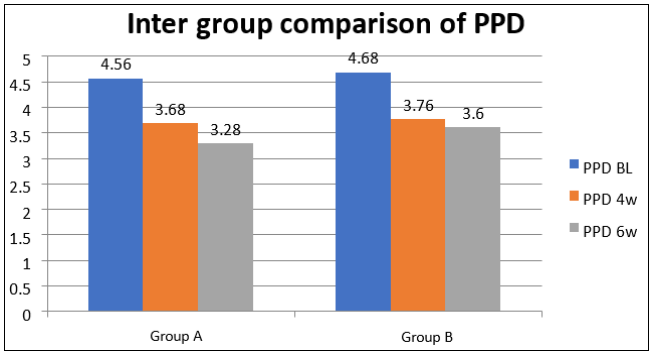
Graph 1: Intra Group Comparison of PPD at Group A and Group B



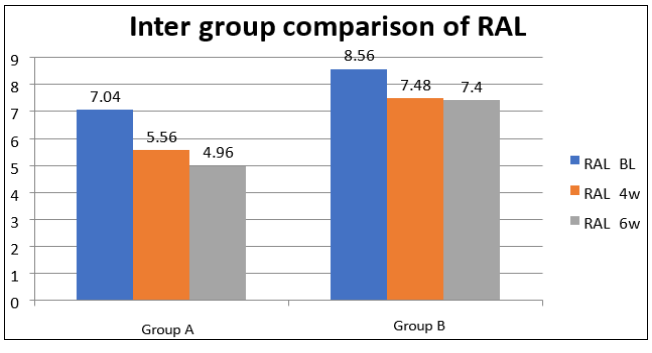
Graph 2: Intra Group Comparison of RAL at Group A (SRP + Human Placental Extract Gel) And Group B (SRP)



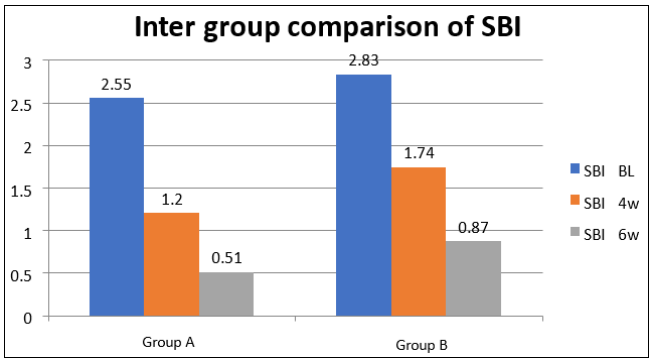
Graph 3: Intra Group Comparison of SBI at Group A and Group B



Graph 4: Inter Group Comparison of PPD at Group A (SRP + Human Placental Gel) and Group B (SRP)



Graph 5: Inter Group Comparison of RAL at Group A (SRP + Human Placental Gel) and Group B (SRP)



Graph 6: Inter Group Comparison of SBI at Group A and Group B

Conclusion

This randomized controlled split-mouth trial investigated the efficacy of human placental extract (HPE) gel as an adjunct to scaling and root planing (SRP) in the non-surgical management of stage II grade B periodontitis. The study compared a total of 50 sites, 25 sites treated with SRP intrapocket application of HPE gel (Group A) to 25 sites treated with SRP alone (Group B) in 15 subjects, assessing probing pocket depth (PPD), relative attachment level (RAL), and sulcus bleeding index (SBI) at baseline, 4 weeks, and 6 weeks. The superior clinical outcomes in Group A align with the regenerative and anti-inflammatory properties of HPE, as supported by prior studies demonstrating its ability to enhance collagen synthesis, reduce pro-inflammatory cytokines, and facilitate wound healing. The absence of adverse effects and ease of HPE gel application highlight its potential for clinical integration. Within the limitations of the study, it can be concluded that HPE gel as an adjunct to SRP significantly enhances clinical outcomes in the non-surgical treatment of Stage II Grade B Periodontitis, offering a promising approach to improve periodontal health and potentially reduce the need for surgical interventions. These findings advocate for further research to establish HPE gel as a standard adjunct in periodontal therapy, paving the way for advanced regenerative strategies in clinical practice.

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