Comparative evaluation of postoperative pain following chemomechanical preparation of single-rooted nonvital teeth with symptomatic apical periodontitis with and without laser irradiation: A double-blind randomized placebo controlled clinical trial

Rahul D. Rao, Shreya Shivangi, Ashish K. Jain, Meenakshi R. Verma, Ananya Guha, Deepak Langade

Department of Conservative Dentistry and Endodontics, Bharati Vidyapeeth Dental College and Hospital, 1Department of Pharmacology, D. Y. Patil Medical College, Navi Mumbai, Maharashtra, India

Abstract

Background: Postoperative pain can occur because of residual infection even after effective chemomechanical preparation. This study aimed to compare postoperative pain after chemomechanical preparation with placebo and laser irradiation in nonvital teeth having symptomatic apical periodontitis.

Materials and Methods: Sixty (n = 30) participants after obtaining written consent were enrolled in the study. In Group 1, chemomechanical preparation followed by mock laser therapy was carried out in which laser tip was applied but not activated. In Group 2, chemomechanical preparation followed by a laser irradiation was applied and activated. Postoperative pain scores were evaluated at baseline, 24 h, 48 h, and 72 h using the Visual Analog Scale. Preoperative and postoperative percussion pain scores were also recorded. Subjects needing rescue medication were recorded as well. Mann–Whitney U test and Wilcoxon test were used for intergroup comparison and intragroup comparison. The Chi-square test was used for comparing rescue medication.

Results: There was significant reduction in pain scores in the laser group as compared to placebo group at all time points. There was also significant difference in the preoperative and postoperative percussion pain scores. 9 and 3 subjects required rescue medication in Groups 1 and 2, respectively.

Conclusion: Laser irradiation following chemomechanical preparation led to significant reduction in postoperative pain and can be considered as a valuable adjunct.

Keywords: Chemo-mechanical preparation; diode; laser; postoperative pain

INTRODUCTION

Postoperative pain being a common complication after endodontic treatments affects 3%–58% of the patients manifesting as either pain or swelling or both. The most
common causes of endodontic pain are infected root canals and even with modern techniques total eradication of the bacteria is almost unachievable. Law et al.\(^2\) found that pain which interfered with day-to-day activities with a diagnosis of symptomatic apical periodontitis (SAP) could be regarded as an independent predictor of postendodontic pain intensity.

Diode lasers have gained recently gained acceptance in the endodontic field. It was found by Pawar et al.\(^3\) and Bjordal et al.\(^4\) that the diode laser acted on pain and had an anti-inflammatory effect by decreasing PGE2, bradykinin, acetylcholine, histamine, serotonin, and substance P. Despite studies performed for evaluating postoperative endodontic pain using lasers,\(^5\) it remains debatable whether laser therapy is effective in reducing postoperative pain after endodontic treatment or not.

Our literature search revealed only a few studies\(^5,6\) evaluating the use of lasers for postoperative endodontic pain reduction which were mostly for the international populations. Therefore, this clinical study was undertaken to investigate the incidence of postoperative pain following chemomechanical preparation with and without laser irradiation for the Indian population. The null hypothesis tested was there would be no difference in the pain levels of the two groups at 24 h, 48 h, and 72 h. This article is reported in accordance with CONSORT guidelines.

**MATERIALS AND METHODS**

The present study is in accordance with the latest revised Declaration of Helsinki. It was approved with the Scientific Review Committee and Institutional Ethical Committee (IEC No. 217122019) and is registered with CTRI. (CTRI/2021/03/031957).

**Participants, sample size and study groups**

Sixty eligible subjects were selected from the outpatient department and randomly assigned into two groups (\(n = 30\)):
- Group 1 (Placebo group)-Mock laser therapy
- Group 2 (Test group): Laser therapy was applied and activated.

The sample size is based on the reported data for pain scores on day 1 (24 h) with laser irradiation (17.94 ± 15.91) and without laser irradiation (32.59 ± 20.85) by a previous study conducted by Arslan et al.\(^6\) (Power = 80.32\%, significance level = 0.05).

**Eligibility criteria for participants**

Subjects included were between 18 and 60 years’ age group of either gender, having pulp necrosis with SAP in single rooted tooth that needed primary endodontic treatment and were willing to sign a consent form. Participants with a history of previous endodontic treatment, uncontrolled systemic diseases or allergies, periapical radiolucency other than slight widening of the PDL space, presence of swelling or sinus tracts or severe periodontal disease, or who had taken analgesics within the last 3 days were excluded from the study.

