Clinical Effectiveness of Basic Root Canal Treatment after 24 Months: A Randomized Controlled Trial

Rainer A. Jordan, MSc, DDS, PhD, Anna L. Holzner, DDS, Ljubisa Markovic, DDS, Inga Brueckner, DDS, and Stefan Zimmer, MPH, DDS, PhD

Abstract

Introduction: The purpose of this study was to investigate the effectiveness of basic root canal treatment (BRT) with tactile working length determination in terms of radiographic and clinical outcome parameters compared with endodontic treatment with standard radiographic working length control. Methods: This was a clinical, multicenter, controlled, open-label trial to evaluate BRT effectiveness after 24 months. The primary end point was the apical extension score of the radiographic quality parameter of root canal fillings. The secondary radiographic end point was the periapical index, and the secondary clinical end point was tooth tendency to percussion. The safety end point was tooth loss as a consequence of endodontic failure. Statistical analyses of binary and categoric data were calculated using cross tables and the chi-square test. Results: BRT with tactile working length determination compared with standard radiographic working length control did not significantly differ in terms of radiographic and clinical outcomes after 24 months. The apical extension of the root canal fillings and the periapical anatomic structures showed no significant differences according to radiographic analyses ($P = .5$). Corresponding results were found in clinical aspects of tooth tendency to percussion ($P = .6$) and tooth loss ($P = .7$). Conclusions: Tactile working length determination in BRT resulted in comparable treatment outcomes compared with standard endodontic treatment with radiographic working length control and turned out to be an accurate method in BRT. (J Endod 2014; :1–6)

Key Words

Clinical trial, dental pulp cavity, dental pulp diseases, endodontics, treatment outcome

The prognosis for teeth with advanced dental caries lesions and symptomatic pulpitis in patients living in low-income countries is poor (1). About 90% of the caries burden in Africa remains dentally untreated, and tooth extraction is still the most common treatment (2). The atraumatic restorative treatment (ART) approach evolved into a global milestone in dental caries management with evidence-based medium-term results (3). ART shows its strengths in early dental caries intervention when no pulpal involvement has occurred clinically (4). However, even in established ART oral health care settings, the restoration/extraction ratio remained low with about 1 ART restoration versus 10 tooth extractions (5). The main reason appears to be that dental caries in early disease stages causes neither pain nor impair quality of life and might therefore be undetected by the patient and, consequently, untreated.

To bridge the gap between minimal intervention dentistry with ART and routine tooth extraction in underserved communities, the basic root canal treatment (BRT) approach was introduced to primary oral health care in Gambia (West Africa) in 2006 (6). As a subsequent treatment to ART for prolonged tooth preservation, phase 1 clinical data showed promising clinical outcomes and improvements in the quality of life of patients after 1 year. The treatment concept is characterized by simplicity in instrumentation, independence of an electric power supply, and a rational application. To be operable under different infrastructural preconditions, BRT makes use of tactile working length determination and might dispense with x-ray examination. Under clinical conditions in teeth scheduled for extraction, a high accuracy of 86% for tactile working length determination was shown (7). In vitro, this was even shown in teeth with open apices by 97% (8). However, its accuracy has not yet been investigated under field conditions in a primary oral health care setting.

The purpose of this study was to determine whether the BRT approach using tactile working length determination would result in comparable treatment outcomes with the basic technique using radiographic working length control in a rural African setting. Therefore, we assumed the null hypothesis that there was no statistically significant difference in treatment effectiveness between tactile endodontic working length determination and radiographic working length control in BRT.

Patients and Methods

This was a clinical, multicenter, controlled, open-label trial to evaluate the effectiveness of BRT after 24 months. The study protocol was approved by the Witten/Herdecke University institutional review board (no. 1/3/2007) and the Department of State for Health and Social Welfare of the Republic of the Gambia. All participants gave written informed consent with the assistance of a native speaker before study-related procedures were performed. Figure 1 describes the study design in brief.

Sample Size

Because BRT is a new treatment concept in operative dentistry for underserved communities, a stepwise clinical development and proof procedure according to Food and Drug Administration recommendations for pharmacologic drug admission was chosen. In a so-called phase 1 study, procedure safety and tolerance were clinically monitored in 25 cases observationally as published previously (6). Consecutively, this is a controlled phase 2 study to test the treatment concept, in particular tactile working...
length determination and the clinical and radiographic outcome. According to the recommendations mentioned earlier, the target sample size was predefined with a minimum of 50 cases.

