"Open Flap Debridement Using 810nm Diode Laser and Conventional Surgery in Patients on Low Dose Aspirin– A Comparative Study"

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Abstract: The aim of this study was to evaluate the adjunctive effects of the diode laser in open flap debridement as compared with the conventional surgical techniques. Chronic periodontitis patients on low dose aspirin were randomized into test (diode laser application after flap surgery) and control(flap surgery without laser). The results showed less blood volume lost and better clinical improvements in the test sites. Henceforth the study has proved that lasers can form an integral part of periodontal therapy in patients on low dose aspirin(<150mg) without altering their drug regime.

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I. Introduction

NSAIDs, especially low dose aspirin are one of the frequently prescribed drugs particularly in patients prone to cardio-vascular disorders and arthritis. About 10% of rural and 25% of urban population in India suffer from hypertension¹. Anti-platelet therapy especially low dose aspirin is routinely given in the management of patients suffering from these arterio-vascular diseases. The benefits of antiplatelet therapy for the prevention of thrombotic events in cardiovascular diseases are evident. Statistical studies have shown that secondary prevention by antiplatelet agents reduces the risk of nonfatal myocardial infarctionand stroke by 25% to 30%, and the rate of vascular death by about 15%, resulting in a significant reduction in overallmortality

Earlier recommendations advocated the delay in invasive dental procedures to a minimum of three days following cessation of aspirin therapy.Current consensus favour no discontinuation of aspirin as the risk of developing hemorrhage is greatly outweighed by the risk of developing thrombo-embolic events³. The evolution and incorporation of lasers in the field of dentistry have led to significant advances in patient care and management. The physical principle of laser was developed from Einstein's theories in the early 1900s, and the first device was introduced in **1960 by Maiman⁴**. Since then, lasers have been used in many different areas medicine, surgery and in various specialties in dentistry including Periodontics

The most commonly used lasers in Periodontics include diode lasers, the Nd:YAG laser (neodymium-doped:yttrium, aluminium and garnet), the Er:YAG laser (erbium-doped:yttrium, aluminium and garnet) and the CO_2 (carbon-dioxide) laser with a range from 810to 10,600 nm. Various advantageous characteristics of lasers such as hemostatic effect, selective calculus ablation or bactericidal effects against periodontopathic microorganisms might lead to improved treatment outcomes⁵.

The diode laser is a solid-state semiconductor laser that typically uses a combination of Gallium (Ga), Arsenide (Ar), and other elements such as Aluminum(Al) and Indium (In) to change electrical energy into light energy. he laser is emitted in continuous-wave and gated-pulsed modes, and is usually operated in a contact method using a flexible fiber optic delivery system. The reliable hemostasis achieved with diode lasers has made them a valuable tool during periodontal surgical procedures. Laser induced hemostasis offers an alternative solution in the controversial issue of intra and post operative bleeding control in patients on anti-platelet therapy without altering their medication regime. In addition to this, have been found to enhance healing, reduce pain and have a bactericidal effect.Hence the purpose of this dissertation is to evaluate the effect of 810nm Diode laser in open flap debridement as compared to conventional mechanical debridement in patients on Low dose aspirin (without altering drug regime).

II. Material And Methods

Study Design: This was a double blinded, randomized, comparative, split-mouth clinical trial

Study Location: The study was carried out in the Department of Periodontology, JSS Dental College and Hospital, Mysuru, Karnataka, India.

Study Duration: December 2016 to January 2018.

Sample size: 16 patients.

Sample size calculation: Sample size was estimated using previous literature. Sample size was computed to be 11 per group at 5% α error, 80% power with an effect size of 1.23 to identify a mean difference of 0.8 to be statistically significant. The sample size was finally rounded off to 16 anticipating some degree of drop outs.

Subjects & selection method: By purposive sampling the study population was drawn from consecutive patients on low dose aspirin(<200mg) with chronic periodontitis and having contralateral sites with a pocket depth of more than 5mm who presented to the Department of Periodontology, JSS Dental college and Hospital .Patients were then divided into test and control sites.

Inclusion criteria:

- 1. Patients who were willing to participate in the study and willing to give informed consent low dose aspirin therapy(<150mg/day)
- 2. Male and Female Patients.
- 3. Age range of 35-60 years,
- 4. Patients who had completed initial phase of periodontal therapy and were capable of adequate maintenance.
- 5. Not undergone any regenerative periodontal therapy in the area to be treated 6 months prior to the study
- 6. Moderate Chronic Generalised Periodontitis patients having contra-lateral quadrants having pocket depth more than 5mm
- 7. Probing pocket depth > 5mm and width of attached gingival atleast 2mm

Exclusion criteria:

- 1. Pregnant /lactating women
- 2. Patients with immunologic diseases and on long-term Steroid and antibiotic therapy
- 3. Patients on any anti-coagulant drugs (warfarin , heparin etc), with known bleeding disorders.
- 4. Infectious diseases like (Hepatitis, AIDS, Tuberculosis.
- 5. Systemic blood pressure more than 180/110 mm Hg

Procedure methodology

Patients were subjected to phase I therapy comprising of full mouth scaling, root planing and occlusal correction if required. Mobility and vitality were checked for the teeth with furcation involvement. Patients underwent routine hematological investigations. Oral hygiene instructions were given. After 2 months, patients were evaluated for tissue response and maintenance of oral hygiene. If plaque control and tissue response were found to be satisfactory and pockets > 5mm present, patients were scheduled for surgery.