**Randomization and blinding**

Simple randomization was done using manually generated sealed envelopes enclosing one of the two treatment groups. Double blinding was carried out in which the subjects were unaware whether he/she would receive the laser activation or not. The evaluator and the statistician were also blinded.

**Study procedure**

Single operator (S. S.) carried out the entire procedure in two visits. Local anesthesia was given using 2\% lignocaine solution with 1:200000 adrenaline (Lignox 2\% A, Indoco remedies Ltd). Following rubber dam isolation and standard access cavity preparation, working length was estimated using Dentaport ZX electronic apex locator (J Morita Corp.) Occlusal adjustment was done.

NT Gold rotary files (Nineten Dental Products, India) were used for biomechanical preparation up to the size determined by apical gauging.

Apical patency was maintained using a size 10-k file. During instrumentation, 20 ml of 5.25\% sodium hypochlorite was used and on completion of instrumentation, manual dynamic agitation was done. 5 ml of 5.25\% sodium hypochlorite and 1 ml of 17\% EDTA for 1 min each were used for final irrigation. The canals were then dried with absorbent paper points.

Following safety protocols for laser, Biolase Epic X (Biolase Inc., USA), a 940 nm wavelength laser was used for both groups.

**Group 1**

The attached laser tip of 200 nm diameter was inserted into the root canal but was not activated [Figure 1a].

**Group 2**

The attached laser tip of 200 nm diameter was inserted into the root canal 2 mm short of the apex and an irradiation of 5 s followed by a 10 s break using 1 W power setting in pulsed mode was done four times. The laser tip was moved in an apico-coronal direction in a helical pattern [Figure 1b].

An evaluator (R. R.) blinded to the study assessed the pain scores using Visual Analog Scale (VAS) at baseline, 24 h,
48 h, and 72 h. He also checked the preoperative and postoperative percussion pain scores at 72 h. A printed VAS Scale sheet was given to the subjects after orienting them to the scoring process, with instruction to return the sheet to the investigator at the end of 3 days. Responses were also recorded telephonically at each time point in case the subject did not return to complete the treatment. Ketorol DT 10 mg was given as a rescue medication and subjects were asked to report the analgesic intake. Subjects needing analgesics in both the groups were recorded. After 3 days, they were recalled for obturation and postobturation restoration.

Statistical methods

The data were entered into Microsoft Office Excel spreadsheet and data analysis was done using Windows-based “MedCalc Statistical Software” version 19.0.1 (MedCalc Software bvba, Ostend, Belgium; http://www.medcalc.org; 2019). Normality testing was done using the Shapiro–Wilk test and was found to be nonnormal. The pain scores were compared at each time point using the Mann–Whitney “U” test [Table 1]. The within group comparison was done using the Wilcoxon test [Table 2]. The Chi-square test was done for the comparison of rescue medication required. All testing was done using two-sided tests at alpha 0.05 (95% confidence level).

RESULTS

The mean pain scores between the two groups were not statistically different at 24 h (P > 0.05) but were statistically different at 48 h and 72 h (P < 0.05). However, the change in the pain scores was statistically different (P < 0.05) at 24 h, 48 h, and 72 h [Figure 2a]. The change in mean percussion pain scores from baseline between the two groups was statistically significant at the end of 72 h (P < 0.05) 9 and 3 subjects needed rescue medication in Groups 1 and 2, respectively [Figure 2b]. Therefore, Group 2 performed better than Group 1.

DISCUSSION

There may be many factors contributing to postoperative pain. The factors such as over-instrumentation may result in an increased postoperative pain.[7] Therefore, in the present study, we used a combination of electronic apex locator and periapical radiographs to confirm the working length.

The factors such as age and sex can affect the postoperative pain. Females have a higher predilection as compared to male. In the present study, equal representation of both the sexes was ensured to avoid any bias. No statistical differences were found in terms of mean age and sex between the two groups.

Factors such as multiple operators have also been associated to postoperative pain. Different operators may have different methods of working and managing the patients and thus can influence the postoperative pain.[4] Therefore, in the present study, only one operator (S. S) carried out the endodontic procedure to avoid any discrepancies.

Uncontrolled diabetes has shown to have double the incidence of postoperative pain as compared to healthy adults.[8] Underlying immunosuppressive conditions or treatments have been seen to increase the risk of infection complications and can lack typical signs of severe infection.[9] Therefore, the sample population was limited to healthy patients without any uncontrolled systemic diseases.

Few studies evaluating postoperative pain carried out the root canal treatment in a single sitting.[10,11] In our study, we adopted the two-visit protocol,[6,12] because there is evidence of better disinfection in two visits,[13] especially in heavily infected cases and there may be more chances of flare ups in single visit.

