Research Protocol

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Dentistry Section

Comparison of Open Flap Debridement, with and without Diode Laser in the Management of Chronic Periodontitis: A Randomised Split Mouth Clinical Trial

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ABSTRACT

Introduction: The goals of periodontal therapy include preventing illness, slowing or stopping disease development, replacing lost periodontal tissues, and preserving the therapeutic outcomes. The apical repositioning of the gingival edge during traditional periodontal surgery exposes the root surface to the oral cavity and reduces pocket depth. It may lead to attachment loss, Gingival Recession (GR). It is also commonly recognised that periodontal surgery causes pain and suffering. Laser-assisted periodontal therapy has been the subject of study in an effort to address these drawbacks.

Aim: To compare the efficacy of diode laser as an adjunct to Open Flap Debridement (OFD) with that of OFD alone in the management of chronic periodontitis patients.

Materials and Methods: This randomised clinical trial with split mouth study design will be conducted in Periodontics Department at Sharad Pawar Dental College, Wardha, Maharashtra, India, for a duration of six months. Thirteen patients (26 quadrants) with generalised chronic periodontitis patients will be selected. The Probing Pocket Depth (PPD) ≥5 mm after phase I therapy will be included in the present split mouth study. Diode laser (920 nm) will be used as an adjunct to OFD (test) as compared with conventional flap surgery (control). Clinical parameters like Plaque Index (PI), Papillary Bleeding Index (PBI), PPD, Relative Attachment Level (RAL) and Relative Gingival Marginal Level (RGML) and GR will be recorded at baseline and six months post-therapy. Visual Analogue Scale (VAS) will be used to determine patient discomfort intraoperatively and after one week. A questionnaire for patient-based outcomes will be administered after period of six months postsurgery and response will be recorded. Student's paired t-test will be used, for comparing the treatment groups at baseline and six months.

Conclusion: The results are expected to bring a light on the less mechanical trauma, less postoperative complications and better patient compliance, related to laser-assisted OFD.

Keywords: Periodontal therapy, Periopathogens, Pocket depth, Root planning

INTRODUCTION

Periodontal disease is caused by the intricate interaction of infectious organisms such as bacteria and host factors [1,2]. Periodontitis is commonly recognised as a multi-bacterial infection that requires the action of a relatively less number of members of the anaerobic microorganism inhabiting the subgingival area and leads to the breakdown of the tooth's supporting components [3,4]. Disruption of the biofilm by manual removal of subgingival plaque and, occasionally, additional use of antibacterial medicines, as well as, mechanical surgical debridement of pocket and root surfaces affected by periodontal disease, are the most common procedures used to treat the illness [5].

The non surgical treatment results in inflammation resolution, bacterial load reduction, and Probing Pocket Depth (PPD) reduction. Non surgical therapy, on the other hand, does not always result in the total elimination of bacterial toxins from root surfaces in deep periodontal pockets. Inaccessible parts such as the furcation, grooves, and concavities [6] are not accessible for instrumentation. Furthermore, according to Schenk G et al., periopathogens are not killed by sonic and ultrasonic apparatus [7]. In conditions of chronic inflammation, deeper pockets, class II and III furcation defects, and intrabony defects, surgical treatment is used. It improves access to root surfaces and also to osseous abnormalities [8].

Recently, laser-assisted periodontal therapy has gotten a lot of attention as a possible alternative or supplement to traditional mechanical debridement [9]. The wavelength of a diode laser is 810 nm or 910-980 nm, which has little effect on tooth hard tissues. As a result, the laser is an outstanding soft tissue surgical laser that may be used to cut and coagulate gingiva and oral mucosa, as well as for soft tissue curettage and sulcular debridement. It has an antibacterial action, as well [10].