On the day of the surgery, following site specific clinical parameters were recorded using a UNC-15 probe. The angulation and direction of the probe were standardized by the use of customized acrylic occlusal stents. All parameters like Plaque Index(PI) (Silness and Loe, 1964), Gingival Index (GI)(Loe and Silness, 1963), Sulcus bleeding index (Muhlemann and Son 1971), Probing Depth (PD) using UNC 15 probe and customized acrylic stent, Clinical Attachment Level (CAL) using a UNC 15 probe were repeated at 3 and 6 months intervals:

The surgical sites were randomly allocated by computer generated method to test and the control groups such that Control site(A)- received Modified Widman Flap surgery using conventional methods. Test site (B) - received Modified Widman Flap surgery using 810nm Diode laser as an adjunct. The surgeries were performed 2 weeks apart if the healing was found satisfactory.

The surgical area was anesthetized using 2.7ml Lignocaine 2% with 1:100000 Adrenaline. The procedure was done under proper aseptic precautions using continuous aspiration to keep the surgical site clean. A full thickness mucoperiosteal flap was raised to provide visibility and accessibility to the underlying bone and root surfaces(fig 1) The root surfaces were planed and degranulation was done with the help of curettes and ultrasonic scalers on both sides.

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Fig 1: Full thickness mucoperiosteal flap

The undersurface of the flap was lased with diode laser only in the test site(B) .Diode laser with a wavelength of 810nm and with a power setting of upto 2 W depending on the flap thickness was used in continuous, contact mode with the help of a flexible fiber optic delivery system. The laser safety protocol was followed to avoid the adverse effects of lasers(fig 2).



Fig 2: Diode laser on the undersurface of the flap

The operator, patient and the assistant wore dark glasses which are specifically designed to filter the laser beam of the above wavelength. The lips were reflected by the assistant to avoid any damage. Moist gauze was used to protect the adjacent areas. Alcohol based topical anesthetic or alcohol moistened gauze were not used during the surgery as they are inflammable. High speed evacuation was used to capture the laser plumes. The laser was activated by firing it once on a dark surface preferably blue or black. The fiber was used in a 'brush stroke' motion on the undersurface of the flap to remove the pocket lining. A distinct charred tissue was noticed after lasing the undersurface due to haemostatic and tissue coagulation effect of the diode laser. During the flap surgery, the flaps were thinned, papillae were trimmed, and tissue tags were removed. The flaps were approximated with the help of 4-0 non-resorbable black braided silk sutures.

INTRAOPERATIVE BLEEDING EVALUATION:

The volume of liquid (water or normal saline) used for irrigation during the surgery was noted during and after the procedure. During the surgery, all the water and blood was collected into a graduated beaker(fig 3). The total amount of blood loss was calculated by subtracting the volume of liquid used during the surgery for irrigation from the total volume of fluid that was aspirated in the graduated beaker.

Intraoperative Blood Loss =Total Aspirated Volume – Volume Used During Irrigation

Patients were given routine post-operative instructions. Oral hygiene instructions were reinforced. Patients were recalled after a period of 1 week for suture removal and re-evaluation.

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Fig 3: Graduated beaker

Post operative pain evaluation :

Patients were asked to maintain a diary evaluating intra-operative and postoperative pain or discomfort daily at night time for one week using a visual analogue scale. Patients were kept on a maintenance protocol with regular reinforcement of oral hygiene instructions. At 3 months and 6 months, plaque index, gingival index, bleeding index, probing depth and relative clinical attachment level were measured with the same acrylic stent that was used before.

Statistical analysis

Data was analyzed using SPSS version 22. The data obtained were subjected to descriptive statistics, t test, Mann –Whitney U test, Wilcoxan test and Chi square tests. The statistical significance was set at p<0.05.

