

Article

Postoperative Quality of Life after Single-Visit Root Canal Treatment Performed with Reciprocating Shaping Systems: An Observational Study

Stefania Multari ^{1,*}, Mario Alovisi ¹, Elio Berutti ¹, Stefano Corbella ^{2,3,4}, Silvio Taschieri ^{2,3,4},
Giorgia Carpegna ¹, Nicola Scotti ¹, Allegra Comba ¹ and Damiano Pasqualini ¹

¹ Department of Surgical Sciences, Dental School, Endodontics, University of Turin, 10126 Turin, Italy; mario.alovisi@unito.it (M.A.); elio.berutti@unito.it (E.B.); giorgia.carpegna@unito.it (G.C.); nicola.scotti@unito.it (N.S.); alle_comba@yahoo.it (A.C.); damiano.pasqualini@unito.it (D.P.)

² Department of Biomedical, Surgical and Dental Science, Università degli Studi di Milano, 20122 Milan, Italy; stefano.corbella@unimi.it (S.C.); silvio.taschieri@unimi.it (S.T.)

³ IRCCS Istituto Ortopedico Galeazzi, 20161 Milan, Italy

⁴ Department of Oral Surgery, Institute of Dentistry, I.M. Sechenov First Moscow State Medical University, 119435 Moscow, Russia

* Correspondence: Stefania.multari@unito.it; Tel.: +39-(0)11-6331569; Fax: +39-(0)11-6331570

Featured Application: Root canal shaping techniques influence patients' postoperative quality of life after a primary root canal treatment. The introduction of more flexible reciprocating instruments with different alloy and geometry could lead to a general improvement of the postoperative symptoms. Patient-centered outcomes are crucial to evaluate the quality of the root canal treatment.



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Abstract: Postoperative pain is a frequent complication of root canal treatment. It could worsen patients' quality of life (QoL) and it may be associated to several factors, including the shaping technique. The aim of the study was to compare the impact of WaveOne Gold (WOG) and WaveOne Classic (WOC) reciprocating instrumentation on postoperative QoL after single-visit primary root canal treatment. Healthy subjects with pulp necrosis on multirooted teeth were observed. Canal shaping was performed with WaveOne Gold Primary ($n = 25$) or WaveOne Classic Primary ($n = 29$) and canal filling was completed with a carrier-based technique. Mean and maximum scores for postoperative pain were assessed through a Visual Analogue Scale (VAS) and QoL indicators were evaluated with a self-assessment questionnaire based on a Likert scale. Postoperative pain curves were similar in both groups (mean pain $p = 0.43$; maximum pain $p = 0.27$) and quality of life indicators showed no significant differences ($p > 0.05$). There was a more favourable trend of QoL values in the WOG group, reaching statistical significance on day six posttreatment ($p = 0.021$). Within the limitations of the study, reciprocating instrumentation may have an impact on patients' QoL, but the innovative geometrical and alloy properties of the WaveOne Gold seemed to induce a faster resolution of the postoperative symptoms.

Keywords: patient outcome assessment; postoperative pain; quality of life; root canal shaping; reciprocating instruments

1. Introduction

The World Health Organization (WHO) defines the Quality of Life (QoL) as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" [1]. The chronic oral diseases have been shown to negatively influence patients' QoL [2]. QoL can be analyzed and measured with self-assessment questionnaires [3,4], and it can be considered as the overall result of several aspects, such as the difficulty in

eating, sleeping, speaking, carrying out daily functions, and relating with other people as well as perceived pain [5,6]. Previous studies evaluated the relationship between the root canal treatment and patient QoL and showed that several patients perceive it as a negative event, being frequently associated with pain [3,7]. There is a growing interest in patients' treatment perceptions, and postoperative QoL could be considered as an indicator of the overall quality of the endodontic therapy [4,5]. Root canal treatment aims to resolve pulpal and periradicular diseases and to improve long-term tooth prognosis [8]. However, postoperative pain is a possible complication, and it can worsen patient QoL [9]. Pain can be caused by a phlogistic reaction following the root canal shaping [10–13] and can be influenced by operator experience, preoperative status, and shaping techniques [14]. In particular, the postoperative pain is frequently caused by debris extrusion beyond the apex during root canal shaping, such as dentinal chips, pulp debris, bacteria, and irrigants [9,15,16] and it has a great impact on patients' QoL [9]. The Nickel-Titanium (NiTi) reciprocating shaping instruments are associated with high cyclic fatigue resistance and respect of the canal anatomy [17–19]. However, they are claimed to promote greater debris extrusion and postoperative pain prevalence compared to rotary systems, negatively affecting patients' QoL [20–22]. Recently, the reciprocating WaveOne Gold (WOG) system was introduced with substantial improvements in alloy, taper, and section. The gold NiTi alloy is thermally treated in order to enhance flexibility and shape memory. Moreover, a reduced variable taper compared to WaveOne Classics (WOC) and an off-centered, parallelogram cross-section provides one single contact point between the instrument and the canal walls, leaving more space for debris removal. The new features are supposed to lead to an improved conservative shaping, with a consequent less debris extrusion and a better postoperative trend, if compared to other reciprocating mechanical files. Several studies reported that rotary shaping is associated to better postoperative quality of life, probably due to a lesser amount of debris extrusion beyond the apex during the canal instrumentation [22,23]. However, there are no studies considering instruments with the same type of motion but different design and alloy properties.

