

Comparative Evaluation of 0.8% Hyaluronic Acid Gel and Diode Laser Therapy As An Adjunct To Scaling And Root Planing: A Randomized Clinical Trial

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Abstract

Background: Laser therapy as well as local drug delivery has emerged as a newer treatment modality as adjunct to scaling & root planing(SRP) due to their bactericidal & inflammation reduction properties.

Aim: The aim of the study was to clinically examine and compare the effectiveness of local drug delivery of 0.8% gel and 980nm laser application as an adjunct to SRP in the treatment of chronic periodontitis.

Methods and material: In this split mouth randomized clinical trial 50 sites in 25 patients with a probing depth of 4-8mm after initial SRP were enrolled. Test sites1 received application of Hyaluronic acid gel and the test sites 2 were irradiated with 980nm diode laser, twice with one week interval. Plaque index (PI), gingival index (GI), modified sulcus bleeding index (mSBI), probing pocket

depth (PPD) and clinical attachment levels (CAL) were measured at baseline, 1 week, 3 months and 6 months.

Results: All the clinical parameters improved significantly from baseline to 6 months in both test sites. At 3 months & 6 months test sites2 showed statistically significant reduction in PPD (3.88mm, $p<0.05$) and CAL (3.64mm, $p<0.05$) compared to test site 1.

Conclusion: Diode laser & Hyaluronic acid gel effectively improved clinical parameters. However 980nm diode laser therapy showed improved reduction in PPD & CAL gain when compared to hyaluronic acid gel. Long term clinical trials are required to evaluate the effectiveness of multiple applications of diode laser on microbiological and immunological parameters.

Keywords - periodontal pockets, SRP, diode laser, 0.8% Hyaluronic acid gel.

Introduction

Worldwide one of the most common inflammatory disease affecting adults is periodontitis¹. It is caused due to dysbiosis in periodontal tissues mediated by complex host-microbial interactions, leading to loss of connective tissue attachment to the root surface cementum and adjacent alveolar bone². Its treatment success is dependent on effective removal of supragingival and subgingival bacterial biofilms, calculus and the smear layer by mechanical instrumentation^{3,4} ensuring biologic compatibility of diseased periodontal radicular surface to new connective tissue attachment⁵. However scaling & root planing (SRP) results in wound of already inflamed tissues and pain both during & after treatment. In addition, complete removal of the bacteria biofilm and their endotoxins in deeper areas of the pockets and furcation sites is often difficult to achieve⁶. Several adjunctive treatment modalities have been developed to overcome these limitations. One such possible approach is the application of hyaluronan (HA) and laser. HA is a non-sulfated glycosaminoglycan and a major component in extracellular matrix of most body tissues⁷. Its application has shown a positive effect on the reduction of plaque, bleeding on probing & probing depth in patients with periodontitis⁸⁻¹⁰ possibly due to its anti-inflammatory and wound healing properties¹¹⁻¹³. Diode laser therapy has also been used as an adjunctive treatment to conventional periodontal therapy¹⁴ because of its reported anti-inflammatory, bactericidal and detoxifying effects¹⁵⁻¹⁸. Hence, the purpose of the present study was to clinically examine and compare the effectiveness of local delivery of 0.8%HA gel and 980nm diode laser application in moderately deep periodontal pockets as an adjunct to SRP.

Material & Methods

Twenty five patient with chronic periodontitis aged between 30-65 years, reporting to the Department of

Periodontics, Faculty of Dental Sciences, Bangalore were recruited. This was a comparative, double blind, split mouth, randomized clinical trial. All participants were informed about the nature of the study and gave their consent by signing an informed consent form. The study was approved by the Ethics Committee of Faculty of Dental Sciences, M S Ramaiah University of Applied Sciences, Bangalore.

