Ultrasonic root-end preparation in apical surgery: a prospective randomized study

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Objective. The purpose of this study was to evaluate the potential benefit of an ultrasonic device in apical surgery on the outcome of treatment.
Study design. A randomized prospective design was used in a standardized treatment protocol. Patients were allocated to treatment with an ultrasonic device (P-Max Newtron) or treatment with a bur in an otherwise similar protocol. One year after treatment the results were evaluated by 2 oral and maxillofacial surgeons who were blinded for the therapy.
Results. Out of a total group of 399 patients who were included in the study, adequate follow-up could be obtained in 290 patients. The overall success rate in the ultrasonic group was 80.5% and in the group treated with a bur 70.9% ($P = .056$). In molars, the difference in success rate was significant ($P = .02$).
Conclusion. The use of an ultrasonic device in apical surgery improved the outcome of treatment. In molars this effect was significant.
(Oral Surg Oral Med Oral Pathol Oral Radiol Endod 2007;104:841-5)

Endodontic treatment of teeth is a frequently applied therapy to treat inflammation or necrosis of the contents of the root channel. Overall success rate of an initial endodontic treatment is high (85% to 95%); however, there are failed cases that can be managed by endodontic retreatment or apical surgery.[1] Apical surgery can be performed by apicectomy and conservative preparation of a root-end cavity using a round bur, if possible on a micro contra angle hand-piece, or by the use of an ultrasonic device. These ultrasonic devices were evaluated in several studies that tested their cutting ability, the cleanliness of root-end cavities, or the crack formation after root-end preparation.[2-4] A recently published retrospective study showed a significantly higher percentage of complete healing in patients treated with an ultrasonic device.[5] However, prospective clinical trials comparing the use of a ultrasonic device or a bur in routine apical surgery are nonexistent.

In this study, a prospective randomized clinical trial is presented comparing the results of apical surgery with an ultrasonic device to the results of apical surgery using a bur in a general oral surgery practice.

All ultrasonic devices used in this study were provided by the Satelec Company, Merignac, France.

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Received for publication May 14, 2007; returned for revision May 17, 2007; accepted for publication Jun 27, 2007.
1079-2104/$ - see front matter

doi:10.1016/j.tripleo.2007.06.023

MATERIALS AND METHODS

Null hypothesis

In apical surgery, the use of an ultrasonic device (P-Max Newtron, Satelec, Merignac, France) does not give a significantly better outcome of therapy in comparison with a round dental bur (Hager & Meisinger GmbH, Neuss, Germany.

Power for a test of the null hypothesis

One goal of the study was to test the null hypothesis that the proportion positive is identical in the 2 populations. The criterion for significance (alpha) was set at 0.050. The test was 2-tailed, which means that an effect in either direction was interpreted. The proposed sample size was 140 for each of the 2 groups. The study had a power of 80.1% to yield a statistically significant result. This computation assumed that the difference in proportions was −0.15 (specifically, 0.65 versus 0.80). This effect was selected as the smallest effect that would be important to detect, in the sense that any smaller effect would not be of clinical or substantial significance. It is also assumed that this effect in size is reasonable, in the sense that an effect of this magnitude could be anticipated in this field of research.

Patient selection

All patients were referred for apical surgery on one of their previously endodontically treated teeth. The patients were divided into 2 groups by randomization.

Randomization was carried out after the inclusion and exclusion criteria were checked. Every patient was randomly assigned a number, by drawing a number from a closed box, from a list of 400 numbers that were previously labeled and equally divided into 2 groups. In one group the preparation of the root-end cavity was carried out by a bur and in the other group by the use of a P-Max Newtron ultrasonic device. In all cases the fillings were made of IRM (intermediate restorative material, Caulk Dentsply, Milford, DE).

Inclusion criteria were the following:

- Periapical lesion on one of the teeth, confirmed on radiograph.
- Previous endodontic treatment more than 6 months earlier.

Exclusion criteria were the following:

- Root fracture.
- Periodontal origin of apical infection or absence of marginal buccal bone after flap elevation.
- Root perforation.
- No previous endodontic treatment.
- Previous endodontic surgery.

Treatment protocol

All surgical procedures were performed by 5 oral and maxillofacial surgeons and 2 residents of the department of Oral and Maxillofacial Surgery of the Isala Klinieken in Zwolle, The Netherlands. The following is a description of each treatment protocol.

1. Bur: Local anesthesia, a full mucoperiosteal flap, osteotomy with bur, curettage of granuloma tissue at the apex, root-end resection of 2-3 mm with an angle of approximately 45 degrees with bur (diameter 1 mm), root-end cavity preparation using bur, retrograde filling with IRM, flap reposition, sutures.
2. P-Max Newtron: Local anesthesia, a full mucoperiosteal flap, osteotomy with bur, curettage of granuloma tissue at the apex, root-end resection of 2-3 mm with minimal or no bevel using bur, root-end cavity prepared using ultrasonic diamond coated retro-tips to a depth of at least 3 mm, retrograde filling with IRM, flap reposition, sutures.
   - No magnification devices were used in either group.

