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Comparative Evaluation of Post Instrumentation Pain Using Protaper Gold and Waveone Gold in Mandibular Molars – A Randomized Controlled Trial

Dr.Krishnan Amudhalakshmi[1], Dr.Muniyandi Gokulnath[2],
Dr.Muthukrishnan Sudharshana Ranjani[3],
Dr. P.Shakunthala[4]
[1] Professor,[2] PG Student, [3] Senior Assistant Professor,[4] Associate Professor, Dept.of conservative dentistry & endodontics, Tamilnadu Govt Dental College & Hospital,Chennai.
Corresponding author: Dr.Muthukrishnan Sudharshana Ranjani

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I. Introduction

The aim of Cleaning and Shaping is to debride the intra-radicular contents and render the space suitable for obturation. Postoperative pain is defined as pain of any degree that occurs after initiation of root canal therapy (Sathorn*et al*. 2007).Clinical studies have shown varying degrees of postoperative pain, ranging from 25% to 40%.

Post-operative pain(Seltzer *et al*.1985)is caused mainly due to these factors.

- Micro-organisms
- Extrusion of Irrigant solution
- Extrusion of debris containing necrotic tissue, microorganisms, pulpal fragments and dentine particles.

NiTi rotary instruments have become an imperative adjunct for root canal shaping. Reciprocating files are single file systems with M- wire technology. Reciprocating files have better resistance to file separation & less incidence of dentinal damage.

Variability of debris extrusion has been shown by different NiTi systems. This may be due to the differences in cross- sectional geometry, cutting blade design, taper, flute depth, tip, sequence of files, kinematics, and cutting efficacy. It has been proposed that Reciprocating movement *per* se - pack & push the debris beyond the apical foramen. But the Threshold amount of debris required for inducing pain is unknown.

AIM

The aim of the study is to compare the incidence of post instrumentation pain associated with ProTaper Gold (Rotary kinematic) and WaveOne Gold (Reciprocating kinematic) files, following canal shaping and cleaning in mandibular molars.

OBJECTIVES

1. To evaluate the Post-instrumentation pain following canal shaping and cleaning using ProTaper Gold files in Mandibular Molars.
2. To evaluate the Post-instrumentation pain following canal shaping and cleaning using WaveOne Gold files in Mandibular Molars.
3. To compare the Post-instrumentation pain between the above said two groups.

II. Materials And Methods

This prospective randomized clinical trial was approved by the Institutional Review Board (IRB) for ethical clearance. The study was in accordance with the revised Consolidated Standards of Reporting Trials statement.20 patients of the age group 25-45 years, who fulfilled the inclusion & exclusion criteria were selected for the study. The complete treatment procedure was explained and a written informed consent was obtained from all the patients selected for the study.

INCLUSION CRITERIA

- ❑ Patients of age group 25-45 years of either gender
- ❑ Patients with no systemic disease

- ❑ Periodontally healthy individuals
- ❑ Patients with symptomatic and asymptomatic irreversible pulpitis in mandibular molars
- ❑ Patients with Pulpal necrosis of mandibular molars with or without apical periodontitis
- ❑ Patients willing for voluntary participation and have signed the informed consent
- ❑ Patients with good oral hygiene

EXCLUSION CRITERIA

- Curved root canals of more than 25 degrees.
- Presence of Periapical radiolucency.
- Calcified root canals.
- Open apices.
- Radix Entomolaris or Paramolaris
- Presence of more than two canals in either roots i.e mesial & distal roots.
- Root canal retreatment cases.
- Patients on long term use of steroids, opiods and NSAID's.
- Patients on preoperative NSAID's within the past 12hrs.
- Pregnancy.
- Patients allergic to local anaesthesia.
- Patients with swelling (or) abcess.
- Periodontally&Medically compromised patients.
- Parafunctional habits.
- Multiple deep carious lesions involving more than one tooth in each quadrant.
- Grossly mutilated tooth
- Temporo-Mandibular disorders causing muscular toothache of lower molar.