III. Results

Intra-Group Comparison: Comparison of parameters in control site

Plaque Index (PI) :

The values of PI in the control site **decreased** from 1.2875 ± 0.48 at the baseline to 0.61 ± 0.34 at three months and to 0.2 ± 0.32 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.001), baseline and 6 months (p value 0.000) and 3 month and 6 months (0.001) . (**Table 1**, **Graph 1**)

| | | 6 months | s(6M) | | |
|----------------|-----------|-------------------|--------------------|---------|--------------|
| Site & Pa | rameters | Mean score ± SD | Intervals compared | p-value | Significance |
| | BASELINE | 1.28 ± 0.45 | Baseline - 3M | 0.001 | S |
| Plaque Index | 3M | 0.61 ± 0.34 | Baseline – 6M | 0.000 | S |
| | 6M | 0.20 ± 0.32 | 3M - 6M | 0.001 | S |
| | BASELINE | 1.0438 ± 0.55 | Baseline - 3M | 0.001 | S |
| Gingival | 3M | $.4563 \pm 0.40$ | Baseline – 6M | 0.001 | S |
| Index | 6M | $.1125 \pm 0.27$ | 3M - 6M | 0.014 | S |
| | BASELINE | 2.6000 ± 0.28 | Baseline - 3M | 0.000 | S |
| Bleeding Index | 3M | 1.5063 ± 0.17 | Baseline – 6M | 0.000 | S |
| | 6M | 1.4750 ± 0.39 | 3M - 6M | 0.66 | NS |
| | BASELINE | 5.8125 ± 0.75 | Baseline - 3M | 0.000 | S |
| Probing Depth | 3M | 3.1875 ± 0.54 | Baseline – 6M | 0.000 | S |
| | 6M | 3.1875 ± 0.54 | 3M - 6M | 1.000 | NS |
| Clinical | BASEI INE | 62500 ± 100 | Baseline - 3M | 0.000 | S |

 3.5000 ± 0.63

 3.3125 ± 0.62

 Table 1: Intra- site comparison of periodontal parameters studied in the control site at baseline, 3 months (3M),

Attachment Level

3M

6M

Baseline - 6M

3M - 6M

0.000

0.083

S

NS



1. Gingival Index (GI) :

The values of GI in the control site **decreased** from 1.0438 ± 0.55 at the baseline to 0.4563 ± 0.44 at three months and to 0.1125 ± 0.27 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.001), baseline and 6 months (p value 0.001) and 3 month and 6 months (0.014). (**Table 1, Graph 2**)



Graph2: The comparison of Gingival Index(GI) between test and control sites.

2. <u>Bleeding Index (BI) :</u>

The values of BI in the control site **decreased** from 2.6000 ± 0.28 at the baseline to 1.5063 ± 0.17 at three months and to 1.4750 ± 0.49 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.000) and baseline and 6 months (p value 0.000), but there was no statistically significant difference seen in the BI at 3 month and 6 months (p value 0.666). (**Table 1, Graph 3**)



Graph 3: The comparison of Bleeding Index(BI) between test and control sites

3. Probing Depth (PD):

The values of PD in the control site **decreased** from 5.8125 ± 0.75 at the baseline to 3.1875 ± 0.54 at three months and to 3.1875 ± 0.54 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.000), and baseline and 6 months (p value 0.000) but there was no statistically significant difference seen in the BI at 3 month and 6 months (p value 1.000). (Table 1, Graph 4)



Graph 4: The comparison of Probing Depth (PD) between test and control sites

4. <u>Clinical Attachment Level (CAL) :</u>

The values of CAL in the control site **decreased** from 6.2500 ± 1.00 at the baseline to 3.5000 ± 0.63 at three months and to 3.3125 ± 0.60 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.000), and baseline and 6 months (p value 0.000) but there was no statistically significant difference seen in the CAL at 3 month and 6 months (p value 0.08). (Table 1, Graph 5)



Graph 5: The comparison of Clinical Attachment Level (CAL) between test and control sites.

5. Visual Analogue Scale (VAS) :

In the control site, the mean value of VAS was 4.12 ± 0.71 on the first day after surgery which decreased to 0.00 at 1 week after surgery. The difference was **statistically significant** (p value 0.417). (**Table 3a,3b; Graph 6**)

| Table Sa - C | Table 3a - Comparison of vas score at different time interval in control site | | | | | | | |
|--------------|--|--------|----------------|--|--|--|--|--|
| | Ν | Mean | Std. Deviation | | | | | |
| Day1 | 16 | 4.1250 | .71880 | | | | | |
| Day 2 | 16 | 4.3125 | .94648 | | | | | |
| Day 3 | 16 | 3.1875 | .83417 | | | | | |
| Day 4 | 16 | 1.0000 | 1.15470 | | | | | |
| Day 5 | 16 | .1250 | .34157 | | | | | |
| Day 6 | 16 | .0625 | .25000 | | | | | |
| Day 7 | 16 | .0000 | .00000 | | | | | |

 Table 3a - Comparison of vas score at different time interval in control site

| Ν | 16 |
|-------------|--------|
| Chi-Square | 89.471 |
| df | 6 |
| Asymp. Sig. | .000 |



Graph 6: The comparison of intra-operative VAS and VAS over oneweek between test and control sites

