Pain after single visit endodontic treatment using fifth generation file systems -An invivo study

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Abstract

Aim: To compare the incidence, duration and severity of pain after single visit root canal treatment with three different fifth generation file systems (ProTaper Next, One Shape, and Revo-S).

Materials and Method: Three groups, each consisting of 45 patients with symptomatic irreversible pulpitis and symptomatic peri-apical periodontitis were selected and instrumented. Group I (n = 45) was instrumented with ProTaper Next file system, Group II (n = 45) was instrumented using One Shape file system and Group III (n = 45) was instrumented using Revo-S file system. All canals were instrumented and obturated in the same visit, following treatment patients were discharged with a questionnaire to gather data about the incidence (yes/no), severity (mild, moderate or severe), and duration of pain (days). Postoperative pain response of patients was evaluated at 6, 12, 24 and 48 hrs, using the visual analogue scale (VAS) score. The severity and incidence of pain between groups were compared using the chi-squared test. The statistical significance of differences were estimated by one way ANOVA and *post hoc* Tukey test, $P < 0.05$ was considered as significant.

Results: Highest mean pain (1.378 ± 0.49) was seen in group II, 12 hr post-operatively, while lowest mean pain (0.067 ± 0.25) was seen 48 hr post-operatively in group III. There was highly significant difference ($P<0.001$) in pain between the group I & II (at 24 hours and 48 hours), group II & III (at 6, 12, 24 and 48 hours) and group I & III (at 6 & 12 hours), of post-operative sessions. Group III had lowest mean pain. There was statistically significant difference ($P<0.001$) in intensity of pain between the groups I, II & III at 6 hours, 12 hours, 24 hours & 48 hours.

Conclusion: Tooth instrumented with Revo-S file system were found to be least associated with incidence, duration and severity of postoperative pain at the time points assessed.

Keywords: Pain, Post endodontic pain, Single-visit root canal, Rotary, ProTaper Next, One Shape, Revo-S, Visual analog scale

Introduction

It has been well established over the past 30 years that endodontic disease, has a microbial pathogenesis. Consequently, root canal treatment is performed to treat endodontic disease by eradicating bacteria from the root canal space. It is widely accepted that disinfection and subsequent obturation of the root canal space require mechanical enlargement of the main canals,[(1)] and the vast majority of techniques and instruments are based on these objectives.

Two approaches have been proposed in this regard. In one approach, residual bacteria are eliminated or prevented from repopulating the root canal system by introducing an inter appointment dressing during the root canal treatment in multi visit. The second approach is aimed at eliminating the remaining bacteria or rendering them harmless by entombing them in a complete and three dimensional obturation, finishing the treatment in single visit, to deprive the microorganisms of nutrition and the space required to survive and multiply.[(2)]

Recent clinical reports, have shown that patients generally tolerate and prefer single-visit endodontic therapy.[(3)] Therefore, single-visit root canal treatment has become a common practice and offers several advantages, including a reduced flare-up rate, decreased number of operative procedures, and no risk of inter-appointment leakage through temporary restorations.

A major concern in single visit endodontic therapy is incidence of post-operative pain and healing following the treatment.

Post endodontic pain is clearly multifactorial, and one important cause has been claimed to be the instrumentation process. This may be the result of debris and bacterial extrusion during chemo mechanical preparation, which worsens the inflammatory response and causes peri-radicular inflammation.[(4)]

Major advances in rotary instrumentation and metallurgy have led to the introduction of numerous systems with innovative designs in recent years. Nonetheless, all the preparation techniques and instruments available to date are still associated with some degree of extrusion of debris.[(5,6)]

Fifth generation, the latest generation of shaping files have been designed in such a way that the centre of mass or the centre of rotation, or both, are offset. It includes Revo-S, One Shape and the ProTaper Next file systems. This offset design enhances auguring debris out of a canal which can result in least debris extrusion[(7-9)] and thus reduced postoperative pain.

