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Effectiveness of two integrated systems for the treatment of maxillary central incisors with periapical lesion: an 18-month randomized clinical trial☆

Efficacia di due sistemi integrati per il trattamento di incisivi centrali mascellari con lesione periapicale: Trial clinico randomizzato a 18 mesi

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KEYWORDS
Periapical lesion;
Integrated endodontic techniques;
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Abstract
Aim: To assess the 18-month success rate of root canal treatment with two integrated shaping and filling systems on upper central incisors with chronic periapical pathosis.
Methodology: Sixty patients with an upper central incisors with a chronic periapical lesion smaller than 5 mm in diameter were randomly allocated to two treatment groups, which only differed in terms of canal shaping and filling protocol: G1 (n = 30), Revo-S/One Step Obturator; G2 (n = 30) GTX/GTX Obturator. The patients underwent clinical assessment at baseline and after 6, 12 and 18 months. Radiographic healing was scored according to a previously described scale by two independent examiners, who analysed the periapical radiographs taken at the recall

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visits. Intra- and inter-observer reliability was tested with Kappa statistics. The significance of the differences between the two groups and among time points with regard to clinical and radiographic data was evaluated with non-parametric tests ($p < 0.05$).
Results: All enrolled patients were available for re-evaluation. At the final recall, the cases were scored as total healing, partial healing and failure with the following frequencies: 93.3%, 3.3% and 3.3% of cases in G1 and in 93.3%, 0% and 6.7% of cases in G2. Radiographic healing scores were similar in the two groups irrespective of the experimental time point. The prevalence of symptoms was scarce (0—10%), stable over time and similar in the two groups.
Conclusions: The clinical performance of two considered integrated systems for the endodontic treatment of upper central incisors with periapical lesion was comparable and allowed for high success rates after 18 months.

PAROLE CHIAVE
Lesione periapicale;
Tecniche endodontiche integrate;
Sistemi carrier-based;
Guarigione.

Riassunto
Obiettivi: Valutare il successo a 18 mesi del trattamento endodontico di incisivi centrali superiori affetti da patologia periapicale cronica con tecniche integrate di strumentazione e otturazione.
Materiali e metodi: Sessanta pazienti con un incisivo centrale affetto da lesione periapicale cronica di diametro inferiore a 5 mm sono stati assegnati casualmente a due gruppi di trattamento, diversi tra loro solo per protocollo di sagomatura e otturazione canalare: G1 (n = 30), Revo-S/One Step Obturator; G2 (n = 30) GTX/GTX Obturator. I pazienti sono stati sottoposti a esame clinico iniziale e dopo 6, 12 e 18 mesi. Alla guarigione radiografica è stato assegnato un punteggio sulla base di una scala descritta in precedenza analizzando le radiografie periapicali acquisite ai richiami. Il grado di accordo intra- e interosservatore è stato testato con Kappa di Cohen. La significatività delle differenze tra i due gruppi e tra i tempi in relazione ai dati clinici e radiografici è stata valutata con test non parametrici ($p < 0,05$).
Risultati: È stato possibile rivalutare tutti i pazienti arruolati. Al richiamo finale le lesioni sono state classificate come guarita, guarita parzialmente e non guarita con le seguenti frequenze: 93,3%, 3,3% e 3,3% dei casi in G1 e 93,3%, 0% e 6,7% dei casi in G2. I punteggi di guarigione radiografica sono risultati simili nei due gruppi indipendentemente dal tempo sperimentale. La prevalenza dei sintomi è stata scarsa (0-10%), stabile nel tempo e simile nei due gruppi.
Conclusioni: La performance clinica dei due sistemi integrati considerati nel trattamento endodontico di incisi centrali superiori con lesione periapicale è risultata comparabile e ha permesso tassi di successo elevati dopo 18 mesi.