All included patients had minimum of 20 teeth, with at least 1 tooth with probing depth 4-8 mm in at least two quadrants excluding the third molar and had not undergone any type of periodontal therapy in past 6 months at the time initial examination. Patients who were medically compromised or under therapeutic regimen that decreases the probability of soft tissue and bone healing, who were allergic to materials and drugs used in this study, with unrestorable carious lesions, Smokers, Pregnant or lactating woman were excluded. Also patients who had received antibiotics, anti-inflammatory or Immunosuppressive drug therapy within the past 6 months were excluded. A detailed case history and clinical examination of the patients was recorded by measuring with UNC-15 probe (Hu-Friedy's). Plaque index (Sillness & loe ,1963)¹⁹ Gingival index (Loe and Sillness)²⁰, Modified sulcus bleeding index²¹, probing pocket depth & clinical attachment level were recorded at baseline,1 week,3 months & 6 months. Acrylic occlusal stents were fabricated forpurpose of measurement standardization. All patients received oral prophylaxis with oral hygiene instructions. Periodontal pockets in two different quadrants were selected and randomized to as test site1(0.8% HA) and test site2(980nm laser) in split mouth design by allocation concealment method. Sites with probing depth 4-8 mm were then subjected to either of the treatments immediately after SRP at day 1 & 7.

In test site 2, LASER HF, a Class 2b laser device by HAGER WERKEN was used at 980 nm wavelength. Laser light emitted was in continuous wave mode at 0.66 W power using a 320 micrometer optical fiber and autoclave friendly hand-piece. Both patient and operator wore protective eyewear before commencing the procedure. After isolating with cotton rolls the selected tooth area was then irradiated with a diode laser for a period of 20 seconds twice with an interval of 60 seconds between the two applications, parallel to tooth surface from coronal to apical direction of periodontal pocket in contact mode. The optical fiber was introduced 1mm less than the measured probing depth using the endodontic stop on the fiber.

In test site 1, after thoroughly isolating the area with cotton rolls, pockets received 0.8% hyaluronic acid gel about one drop (0.06 ml) in quantity using a blunt cannula attached to 10 ml plastic disposable syringe. 0.8% HA gel was prepared by completely dissolving weighed quantity of carbopol 930 in water by continues stirring for 30 minutes. Accurately weighed quantity of Sodium Hyaluronate powder was dissolved in prepared solution of carbopol. The pH of the gel formulation was adjusted using Triethanolamine, stirred slowly until a gel was obtained. Weighed quantity of methyl Paraben and Propyl paraben were added as preservatives.

Post operatively patients were asked not to eat or rinse their mouth for 1 hour after the procedure. Oral hygiene instruction were reinforced for good home care dexterity & they were also asked to report back if any complications occur.

Statistical Analysis

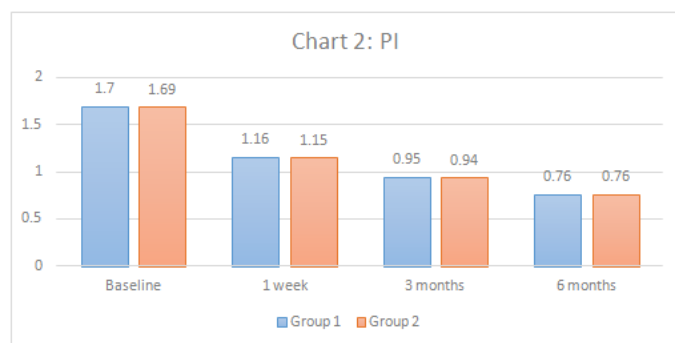
Data collected from clinical parameters recording was analyzed using SPSS version 22 software. Means between the groups was compared using student-t test at each visit. Within the group change from baseline was compared

using sample t-test. Intra-group analysis was done using repeated measures ANOVA with post-hoc Bonferroni test. The difference between the test groups was compared using Kruskal Walis test. P-value<0.05 was considered as statistically significant.

Results

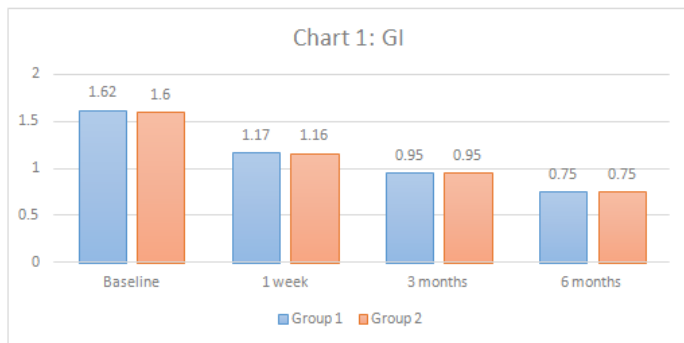
The purpose of this clinical trial was to determine the efficacy of two applications of subgingivally delivered 0.8% Hyaluronic acid gel and 980nm diode laser therapy in patients with chronic periodontitis and to compare the efficacy of both. In the present study, 25 patients in the age group of 30-65 years, fulfilling the inclusion and exclusion criteria were recruited and were randomly treated in split mouth design by HA gel(test site 1) and laser therapy(test site 2). All 25patients (13 females and 12 males) completed the study with 6months follow up. The mean age of patients was 38.00 years and the female: male ratio was 13(52%):12(48%). No statistical difference at baseline values between the two groups was observed.