Study Population

Eligible participants were adults from 18–65 years living in Gambia with an indication for root canal treatment in at least 1 single-rooted tooth. The inclusion criterion was BRT performed when a vital tooth and bleeding coronal pulp tissue was clinically diagnosed. Clinical symptoms were as follows:

1. Symptomatic irreversible pulpitis (localized, spontaneous, or continuous, acute pain increasing at night, no periapical involvement, with a short pain history)
2. Asymptomatic irreversible pulpitis (no clinical symptoms of tooth or periapical pain in case of deep dental caries with pulp exposure during caries excavation)

Exclusion criteria included the following: no root canal treatment was given in case of necrotic pulp tissue, pulp polyp, tooth tender to percussion, or clinical progression into abscess formation.

Study End Points

To measure the effectiveness of working length determination, the apical extension of the root canal filling was chosen as the primary end point as defined by Santos et al (9). Secondary end points were as follows:

1. The periapical index (PAI) (10) to determine the extent of healing periapically after 24 months
2. Tenderness to percussion as a clinical test
3. Tooth loss as a consequence of failure of the endodontic treatment

Participant Screening

Participants were screened, recruited, and treated at public outpatient dental clinics in Gambia between March 2010 and January 2011. The screening was part of the first visit of each patient at the dental clinic. Two dentists experienced in endodontics for several years performed dental treatment. They were equally trained in ART in advance of the study according to the ART training manual (11).

Randomization and Allocation Concealment

The technical and electrical infrastructure still remains unstable in Gambia. Therefore, block randomization was chosen. Patients included in 2010 were treated according to the original BRT method with tactile working length determination, whereas patients included in 2011 were treated with radiographic working length control. During the latter study period and the 24-month evaluation, a generator was provided to ensure sufficient power supply to run a radiographic unit.

Interventions

BRT was performed according to the BRT manual (Table 1). (Supplemental Appendix S1 is available online at www.jendodon.com.) Participants receiving endodontic treatment with tactile working length determination, the original BRT method, represented the test group. During this treatment procedure, no accompanying radiographs or other electrically driven equipment was used until the 24-month follow-up. Control group participants received the identical endodontic treatment according to the BRT treatment manual, but the working length was controlled using radiographs. Radiographs were taken using a mobile long cone x-ray unit (Port-X II; Genoray EU, Berlin, Germany) with the parallel Rinn technique using standardized holders (XCP System; Dentsply Rinn, Elgin, IL).

Root canals were obturated using ISO standardized gutta-percha cones and a modified Grossman root canal cement based on a zinc oxide–eugenol (Canal Sealer; Sybron Dental Specialties, Orange, CA). Coronal restoration was performed according to a modified ART using an adhesive restoration material. Futurabond NR single dose (Voco, Cuxhaven, Germany) was used as self-etching dentine and enamel bonding material. Grandio (Voco) was used as a universal nanohybrid composite restoration material. Polymerization was activated using a wireless light-emitting diode curing light (Translux
PowerBlue; Heraeus Kulzer, Hanau, Germany). A composite was used for coronal restoration because previous evidence showed that glass ionomers showed no favorable long-time stability in multisurface ART restorations, especially in single-rooted teeth (12, 13). After 24 months, test and control participants were followed up by an independent investigator who was not part of the operative staff. Participants were clinically examined for tooth preservation and tooth tender to percussion, and a dental x-ray was taken. No other clinical criteria were used.

Study Settings

According to the block randomization procedure, participants of the test group were treated at the public outpatient dental unit of Kindergarten Wattenscheid in Gambia dental station in Brikama-Kabafita, Western Region, Gambia. The control group was treated, and all follow-up examinations were performed at the public Swedish clinic in Kotu, Greater Banul Area, Gambia. The study was executed between 2010 and 2013.

Statistical Analysis

The end points were calculated with cross tables and a 2-sided significance level of .05. The primary end point, clinical secondary end point, and safety end point were calculated binarily. The radiographic secondary end point was calculated ordinally. Data were analyzed using the chi-square test according to Pearson when 2 categories were compared. In case of more than 2 categories, the Fisher exact test was computed. IBM SPSS software (version 21; International Business Machines Corp, Armonk, NY) was used for computing statistical analysis.