The aim of this preliminary observational study was to evaluate patients' postoperative QoL after root canal treatments performed with two different reciprocating shaping systems and the impact of the instrument design and alloy properties on postoperative pain.

2. Materials and Methods

This observational study was performed according to the principles of the last update of the Helsinki Declaration [24]. The study was authorized by Local Ethics Committee and Review Board (Acceptance protocol no. 0000184, Appendix A). Root canal treatment was carried out with the patients' informed consent to participate in the study.

Fifty-four healthy subjects who received a diagnosis of pulp necrosis with or without symptomatic or asymptomatic apical periodontitis in a multirouted tooth were observed after primary root canal treatment. Clinical cases in which sinus tract, facial cellulitis, or acute periapical abscesses meant as exacerbation of apical periodontitis and manifesting with swelling were detected were excluded from the analysis, due to the possibility of confounding QoL records, regardless of the treatment received. Patients with physical or psychological disabilities or an inability to understand study instructions were excluded, as well as those who received emergency treatments.

2.1. Sample Size Calculation

The sample size was calculated assuming the aim of detecting a between-group difference of 5% (0.5 on visual analogue scale, VAS scale) in postoperative pain ($\alpha = 0.05$, power = 80%) [14]. The required sample was 23 patients for each group. Hypothesizing a loss of 15% subjects to follow-up, a minimum of 29 subjects per group was enrolled.

2.2. Clinical Intervention

Medical and dental anamneses were collected for each patient prior to intra-oral examination and assessment of periodontal status with a periodontal chart.

The pulpal and periradicular status of each tooth was clinically verified with palpation, percussion, and thermal and electric pulp tests (Diagnostic Unit, Sybron, Orange, CA, USA).

Radiographic analyses were performed with periapical radiographs using phosphor storage imaging plates (Comfort Occlusal™ OpTime Soredex, Tuusula, Finland) and Rinn XCP devices (Rinn Corp., Elgin, IL, USA). The data were processed and archived with a dedicated scanner and software interface (OpTime Soredex, Tuusula, Finland). For each tooth, the loss of lamina dura and periodontal ligament enlargement (>2 mm) were verified using periapical radiography and eventually classified as lesion of endodontic origin (LEO). Radiographic images with periapical index (PAI) 1 or 2 were classified as no LEO, while those corresponding to PAI 3, 4, or 5 were catalogued as LEO. Three endodontists with at least 10 years of experience analyzed clinical and radiological status. When opinions were not unanimous, consensus agreement was reached through discussion. Examiners were calibrated to the evaluation criteria through a case series presentation and concordance was analysed by the Fleiss' K score until inter-examiner reliability ($K > 0.70$) was expected.

Moreover, before starting root canal treatment, the American Association of Endodontists (AAE) Endodontic Case Difficulty Assessment was filled in to classify each treatment as minimal, moderate, or high difficulty [25]. All treatments were performed by the same experienced operator who had completed a postgraduate course in Endodontics and had more than 10 years of experience. All the clinical procedures are summarized in Table 1.

Table 1. Root canal treatment.

	Group 1	Group 2
Canal Scouting	K-File #10	K-File #10
Mechanical Glide Path	Proglider #16.02	Proglider #16.02
Irrigants	NaOCl 5% EDTA 10%	NaOCl 5% EDTA 10%
Root Canal Shaping	WaveOne Classic Primary (25.08)	WaveOne Gold Primary (25.07)
WL Measurement	Electronic and Radiographic	Electronic and Radiographic
Root Canal Filling	Thermafil Technique	Thermafil Technique

Root canal treatment protocol for each group. EDTA, ethylenediaminetetraacetic acid; NaOCl, sodium hypochlorite; WL, working length.

After local anaesthesia and rubber dam isolation, access cavity preparation and endodontic pretreatment restoration were performed.