Plaque index: Both the test groups showed statistically significant intra group improvements in PI scores at 1 week, 3 months & 6 months from baseline levels($p < 0.001$). On comparison between the test groups no statistically significant differences were seen in mean plaque index scores at each follow up visits($p = 0.965$)as shown in graph below(Graph 1).



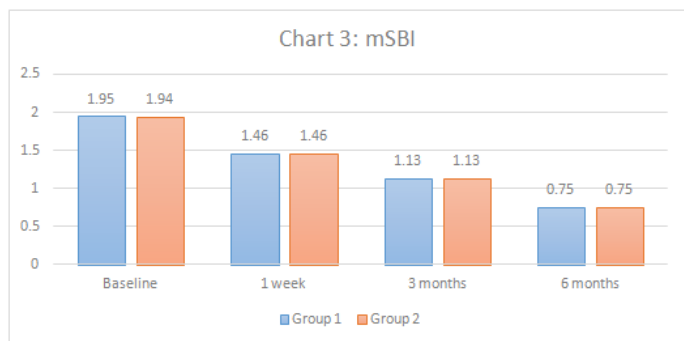
Graph 1: Comparison of Mean Values of Plaque Index at Different Visits between the study groups

Gingival index: Both the test groups showed statistically significant intra group improvements in GI scores at 1 week, 3 months & 6 months follow up visit from baseline levels($p < 0.001$). However on intergroup comparison no statistically significant difference was observed in mean gingival index scores at all visits($p = 0.904$)(Graph 2).



Graph 2: Comparison of Mean Values of Gingival Index at Different Visits

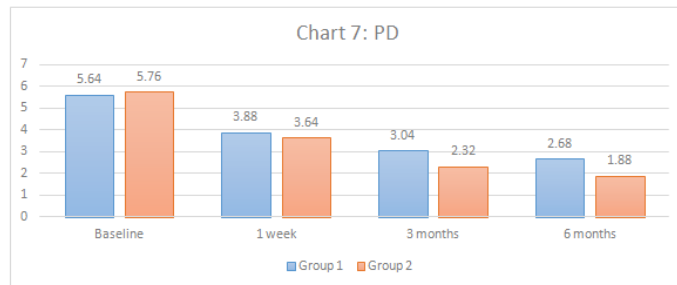
Modified sulcus bleeding index: Both the test groups showed statistically significant intra group improvements in mSBI scores at 1 week, 3 months & 6 months follow up visit when compared to baseline levels($p < 0.001$). On intergroup comparison no statistically significant difference were seen in mean mSBI scores at each visit($p = 0.904$)(Graph 3)



Graph 3: Comparison of Mean Values of modified sulcus Bleeding Index at Different Visits

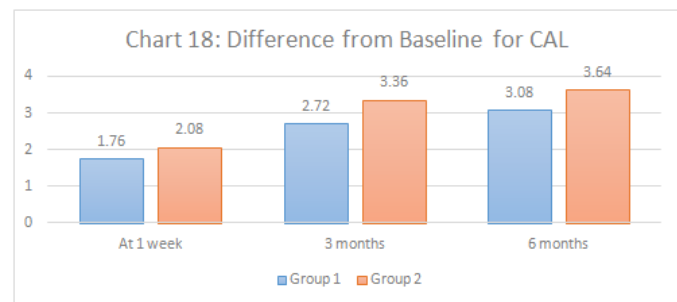
Probing depth: Both the treatment groups showed significant reduction in PPD from baseline to 1 week, 3 months and 6 months($p < 0.001$). On intragroup comparison at 1 week no statistically significant

difference were seen. However statistically significant reduction in probing depth was seen at 3 & 6 months in test group 2 compared to test group 1($p < 0.001$)(Graph 4).