In absence of in vivo studies that compare pain after root canal treatment using fifth generation file systems namely ProTaper Next, One Shape and Revo-S, a study was designed to compare incidence, severity and

duration of postoperative pain after single visit root canal treatment.

Materials and Method

The study was conducted with the approval of the institutional ethical committee, all patients received the proposed treatment by a single operator at the Post-graduate clinic in the department of conservative dentistry and endodontics, Al Badar rural dental college and hospital, Gulbarga, Karnataka from February 2015 to December 2016. (Fig. 1)

Patient Selection: One hundred and thirty five systemically healthy patients whose permanent maxillary and mandibular single canal teeth diagnosed as symptomatic irreversible pulpitis with symptomatic apical periodontitis referred to the Department of Conservative Dentistry and Endodontics, seeking root canal therapy in accordance with inclusion and exclusion criteria described later, was randomly selected for the study and divided into three groups each consisting of 45 patients. Group I (n = 45) were instrumented with ProTaper Next file system, Group II (n = 45) were instrumented using One Shape file system, Group III (n = 45) were instrumented using Revo-S file system. All patients received single visit root canal treatment.

Inclusion Criteria:

1. Patient should freely accept the proposed single visit treatment with the criteria for post-operative pain evaluation.
2. Patients within the age group of 20 to 70 years
3. Maxillary and mandibular tooth with single canal, with a diagnosis of symptomatic irreversible pulpitis with symptomatic apical periodontitis.
4. Preoperative pain categorized as severe on the visual analogue scale
5. Positive response on cold testing
6. Ability to apply rubber dam

Exclusion Criteria:

1. Radiographic evidence of periapical changes
2. Root resorption
3. Open apices
4. Retreatment cases
5. Pulp necrosis
6. Patients who were on antibiotics, analgesics or corticosteroids for chronic pain
7. Teeth with difficult root canal anatomy
8. Two or more adjacent teeth requiring root canal therapy
9. Periapical abscess
10. Presence of sinus tracts
11. Absence of occlusal contacts
12. Tooth malposition
13. Medically compromised patients
14. Pregnant patients
15. Failure to sign informed consent
16. Teeth with calcified canals

Treatment Procedure: Before initiation of treatment, the whole procedure and design of the study was explained to the patients. Then the patient signed an informed consent form. Thorough medical and dental history was taken. For each patient, preoperative data was recorded in the patient's history sheet which includes age, sex and intensity of pain before the treatment. The intensity of preoperative pain was measured using the visual analog scale in the presence of the clinician to ensure that they understood the instruction.

The common procedure for all the three Groups was administration of local anaesthesia followed by rubber dam application, caries excavation if present and access cavity preparation. Canal patency was checked with a size 10 K file. Working length was determined using radiographic method and apex locator and the canals of all teeth were prepared using three different instruments as follows. The instrumentation sequence used during the treatments in each group followed the procedure recommended by the respective manufacturer.

Group I: ProTaper Next files were used with the sequence PU SX, PTN X1, and X2 at a rotational speed of 300 rpm along with torque values of 200 gcm. Each file was used with a brushing motion similar to the PU files

Group II: One Shape file having a taper of 0.06 and a size of 25 was used with in and out movements without pressure at a rotational speed of 400 rpm along with torque values of 400 gcm.

Group III: Revo-S was used with slow and unique downward movement in free progression and without pressure (up and down movement) with a rotation speed ranging between 250 and 400 rpm.

Irrigation was done using 5 ml, 3% sodium hypochlorite and EDTA was done alternatingly after instrumentation with each file system. An irrigating needle of 30 gauge was used passively without forceful dispensing of the irrigant 1.5 mm short of its binding point. Intermittent agitation using a 15 number k file was done to prevent apical debris accumulation and coronoapical movements of the needle were done to agitate the irrigant manually.