Canal scouting was accomplished with a size #10 stainless steel K-file (Dentsply Sirona) and mechanical glide path was achieved with ProGlider (Dentsply Sirona) using an endodontic motor (X-Smart Plus, Dentsply Sirona) and a 16:1 contra angle at the suggested settings (300 rpm and 4 Ncm) up to the working length (WL).

Root canal shaping was performed with WaveOne Classic Primary (WOC) (tip size #25, taper 0.08) (Dentsply Sirona) ($n = 29$) or WaveOne Gold Primary (WOG) (tip size #25, taper 0.07) (Dentsply Sirona) ($n = 25$) reciprocating files.

Instruments were removed from the root canal every three pecking motions to clean the blades and remove dentinal debris, as recommended in the manufacturer's instructions. The manufacturer's configuration setup was used to determine the dedicated reciprocating settings of the endodontic motor (X-Smart Plus, Dentsply Sirona).

Apical patency was established two times, at the end of glide path and root canal shaping, with a size #10 K-file 0.5 mm beyond the apex.

Electronic WL was recorded with an apex locator (Diagnostic Unit, Sybron, Orange, CA, USA) three times:

- (1) During canal scouting with a size #10 stainless-steel K-file,
- (2) At the end of glide path with a size #15 stainless-steel K-file, and
- (3) 3 mm before reaching the WL during shaping with a size #15 stainless-steel K-file.

At the end of the glide path, a radiographic check of WL was performed using a size #15 stainless steel K-file.

Irrigation was accomplished with 5% NaOCl (Nicolor 5, OGNA, Muggiò, Italy) and 10% EDTA (Tubuliclean, OGNA, Muggiò, Italy), for a total of 20 mL for 30 min using a 30-G endodontic needle.

Before root canal filling, canals were dried with fine or medium sterile paper points. During the same session, root canal filling was completed with an endodontic sealer (Pulp Canal Sealer EWT, Kerr Endodontics, Orange, CA, USA) and Thermafil (Dentsply Maillefer) technique. The access cavity was sealed with a temporary filling (IRM, Dentsply International Inc., York, PA, USA) and patients were scheduled for subsequent postendodontic restoration. No occlusal adjustments were performed.

2.3. Outcomes

Patients were dismissed with postoperative instructions and a prescription for optional analgesics. Each patient received a questionnaire (Appendix B) to evaluate QoL at the same time every day for seven days posttreatment. A Likert scale from 0 (none) to 10 (the worst ever perceived) was used to evaluate difficulty in chewing, speaking, sleeping, carrying out daily functions, social relations, and overall QoL. Mean and maximum scores for postoperative pain were assessed through a Visual Analogue Scale (VAS) made of a 10-cm line, where 0 = no pain and 10 = unbearable pain. At the time of the delivery of the questionnaire, it was explained to the patient how to fill it in, being careful to separate each aspect from the other, explaining the differences between postoperative pain and quality of life, in order to avoid bias in the results.

Preoperative status was collected, recording also prevalence and entity of preoperative pain and clinical diagnosis. The number of analgesic tablets taken during the postoperative period and the number of days necessary to reach a complete resolution of pain after treatment were recorded.

Also, clinician had to fill in a form for each clinical case, in order to record diagnosis, operating times, and eventually difficulties or mistakes that occurred during the root canal treatment and that could influence postoperative trend.

2.4. Statistical Methods

Mean and standard deviation (SD) statistics were calculated for each variable at baseline and for each posttreatment day. The normality of variable distribution was assessed through the Kolmogorov–Smirnov test. Repeated-measures, two-way analysis of variance (ANOVA) was used to evaluate any differences over time between QoL indicators reported by each group. To analyze the continuous variables normally distributed, the Student's *t* test was adopted (i.e., analgesics' intake and pain stop values). The baseline variables for each group were compared using the Mann–Whitney U-test, and the chi-squared test was used to evaluate categorical variables (diagnostic and clinical variables, prevalence of postoperative pain). The level of statistical significance was set, a priori, at $p < 0.05$. The analyses were made using SPSS for Windows 17.0 software (SPSS, Inc., Chicago, IL, USA).

3. Results

Data from 29 subjects in the WOC group and 25 in the WOG group were statistically analysed (Figure 1). Baseline characteristics and demographics did not significantly differ between the groups (Tables 2 and 3).