The uniqueness of the study is that patients for this split mouth trial from rural areas will be selected to promote the oral hygiene awareness among rural population. After periodontal flap surgery, the patient's perspective will also be taken into account using a questionnaire. The study is required to determine the laser's effectiveness in terms of PPD reduction and Clinical Attachment Level (CAL) gain, patient perception as measured by a questionnaire, and patient pain tolerance as measured by a Visual Analogue Scales (VAS) score [11].

There is no other study including laser-assisted periodontal flap surgery which includes patients only from rural population measuring VAS score with a questionnaire for patient-based outcomes [12] after periodontal therapy. Hence, the present study will be conducted to compare the added effects of a laser in Open Flap Debridement (OFD) to conventional manual debridement using clinical variables such as periodontal pocket depth and CAL.

Study Objectives

1. To evaluate periodontal PPD, CAL gain after conventional periodontal flap surgery.
2. To evaluate periodontal PPD, CAL gain after diode laser assister periodontal flap surgery.

3. To compare the periodontal PPD, CAL gain after conventional periodontal flap surgery and diode laser-assisted periodontal flap surgery.

Null hypothesis: OFD in conjunction with laser may not result in significant PPD reduction and CAL gain as compared to OFD alone.

Alternate hypothesis: OFD in conjunction with laser, may result in significant PPD reduction and CAL gain as compared to OFD alone.

MATERIALS AND METHODS

This randomised split mouth clinical trial will be conducted in Periodontics Department at Sharad Pawar Dental College, Wardha, Maharashtra, India, for a duration of six months. Ethical clearance was obtained from DMIMS (DU) {(DU)/IEC/2022/753}, Sawangi (Meghe), Wardha. Patients will be given further information about the study's purpose and will be asked to sign an informed consent form.

Inclusion criteria: Participants aged between 30 to 55 years with chronic periodontal disease characterised by the presence of ≥5 mm or periodontal pockets indicated for flap surgical procedures based on clinical and radiographical confirmation of horizontal bone loss will be included in the study.

Exclusion criteria: Individuals with poor oral hygiene {Plaque Index (PI) ≥1}, patient who smoke (with a recent history of consuming more than 10 cigarettes per day) or use tobacco products of any kind.

Patients with poor endodontic/restorative treatment. Patient's teeth with more than grade II mobility and a class III or class IV furcation defect. Patient's with past surgery in the site chosen for investigation; females who are pregnant or nursing. The untreated acute infection determined clinically and/or radiographically in a specific location. If apical pathology, cemental pearls, root abnormalities, and fracture that makes removal difficult by odontoplasty, untreated decaying tooth at Cementoenamel Junction (CEJ) or root surface will be excluded from the study. Patients with any systematic disorder will also be excluded.

Sample size calculation: Sample size is determined using the following formula:

$$n=(z_{1-\alpha/2})^2\ p(1-p)\div d^2$$

where,

p=previous expected values 0.54, d=desired margin of error

$Z_{1-\alpha/2}$ 2 confidence interval of 95%, n=sample size, Effect size dz=0.5

α err prob= 0.16, Power (1-β err prob)=0.95, Output: Non centrality parameter δ=2.737

Critical t=1.054, Df=22

Total sample size= 26

Actual power=0.90 [13]

Considering two groups the sample size is 13 in each group, hence, the total sample size is 26.

Study Procedure

Thirteen patients (26 quadrants) with generalised chronic periodontitis patients from only rural population to create the awareness of oral hygiene will be selected. The PPD ≥5 mm after phase I therapy from rural population will be included in this split mouth study.

Diode laser (Biolase) (920 nm) will be used as an adjunct to OFD (test) as compared with conventional flap surgery (control). Clinical parameters: Plaque Index (PI), Papillary Bleeding Index (PBI), PPD, Relative Attachment Level (RAL) and Relative Gingival Marginal Level (RGML) will be recorded at baseline and six months posttherapy. VAS will be used to determine patient discomfort intraoperatively and after one week. It consists of 10 cm scale which had markings from 0 to 10 depicting the pain intensity from minimal to maximal [11]. A pretested and prevalidated questionnaire will be used to assess the patient's perception [12]. Fourteen questions will be used, to evaluate the patients' opinions on the status of gingival bleeding, the amount of food that gets stuck between their teeth, the amount of bad breath they experience, how clean they feel about their teeth, how confident they feel when smiling, how mobile their teeth are, how comfortable they are when chewing, how well they are able to chew hard, fibrous foods, whether they are in pain, how sensitive their teeth are, and overall gain of self-confidence. The patients will be given the questionnaire, after period of six months postsurgery and responses will be scored with a maximum of 5 and a minimum of 1 [12].