After completion of biomechanical preparation, canals were flushed with 5 ml saline. Final irrigant used was 5 ml of 17% ethylenediaminetetraacetic acid.

After this, the canals were obturated with respective guttapercha cones and AH Plus sealer using lateral condensation technique and temporary restoration was done. Post obturation radiograph was taken. All canals were instrumented and obturated in the same visit and the patients were informed that they could experience pain in the days immediately following treatment and were discharged with a questionnaire to gather data about the incidence (yes/no), severity (mild, moderate or severe), and duration of pain (hours). Postoperative pain response of patient was evaluated at 6, 12, 24 and 48 hrs respectively, using the visual analogue scale score,[10]

- No pain: The treated tooth felt normal. Patients do not have any pain

- Mild pain: Recognizable, but not discomforting, pain which required no analgesics
- Moderate pain: Discomforting, but bearable pain (analgesics if used, were effective in relieving the pain)
- Severe pain: Difficult to bear (analgesics had little or no effect in relieving the pain).

Telephonic reminder was given to them to note their pain readings and return the form duly filled and submit after three days. Each patient was given a prescription of Ibuprofen (600 mg, 8-12hrs) with instructions to avail the same only if needed for pain.

Statistical Analysis: Statistical analysis was performed by using SPSS 20.0 version.

The incidence of pain (yes/no) and difference between the groups considering severity of pain (mild, moderate, severe) as variable were compared using the chi-squared test.

The statistical significance of difference was estimated by one-way ANOVA and post hoc *tukey* test. A *p* value less than 0.05 was accepted as significant.

Results

A total of 61 males (45.18%) and 74 (54.81%) females, with mean age of 43.7±16.45 years completed the questionnaire. In Group I, 18 male & 27 females, Group II, 21 males & 24 females and in Group III, 22 male & 23 females participated with mean age of 47.4±17.51, 42.3±15.08 and 41.4±15.52 years respectively. ANOVA analysis of age and sex revealed there was no statistically significant difference between the groups. Table 1 and 2

Comparison of Mean pain between the groups at different time intervals: Pre-operative comparison of mean pain between the groups (I, II, III & IV) with different time intervals suggested that there was no significant difference (P>0.05). However significant difference in pain between the groups at 6, 12, 24 & 48 hours post-operatively was note. Highest mean pain (1.378 ± 0.49) was experienced in group II, at 12 hr post-operatively, while lowest mean pain (0.067 ± 0.25) was seen at 48 hr post-operatively in group III as indicated in Table 3.

There was no statistical significant difference in pain between the group I & II for post-operative period of 6 hours and 12 hours. And between the group I & III for post-operative period of 24 hours and 48 hours. (P>0.05) (Table 3 and Graph 1).

There was a highly significant difference in pain between the group I & II at 24 and 48 hours. And between the group II & III at 6, 12, 24 and 48 hours. And between the group I & III at 6 hours & 12hours, of post-operative sessions. (P<0.001). Group III has lowest mean pain when compared with group I and group II at all time intervals (Table 4).

Comparison of severity of pain between the groups at different time intervals: There was statistical significant difference in intensity of pain between the groups I, II & III at 6, 12, 24 & 48 hours of post-operative session (P<0.001) (Table 5).