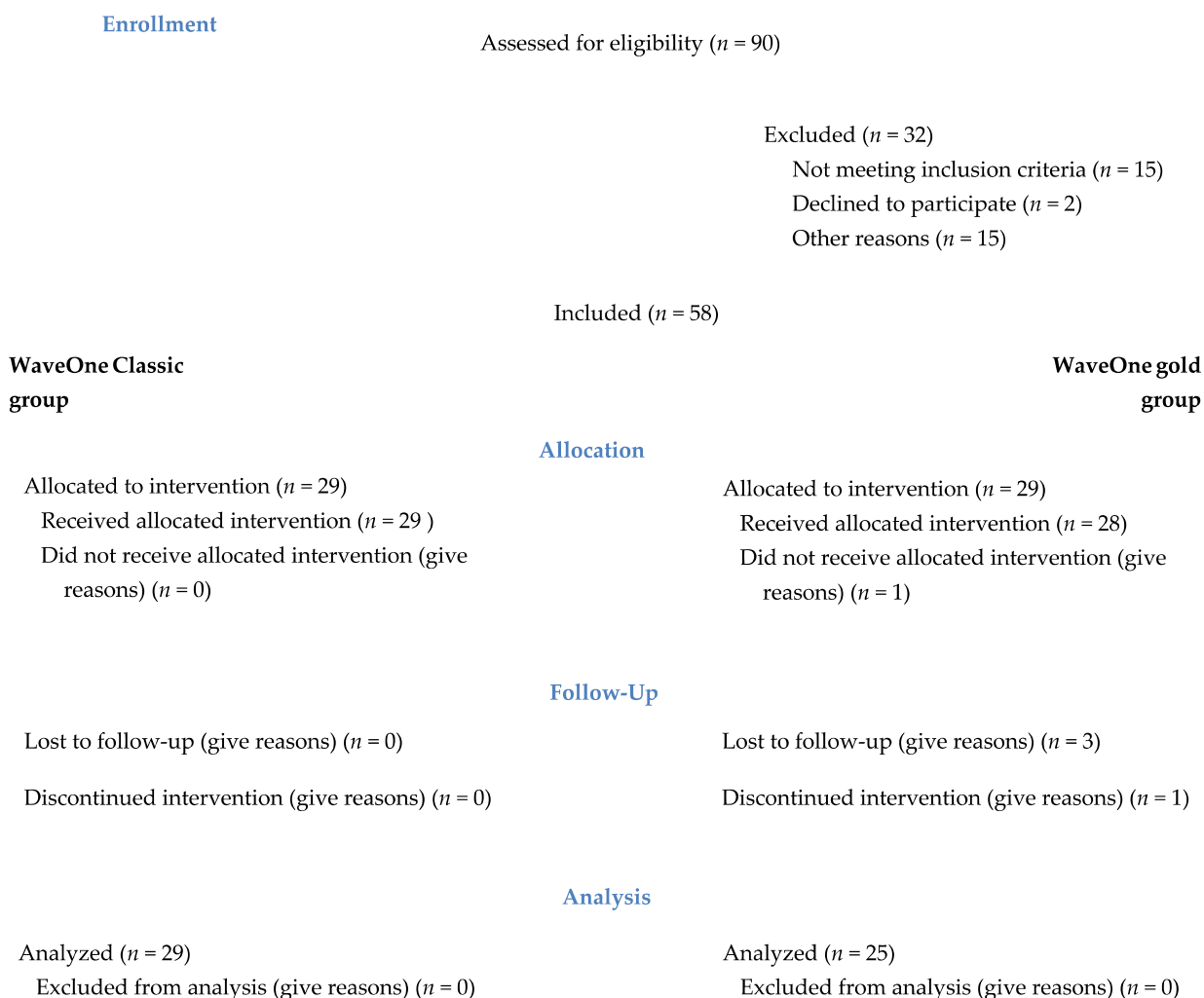


Figure 1. Observational study flowchart divided for each group.

Table 2. Baseline patient demographics and characteristics.

Pre-Operative Status	Group 1 (<i>n</i> = 29) WOC	Group 2 (<i>n</i> = 25) WOG	<i>p</i>
AAE difficulty (minimal/moderate/high) (n)	8/20/1	6/18/1	NS
Type of tooth (maxillary molars/mandibular molars)	18/11	10/15	NS
Pulp necrosis	100%	100%	NS
Symptomatic apical periodontitis	54.2%	48.0%	NS
LEO prevalence	25.0%	20.0%	NS
Pain prevalence	83.3%	80.0%	NS
Mean pain score (VAS)	3.84 ± 3.12	2.90 ± 2.51	NS
Maximum pain score (VAS)	5.24 ± 3.76	4.28 ± 3.30	NS
Quality of life (LS)	2.92 ± 2.60	2.10 ± 2.92	NS

WOC, WaveOne Classic; WOG, WaveOne Gold; AAE, American Association of Endodontists; LEO, lesion of endodontic origin with periapical radiolucency > 2 mm; VAS, Visual Analogue Scale; LS, Likert Scale Values; NS, not statistically significant (*p* > 0.05).

Table 3. Patient age and gender.