Table 1: Between group comparison using Mann–Whitney U-test

| Timepoints       | Group             | n   | Mean±SD | SEM  | Z    | P     | Mean difference | 95% CI          |
|------------------|-------------------|-----|---------|------|------|-------|----------------|-----------------|
| Baseline         | Placebo           | 30  | 6.50±0.94| 0.17 | −2.168| 0.030 | −0.800         | −1.457 to −0.143|
|                  | Laser activation  | 30  | 7.30±1.53| 0.28 |       |       |                |                 |
| 24 h             | Placebo           | 30  | 4.67±1.65| 0.30 | −1.185| 0.236 | 0.500          | −0.571 to 1.571 |
|                  | Laser activation  | 30  | 4.17±2.42| 0.44 |       |       |                |                 |
| 48 h             | Placebo           | 30  | 3.03±1.50| 0.27 | −2.926| 0.003 | 1.133          | 0.373 to 1.894  |
|                  | Laser activation  | 30  | 1.90±1.45| 0.26 |       |       |                |                 |
| 72 h             | Placebo           | 30  | 2.27±1.37| 0.21 | −5.276| <0.0001| 1.767          | 1.253 to 2.281  |
|                  | Laser activation  | 30  | 0.50±0.78| 0.14 |       |       |                |                 |
| Change at 24 h   | Placebo           | 30  | −1.83±1.51| 0.28 | −3.055| 0.002 | 1.300          | 0.432 to 2.168  |
|                  | Laser activation  | 30  | −3.13±1.83| 0.33 |       |       |                |                 |
| Change at 48 h   | Placebo           | 30  | −3.47±1.48| 0.27 | −4.558| <0.0001| 1.933          | 1.188 to 2.679  |
|                  | Laser activation  | 30  | −5.40±1.40| 0.26 |       |       |                |                 |
| Change at 72 h   | Placebo           | 30  | −4.23±1.28| 0.23 | −5.410| <0.0001| 2.567          | 1.835 to 3.298  |
|                  | Laser activation  | 30  | −6.80±1.54| 0.28 |       |       |                |                 |
| Change in percussion | Placebo     | 30  | −3.30±1.68| 0.31 | −4.640| <0.0001| 1.967          | 1.210 to 2.723  |
|                  | Laser activation  | 30  | −5.27±1.20| 0.22 |       |       |                |                 |

SD: Standard deviation; SEM: Standard error of mean, CI: Confidence interval
Hayes and Patterson[14] first used the VAS. In the present study, VAS was used for rating pain scores. The patients were given the VAS sheet to mark the pain scores at 24 h, 48 h, and 72 h postoperatively and the data were obtained telephonically at each time point. This provided a real-time tracking of pain scores and helped in avoiding any recall bias.

A newly introduced rotary file system NT Gold rotary files (made in Romania, Europe) were used in this study for mechanical instrumentation. These are advanced heat treated NiTi file system having uniform taper design and triangular cross section with sharp cutting edges. They also have controlled memory property and offers enhanced flexibility.

Residual microorganisms represent another factor responsible for postoperative pain. The use of lasers as an adjunct to root canal irrigation methods results in a reduced microbial load.[16] A study by Wang et al.[17] showed that diode lasers cannot effectively remove the smear layer, therefore in the present study we performed diode laser irradiation after conventional chemomechanical irrigation and smear removal procedures.

The safety measurements for laser were followed and both the operator and the subjects wore eyewear for protection. Laser application was done in a separate room with no reflective surfaces around the working field. The operator (S. S) had undergone laser safety training conducted by Biolase Inc, India.

Similar to previous studies,[18,19] intracanal laser irradiation was performed in Group 2 using Biolase Epic X after instrumentation. A 10 s resting time between cycles was followed in accordance with a recent study by Trisˇic´ et al.[20] that showed leaving 10-s passive cooling period between irradiation cycles of the 940 nm diode laser allows temperature decrease on the external root surfaces. In the present study, no adverse effects related to heating were observed.

Laser therapy increases the amount of prostaglandins that exhibits anti-inflammatory effects, immunoglobulins and lymphokines that play a role in the immune system, and beta-endorphins that are involved in analgesia.[21] Laser therapy can also affect the permeability of the cell membrane to calcium, sodium, and potassium ions. This permeability change decreases the activity of C fibers and increases the action potential of neurons.[22] All of these biological activities could explain the favourable results obtained in this study.