Comparison of parameters in test site

1. Plaque Index (PI)

The values of PI in the test site **decreased** from 1.3500 ± 0.53 at the baseline to $.4688\pm0.30$ at three months and to 0.21 ± 0.31 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.000), baseline and 6 months (p value 0.000) and 3 month and 6 months (0.05). (**Table 2, Graph 1**)

| Table 2: | Intra- | site | compari | ison c | of period | lontal | parameters | studied | l in the | Test | site at | baseline | , 3 1 | months | (3M), | 6 |
|----------|--------|------|---------|--------|-----------|--------|------------|----------------|----------|------|---------|----------|-------|--------|-------|---|
| | | | | | | | | (\mathbf{M}) | | | | | | | | |

| | | monuis(or | VI) | | |
|---------------------|----------|---------------------|--------------------|---------|--------------|
| Site & Par | rameters | Mean score \pm SD | Intervals compared | p-value | Significance |
| | BASELINE | 1.3500 ± 0.53 | Baseline - 3M | 0.000 | S |
| Plaque Index | 3M | 0.4688 ± 0.31 | Baseline – 6M | 0.000 | S |
| | 6M | 0.2188 ± 0.30 | 3M - 6M | 0.05 | S |
| | BASELINE | 1.0438 ± 0.57 | Baseline - 3M | 0.001 | S |
| Gingival | 3M | 0.4563 ± 0.40 | Baseline – 6M | 0.001 | S |
| Index | 6M | 0.1125 ± 0.28 | 3M - 6M | 0.016 | S |
| | BASELINE | 2.6063 ± 0.27 | Baseline - 3M | 0.000 | S |
| Bleeding Index | 3M | 1.2688 ± 0.13 | Baseline – 6M | 0.000 | S |
| | 6M | 1.1063 ± 0.11 | 3M - 6M | 0.002 | S |
| Probing Depth | BASELINE | 5.8750 ± 0.95 | Baseline - 3M | 0.000 | S |
| | 3M | 3.0000 ± 0.63 | Baseline – 6M | 0.000 | S |
| | 6M | 2.7500 ± 0.57 | 3M - 6M | 0.285 | NS |
| Clinical Attachment | BASELINE | 5.8750 ± 0.95 | Baseline - 3M | 0.000 | S |
| Level | 3M | 3.0000 ± 0.63 | Baseline – 6M | 0.000 | S |
| | 6M | 2.7500 ± 0.47 | 3M - 6M | 0.285 | NS |

2. Gingival Index (GI)

The values of GI in the test site **decreased** from 1.0938 ± 0.57 at the baseline to 0.45 ± 0.40 at three months and to 0.14 ± 0.28 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.001), baseline and 6 months (p value 0.001) and 3 month and 6 months (0.016). (**Table 2**, **Graph 2**)

3. Bleeding Index (BI)

The values of BI in the test site **decreased** from 2.6000 ± 0.27 at the baseline to 1.268 ± 0.13 at three months and to 1.1063 ± 0.11 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.000) and baseline and 6 months (p value 0.000), and 3 month and 6 months (0.002). (**Table 2, Graph 3**)

4. <u>Probing Depth (PD):</u>

The values of PD in the test site **decreased** from 5.8750 ± 0.95 at the baseline to 3.0000 ± 0.63 at three months and to 2.7500 ± 0.57 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.000), and baseline and 6 months (p value 0.000) but there was no statistically significant difference seen in the BI at 3 month and 6 months (p value 0.285). (**Table 2, Graph 4**)

5. <u>Clinical Attachment Level (CAL) :</u>

The values of CAL in the test site **decreased** from 5.8750 ± 0.95 at the baseline to 3.0000 ± 0.63 at three months and to 2.7500 ± 0.57 at six months. The difference was found to be **statistically significant** between baseline and 3 months (p value 0.000), and baseline and 6 months (p value 0.000) but there was no statistically significant difference seen in the CAL at 3 month and 6 months (p value 0.285). (Table 2, Graph 5)

6. <u>Visual Analogue Scale (VAS) :</u>

In the test site, the mean value of VAS was 1.50 ± 0.81 on the first day after surgery which decreased to 0.25 ± 0.44 on the third day after surgery which was **statistically significant** (p value 0.003). The VAS further decreased to 0.00 at 1 week after surgery. This difference was also **statistically significant** (p value 0.000). (Table 4a,4b; Graph 6)

| | N | Mean | Std. Deviation |
|-------|----|--------|----------------|
| Day1 | 16 | 1.5000 | .81650 |
| Day 2 | 16 | 1.4375 | .72744 |
| Day 3 | 16 | .2500 | .44721 |
| Day 4 | 16 | .1250 | .34157 |
| Day 5 | 16 | .0000 | .00000 |
| Day 6 | 16 | .0625 | .25000 |
| Day 7 | 16 | .0000 | .00000 |

Table 4a - Comparison of VAS Score at different time Interval in Test Site

| Table 4b – Test statistics of | VAS Score at diffe | erent time interval in | Test Site |
|-------------------------------|--------------------|------------------------|-----------|
|-------------------------------|--------------------|------------------------|-----------|

| Ν | 16 |
|-------------|--------|
| Chi-Square | 72.625 |
| df | 6 |
| Asymp. Sig. | .000 |