	Group 1 (<i>n</i> = 29) WOC	Group 2 (<i>n</i> = 25) WOG	<i>p</i>
Age (<30/30–45/45–60/>60)	9/10/7/3	8/9/6/2	NS
Gender (M/F)	12/17	10/15	NS

NS, not statistically significant (*p* > 0.05).

3.1. Postoperative Pain, Analgesic Intake, and Pain Stop Value

Changes in mean and maximum postoperative pain (Figures 2 and 3) over time were not significantly different between the two groups (p values are presented in figure legends). Mean (\pm SD) pain stop values were 4.3 ± 2.3 days for the WOC group and 3.9 ± 1.8 days for the WOG group ($p = 0.44$). The mean analgesic intake did not significantly differ between the groups (5.1 ± 4.4 for subjects in the WOC group and 4.6 ± 3.8 for those in the WOG group; $p = 0.66$).

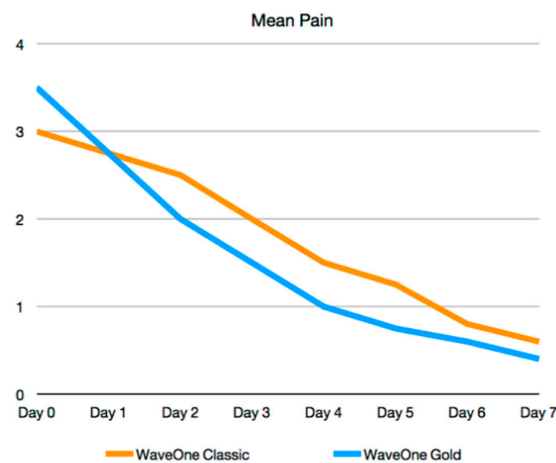


Figure 2. Mean pain curve ($p = 0.43$).

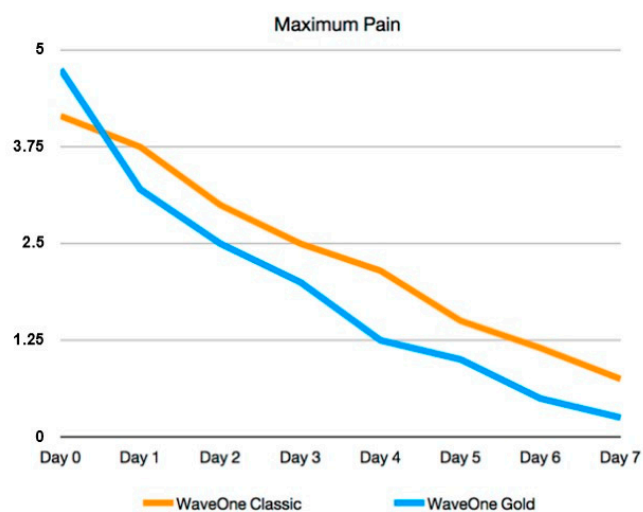


Figure 3. Maximum pain value ($p = 0.27$).

3.2. Postoperative Quality of Life Indicators

QoL indicators following the root canal treatment for both groups are presented in Figure 4. There was a more favorable trend of patient QoL in the WOG group, reaching statistical significance on day six ($p = 0.021$). No differences were found in eating ($p = 0.5$), carrying out daily functions ($p = 0.78$), speaking ($p = 0.81$), sleeping ($p = 0.79$), and social relating ($p = 0.91$) between groups.

3.3. Number of Pecking Motions

Fewer pecking motions were required to reach the full WL in the WOG group ($p = 0.041$). The mean number (\pm SD) of pecking motions was 8.3 ± 1.8 for the WOG group and 9.8 ± 2.1 for the WOC group.

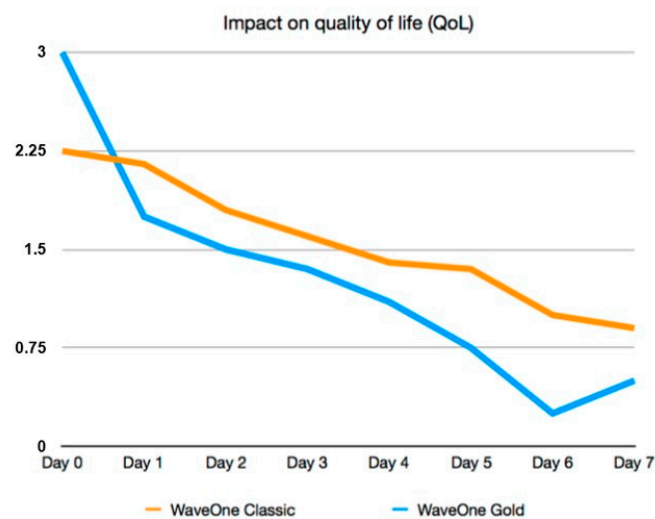


Figure 4. Quality of life value. Statistical significance on day six after treatment ($p = 0.021$).