Outcome of therapy

A radiograph of the treated tooth was taken directly postoperative and 6 months and 1 year after treatment. Clinical examination was performed at 6 months and 1 year after therapy. Assessment of the operation site was carried out blinded from the applied therapy and recorded on a screening formulary with the patient's number.

The following radiological criteria for success were described by Rud et al.[6] in 1972:

- Lamina dura around the apex of the tooth is visible, all roots are investigated separately.
- The periodontal space around the apex is $\leq$2 times the periodontal space at the nontreated part of the root.
- The bone defect that was seen right after treatment is filled with new bone that is not necessarily of the same opacity as the surrounding bone.
- A small apical defect in the lamina dura of maximal 1 mm^2 at the side of the apical filling is acceptable.

The following clinical criteria for success were formulated as:

- No fistula or pockets to the apex.
- No percussion sensitiveness of the tooth.
- Tooth is functional and without impairment or complaints.
- Aspect of the scar tissue and gingival tissue (no signs of infection).

All radiographs were assessed by 2 maxillofacial surgeons who were at the time of assessment blinded for the applied therapy. Assessment took place for each individual treated tooth. In case of a different outcome, the assessment of a third maxillofacial surgeon was final. Only when all the criteria, summarized above, were met, was the treatment considered successful. One year after the last patient was included, the randomization code was broken.

Statistical analysis

The data were analyzed using SPSS 13.0 (SPSS Inc, Chicago, IL) software. The influence of treatment technique, gender of the patients, tooth type, and number of roots were analyzed by Pearson chi-square test. Statistical significance was set as $P < .05$.

RESULTS

In a period of 14 months, 399 patients could be included. Adequate follow-up was obtained from 290 patients (141 bur and 149 ultrasonic). The relatively large number of patients who were lost to follow-up was categorized as "missing at random" with no relation to the outcome of treatment. In the group treated with the ultrasonic device, 24.4% were lost to follow-up and in the group treated with a bur, 30.2% of cases had no adequate follow-up. This difference was not significant ($P = .191$). Moreover, there was no difference in the distribution of the type of teeth that were treated between groups (i.e., lost to follow-up,

Table I. Age distribution of the 290 included patients

N	290
Mean age	42.7
Median	43.0
Range	70
Minimum	9
Maximum	79

Table II. Gender distribution of the 290 included patients

	Frequency	*Percent*
Valid		
Male	117	40.3
Female	173	59.7
Total	290	100.0

Table III. Outcome of treatment for all included patients

	Appliance		
	Boor	*Satelec*	*Total (%)*
Result			
Failure	41 (29.1%)	29 (19.5%)	70 (24.2)
Success	100 (70.9%)	120 (80.5%)	220 (75.8)
Total (%)	141	149	290

adequate follow-up, bur, and ultrasonic) and the number of dropouts was due to factors unrelated to the intervention of the treatment.

Mean age was 42.7 years (median: 43 years) and male-to-female ratio was 40.3%: 59.7% (Tables I and II). In 58 patients a frontal tooth was treated (incisor or cuspid), in 97 patients an apicectomy of a premolar was carried out, and in 135 cases a molar was treated. The overall success rate was 75.8%; in the ultrasonic group the success rate was 80.5% while the group of patients treated with a bur showed success in 70.9% of cases ($P = .056$) (Table III). Success rate for frontal teeth was 84.5%, for premolars 81.4%, and for molars 68.1% (Table IV). In the molar group, the difference in treatment outcome between ultrasonic (76.7% success) and bur (58.1% success) was significant ($P = .020$).

When looking at the number of roots of the individual teeth, 165 teeth with 1 root were treated and in 111 cases 2 roots were treated. In a small number of teeth 3 roots were treated (13) and in 1 case 4 roots were treated (Table V). In the group with 2 roots treated, the difference between ultrasonic (81.5%) and bur (64.9%) was significant ($P = .049$). Also, all teeth with 2 or more roots treated (n = 125) showed a significantly better result for the ultrasonic device ($P = .042$) (Table VI).