Inter-Group Comparison

1. Plaque Index (PI)

The difference in PI between the control and test site at three months (p value 0.266) and at six months (p value 0.822) was **not statistically significant.** (Table 5, Graph 1)

| | | ···· · · · · · · · | | | |
|---------------------|----------|--------------------|-------------------|---------|--------------|
| Param | neters | Control Site | Test Site | p-value | Significance |
| | BASELINE | 1.28 ± 0.45 | 1.3500 ± 0.53 | 0.782 | NS |
| Plaque Index | 3 Months | 0.61 ± 0.34 | 0.4688 ± 0.31 | 0.266 | NS |
| | 6 Months | 0.20 ± 0.32 | 0.2188 ± 0.30 | 0.822 | NS |
| | BASELINE | 1.0438 ± 0.55 | 1.0438 ± 0.57 | 0.936 | NS |
| Gingival Index | 3 Months | 0.4563 ± 0.40 | 0.4563 ± 0.40 | 0.937 | NS |
| | 6 Months | 0.1125 ± 0.27 | 0.1125 ± 0.28 | 0.677 | NS |
| Bleeding Index | BASELINE | 2.6000 ± 0.28 | 2.6063 ± 0.27 | 0.924 | NS |
| | 3 Months | 1.5063 ± 0.17 | 1.2688 ± 0.13 | 0.000 | S |
| | 6 Months | 1.4750 ± 0.39 | 1.1063 ± 0.11 | 0.001 | S |
| | BASELINE | 5.8125 ± 0.75 | 5.8750 ± 0.95 | 1.000 | NS |
| Probing Depth | 3 Months | 3.1875 ± 0.54 | 3.0000 ± 0.63 | 0.382 | NS |
| | 6 Months | 3.1875 ± 0.54 | 2.7500 ± 0.57 | 0.037 | S |
| Clinical Attachment | BASELINE | 6.2500 ± 1.00 | 5.8750 ± 0.95 | 0.968 | NS |
| Level | 3 Months | 3.5000 ± 0.63 | 3.0000 ± 0.63 | 0.126 | NS |
| | 6 Months | 3.3125 ± 0.62 | 2.7500 ± 0.47 | 0.014 | S |

 Table 5: Inter- site comparison of periodontal parameters studied

2. Gingival Index (GI)

The difference in GI between the control and the test site at three months (p value 0.937) and at six months (p value 0.677) was **not statistically significant.** (Table 5, Graph 2)

3. Bleeding Index (BI)

The reduction in BI of the test site was more than the reduction in the BI of the control site at both three months and six months. This difference in the BI between the control and test site at three months (p value 0.000) and at six months (p value 0.001) was **statistically significant. (Table 5, Graph 3)**

4. **Probing Depth (PD)**

The reduction in the PD was more in the test site when compared to the control site at the six months after surgery and this difference was **statistically significant** (p value 0.037). Although there was a reduction in the PD at 3 months within both the groups, But **no statistically significant difference** was seen in the PD reduction between the test and control site at three months after surgery (p value 0.382). (**Table 5, Graph 4**)

5. Clinical Attachment Level (CAL)

The gain in the CAL was more in the test site when compared to the control site at the six months after surgery and this difference was **statistically significant** (p value 0.014). However, **no statistically significant difference** was seen in the CAL gain between the test and control site at three months after surgery (p value 0.126). (Table 5, Graph 5)

6. Visual Analogue Scale (VAS)

The mean intra-operative rank of VAS in the control site was 16.50 and that of the control site was 16.50 and this difference between VAS between the control and test site was not statistically significant intra-operatively (p value 1.000).

However, the mean rank of VAS for post operative pain at 1 week was 24.19 in the control site when compared to the mean VAS rank of 8.81 for the control site and this was statistically significant (p value 0.000). (Table 6a, 6b; Table 7a, 7b; Graph 6)

| Table 6a: Inter-site comparison of VAS intraoperatively | | | | | |
|--|---------|----|-----------|--------------|--|
| | Site | Ν | Mean Rank | Sum of Ranks | |
| | Control | 16 | 16.50 | 264.00 | |
| VAS Score | Laser | 16 | 16.50 | 264.00 | |
| VAS SCOLE | Total | 32 | | | |