4. Discussion

This study evaluated the impact of two different reciprocating shaping systems on patients' postoperative QoL using systematic postoperative surveys. Patients' perspectives should be considered during the analysis of the endodontic clinical outcomes [3,4,26] and standardized assessment methods are extensively reported [27]. Postoperative pain can be influenced by occlusion, preoperative pain, periapical radiolucency, type of tooth, and previous emergency intervention [28]. However, the factors related to the chemo-mechanical root canal debridement are the main contributors to postoperative pain due to the extruded dentinal debris that could induce periradicular inflammation [15,16].

This study considered only teeth with a diagnosis of pulp necrosis in order to achieve similar baseline characteristics [29]. Only multirooted teeth were selected, since it has been reported that molars experienced postoperative pain more frequently [28,30]. A systematic balance between maxillary and mandibular molars was investigated and no significant differences were found between groups. During the clinical examination, the presence of periapical radiolucency was recorded, due to the correlation with the severity of the infection. A higher bacterial load increases the possibility of infected debris extrusion, with a subsequent inflammatory periapical reaction and worse postoperative trend [9]. Moreover, the preoperative pain at baseline could moderately influence postoperative pain [9]. Although some studies have reported no significant differences in terms of postoperative pain after root canal treatment completed by generalists or endodontics specialists, this study employed a single expert operator to perform all clinical cases [3,31]. Previous studies reported that NiTi reciprocating single-file systems may be correlated to a stronger postoperative pain than rotary instruments [19,22,23]. Although they may be associated with a more conservative root canal preparation, reciprocating single-file systems may cause greater debris extrusion and, consequently, a higher degree of postoperative pain [17,21]. It has been shown that the number of files used to reach the working length, the type of motion, and the instrument design can modulate the expression of neuropeptide in the periodontal ligament [29,32].

In the present study, a core carrier obturation technique was performed for all clinical cases, with the aim of adopting a predictable method and avoiding bias linked to the root canal filling technique. The choice was supported by a systematic review and meta-analysis, reporting that a core carrier obturation does not influence negatively postoperative symptoms, even if compared with cold lateral condensation [33]. However, thermafil technique has been associated to a more frequent incidence of overfilling, causing more intense postoperative symptoms [31]. In this observational study, for each clinical case the operator had to record in the relevant form (Appendix C) any complication, mistake, or difficulty. All the root canal treatments were performed by the same expert operator and

no overfilling was recorded. Nevertheless, to prevent this complication, the Thermafil core carrier size was chosen based on the diameter of the apical foramen and an X-ray confirmation was performed. Moreover, each Thermafil was adjusted in order to standardize a small amount of gutta-percha beyond the carrier. Apical patency was performed twice during each root canal treatment, in order to standardize the clinical protocol and to ensure the right detection of the working length. This procedure seems not to increase postoperative pain since it can promote the correct cleaning of the apical portion of the root canal walls, preventing the creation of blocks, ledges, perforations, or apical transportation. Rather, it has been reported that apical patency is associated with less postoperative pain after primary root canal treatments performed in multirooted necrotic teeth. [28] In addition, a systematic review reported that single-visit root canal therapy has a slightly negative influence on postoperative pain [34], even if Manfredi et al. demonstrated that there is no difference in terms of postoperative pain between single- and multiple-visit root canal treatment [35]. Furthermore, previous studies reported that the use of single-file reciprocating instruments in a multiple- or single-visit approach is related to a significantly higher use of analgesics [19,22,23].

In the present study, there were no significant differences in terms of postoperative pain between two different single-file reciprocating systems. As no control group was established, it cannot be concluded that reciprocating instrumentation has a positive outcome on postoperative pain and patients' QoL. The WOG group showed a faster improvement of the postoperative conditions, associated with a better QoL value in the first days posttreatment compared with the WOC group, probably due to less debris extrusion. This section may provide a larger room for debris removal and an improved cutting efficiency, resulting in less debris extrusion [36]. Moreover, the new Gold-Wire technology-enhanced instrument flexibility may reduce the amount of dentinal debris created during shaping with a subsequent reduction of postoperative pain and a greater respect of the root canal anatomy [37]. This aspect may be correlated also to a reduced number of pecking motions required to complete the shaping, and this parameter could reduce the operating time, positively influencing patients' apprehension [16,30].