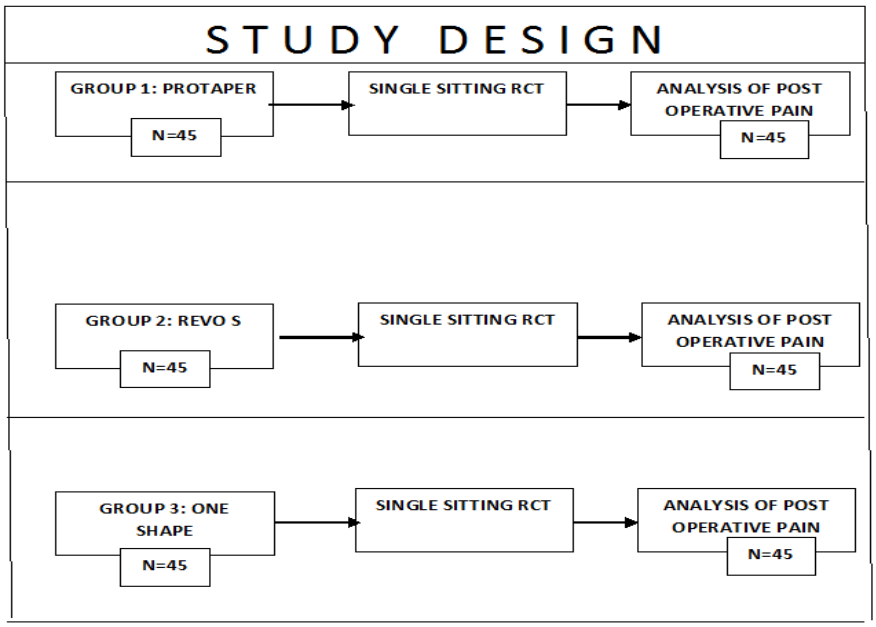


Fig. 1

Table 1: Age wise distribution of samples

Age	Group I	Group II	Group III	Total
≤39	26	25	23	74
40-69	18	20	21	59
≥70	1	0	1	2
Total	45	45	45	135
Mean±SD	47.4±17.51	42.3±15.08	41.4±15.52	43.7±16.45

ANOVA F=4.65 P>0.05 Not Significant
There is no statistically significant difference of age between the groups.

Table 2: Sex wise distribution of samples

Sex	Group I	Group II	Group III	Total
Male	18	21	22	61
Female	27	24	23	74
Total	45	45	45	135

Comparison between groups χ^2 =2.92 p>0.05 Not significant
There is no statistically significant difference of sex between the groups.

Table 3: Comparison of Mean pain between the groups at different time intervals

Groups	Pre-OP pain	Post-OP pain at 6hours	Post-OP pain at 12hours	Post-OP pain at 24hours	Post-OP pain at 48hours
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
I	3.0 ± 0.0	1.13 ± 0.072	1.244 ± 0.67	0.378 ± 0.49	0.089 ± 0.28
II	3.0 ± 0.0	1.26 ± 0.65	1.378 ± 0.49	0.911 ± 0.09	0.261 ± 0.45
III	3.0 ± 0.0	0.689 ± 0.68	0.600 ± 0.68	0.240 ± 0.57	0.067 ± 0.25
ANOVA Test	F=0.0	F=8.819	F=19.881	F=12.21	F=4.68
P-value	P>0.05 NS	P<0.001 HS	P<0.001 HS	P<0.001 HS	P<0.01 HS

NS=Not significant S=Significant HS=highly significant

Table 4: Comparison of Mean pain between the groups at different time intervals

Groups	Pre-OP pain ANOVA Test & P-value	Post-OP pain at 6hours ANOVA Test & P-value	Post-OP pain at 12hours ANOVA Test & P-value	Post-OP pain at 24hours ANOVA Test & P-value	Post-OP pain at 48hours ANOVA Test & P-value
I & II	F=0.0 P>0.05, NS	F=0.838 P>0.05, NS	F=1.140 P>0.05, NS	F=12.185 P<0.001, HS	F=5.023 P<0.01, HS
II & III	F=0.0 P>0.05, NS	F=17.19 P<0.001, NS	F=38.17 P<0.001, HS	F=17.616 P<0.001, HS	F=6.82 P<0.001, HS
I & III	F=0.0 P>0.05, NS	F=9.129 P<0.001, HS	F=20.002 P<0.001, HS	F=1.414 P>0.05, NS	F=0.153 P>0.05, NS

NS=Not significant S=Significant HS=highly significant

Graph 1: Multiple bar diagram represents comparison of Mean pain between the groups with different time periods