STUDY PROTOCOL

- PRE – OPERATIVE ASSESSMENT
- RANDOMIZATION
- ENDODONTIC PROCEDURE
- POST – INSTRUMENTATION PAIN ASSESSMENT
- STATISTICAL ANALYSIS

Pre-operative assessment of patients

For all patients selected for the study, medical and dental history was recorded.Intraoral examination was done to assess the nature of presenting illness, oral hygiene status, periodontal status and restorability of tooth. Electric and Thermal (Cold) pulp testing was performed to assess the vitality of the pulp.Oral prophylaxis was done prior to the commencement of the treatment. Preoperative pain was recorded using a questionnaire based on functional pain scale.

Randomization

The patients were randomly assigned to two groups using random table numbers.
Group A (n=10) : cleaning & shaping done using ProTaper Gold
Group B (n=10) : cleaning & shaping done using WaveOne Gold
Opaque envelopes containing a slip that mentions either Group I or Group II were numbered according to the randomization schedule. The randomization was done by a third person other than the operator and investigator

Endodontic procedure

Inferior Alveolar Nerve Block with 1.8 ml of local anaesthesia (2% lignocaine with 1:80,000 adrenaline) was administered. Under Rubber dam isolation, Carious tooth structure removed using sterile round bur (BR 41 Mani Dia-Burs).
Access cavity was prepared using sterile Endo access burs (FG1,2,3) and Endo Z burs.
Patency was established using a 10 size hand K file.
Working length was determined by an EAL (Propex Pixie - Dentsply, Maillefer) and confirmed radiographically.
Glide path established upto 20 size hand K file.
ProTaper Gold

In the Endomotor(X-Smart Plus),ProTaper Gold settings was selected.thecoronal part was funneled using ProTaper Gold SX file [0.19mm, 0.04 taper] . Then Shaping files - S1 [size18, 0.02 taper] - S2 file [size20, 0.04 taper] was used till the full working length. Finishing files - F1 file [size 20, 0.07 taper] - F2 file

[size 25, 0.08 taper] were then used till the full working length in mesial canals and F3 file [size 30, 0.09 taper] in distal canal. If there were presence of two distal canals, they were enlarged only upto F2 file

WaveOne Gold

In the Endomotor(X-Smart Plus),WaveOne Gold settings selected.Glide path preparation was done using 20 size K file or the ProGlider file. All canals were enlarged using Primary WaveOne Gold file [size 25, 0.07 taper] till full working length.

On each instrumentation change for both groups,3% NaOCl (Parcan, Septodont) and 0.9% saline was used as intracanalirrigant. At the end of BMP, each canalIrrigated with 3ml of 3% NaOCland 5ml of 17% EDTA solutions followed by 0.9% physiological saline and a final rinse with 2ml of 2% CHX.The access cavity was then closed with the temporary restorative material Cavit (3M ESPE) and the treated tooth was relieved from occlusion.