Following root canal debridement, Levy[23] found that the degree of root canal cleanliness was greater due to debris evaporation and dentinal tubules sealing after using laser than what is seen with conventional methods. Coupling laser irradiation with chemomechanical preparation allows greater accessibility to unreachable parts of the root canals, thus resulting in a superior bactericidal effect. This effect can be attributed to the greater depth of penetration-up to

---

**Table 2: Within group comparisons for Group 1 and Group 2 using Wilcoxon test**

| Group 1          | Mean±SD | SEM | 95% CI of the difference | Wilcoxon test | Z    | P     |
|------------------|---------|-----|--------------------------|---------------|------|-------|
| Pain             |         |     |                          |               |      |       |
| Baseline - 24 h  | 1.833±1.510 | 0.276 | 1.269 - 2.397            | -4.207        | <0.0001 |
| Baseline - 48 h  | 3.467±1.479 | 0.270 | 2.914 - 4.019            | -4.812        | <0.0001 |
| Baseline - 72 h  | 4.233±1.278 | 0.233 | 3.756 - 4.711            | -4.825        | <0.0001 |
| Percussion       |         |     |                          |               |      |       |
| Baseline - 72 h  | 3.300±1.685 | 0.308 | 2.671 - 3.929            | -4.569        | <0.0001 |
|                   | Friedman test (baseline, 24, 48 and 72 h comparison) | χ²=80.068; P<0.0001 |

| Group 2          | Mean±SD | SEM | 95% CI of the difference | Wilcoxon test | Z    | P     |
|------------------|---------|-----|--------------------------|---------------|------|-------|
| Pain             |         |     |                          |               |      |       |
| Baseline - 24 h  | 3.133±1.833 | 0.335 | 2.449 - 3.818            | -4.597        | <0.0001 |
| Baseline - 48 h  | 5.400±1.404 | 0.256 | 4.876 - 5.924            | -4.846        | <0.0001 |
| Baseline - 72 h  | 6.800±1.540 | 0.281 | 6.225 - 7.375            | -4.834        | <0.0001 |
| Percussion       |         |     |                          |               |      |       |
| Baseline - 72 h  | 5.267±1.202 | 0.219 | 4.818 - 5.715            | -4.816        | <0.0001 |
|                   | Friedman test (baseline, 24, 48 and 72 h comparison) | χ²=84.032; P<0.0001 |

SD: Standard deviation, SEM: Standard error of mean, CI: Confidence interval
The results of this study are in accordance with Arslan et al.,[6] Hence, the null hypothesis is rejected.

None of the patients experienced severe postoperative pain or swelling that necessitated an emergency visit. If the participants reported more than mild discomfort, Ketorol DT 10 mg was given as rescue medication and were asked to report the analgesic intake. 9 and 3 subjects required analgesic intakes in Group 1 and 2, respectively. This is in accordance with studies conducted by Genc Sen and Kaya[25] and Arslan et al.,[6] who reported lesser analgesic intake in laser groups. Neither group required more than 1 tablet as rescue medication.

The strength of our study was its study design. It was a placebo-controlled, parallel-arm randomized controlled study. The participants, the evaluator, and statistician were blinded to the groups to minimize bias.

A major limitation of this study is different pain thresholds of the subjects. Subjects’ anxiety levels as well as tissue damage during local anesthesia or during rubber dam application can possibly give rise to postoperative pain. Postoperative pain scores were only evaluated following the first visit since factors such as obturation and occlusal adjustments might affect the postoperative pain as well.

CONCLUSION

It can be concluded that intracanal laser irradiation with a diode laser subsequent to routine chemomechanical procedures can efficiently reduce pain and provide comfort to the patient after endodontic treatment. Further in vivo studies with larger sample size are required to study the effect of laser irradiation on postoperative pain.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