. C 1 7 A G 1 4

| Table 6b: Inter- site comparison of VAS intraoperatively | | | | |
|--|--------------------|--|--|--|
| Tests | VAS score | | | |
| Mann-Whitney U | 128.000 | | | |
| Wilcoxon W | 264.000 | | | |
| Z | .000 | | | |
| Asymp. Sig. (2-tailed)/ p value | 1.000 | | | |
| Exact Sig. [2*(1-tailed Sig.)] | 1.000 ^b | | | |

| Table 7a: Inter- site comparison of VAS over 1 week. | | | | |
|--|---------|----|-----------|--------------|
| VAS Score | Site | Ν | Mean Rank | Sum of Ranks |
| | Control | 16 | 24.19 | 387.00 |
| | Laser | 16 | 8.81 | 141.00 |
| | Total | 32 | | |

| Tuble 701 litter bite comparison of 7718 over 1 week | |
|--|-------------------|
| Tests | VAS score |
| Mann-Whitney U | 5.000 |
| Wilcoxon W | 141.000 |
| Z | -4.865 |
| Asymp. Sig. (2-tailed)/ p value | 0.000 |
| Exact Sig. [2*(1-tailed Sig.)] | .000 ^b |

Table 7b: Inter- site comparison of VAS over 1 week

7. **Tissue Oedema (TO)**

The control site had a higher mean rank of 22.88 than the mean rank of 10.88 indicating higher tissue oedema in control site than test site which was statistically significant (p value 0.000). (Table 8a, 8b; Graph 7)

| Table Sa . Inter site comparison of Tissue ocdema | | | | |
|---|---------|----|-----------|--------------|
| | Site | Ν | Mean Rank | Sum of Ranks |
| Tissue | Control | 16 | 22.88 | 366.00 |
| oedema | Laser | 16 | 10.13 | 162.00 |
| | Total | 32 | | |

Table 8a : Inter site comparison of Tissue ordema

| Table 8b: Inter | r site comparision of ' | Tissue oedema | |
|-----------------|-------------------------|---------------|--|
| Tests | | VAS score | |
| Mann-Whitney U | | 26.000 | |
| Wilcoxon W | | 162.000 | |
| Z | | -4 099 | |

Asymp. Sig. (2-tailed)/ p value

Exact Sig. [2*(1-tailed Sig.)]

0.000

.000^t



Graph 7: The comparison of Tissue Oedema after one week between test and control sites.

8. <u>Blood Loss (BL) :</u>

The control site had mean intra-operative Blood loss of 55.53 ± 9.11 which was higher than the mean intraoperative blood loss in the test site of 38.27 ± 7.37 and this difference was **statistically significant** (p = 0.000). (**Table 9, Graph 8**)

Table 9 : Inter site comparison of blood loss

| Site | Ν | Mean | P value | |
|--------------|----|--------------------|---------|--|
| Control Site | 16 | 55.5375 ± 9.11 | 0.000 | |
| Test Site | 16 | 38.2750 ± 7.37 | | |



Graph 8: The comparison of Intra-operative Blood Loss in test and control sites.

IV. Discussion

This was a double blinded, randomized, comparative, split-mouth clinical trial to evaluate and compare Open Flap Debridement using 810nm diode laser and conventional surgery in patients on long term aspirin therapy. The randomisation was done by computer generated method into test site (modified Widman flap with diode laser) and control site (modified widman flap with conventional techniques).

Anti-platelet therapy is routinely given in the management of patients suffering from arterio-vascular diseases. Thus, management of such patients who are on low dose aspirin remains a challenge for the periodontist because of the increased risk of intra-operative bleeding.¹A clinical dilemma exists whether or not to discontinue the anti-platelet therapy during the routine and invasive dental procedures. Although earlier it was recommended to discontinue the anti-platelet therapy for a minimum of 3 days, current consensus advocate no discontinuation of the drug for any dental procedures. Thus, in this study, patients did not discontinue the low dose aspirin when the periodontal flap surgery was performed. These subjects were at an increased risk of bleeding due to the anti platelet effect of the low dose aspirin.²

The primary outcome of this study was to evaluate and compare blood volume lost and clinical parameters during laser assisted periodontal flap surgery and conventional flap surgery methods

To the best of our knowledge this is the first study which evaluates the blood volume lostwhile using a 810nm diode laser for periodontal flap surgery in patients on low dose aspirin without altering its dosage and intake regime. As the incorporation of lasers in the field of dentistry have led to significant advances in patient care and management, Diode lasers have been found to promote haemotasis and thus they provide an alternative solution in the controversial issue of intra and post operative bleeding in such patients.

In this study, it was seen that the blood volume lost was significantly less in the test sites when compared to the control sites.

This can be explained by the fact that a diode laser with a wavelength of 810nm, continuous contact mode at 2.5W with a flexible fiber optic delivery system was used in this study. It is an excellent soft tissue laser.. The radiation of diode laser shows greater absorption and less penetration as compared to Nd:YAG laser, especially in blood rich tissue. The wavelength of diode laser is absorbed by the hemoglobin which leads to tissue coagulation and formation of charred layer. Diode leads to thermocoagulation of the blood vessels which could have led to its haemostatic effect.³ Thus diode laser is an excellent soft tissue laser because of its tissue coagulating and hemostatic properties.

So, the better hemostatic effects in the test group could be attributed to the above mentioned properties of the diode laser.