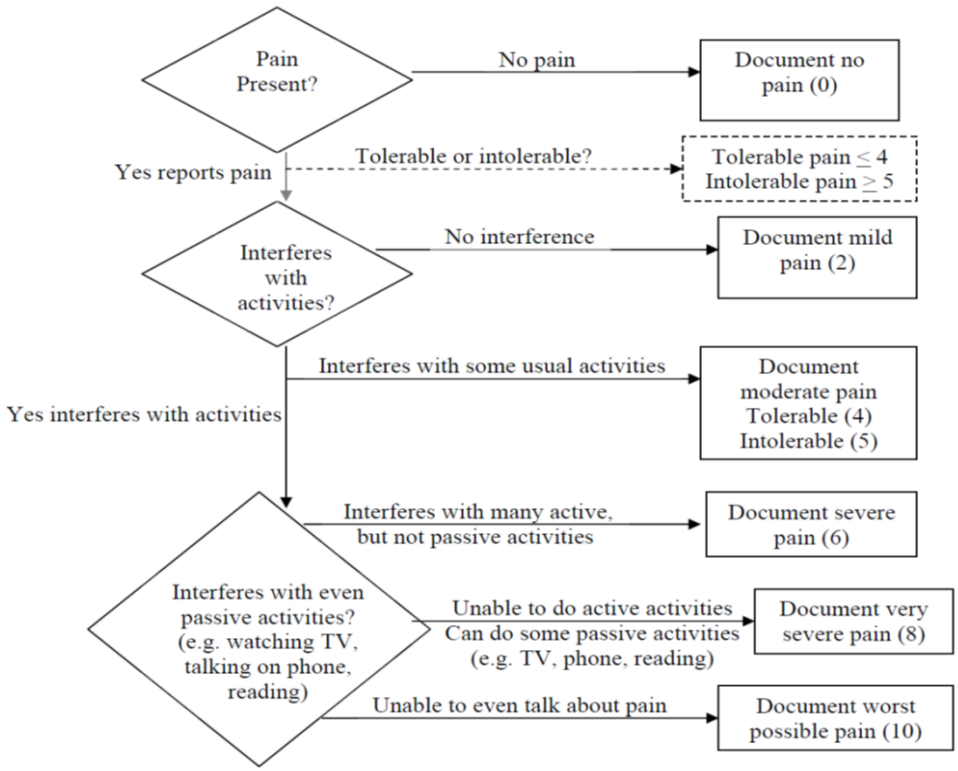
Post - instrumentation pain assessment

All patients were prescribed ibuprofen 400 mg twice a day and was asked to take only in the event of severe pain. The patients were contacted through phone calls by the outcome assessor and the pain scoring based on the functional pain scale questionnaire was recorded at 6h, 12h, 24h,and 48 h, respectively.The outcome assessor was blinded from which group each patient belonged.

Functional Pain Scale (FPS)

(0)	(2)	(4)	(6)	(8)	(10)
No Pain	**Tolerable activities not prevented**	**Tolerable prevents some active activities**	**Intolerable prevents many active, (not passive) activities**	**Intolerable prevents all active and many passive activities**	**Intolerable incapacitated, unable to do anything or speak due to pain**

Active activities : usual activities or those requiring effort (turning, walking, etc)
Passive activities: talking on phone, watching TV, reading



STATISTICAL ANALYSIS

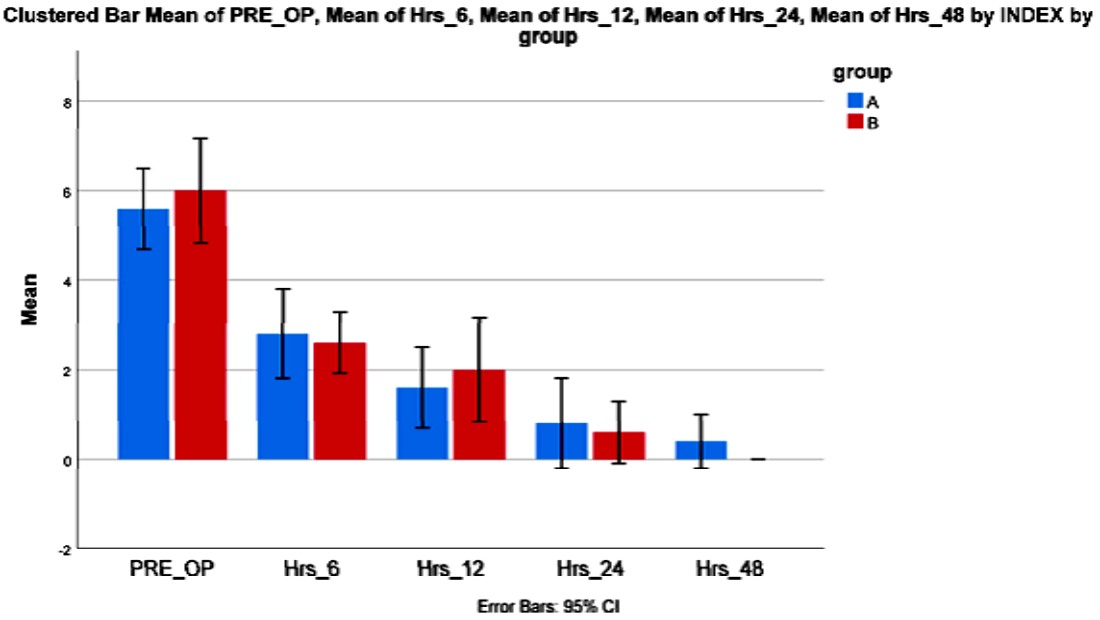
The data collected was statistically analysed using statistical software SPSS version 21. Nonparametric statistical analysis was planned in this study as the data was ordinal.Mann Whitney U test was carried out to determine significant differences at $P<0.05$ for intra group comparison.Friedman test was carried out for comparison between different time intervals with each file system.