5. Conclusions

Within the limitations of this study, both reciprocating systems showed a similar postoperative patients' experience after a single-visit root canal treatment. The WaveOne Gold geometrical and alloy properties seemed to induce a more favorable patients' QoL trend, although a significant difference between the two groups was detected only on day six after treatment. The limitations of this observational study can be correlated to the psychological status of the patients, their subjective quantification of pain, and their perception of root canal treatment. Moreover, a greater sample should be investigated to confirm the present preliminary results.

Author Contributions: Conceptualization, E.B., D.P., and M.A.; methodology, A.C., G.C., and N.S.; software, S.M., S.T., and S.C.; validation, A.C. and S.T.; formal analysis, S.C. and D.P.; investigation, S.M., G.C., and M.A.; resources, E.B., D.P.; data curation, D.P. and S.C.; writing—original draft preparation, S.M. and A.C.; writing—review and editing, N.S., D.P., and S.T.; visualization, E.B. and S.C.; supervision, M.A. and G.C.; project administration, E.B. and D.P.; funding acquisition, none. All authors have read and agreed to the published version of the manuscript.


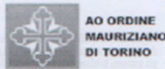
Funding: This research received no external funding.

Institutional Review Board Statement: The institutional Review Board Statement is attached in the appendix A, acceptance protocol No. 0000184.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Conflicts of Interest: The authors declare no conflict of interest.

Appendix A

COMITATO ETICO INTERAZIENDALE
 A.O.U. CITTÀ DELLA SALUTE E DELLA SCIENZA DI TORINO -
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 Centralino: tel. +39 011 6331633 PL.Cod. Fis. 10771160014
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Prot. n° **0000184** del **02 GEN. 2019**
 Titolario A2.4.8
 Pratica N. CS2/1053

Dott. S. Falco
 Direttore Generale
 AOU Città della Salute e della Scienza di Torino

OGGETTO: Richiesta parere pervenuta
 in data 19/11/2018

Prof. E. Berruti
 Sperimentatore Principale
 SC Odontostomatologia Preventiva e Restaurativa
 Dental School

DOCUMENTAZIONE:

- Protocollo di studio dal titolo: *Influenza del dolore postoperatorio a seguito di strumentazione rotante reciprocante sulla qualità della vita del paziente. Uno studio osservazionale prospettico.*
- Promotore: AOU Città della Salute e della Scienza di Torino - Dental School Lingotto Torino;
- Sinossi del protocollo di studio;
- Lettera di intenti;
- Dichiarazione sulla natura No Profit dello studio;
- Dichiarazione sulla natura osservazionale dello studio del 19/11/2018;
- Elenco con firma dei partecipanti (Prof. E. Berruti, Dott. D. Pasqualini, Dott. M. Alroviti, Dott.ssa G. Carpegna, Dott.ssa S. Molinari)
- Curriculum Vitae dello Sperimentatore Principale ;
- Dichiarazione pubblica sul conflitto di interessi dello Sperimentatore Principale datata 19/11/2018;
- Informativa al paziente;
- Lettera di consenso informato;
- Modello informativo sulla privacy;
- Lettera informativa per il medico curante;
- Scheda Raccolta Dati

Il Comitato Etico Interaziendale A.O.U. Città della Salute e della Scienza di Torino - A.O. Ordine Mauriziano - A.S.L. "Città di Torino", istituito in conformità a quanto previsto dal D.M. 8 febbraio 2013 attuato con DGR 25-6084 del 25/06/2013, nella seduta del 17/12/2018 esaminata la documentazione prodotta, nell'intesa che lo studio clinico sia esplicito in conformità ai principi etici che reggono la loro origine dalla Dichiarazione di Helsinki nella sua ultima versione, e che rispetti le GCP e le disposizioni delle normative vigenti, ritiene di esprimere

PARERE FAVOREVOLE.

Questa Commissione dovrà essere informata dell'inizio della sperimentazione e della sua conclusione od eventuale interruzione nonché di ogni eventuale emendamento al protocollo. Al momento della chiusura dello studio sarà cura del ricercatore inviare allo stesso Comitato, secondo quanto previsto dalla normativa vigente e ribadito dalla

Circolare della Regione Piemonte Prot. 14590/UC/SAN del 24/07/2009 a firma dell'Assessore Ekonomu

Attesa una relazione sintetica dei risultati ottenuti presso il proprio ambito di sperimentazione e comunicare gli estremi bibliografici di eventuali pubblicazioni che verranno prodotte sulla base della ricerca stessa.

Il Comitato Etico ricorda altresì che deve essere garantito il diritto alla diffusione o pubblicazione dei risultati favorevoli o non favorevoli da parte degli sperimentatori che hanno condotto lo studio, nel rispetto delle disposizioni vigenti in tema di riservatezza dei dati sensibili e di tutela brevettuale e che non devono assistere vincoli di diffusione e pubblicazione dei risultati da parte del Promotore.