Introduction

A trend of simplification of root canal shaping and filling techniques has arisen in the field of Endodontics.[1] The rotary file sequences of modern Ni-Ti systems are composed of fewer instruments in comparison to the past.[1] Similarly, canal filling can be simplified and performed in a single step using of carrier-based systems, which might introduce less filling defects compared to multi-step techniques, especially when used by novices.[2] Even if there is no doubt that a wide array of technological advances has improved the treatment delivery in the field of Endodontics, the scientific community is still questioning whether using modern techniques and instruments implies also better success rates, even more in case of periapical pathosis.[3] This work presents the updated findings of a previously published trial, in which two simplified techniques were clinically tested.[1] These techniques are found on similar principles but are proposed by different manufacturers. They consist in a shaping protocol with rotary files composed of a standard sequence of few instruments, namely the Revo-S (Micro-Mega, Besançon, France) and GTX (Dentsply Tulsa Dental Specialties, Tulsa, OK, USA) files systems. Both shaping protocols are followed by root canal filling by means of carrier-based dedicated systems, the One-Step Obturator (CMS Dental ApS, Copenhagen, Denmark) and GTX Obturator (Dentsply Tulsa Dental Specialties), respectively.

The aim of the present study was to assess the 18-month success rate of root canal treatment with the two aforementioned integrated shaping and filling systems of upper central incisors with chronic periapical pathosis.

Materials and methodology

The present randomized controlled trial was conducted in accordance with the principles expressed in the CONSORT statement[4] and the last update of the Helsinki Declaration. The primary outcome measures were the radiographic healing and the sensitivity to tooth percussion and palpation of the buccal sulcus. The trial recruited patients affected by chronic or asymptomatic apical periodontitis, according to the definition given by Gutmann et al.[5] Sixty adult patients needing a primary endodontic treatment on a maxillary

central incisor with a chronic periapical lesion smaller than 5 mm in diameter were enrolled in the trial and received a single-session root canal treatment by an experienced operator. They were randomly allocated to two groups, which only differed in terms of canal shaping and filling protocol: group 1 (G1, $n = 30$), Revo-S/One Step Obturator; group 2 (G2, $n = 30$), GTX/GTX Obturator. Randomization, sequence generation and allocation to groups were conducted in advance by subjects not directly involved in the experimental part. Restricted randomisation was carried out assuming a block size that was a multiple of the number of treatments.

Before root canal treatment, all teeth were isolated with rubber dam. If needed, the teeth to be treated received a composite resin build-up. After standard access cavity preparation, the canal was scouted with a size 10 K file (Dentsply Maillefer, Ballaigues, Switzerland) and the electronic length determined electronically (Root ZX, Morita Co., Tokyo, Japan). The irrigation protocol was standardised and consisted of rinses with 2.5 ml 5.25% sodium hypochlorite (Niclor 5, Ogna, Muggiò, Italy) after each instrument. In G1, canals were shaped with SC 1 (25/.06), SC 2 (25/.04) and SU (25/.06) Revo-S files (Micro-Mega) and then filled with One-Step Obturators (CMS Dental ApS). Similarly, 20/.04, 20/.06, 30/.04 and 30/.06 GTX rotary files (Dentsply Tulsa Dental Specialties) were used in combination with GTX Obturators (Dentsply Tulsa Dental Specialties) to perform canal shaping and filling in G2. Prior to root canal filling, in both groups the apex was manually gauged (Mity Turbo, JS Dental, Ridgefield, CT, USA) and then enlarged with the rotary finishing files belonging to the respective file system.

Sensitivity to percussion of the designated tooth and palpation of the buccal sulcus was tested before the treatment, after 6, 12 and 18 months by a single operator wearing 4× magnifying loupes, who was unaware of the allocation to groups.

To ensure reliability and repeatability of film positioning during the radiographic analysis, Rinn XCP devices (Rinn Corp., Elgin, IL, USA) were customized with a silicon registration and used with a paralleling technique. The image plates of a digital X-ray system (Vistascan Dental Perio, Dürr Dental AG, Bietigheim, Germany) were exposed to an X-ray source (2200 Intraoral X Ray System, Kodak Dental Systems, Rochester, NY, USA) set at 70 kVp, 10 mA, and 0.20 s exposure time. All the images were registered in "Endo" mode to enhance readability.[6]

The radiographic healing was scored by two blind examiners on the periapical radiographs taken at the recall visits according to the scale by Katebzadeh et al.[7], which contemplates the following four scores:

1. healing: normal trabecular bone and physiological periodontal ligament width;
2. improvement: decrease of the lesion size;
3. failure: increase of lesion size or absence of changes from the initial status;
4. unreadable radiograph.

Table 1 Frequency of the radiographic healing scores at the different observation time points.