The mean and standard deviation (Mean±SD) values will be calculated for response of Questionnaire to assess the Patient- Based Outcomes following Periodontal Therapy (QPBOPT) questionnaire [12] and also for all clinical parameters including PI, PBI, RGML, RAL, PPD, and Gingival Recession (GR).

Primary outcome: Will be reduction in PPD and gain in CAL. Secondary outcome will be reduction in PI, PBI, and patient's perception after flap surgery.

Two surgical sites requiring periodontal flap surgeries will be selected and these surgical sites will be randomly assigned to the test and control groups by simple randomisation method using coin toss. The conventional access flap surgery (Control group 0 will be performed first and the second periodontal flap surgery (laser-assisted access flap surgery) (Test group) will be done after the first surgery.

Initial therapy: Full mouth scaling will be performed on the initial appointment, along with root planing under local anaesthetic, if necessary. A coronoplasty will be performed, and the patient will be given oral hygiene recommendations. Plaque control methods will be repeated until the plaque score drops to less than one. Periodontal examination will be done every two weeks, after the initial treatment. A custom built occlusal acrylic stent will be made for the standardisation of probe angulations and correct positioning.

An alginate impression will be taken for the preparation of the cast model, on which the occlusal stent will be created using acrylic material. The stent should cover the occlusal surface of the test tooth, atleast one adjacent tooth, and the coronal third of the teeth. To allow consistent periodontal probe settings, a reference point (slot) will be marked on the stent at the deepest site of the affected tooth. The apical border will be a fixed reference point and will be linear.

Clinical Measurements

PI, PBI, PPD, RCAL, RGML and GR will be documented at baseline and after six months. PI, which depicts plaque build-up over the gingival edge of teeth, will be utilised to evaluate the patient's oral health. PBI will be used to assess gingival inflammation [13].

A. Indices

1. Plaque Index (PI)- (Turesky Gillmore Glickman Modification of Quigley-Hein 1970) [14];

2. Papillary Bleeding Index (PBI)- (Muhlemann HR 1977) [15].

B. Probing measurements

Both the groups will be documented in order to analyse the results. The PPD will be measured from the bottom of the pocket to the gingival margin. This measurement will be taken by a UNC-15 (University of North Carolina, Hu-Friedy) periodontal probe. These clinical parameters will be collected at baseline and six months following surgery after the creation of an acrylic stent [13].

Surgical procedure: Before surgery, individuals will be asked to rinse their mouths with 0.2% Chlorhexidine (CHX) gluconate solution for 1-2 minutes. Under all aseptic circumstances, nerve block will be administered using a local anaesthetic solution of 2% xylocaine with 1:1,000,000 epinephrine.

Flap design (Incisions): For the reflection, Bard-Parker no. 12 or 15 surgical blades will be employed. Intra-crevicular incisions will be made on the buccal and lingual surfaces to reflect the flap. The incisions should be made as far interproximally as possible to promote primary wound closure and preserve entire interdental papillae. Vertical releasing incisions will be made on adjacent teeth to increase exposure.

Flap reflection: A periosteal elevator (24G Hu Friedy, USA) will be utilised to lift the full thickness flap in order to acquire access to alveolar bone in the location of the bone defect. Debridement of the defect will be completed by removing sick tissue from the flap's under-surface while also taking precautions to preserve the flap from rupturing or papillae loss.