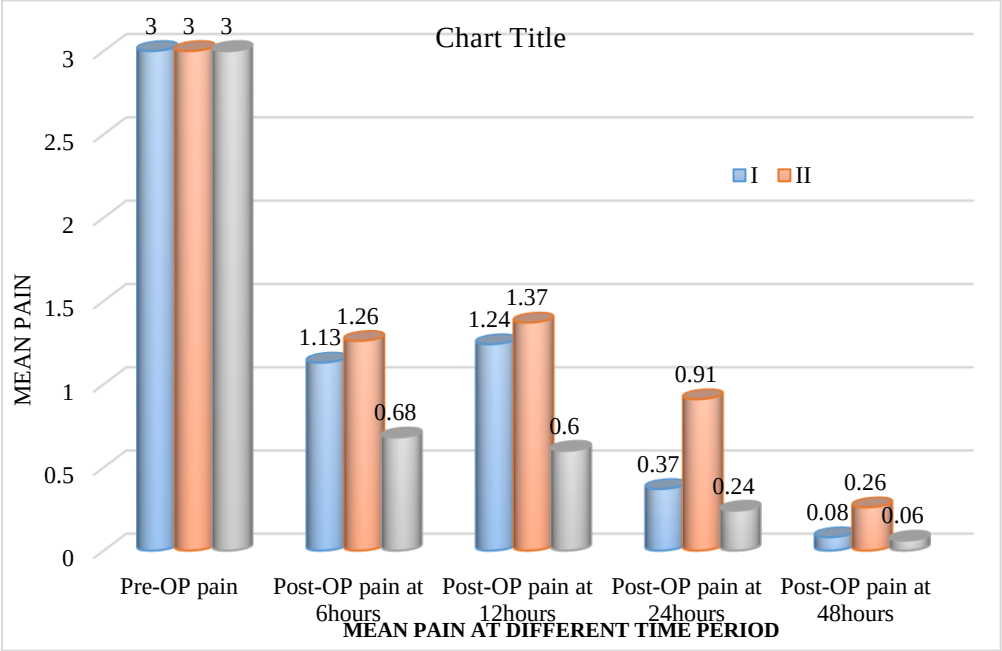
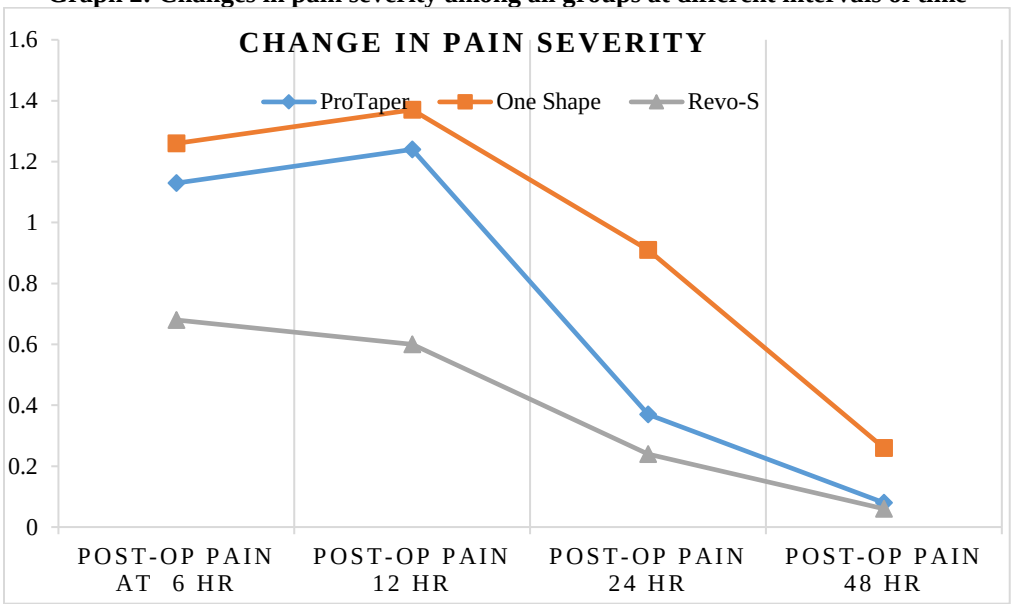