Il responsabile dello studio dovrà, inoltre, far pervenire una relazione annuale sull'andamento dello stesso.

In ogni successiva comunicazione dovrà essere indicato il numero di pratica assegnato a questa sperimentazione.

Il Presidente
 Dott. Marcello M. BALBENA

I componenti

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- Prof. A. PIRELLI in qualità di Clinico di Area Medica Specialistica - Vice Presidente (Presente)
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- Prof. L. CASTEL in qualità di Farmacologo (Presente)
- Prof. T. CASILLI in qualità di Biostatistico (Presente)
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- Prof. G. DE VELLA in qualità di Medico Legale (Assente)
- Prof. E. FANTOZZI in qualità di Farmacologo (Presente)
- Prof. D. FORTANA in qualità di Clinico di Area Chirurgica (Presente)
- Dott.ssa S. FROSIO in qualità di Esperto in gestione dell'Unità delle Professioni Sanitarie (Presente)
- Rag. S. GARZITI in qualità di rappresentante del Volontariato Associazionista Turin del Pacienti (Presente)
- Dott.ssa G. LUCIFERA in qualità di Clinico di Area Medica Specialistica (Presente)
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- Prof.ssa B. PASINI in qualità di Esperto in Genetica (Assente)
- Dott.ssa C. RICCI in qualità di Esperto in Oncologia (Presente)
- Prof. R. ROMANZONI in qualità di Esperto Clinico del settore nuove procedure tecniche, dispositivi e tecnologie innovative in area (Presente)
- Ing. T. A. SABBIONI in qualità di Esperto in Chimica (Assente)
- Prof. S. SANDRECCI in qualità di Clinico di Area Chirurgica (Assente)
- Dott. M. STOLA in qualità di Pediatra (Assente)
- Dott. F. TALARICO in qualità di Medico di Medicina Generale (Assente)

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Figure A1. Institutional Review Board Statement.

Appendix B

Postoperative Quality of Life Evaluation

Clinician Code:	
Patient Code:	
Date:	

Please assign, for 7 days after treatment, a numerical value for each item, from 0 (which represents the absence of any impact on the quality of life) to 10 (which represents the maximum impact on the quality of life).

	BASELINE	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
Mean pain perceived								
Maximum pain perceived								
Difficulty in eating								
Difficulty in carrying out daily functions								
Difficulty in speaking								
Difficulty in sleeping								
Difficulty in relating with other people								
Overall quality of Life								
Number of analgesic intake								

Date:	
Patient sign:	

Figure A2. Postoperative Quality of Life form.

Appendix C

Operator Form

Clinician Code					
Patient Code	M	F	AGE		
Date					
Group:	WaveOne Classic		WaveOne Gold		
Tooth:	18 - 17 - 16 - 15 - 14 - 13 - 12 - 11	21 - 22 - 23 - 24 - 25 - 26 - 27 - 28			
	48 - 47 - 46 - 45 - 44 - 43 - 42 - 41	31 - 32 - 33 - 34 - 35 - 36 - 37 - 38			
Occlusion:	DENTATUS	OMOLATERAL EDENTULOUS	CONTROLATERAL EDENTULOUS		
	IN OCCLUSION		NOT IN OCCLUSION		
	OCCLUSAL ADJUSTMENT		NO OCCLUSAL ADJUSTMENT		
Diagnosis:	APICAL PERIODONTITIS [PERCUSSION +]		NO APICAL PERIODONTITIS [PERCUSSION -]		
	LESION OF ENDODONTIC ORIGIN (LEO) [NO < 2 MM]		LESION OF ENDODONTIC ORIGIN (LEO) [YES =>2 MM]		
AMERICAN ASSOCIATION OF ENDODONTICS Case Difficulty Assessment					
MINIMAL DIFFICULTY		MODERATE DIFFICULTY		HIGH DIFFICULTY	
SELF ASSESSMENT QUALITY OF TREATMENT					
TO REATREAT (>1 mm)	ADEGUATE (within 1 mm)	ACCURATE	OVERFILLING (beyond 1 mm from the apex)		
VISIT	Pain:	0 1 2 3 4 5 6 7 8 9 10			
	Intervention:	Access Cavity	Root Canal Shaping	Root canal Filling	Coronal Restoration
	Time (min):				
Date: __ / __ / __	Easiness:	0 1 2 3 4 5 6 7 8 9 10			
	Accuracy:	0 1 2 3 4 5 6 7 8 9 10			
	Complications:	Canal block with recover Canal Block without recover Ledge Instrument Strain Instrument Fracture			

Figure A3. Operator Form.

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