III. Results

All the patients who underwent endodontic treatment answered the questionnaire satisfactorily at all the time points assessed (6 h, 12 h, 24 h, and 48 h). The post-instrumentation pain values were lower than pre-instrumentation values.There was no statistically significant difference in post-instrumentation pain between groups with regards to gender.There was no statistically significant difference (P > .05) among ProTaper Gold and WaveOne Gold systems in regard to the incidence of post-instrumentation pain at any of the 4 time points assessed.

	AGE	PRE_OP	Hrs_6	Hrs_12	Hrs_24	Hrs_48
Mann-Whitney U	43.000	43.000	48.500	45.000	48.500	40.000
Wilcoxon W	98.000	98.000	103.500	100.000	103.500	95.000
Z	-.533	-.577	-.141	-.448	-.141	-1.453
Asymp. Sig. (2-tailed)	.594	.564	.888	.654	.888	.146
Exact Sig. [2*(1-tailed Sig.)]	.631[b]	.631[b]	.912[b]	.739[b]	.912[b]	.481[b]

group		AGE	PRE_OP	Hrs_6	Hrs_12	Hrs_24	Hrs_48
A	Mean	28.90	5.60	2.80	1.60	.80	.40
	Std. Deviation	4.254	1.265	1.398	1.265	1.398	.843
	N	10	10	10	10	10	10
	Median	27.50	6.00	2.00	2.00	.00	.00
	Minimum	25	4	2	0	0	0
	Maximum	40	8	6	4	4	2
B	Mean	31.20	6.00	2.60	2.00	.60	.00
	Std. Deviation	5.922	1.633	.966	1.633	.966	.000
	N	10	10	10	10	10	10
	Median	31.50	6.00	2.00	2.00	.00	.00
	Minimum	25	4	2	0	0	0
	Maximum	42	8	4	6	2	0
Total	Mean	30.05	5.80	2.70	1.80	.70	.20
	Std. Deviation	5.155	1.436	1.174	1.436	1.174	.616
	N	20	20	20	20	20	20
	Median	28.50	6.00	2.00	2.00	.00	.00
	Minimum	25	4	2	0	0	0
	Maximum	42	8	6	6	4	2



IV. Discussion

One problem encountered when studying pain is the difficulty in evaluation due to the varying threshold range. This issue is confused by single and variable experience; and pain modulation by various physical and psychological factors.

The Functional Pain Scale (FPS) used in the present study as it incorporates both subjective and objective components to assess pain, based on the pain's perceived tolerability and interference with functioning. The FPS has been tested to be a reliable pain assessment tool in the adult and geriatric population.

A study by Gloth*et al* (2001) compared the Functional Pain Scale, the Present Pain Intensity scale, the Visual Analogue Scale, the McGill Short-form questionnaire and the Numeric Pain Scale. The highest responsiveness was found in the Functional Pain Scale.

Statistical analysis of the baseline parameter showed no significant difference among the groups, thus confirming equal and homogeneous distribution of the samples among two groups.The principal investigator, outcome assessor, and the patients were blinded in this clinical trial.