Procedure for test groups: The 920 diode laser at power of 1.5 W in contact mode will be used by placing the fiberoptic tip at a 45° angle to the inner aspect of the flap, avoiding directing it toward the bone and teeth. Horizontal overlapping strokes will be used on the inner lining of both facial and palatal flaps for about 10 seconds in relation to each tooth. Following this, the site will be irrigated with normal saline. Sutures {Johnson and Johnson Ethicon Mersilk non absorbable surgical suture (4-0)} will be used to close the flaps, and a periodontal pack will be applied for seven days.

Procedure for control group: Hand scalers and curettes (Gracey curettes, Hu-Friedy, United States of America) will be used to debride the osseous defect first, then by power driven scalers. To avoid over-trimming the flap, the inner surface of the flap or papillae will be debrided cautiously. Hand instruments will be used to accomplish a thorough root planing. Sutures will be used to close the flaps, and a periodontal pack will be applied for seven days.

Postoperative care: Antibiotics and analgesics will be administered for five days as part of the postoperative treatments. For roughly six weeks, patients will be instructed to swish with 0.2% chlorhexidine mouthwash. Eight to 10 days after surgery, the periodontal dressing and sutures will be removed. For the next six weeks, no teeth cleaning or biting will be permitted in the surgical site. Individuals will be instructed to clean the surgical site in an apicocoronal orientation for a further 2-3 weeks using cotton pellets dipped in 0.2% chlorhexidine. Following that, oral hygiene procedures such as brushing and interdental cleaning aids will be reintroduced, along with the use of chlorhexidine mouthwash.

Maintenance care: Patients will be evaluated for PI and PBI at six months after surgery. At visit the patient will receive oral hygiene care, as well as, ultrasonic scaling. Upto six months after surgery, no probing will be done. VAS score will be recorded for patient's discomfort intraoperatively and after one week.

Re-examination: At six months after surgery, a full postoperative examination will be performed. All clinical measurements and parameters will be re-evaluated. At six months after surgery, clinical pictures will be taken. Questionnaire for patient-based outcomes after periodontal therapy will be administered to patients and response will be recorded.

STATISTICAL ANALYSIS

The mean and standard deviation (Mean±SD) values will be calculated for PI and PBI, response of QPBOPT questionnaire and also for all clinical parameters including RGML, RAL, PPD. Association will be done with baseline data to six months data for each treatment group by the use of Student's paired t-test. This test will be used for comparing the treatment groups at baseline and six months. If the probability value p-value >0.05, the difference seen will be measured as insignificant and if p-value <0.05, it will be considered significant.

DISCUSSION

Behdin S et al., investigated the efficacy of dental lasers as an addition to resective or regenerative surgical periodontal treatment in a systematic review and meta-analysis [16]. The researcher found that there is inadequate data to demonstrate the usefulness of dental lasers as an addition to resective or regenerative surgical periodontal treatment. Lobo T and Pol D studied the role of diode laser irradiation in OFD in the treatment of chronic periodontitis in 2015 [17]. After therapy, all clinical metrics improved dramatically, with no statistically significant differences between the two groups for any of the aspects. The only difference was that the laser-treated group had a significantly lower level of gingival inflammation. The laser treatment was well received by the patient and had no side effects. The researchers found that the diode laser can be employed as an additional to the treatment of chronic periodontitis, while also reducing gingival inflammation.

On the basis of clinical indicators and microbiological investigation, Gokhale SR et al., investigated the effectiveness of diode laser as an adjuvant to manual debridement in periodontal flap surgery [13]. The study comprised 30 patients with generalised chronic periodontitis who had a Probing Depth (PD) of more than 5 mm following phase I therapy. In a split-mouth trial, a laser was employed as an adjuvant to OFD (group A) vs conventional flap surgery (group B). At baseline and three months after treatment, clinical data (PI, GI, PD, and CAL), as well as, subgingival plaque samples from group A and groups B were evaluated. The difference in clinical aspects between the group A and group B was not statistically significant. However, the group A had a significant decrease in colony forming units of obligate anaerobes as compared to the group B. According to the VAS, the diode laser was well tolerated by the individuals. The authors found that the diode laser's antibacterial impact was clearly demonstrated by a larger reduction in Colony Forming Unit (CFU) of obligatory anaerobes in the group A than in group B.