There are many factors which can affect bleeding during surgery, such as the general health of the patient; time of day the surgery is performed; gender; hormones; type, duration, and anatomical location of the surgery. This study was designed as a split mouth study which eliminated many of these confounders by each subject acting as both the test and control. The two surgeries performed on each subject were of the same type and duration, and mirrored anatomical locations. The quantity of anesthetic with epinephrine used for each paired surgery was also the same. Furthermore, the patents were blinded to both the procedures by the application of a sham laser at the control sites.

Various methods of intra-operative blood loss estimation are available in literature which include volumetric, colorimetric, hematocritic and gravimetric.⁴

In this study, the volumetric method was used which is advantageous because it is not dependant on weighing of materials and is not subject to the biochemicalreaction that occur due to the various molecules (hemoglobin, fructosamine) like in the other methods. Also, any saliva generated during the procedure was considered negligible since the patient served as his/her own control.

Thus, the results of this study also revealed that no bleeding events were observed in both the control and test sites. Hence, we can infer that periodontal flap surgeries can be performed in patients on low dose aspirin without discontinuing their medication prior to the surgery. The significantly less blood volume lost in the test(Diode Laser) group further advocates the use of diode laser as an excellent adjunct to periodontal flap surgery in patients who have an increased risk of bleeding while using conventional methods.

In the study, Modified Widman Flap surgery was carried out in either maxilla or mandible. The main advantage of the modified Widman flap surgery over any other periodontal surgical procedure is the intimate postoperative adaptation of healthy collagenous tissues to all tooth surfaces. It has been shown experimentally in animals1 1 and humans that with a close adaptation of gingival tissues to the tooth surface, a marginal new epithelial attachment forms which tends to seal off the deeper areas of separation between the tooth and the surrounding tissues.12

Caffesse and Ramfjord and Nasjletti(1968)⁵, performed a study to assess healing following inverse bevel periodontal flap surgery. They concluded that the transient lowering of the attachment level and bone resorption at the alveolar crest 3 to 4 weeks following flap surgery tend to heal back to the pre-surgical level within 10 weeks after the surgery. Based on the above mentioned results and conclusions regarding the healing and bacterial recolonization after periodontal therapy, the improved measurements of probing depth and clinical attachment level after 3 month and 6 months of surgical therapy in both the groups is justified.

In the present study, plaque index was used to monitor the oral hygiene status of the patients. The results demonstrate that, there was statistically significant difference in the PI at baseline, at 3 months and at 6 months within the control and the test sites. The PI score was less than 1 suggesting maintenance of fair oral hygiene by the patients throughout the study.

Also, gingival index decreased significantly from baseline to 3 months and to 6 months in the control and the test group. This suggests the effectiveness of access flap surgery in reducing the signs of inflammation due to effective removal of calculus and infected granulation tissue (Lindhe and Nyman 1985)⁶.

The results of the present study have shown that there is no statistically significant difference betweenthe test and the control group with respect to PI, GI. This could be explained by the fact that it was a split mouth study and thus oral hygiene measure used by patients would be similar in both the sites

However, there was a greater reduction in PD and greater gain in CAL after 6 months in the test sites when compared to the control sites.

This was also observed by Salaria KS et al (2013)⁷ who reported a case where a modified widman flap was performed with the help of a 980nm diode laser. It resulted in significant pocket depth reduction, gain in clinical attachment level and radiographic evidence of bone fill.

In another study it was reported that (Shah KJ et al (2013)⁸ the in the adjunctive use of diode laser in open flap debridement as compared to conventional mechanical debridement, the laser treated group was marginally better as compared to the control group in terms of PD reduction and gain in CAL and a clear bactericidal effect of the diode laser was seen in terms of greater reduction of CFU of obligate anaerobes in the test group as compared to the control group

Another study by **Gaspirc et al.(2007)**⁹ reported the long-term clinical outcome comparing the Er:YAG laser-assisted periodontal flap surgery with conventional treatment using the modified Widman flap procedure. In this investigation, the reduction of pocket depth and the gain of clinical attachment level were significantly greater in the laser group at 6-36 months after surgery.

(Moritz et al. $(1997)^{10}$ reported observation of another study which used a diode laser(805 nm) following scaling at a power output of 2.5 W in pulsed mode (50 Hz, pulse duration 10 ms that the bactericidal effect in periodontal pockets was higher than the scaling alone group, especially in terms of gram-negative organisms.

Also various histological studies have shown that a charred layer formed on the undersurface of the flap prevented the epithelial migration and promoted new attachment. **Crespi et al.** (1997)¹¹ provided histological evidence of formation of new cementum, periodontal ligament and bone when CO₂ laser was used for debridement in Class III furcation defects in dogs. **Mizutani et al.** (2006)¹² used Er:YAG laser for debridement during access flap surgery in monkeys and noted that laser promoted more new bone formation. However, in this study no histological evaluation was done, but, the above mentioned hypothesis may be a explanation for the improved clinical parameters at the test site.