Graph 4: Comparison of mean pocket depth measurements between test 1 and test 2 at different visits

Clinical attachment level: Both the treatment groups showed significant improvement in CAL from baseline to 1 week, 3 months and 6 months ($p < 0.001$). On intragroup comparison at 1 week no statistically significant difference were seen. However borderline significant reduction in CAL was seen at 3 & 6 months in test group 2 compared to test group 1($p < 0.05$)(graph 5).



Graph 5: Comparison of changes in CAL measurements from baseline between test 1 and test 2

Discussion

Primary recommended approach of non-surgical periodontal therapy is based on the removal of supragingival or subgingival calculus and bacterial biofilms using hand instruments and ultrasonic scalers along with instructions in self-administered oral health care measures. Subgingival SRP is a technically demanding procedure and complete removal of the bacteria biofilm and their endotoxins in deeper areas of

the pockets and furcation sites is often difficult to achieve. It is, therefore, logical that different modalities or local subgingival application of chemotherapeutic agents may enhance benefits of mechanical debridement. Diode laser is also indicated for the treatment of gingival soft tissues, but does not ablate the root surface, therefore it may be useful as an adjunctive means for scaling and root planing due to its bactericidal and detoxification effects. Therefore, the **aim of this study** was to investigate the effectiveness of the application of 980nm diode laser and 0.8% Hyaluronic acid gel following conventional scaling and root planing in treatment of moderate pockets in patients with chronic periodontitis

No significant difference were seen in subjects' age, gender, teeth with periodontal pockets and periodontal parameter at baseline. Each subject demonstrated good oral hygiene and generally healthy gingival condition throughout the study.

In the present study sites treated with hyaluronic acid gel showed significant improvement in plaque index and gingival index score from baseline to 6 months. These findings were in agreement with study conducted by **Abdulhameed et al²²**, in which adjunctive effects of 0.8% HA gel to SRP was evaluated in thirty patients for 4weeks. Also statistically significant improvements in bleeding scores at 6 months follow up visit was noticed. This is in accordance with the studies by **Sahayata Vishal N²³ et al** and **Yashika Jain²⁴ et al** where 0.2% hyaluronic acid gel was used in treatment of chronic gingivitis. This significant reduction in inflammation could possibly be due to anti-inflammatory and wound healing properties of Hyaluronic acid (**Jentsch²⁵ et al**). Twice applications of 0.8% HA gel together with SRP at baseline resulted in a statistically significant reduction in probing depth at the end of 6 months in this study which is in agreement with results by **Sigrun Eick²⁶ et al** wherein changes in PD and

the reduction of the number of pockets with PD >5 mm were significantly higher in the Hyaluronan group after 3 & 6 months. Applications of 0.8% HA gel also resulted in a statistically significant gain in clinical attachment level at the end of 6 months in this study. This is in accordance with a randomized controlled trial by **El-Sayed²⁷ et al** evaluating the effect of local application of 0.8% Hyaluronan gel in conjunction with periodontal surgery. However in studies carried out by **Engstoem²⁸ et al** and **Xu²⁹ et al** who evaluated potential benefits of local subgingival application of HA gel adjunctive to SRP did not find any clinical improvement by use of HA gel compared to SRP alone. **Gauri Goutiya³⁰ et al** also did not report significant differences in the PPD and RAL between control and HA treated sites at 4th, 6th, and 12th week time interval.

In sites treated with 980nm diode laser therapy, significant improvement was seen in plaque index and gingival index score from baseline to 6 months which were in agreement with studies by **Ugo Caruso³¹**. This change could also be attributed to the rigorous oral hygiene maintenance regime, regular follow-up visits and reinforcement of oral hygiene instructions for the patients throughout the study period. In contrast no significant difference in PI and GI was seen at follow up visits in study conducted by **Chirag Shah³² et al**. Reduction in BOP in present study concur with the study done by **Davoud Zare³³ et al** which showed improvement in BOP from 66% to 25 % at 2 months following 980nm laser therapy adjunct to SRP. Two times irradiation of 4-8mm periodontal pockets with 980nm diode laser together with SRP resulted in improved reduction in probing depth at the end of 6 months in this study. Thus, a greater number of sites initially targeted for surgical periodontal therapy, had improved to the extent that no further active therapy was needed. Also, it limited the patient morbidity, time and cost of the treatment.