Table 5: Comparison of severity of pain between the groups with different time intervals

Groups	Intensity of pain	Pre-OP pain No. of cases	Post-OP pain at 6hours No. of cases	Post-OP pain at 12hours No. of cases	Post-OP pain at 24hours No. of cases	Post-OP pain at 48hours No. of cases
I	Sever(3)	45	0	0	0	0
	Moderate(2)	0	15	17	0	0
	Mild(1)	0	21	22	17	9
	No pain(0)	0	9	6	28	41
II	Sever(3)	45	0	0	0	0
	Moderate(2)	0	17	17	16	0
	Mild(1)	0	23	28	9	12
	No pain(0)	0	5	0	20	33
III	Sever(3)	45	0	0	0	0
	Moderate(2)	0	6	0	3	0
	Mild(1)	0	20	17	5	3
	No pain(0)	0	19	13	37	42

(Chi-Square) X^2=43.31 P>0.001 Highly Significant

Graph 2: Changes in pain severity among all groups at different intervals of time



Discussion

Endodontic treatment, or root canal treatment, entails the removal of the dental pulp and the subsequent shaping, cleaning, and obturation of the root canals of a tooth. One of the important objective of root canal treatment is to give patient complete relief from pain. The exact causes of pain following root canal treatment have not been adequately reported. Root canal treatment can be done in single visit or multi visit.There are a number of advantages to single-visit endodontic treatment such as immediate familiarity with the internal anatomy, canal shape and contour facilitates obturation; no risk of bacterial leakage beyond a temporary coronal seal between appointments; reduction of clinic time; patient convenience –no additional appointment or travel; reduce patient discomfort and risk with local anaesthesia; reduce possible chance of iatrogenic error (e.g. perforation, ledging, stripping and extension of antimicrobial irrigants).[11-15]

Single-visit endodontic treatment, however, has some disadvantages.[12,13] Completing treatment in a single appointment may involve time restraints and causes fatigue in both the clinician and the patient. There are studies reporting an increase in postoperative pain and flare-up rate by one visit for endodontic treatment, but there are also studies reported no increase in postoperative complication.

According to Oliet,[16] case selection for single visit root canal therapy is as follows:

1. Positive patient acceptance.
2. Sufficient available time to complete the procedure properly.
3. Absence of acute symptoms requiring drainage via canal and of persistent continuous flow of exudates or blood.
4. Absence of anatomical obstacles (calcified canals, fine tortuous canals, bifurcated or accessory canals) and procedural difficulties (ledge formation, blockage, perforations, inadequate fills).

In the present study, inclusion and exclusion criteria was based on above mentioned indications and contraindications.

The results of laboratory studies demonstrate that all canal preparation techniques are associated with dentin debris extrusion from the root canal system even if the preparation ends shorter than the apical terminus.[7,9] It has been reported that extrusion of microorganisms, materials, or dentin debris into the periradicular area causes inflammation and may be related to postoperative pain and flare-ups. forcing of these irritants leading to elicit inflammation whose intensity depend on the quantity and the quality of the extruded debris, The greater the amount of extruded debris, the greater severity of reaction will be.[8] The amount of debris extrusion and neuropeptides released from C-type nerve fibers present in the periodontal ligament differ between instrumentation techniques, and this difference has been suggested as a reason why there are differences in postoperative pain experienced by patients.[17]

According to some authors,[14-16] the variation observed could be attributed to differences in the cross section, cutting-edge design, taper, tip type, configuration, use concept, flexibility, alloy type, number of files used, kinematics, or cutting efficacy.