Also, it can be said that in our study the reduction in PD and gain in CAL could be due to Bactericidal effect of laser as:

Laser radiation affects equally extracellular and intracellular pigmented pathogens and can access other privileged sites such as calculus and dentinal tubules.Laser energy has the potential to breach the protective mechanisms of biofilms (Lewis et al 2001).¹³

The use of diode laser as an adjunct to modified widman flap surgery neither lead to postoperative complications nor delayed healing. This indicates that diode laser did not seem to have any detrimental effect when employed in conjunction with periodontal surgery.

The secondary outcomes evaluated and compared in this study were post-operative pain and tissue oedema at the control and test sites.

Visual Analogue Scale $(VAS)^{14}$ was used to determine the pain perception by the patient during the procedure and 1 week post-operatively.

It has been reported by various studies that the visual analogue scale is the most frequently used scale to measure pain response. The readings were in the range of 0 to 3 for both the groups during the surgery. These readings were interpreted as mild pain. There was no statistically significant difference in the readings of VAS in both the groups indicating that level of patient comfort was similar in both groups. This can be explained by the use of standard similar dose of local anesthetic agent used during the procedures for both the groups (2ml lignocaine with 1:100000 epinephrine).

However, it was seen that postoperative pain on day 1 after surgery was mild in the test site and moderate in the control sites. It was also seen that the post operative pain decreased completely to no pain on day 4 in the test sites whereas in the control sites mild postoperative pain was present till the 6^{th} day. This can be explained by the anti-inflammatory property of the diode laser and its ability to be localized in the tissue where it is used such that it causes no or minimum damage in adjacent tissue sites thus preventing an exaggerated inflammatory response

The next parameter evaluated in this study was the post operative tissue oedema and it was seen that the 1 week post-operative tissue oedema was significantly less in the test sites when compared to the control sites.

Similar results were seen in a study performed on 13 chronic generalized Periodontitis patients where the diode laser (810 nm) (DL) was used as an adjunct to modified Widman flap (MWF) surgery and it was seen that the laser provided additional benefits to MWF surgery in terms of less edema and postoperative pain **Moliner et al (2013)**

The present study evaluated the adjunctive use of diode laser in open flap debridement when compared to conventional surgical techniques of debridement. The results of the present study are definitely encouraging. The possible role of diode laser in promoting formation of new attachment can also be contemplated.

Laser assisted periodontalflap surgery showed more promising results than conventional surgery alone. It can be used in patients on aspirin therapy without discontinuing the drug prior to the surgery.

V. Summary

Diode laser was found to show good results regarding intra-operative and post-operative pain as well as tissue oedema, thus being more comfortablefor the patients. As histological and microbiological evaluation were not donein this study it is difficult to confirm the reason for the improved clinical parameters in the test sites. The diode laser is the most commonly used soft tissue laser due to its portability, ease of use, multiple

applications in soft tissue surgeries and cost effectiveness as compared to other laser systems. This study highlighted the excellent hemostatic capability of the diode laser. As there are very limited studies of its use in periodontal flap surgery, this dissertation was undertaken to prove the same.

However, further longitudinal studies are required to evaluate the long term effects of diode laser on clinical as well as microbiological parameters. The bactericidal effect of diode laser on specific microorganisms and viruses and time taken for microbial recolonization needs to be determined by further studies.

VI. Conclusion

The present study evaluated the use of diode laser in open flap debridement as compared to conventional surgery. This was a split-mouth study and 16 patients with Chronic Generalised Periodontitis who were on low dose aspirin (<200mg) were included in this study. The wound healing was assessed by evaluating clinical parameters at baseline and after 3 and 6 months were plaque index (PI), gingival index (GI), bleeding index(BI), probing depth (PD) and relative Clinical Attachment Level(CAL). Intra-operative Blood Volume Lost (BL) was recorded during the surgical procedure. Visual analogue scale (VAS) was used to evaluate the pain perception by the patient in the test and control sites during the surgical procedure and everyday till 1 week post-operatively. Post-operative Tissue Oedema(TO) was evaluated after one week It may be concluded from the present study that:

Primarily:

- 1. The hemostatic and tissue coagulating properties of the diode laser were clearly appreciated during the study. It was seen that the blood volume lost was significantly less at the test sites when compared to the control sites. (p value 0.000)
- 2. The healing of the laser treated sites was better as compared to the control sites in terms of PD reduction and gain in CAL at 6 months and this was statistically significant. (p value 0.001)

Secondarily:

- 1. The diode laser was well tolerated during the surgery by the patients as determined by the similar readings of the VAS in the test and control sites intra-operatively. Also, post operative pain was less in the laser sites when compared to the test sites.
- 2. The diode laser treated sites also had significantly less postoperative tissue oedema as compared to the control sites thus demonstrating a better wound healing following the use of lasers

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