In the endodontic literature, a study (Walton R, Fouad A. 1992) have shown that female patients experience higher levels of postoperative pain compared to males. However, in this study, gender did not play a role in post-instrumentation pain.

The results of this study showed a significant reduction in post-instrumentation pain score values when compared to pre-operative pain values irrespective of file system used. This concept is supported by many previous studies [Levin et al.(2009); Pak JG,White SN (2011); Ng et al (2004)] proving that endodontic procedure of a diseased tooth helps in alleviation of symptomatic pulpitis.Few *in-vitro* studies [Nayak*et al.(*2014), Karatas*et al*.(2016)] proved that the extrusion of debris is more with reciprocating files when compared to continuous rotary files.

WaveOne Gold files and ProTaper Gold files were taken for the study to evaluate the influence of motion kinematics on post-instrumentation pain.

Post-instrumentation pain can be multifactorial.The two most significant factors can be divided as microbial and non-microbial. In the present study, Care was taken to rule out the non-microbial factors such as

- Preoperative factors - difference in the age of the patient, the anatomy of root canal both in terms of number of canals & canal type.
- Intraoperative causes - maintenance of working length, similar usage of irrigants and irrigation protocol.
- The microbial factors include Apical debris extrusion, Incomplete instrumentation and Secondary intraradicular infection.

Interappointmentintracanal medication such as $Ca(OH)_2$ eradicates the residual bacteria in the canal space. But it was not used in our study due to the fact that it may become a confounding variable on pain assessment.

All instrumentation techniques produce some extrusion of debris, but quantity of material extruded differs depending on preparation technique and instrument [Tinaz*et al*(2005), Tanalp*et al*(2006)].

In the present study, there was no statistically significant difference among the two instrumentation systems assessed.

This is in contrary with the following studies by
Nekoofar*et al*(2015) in his randomized clinical trial showed that postoperative pain was lower in patients treated with the ProTaper Universal rotary system than in those treated with the WaveOne reciprocating system.
Beurklein and Scheafer(2012) - in an *in vitro* comparison of debris extrusion using 2 rotary systems (Mtwo and ProTaper Universal) and 2 reciprocating systems (Reciproc and WaveOne) showed that full-sequence rotary instrumentation was associated with less extruded debris.
But the results were in accordance with the following studies by
Tinoco*et al*(2014) - in an *ex vi*vo assessment of the apical extrusion using reciprocating files of the Reciproc and WaveOne systems and rotary files of the BioRace system observed less extrusion of bacteria when single-file systems were used.
Karatas*et al*(2016) – in vitro assessment on the amount of apically extruded debris using ProTaper Gold, WaveOne Gold, ProTaper Universal, and WaveOne instruments and showed that WaveOne Gold system extrudes less debris than WaveOne system and ProTaper Gold system extrudes less debris than ProTaper Universal system
The current result from our study might be due to the improved design characteristics and metallurgy of WaveOne Gold file compared to its predecessor WaveOne.
Advantages in design characteristics

- The Gold wire technology makes it better than its predecessor the WaveOne , especially, the Primary WaveOne Gold file being80% more flexible, 50% more resistant to cyclic fatigue,23% more efficient.Fixed taper from D1-D3, but progressively decreasing percentage tapered design from D4-D16.
- Alternating offset parallelogram-shaped cross-section causing only 1 or 2 points of contact at any given cross-section, thereby reducing taperlock and the screw-effect.
- New cross-section improves safety, increases cutting efficiency, and provides more chip space to auger debris coronally.semi-active guiding tip – enabling the file to more readily follow and safely progress along manually reproduced and secured canals.

The results may also be a reflection of the smaller sample size (n=10) in each group.Larger sample sizes provide more accurate mean values, identify outliers that could skew the data in a smaller sample and provide a smaller margin of error.

V. Conclusion

Under the limitations of this study, it can be concluded thatBoth ProTaper Gold files and WaveOne God files produced similar amount of post instrumentation pain.

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