REFERENCES

1. Sathorn C, Parashos P, Messer H. The prevalence of postoperative pain and fare-up in single-and multiple-visit endodontic treatment: A systematic review. Int Endod J 2008;41:91-9.
2. Law AS, Nixdorf DR, Aguirre AM, Reams GJ, Tortomasi AJ, Manne BD, et al. Predicting severe pain after root canal therapy in the National Dental PBRN. J Dent Res 2015;94 Suppl 1:375-435.
3. Pawar SS, Pujar MA, Makandar SD, Khaier ML. Postendodontic treatment pain management with low level laser therapy. J Dent Lasers 2014;8:60-3.
4. Bjordal JM, Johnson MI, Iversen V, Aimbire F, Lopes-Martins RA. Low-level laser therapy in acute pain: A systematic review of possible mechanisms of action and clinical effects in randomized placebo-controlled trials. Photomed Laser Surg 2006;24:158-68.
5. Asnaashari M, Ashraf H, Daghayehgi AH, Mojahedi SM, Azari-Marhabi S. Management of post endodontic retreatment pain with low level laser therapy. J Lasers Med Sci 2017;8:128-31.
6. Arslan H, Doğanay E, Karataş E, Ünlü MA, Ahmed HM. Effect of low-level laser therapy on postoperative pain after root canal retreatment: A preliminary placebo-controlled, triple-blind, randomized clinical trial. J Endod 2017;43:1765-9.
7. Arias A, Azabal M, Hidalgo JJ, de la Macorra JC. Relationship between postendodontic pain, tooth diagnostic factors, and apical patency. J Endod 2009;35:189-92.
8. Chowdhury SS, Howlader MR, karim AA, Quader SM. Incidence of postendodontic flare-up in diabetic and normal individual: A 100 case study. Update Dent Coll J 2019;9:3-6.
9. Parikka M, Norppa A, Välimaa H, Huttunen R, Järvinen A, Richardson R. Treatment of acute dental infections. Nor Tannlegeforen Tid 2019;129:216-22.
10. Ramalho KM, de Souza LM, Tortamano IP, Adde CA, Rocha RG, de Paula Eduardo C. A randomized placebo-blind study of the effect of low power laser on pain caused by irreversible pulpitis. Lasers Med Sci 2016;31:1899-905.
11. Dagher J, El Feghali R, Parker S, Benedicenti S, Zogheib C. Postoperative quality of life following conventional endodontic intracanal irrigation compared with laser-activated irrigation: A randomized clinical study. Photobiomodul Photonmed Laser Surg 2019;37:248-53.
12. Ramamoorthy S, Niveditha MS, Divyanand MJ. Comparative evaluation of postoperative pain after using endodontic needle and EndoActivator.
13. Bansode PV. Single-visit versus multiple-visit root canal treatment – A review article. IQR J Dent Med Sci 2018;17:70-4.
14. Hayes MH, Patterson DG. Experimental development of the graphic rating method. Psychol Bull 1921;18:98-9.
15. Krithikadatta J, Sekar V, Sudharsan P, Velumurugan N. Influence of three NiTi cleaning and shaping files on postinstrumentation endodontic pain: A triple-blinded, randomized, controlled trial. J Conserv Dent 2016;19:311-6.
16. Morsy DA, Negm M, Diab A, Ahmed G. Postoperative pain and antibacterial effect of 980 nm diode laser versus conventional endodontic treatment in necrotic teeth with chronic periapical lesions: A randomized control trial. F1000Res 2018;7:1795.
17. Wang X, Sun Y, Kimura Y, Kinoshita J, Ishizaki NT, Matsumoto K. Effects of diode laser irradiation on smear layer removal from root canal walls and apical leakage after obturation. Photonmed Laser Surg 2005;23:575-81.
18. Gutknecht N, Franzen R, Meister J, Vanweersch L, Mir M. Temperature evolution on human teeth root surface after diode laser assisted endodontic treatment. Lasers Med Sci 2005;20:99-103.
19. Alfredo E, Marchesan MA, Sousa-Neto MD, Brugnera-Júnior A, Silva-Sousa YT. Temperature variation at the external root surface during 980-nm diode laser irradiation in the root canal. J Dent 2008;36:629-34.
20. Trišić D, Četenović B, Jovanović I, Gjorgjevska E, Popović B, Marković D. Diode Laser Irradiation in Endodontic Therapy through Cycles - in vitro Study. Balk J Dent Med 2017; 21(2), doi:10.1515/bjdm-2017-0016.
21. Sakurai Y, Yamaguchi M, Abiko Y. Inhibitory effect of low-level laser irradiation on LPS-stimulated prostaglandin E2 production and cyclooxygenase-2 in human gingival fibroblasts. Eur J Oral Sci 2000;108:29-34.
22. Pires D, Xavier M, Araújo T, Silva JA Jr., Aimbire F, Albertini R. Low-level laser therapy (LLLT; 780 nm) acts differently on mRNA expression of anti- and pro-inflammatory mediators in an experimental model of collagenase-induced tendinitis in rat. Lasers Med Sci 2011;26:85-94.
23. Levy G. Cleaning and shaping the root canal with a Nd: YAG laser beam: A comparative study. J Endodont 1992;18:123-7.
24. Scolastra F, Petrucci A, Gatto R, Monaco A. Effectiveness of laser in dentinal hypersensitivity treatment: A system review. J Endod 2011;37:297-303.
25. Genc Sen O, Kaya M. Effect of root canal disinfection with a diode laser on postoperative pain after endodontic retreatment. Photobiomodul Photomed Laser Surg 2019;37:85-90.