	Radiographic score	Months		
		6	12	18
G1	Total healing	43.3%	80.0%	93.3%
$n = 30$	Partial healing	53.3%	16.7%	3.3%
	Failure	3.3%	3.3%	3.3%
G2	Total healing	43.3%	73.3%	93.3%
$n = 30$	Partial healing	50.0%	20.0%	0%
	Failure	6.7%	6.7%	6.7%
Diff.		NS	NS	NS

Intra- and inter-observer reliability was assessed by weighted Cohen's Kappa. The absence of differences in terms of baseline clinical parameters between the two groups (age, apical gauging, tenderness to percussion and palpation) was verified by means of non-parametric statistics. A Mann–Whitney and a Friedman test served to compare the radiographic healing scores between groups and time points, respectively. The clinical data registered in the two groups at the recalls were compared with a chi-squared test; the comparison between time points was carried out with a Cochrane test ($p < 0.05$).

Results

No drop-outs or withdrawals occurred. The baseline parameters were comparable in the two groups. Radiographic healing was progressive during the observation period. After one year and a half, the cases were scored as total healing, partial healing and failure in 93.3%, 3.3% and 3.3% of cases in G1 and in 93.3%, 0% and 6.7% of cases in G2 (Table 1). There was no difference in radiographic healing between the groups at any of the assessment time points. During the follow-up period, the patients were infrequently reporting symptoms (0–10% of cases); the prevalence of symptoms did not vary over time and was similar in the two groups (Table 2).

Table 2 Comparison of the clinical data registered in the two groups.

	Age (y)	Apical gauging (10^{-2} mm)	Baseline		6 months		12 months		18 months	
			Positivity to percussion	Positivity to palpation	Positivity to percussion	Positivity to palpation	Positivity to percussion	Positivity to palpation	Positivity to percussion	Positivity to palpation
G1 $n = 30$	46.3 ± 19.4	37.8 ± 5.8	6.7%	6.7%	6.7%	6.7%	6.7%	10.0%	3.3%	3.3%
G2 $n = 30$	50.8 ± 19.6	39.2 ± 5.3	3.3%	10.0%	3.3%	6.7%	3.3%	6.7%	0%	6.7%
Diff.	NS	NS	NS	NS	NS	NS	NS	NS	NS	NS

Discussion

Primary and secondary research studies have taken into account the success rate of the endodontic treatment, reporting its remarkable variability.[8–10] With regard to the six-month results on persistent tooth symptoms after endodontic treatment, our data are in accordance with the tooth pain prevalence reported in literature,[11] equal to 5.3% after 6 months. To the best of our knowledge, no systematically gathered information concerning tenderness to palpation or percussion is available for longer periods of observation.

Irrespective of the integrated system being used, the present study on upper central incisors demonstrated that even simplified techniques can lead to treatment success almost in all cases. The final success rate obtained in the present study is superior to that obtainable with teeth with necrotic pulp and periapical lesion according to the systematic review by Ng et al.[10] An explanation to this finding may be that, in absence of particular obstacles or anatomic aberrations, maxillary central incisors rarely present peculiar hindrances to a standardized root canal treatment so that they can have a better prognosis than other tooth types.

The present trial also attests that some lesions undergo a progressive healing that may require more than one year. An extended follow-up period is advisable for these patients. When planning the radiographic monitoring of periapical lesions, an open question is whether extending the follow-up of lesions that have completely disappeared after one year is appropriate or not, because it is known that late endodontic failure is rare. However, cases presenting partial healing may come to a complete resolution even after way longer periods and should be followed-up further, as suggested by review papers and endodontic scientific societies.[9,12] Furthermore, it is interesting that almost all the lesions scored as partially healed reached the status of complete radiographic healing. Nevertheless, since it has not been demonstrated yet whether a lesion that starts to diminish in size will always result in complete resolution, further studies are needed to address this issue.

The cases consistently scored as radiographic failures after 18 months were not subjected to retreatment, because the patients were not willing to undergo such therapy given the absence of major complications. Indeed, the authors agree with the concepts already expressed by other researchers[13,14] that state that from the patient's perspective a functional tooth may be acceptable even with an imperfect periapical status. Furthermore, the hurry to proceed with a surgical or non-surgical retreatment may lead to an overtreatment.

Conclusions

The present trial registered high 18-month success rate of endodontic treatments performed with the two considered integrated systems on central incisors with periapical pathosis. The clinical performance of the two techniques was similar.

Conflict of interest

The authors have no conflicts of interest to declare.

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