The clinical results of Er, Cr:YSGG Laser Aided Pocket Treatment (ELAPT) against OFD were examined by Gupta M et al., [18]. At two sites, fifteen patients with PD of 5 mm and 8 mm were chosen. ELAPT was used on the test sites (group 1), while OFD was used on the control sites (group 2). PI, Gingival Index (GI), modified Sulcular Bleeding Index (mSBI), PD, CAL, and GR were measured at baseline, three months, and six months. The mean gain of CAL in group 1 at three and six months (1.60±0.78 and 1.80±0.63) was similar ($p>0.05$) to the value of group 2 (1.93±0.88 and 2.00±0.54). GR increased significantly ($p<0.05$) only in group 2 at 3 and 6 months (1.80±0.56 and 1.87±0.64) compared to group 1 (0.50±0.68 and 0.60±0.74).

The therapeutic efficacy of laser-assisted and conventional OFD operations was compared by Shetty S et al., [19]. In a split-mouth design, 30 sites in 15 patients (nine males and six females) with chronic periodontitis and a PD of less than 5 mm following initial therapy was randomly assigned to the group A (laser-assisted flap debridement) or the Group B (traditional OFD). At baseline, three months, and six months, clinical and microbiological data were examined. The healing index was also used to assess soft tissue recovery at one week, two weeks, one month, three months, and six months.

The alteration in clinical features in the group A and group B was not significant at different time periods. The microbiological study demonstrated a significant decrease in periodontal pathogen colony forming units in the group A when compared to group B at immediate postoperative and six months. When compared to traditional OFD, laser aided flap surgeries had higher therapeutic effects in terms of microbiological parameters.

In a split-mouth randomised control trial, Torkzaban P et al., compared the efficacy of Er,Cr: YSGG laser treatment to the usual approach in periodontal flap surgery [20]. The three-month follow-up period revealed decreases in PI and GI in both treatment groups. When compared to the control group, the laser-treated sides had much lower indices. The authors found that Er,Cr:YSGG laser-

assisted periodontal flap surgery produced identical treatment results to the traditional method, and that it might be regarded a safe and effective therapy option. OFD with laser is a more effective procedure than OFD alone because patients experience less pain, there is less bleeding and there is less intraoperative time. It is also a safer method.

CONCLUSION(S)

There is less mechanical trauma, fewer postoperative complications like pain and swelling, and being a minimally invasive procedure with better patient compliance, shorter procedure times, minimal bleeding, and an added antimicrobial effect seem to be additional benefits of laser-assisted OFD. As a complement to other treatments for chronic periodontitis, the diode laser can be used safely and efficiently.

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Questionnaire to assess the patient-based outcomes following periodontal therapy.

S. No.	Question	Strongly disagree 1	Disagree 2	Neutral 3	Agree 4	Strongly agree 5
1	Is there a reduction in bleeding of gums?					
2	Is there a reduction in food lodgement between teeth?					
3	Is there a reduction in bad breath after the procedure?					
4	Did your teeth feel clean after the procedure?					
5	Have you gained confidence in showing your teeth while smiling?					
6	Is there a reduction in perceivable mobility?					
7	Are you able to chew food comfortably?					
8	Are you able to chew hard food more comfortably as compared to before procedure?					
9	Is there a reduction in pain in gums and teeth after the procedure?					
10	Are you satisfied with the appearance of gums after the procedure?					
11	Did the appearance of your gums after the procedure help you interact with people more confidently?					
12	Are you satisfied with the position of your gums?					
13	Is there a reduction in sensitivity of teeth as compared to before the procedure?					
14	Have you gained self-confidence after the treatment?					