Similar results were obtained in studies by **Walter Dukic³⁴ et al & Alireza Fallah³⁵ et al.** The clinical attachment gain in the present study are also in agreement with the results obtained in the studies by **Moritz³⁶ et al & Kamma³⁷ et al.** Better results were reported in study by **Reza Birang³⁸ et al** at 3 months in laser with SRP group. However **Kreisler³⁹ et al** studied the clinical efficacy of diode laser as an adjunct to SRP found no significant differences for PI, GI, BOP, and the sulcus fluid flow rate. In contrast to our findings, **De Micheli⁴⁰ et al** also did not report additional enhancement of clinical parameters 6 weeks after the use of a high-power diode laser in combination with SRP. **Yilmaz⁴¹ et al** found no improvement in PPD when diode laser was used adjunct to scaling and root planning over SRP alone. **Crispino⁴² et al** found in his study that laser diode gave an evident result in periodontal indices (GI, PI, PD). **Matarese⁴³ et al** found an improvement in periodontal parameters at one year clinical trial but did not found significant effect on microbial and inflammatory mediators as compared to SRP alone.

On comparison between the test sites, statistically significant reduction in pocket probing depth and gain in clinical attachment level was achieved in test sites irradiated with 980nm diode laser which is in accordance with the study by **Soliman⁴⁴ et al. Raed Aziz Badeia⁴⁵ et al** in his study on adjunctive use of low level (635nm) & high level laser (980nm) pocket achieved mean CAL gain of 4 mm at 6 months in high level laser group. This reduction could be due to decrease in periodontal pathogens as substantiated by the study conducted by **Mirjana Gojkov-Vukelic⁴⁶ et al.** In support of using 980nm diode laser at 0.6W, **Coluzzi⁴⁷ et al** recommended laser soft tissue curettage at 0.6 W afterwards for hemostasis and bacterial reduction. **Gutknecht⁴⁸ et al** demonstrated that the use of a 980nm diode laser in

continuous wave mode for curettage to reduce the risk of bacteremia and facilitate mechanical debridement. Whereas **Ryden⁴⁹ et al.** reported that the use of diode laser had no significant additional effects on clinical parameters.

Conclusion

It can be concluded that both 0.8% HA gel & 980nm Diode Laser has effectively reduced plaque accumulation, gingival inflammation, bleeding on probing, probing depths and improved clinical attachment level at 6 months. However 980nm Diode Laser proved superior in the treatment of moderately deep periodontal pockets. It can be advocated in patients who are apprehensive to surgical procedures & esthetically conscious. Multiple cycles of Laser application may be required for long term benefits. Further clinical trials are required to evaluate its effectiveness for long term by rendering cycles along with microbiological and immunological analysis of the treated sites.

Ethical Approval: taken from institutional ethical committee.

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Legends Figure



Pre-op probing depth



0.8% HA gel application on first visit



Probing Pocket depth at 1 week



Probing Pocket depth at 6 months



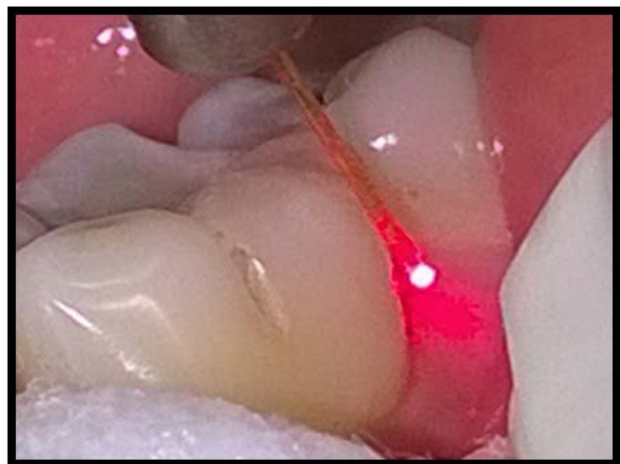
Re-application of 0.8% HA gel at 1 week



Pre-op probing depth



Probing Pocket depth at 3 months



980nm Laser pocket therapy on first visit



Probing Pocket depth



Probing Pocket depth at 6 months



Laser pocket therapy at 1 week



Probing Pocket depth at 3 months