Table IV. Outcome of treatment specified in different types of teeth

	Appliance		
Position	*Boor*	*Satelec*	*Total*
Front			
Result, n (%)			
Failure	6 (20.0)	3 (10.7)	9 (15.5)
Success	24 (80.0)	25 (89.3)	49 (85.5)
Total	30	28	58
Premolar			
Result, n (%)			
Failure	9 (18.4)	9 (18.8)	18 (18.6)
Success	40 (81.6)	39 (81.2)	79 (81.4)
Total	49	48	97
Molar			
Result			
Failure	26 (41.9)	17 (23.3)	43 (31.9)
Success	36 (58.1)	56 (76.7)	92 (68.1)
Total	62	73	135

Table V. Outcome of treatment specified in number of roots

	Result		
	Failure	*Success*	*Total*
Roots, n (%)			
1	36 (21.8)	129 (78.2)	165 (56.9)
2	30 (27)	81 (73)	111 (38.3)
3	3 (23.1)	10 (76.9)	13 (4.5)
4	1 (100)	0	1 (0.3)
Total	70	220	290

Table VI. Outcome of treatment for all teeth with 2 or more roots

	Appliance		
	Boor	*Satelec*	*Total*
Result, n (%)			
Failure	23 (34.8)	11 (18.6)	34 (27.2)
Success	43 (65.2)	48 (81.4)	91 (72.8)
Total	66	59	125

DISCUSSION

Root-end preparation using an ultrasonic device was introduced in 1976 and some 15 years ago endodontic microsurgical tips for ultrasonic devices became widely available.[7] Theoretically, advantages of this technique would be a minimal or no bevel after resection of the root-end, smaller cavities with more preservation of dental material, a deeper preparation in the root-end that is better directed into the root channel, and a better preparation of anatomical difficulties, such as an isthmus. However, whether all the advantages mentioned above lead to better clinical results remains questionable. The main disadvantage of the technique seems to

be the occurrence of microfractures and chipping in the root-end cavity after preparation[8-10]; however, the clinical significance of this phenomenon is not clear.[11] Others have argued that ultrasonic devices are not responsible for increased cracking of the root-end.[12,13] Therefore, at present, no definitive conclusions on the possible negative effects of ultrasonic devices can be made.

In this study, a standardized treatment protocol was used to evaluate the success rate of an ultrasonic device in comparison to a traditional bur. In both groups, IRM was used as retrograde filling material in all patients to eliminate the possible influence of different filling material on the outcome of treatment. IRM is a widely used root-end filling material with success rates superior or equal to amalgam.[14,15] All patients were clinically and radiologically examined after 6 and 12 months. A final radiographic analysis of the treatment outcome was performed by 2 surgeons who were blinded for the therapy, using the criteria described by Rud et al. in 1972.[6] Using this protocol in a large number of patients provided a clear indication of the influence of the ultrasonic preparation technique on the outcome of treatment. In the whole group, the difference in treatment outcome was borderline significant ($P = .056$), but when looking at specific teeth or number of roots the outcome was very clearly in favor of the ultrasonic device. In molars, the difference was very significant ($P = .02$), which is probably due to better access of the root canals and deeper preparation of the root-end using the ultrasonic device. When looking at all teeth with 2 or more roots treated, the difference is also significant ($P = .042$), which emphasizes the advantage of the ultrasonic device when the access of the root-end becomes more difficult. In frontal teeth and premolars, there was no difference in treatment outcome between the ultrasonic device and the bur. This underlines the hypothesis that an ultrasonic device becomes more beneficial when access is hampered.

In current literature, no clinical prospective randomized study comparing an ultrasonic device and traditional technique, exists. In a retrospective evaluation, a very large difference in outcome of treatment was found between the traditional and ultrasonic technique.[5] In this study, patients treated with an ultrasonic device were also treated with the help of a microscope, in contrast with patients treated with the traditional (bur) technique, where no microscope was used. Moreover, the ultrasonic group was treated by endodontists and the traditional group by oral surgeons. This means that from this study no definitive conclusion can be drawn on the benefit of the ultrasonic device. In another retrospective evaluation,[16] there was also a clear difference in outcome of treatment in favor of the ultrasonic technique (85% versus 68%). However, also in this study there were more variables that could affect the outcome of treatment as all traditional treated root-ends were filled with amalgam and all ultrasonically treated root-ends were filled with Super-EBA (Harry J. Bosworth Co., Skokie, IL).

Overall success rates of endodontic surgery reported in literature range from 44% to 95%.[17] This wide range is probably due to differences in methods and criteria for assessment of success. An overall success rate of 75.8% seems a representative result and underlines the value of this type of surgery after failure of the initial endodontic treatment. Success rate in molars (68.1%) was considerably lower than in frontal teeth (84.5%) and premolars (81.4%). This is probably caused by more difficult surgical access, more infected roots, and decreased visibility, especially in mandibular molars. Moreover, the primarily performed endodontic treatment in molars is also more complicated than in single-root teeth, often leading to a more compromised situation at the start of the endodontic surgery.

In conclusion, the use of an ultrasonic device in apical surgery showed a clear benefit over the traditional treatment. Especially in molars, the results were significant.

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