In our study all the procedures were performed by one clinician in order to eliminate or minimize interpersonal variability in the treatment procedures.

One of the major obstacles to assessing postoperative pain encountered in clinical studies conducted for this purpose is the subjective nature of this evaluation and the inherent difficulty in measuring pain.

Therefore, designing the most adequate questionnaire to be applied is a critical step in these studies. The questionnaires must be fully understood by patients and lend themselves to straightforward interpretation. In the current study, the VAS was selected based on its confirmed reliability for pain assessment.

In the ideal clinical setting, one objective of performing root canal treatment is to bring about reduction of pain. Hence, only patients with a pain score categorized as severe were included in this study. Since the objective was primarily to assess postoperative pain after root canal instrumentation, patients were advised to take analgesics only in the case of severe pain.

In addition, the type of tooth, pulp and periapical status, and the type and the volume of the irrigants used were matched between the two groups in the present study to reduce the confounding variables during the preparation steps, except for the instrument design. While occlusal reduction has been suggested as a means of managing post endodontic pain, this was not performed on patients in this work as it has not been shown to bring about any reduction of postoperative pain in patients with irreversible pulpitis with symptomatic apical periodontitis.[11]

In our study One Shape was associated with highest incidence, duration and severity of postoperative pain which is accordance with other studie.[7,9,17] However this severity was not statistically significant when compared with ProTaper next.[18] On comparison of Post-operative pain with Revo-S it was statistically significant.

One Shape file (Micro Mega, Besancon, France) is few single file instruments used in continuous clockwise rotational motion for quick and safe root canal preparation.[19] One Shape file has an asymmetric cross-sectional geometry that generates traveling waves of motion along the active part of the file.

Revo-S was significantly least associated with intensity, duration and severity of postoperative pain when compared to ProTaper Next and One Shape, which may be attributed to design of the file.[20,21]

Revo-S is a sequence of 3 NiTi with an asymmetric cross section which facilitates penetration by a snake like movement and offers root canal shaping which is adapted to biological and ergonomic imperatives. This sequence has debris elimination, cutting and cleaning cycle which improves root canal cleaning by facilitating upward removal of generated dentin debris.[22]

Further clinical trials are needed to compare the pain after single visit endodontic treatment. in vital versus no vital teeth, single rooted versus multirooted teeth, incorporating all variables like age, sex, occlusal reduction, presence of radiolucency, irrigation protocol, the final apical size, and duration of time spent on root canal instrumentation.

Conclusion

Irrespective of age and sex pre-operative pain was designated as sever in all groups. Severity of Pain reduced significantly in all groups indicating that single visit endodontic treatment effectively reduced pain and can be considered as standard of care. Mean post-operative pain in ProTaper and One Shape group reduced in first 6 hr (1.13 ± 0.072 and 1.26 ± 0.65 respectively) then showed a slight peak in next 6 hr (1.244 ± 0.67; 1.378 ± 0.49) before gradually tapering off graph No 2. However, reduction in severity of pain was seen to be exponential in Revo-S group as assessed at intervals of 6,12,24 and 48 hrs (0.689 ± 0.68; 0.600 ± 0.68; 0.240 ± 0.57 and 0.067 ± 0.25). At all the intervals of time, pain associated with ProTaper and One Shape files was approximately twice that of Revo-S. Duration of pain lasted for just 12 hr in Revo-S group were as it lasted for 48 hr in remaining groups. Hence within the confines of present study following conclusions were drawn.

- One Shape file system was associated with highest incidence, duration and severity of postoperative pain
- Post-operative pain caused by ProTaper File system was more than Revo-S but less than One Shape file system.
- Revo-S file system was found to be least associated with the incidence, duration and severity of postoperative pain at all the time points assessed.
- Single visit Endodontic treatment with Revo-S caused minimal pain as assessed on Visual analog scale.

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