Results

Thirty-eight eligible participants were recruited in 2010 and allocated to the test group according to the block randomization protocol, and 33 eligible participants were recruited in 2011 and allocated to the control group. There was 1 treatment protocol deviation in a man in the control group who was endodontically treated in a lower first molar. During follow-up, there were 13 protocol deviations because of a lack of temporary power supply. Therefore, in 11 test group participants and 1 control group participant, no radiographic images could be taken at the 24-month follow-up appointment. The primary analysis was intention to treat and involved all patients who were randomly assigned, and, consequently, 54 participants remained for per-protocol analyses because of the lack of radiographic study end point data (Fig. 2). Qualitative analyses were performed in 24 cases in the test group after 1 tooth extraction during the study and for 29 cases in the control group.

Primary End Point

Apical extension of the root canal filling achieved the ideal standard (filling 0.5–1.5 mm from the apex) in 11 teeth in the original BRT group and in 16 teeth in the control group. The ideal standard was not achieved in 13 teeth in each group. Over- or underfilling more than 1 mm was diagnosed in 9 teeth in the original BRT group and in 11 teeth in the control group. The primary end point differences were not statistically significant (P = .5) (Table 2).

Secondary End Points

Radiographic analyses of the periapical tooth regions by means of the PAI showed the following distributions. In the original BRT group, 15 teeth showed no appreciable diseases (PAI-NAD), and in the control group 14 teeth showed no appreciable diseases. Suspected or unsure periapical lesions (PAI 1–3) were seen in 6 teeth in the original BRT group and in 12 teeth in the controls. Probable and severe periapical destruction (PAI 4–5) was observed in 3 teeth in each group. The prevalence between the groups showed no statistically significant difference (P = .5) (Table 3).

Tooth tender to percussion as a clinical effectiveness criterion was observed 3 times (12.5%) in the original BRT group and twice in the control group (6.9%) at the 24-month follow-up (P = .6).

Safety End Point

During the study, 1 lateral upper incisor was extracted in the test group because of endodontic failure; no tooth loss occurred in the control group (P = .7).

Discussion

This study showed that the BRT approach with tactile working length determination compared with the standard radiographic working length control did not significantly differ in terms of radiographic and clinical outcomes after 24 months. Apical extension of the root canal fillings as well as periapical anatomic structures showed no significant differences according to radiographic analyses. Corresponding results were found in clinical aspects of tooth tender to percussion and tooth loss. Based on these results, we failed to reject the null hypothesis.

Strengths and Limitations of the Study

There are several strengths and limitations that need to be addressed. First, only single-rooted teeth were included in the study; BRT has only been tested in incisors and premolars but not in molars so far. Endodontic treatment of molars includes several challenges and difficulties such as complex root canal anatomy and is therefore a very ambitious treatment that might not be compatible with the principles of ART/BRT concerning simplicity and convenience. Indications for BRT in low-income countries are limited. Second, a rubber dam is a measure of quality assurance in endodontic treatment but might not be available in underserved areas like Gambia and many other low-income countries. Therefore, we defined the relative drainage with cotton rolls as a minimum standard for BRT. This drainage technique implies a mandatory physical protection of endodontic instruments with dental floss for aspiration control on the one hand. On the other hand, we
decided on the use of 0.2% chlorhexidine digluconate solution for irrigation instead of sodium hypochlorite for the following reasons:

1. There is a risk of a potential spill of sodium hypochlorite into the patient’s mouth if it overflows the access preparation.
2. There was no possibility to guarantee a stability of temperature of sodium hypochlorite in terms of cooling.

In infrastructural health care settings in which a rubber dam and cooled storage of sodium hypochlorite solution can be provided, we encourage clinicians to outperform the minimum standards of BRT toward a higher process quality.

Third, BRT is a strict single-visit treatment approach although Parades-Vierya and Jimenez Enriquez (14) showed no significant differences in radiographic evidence of periapical healing between single-visit and 2-visit root canal treatment even in teeth with apical periodontal disease. With respect to infrastructure conditions and according to other endodontic treatment recommendations (15), only teeth with symptomatic irreversible pulpitis or with asymptomatic irreversible pulpitis were treated in our study. Other forms of inflammation that indicate multivisit endodontic treatment, such as abscess formation and tooth tender to percussion, have not been tested with BRT. In the long-term, single-visit endodontic treatment in molars might be further tested because there are no conceptual differences in the treatment.

Finally, block randomization as performed in our study might be seen as a limitation. Radiographic examination could not be done for every endodontic treatment because an electric power supply was not available in all our study settings. The lack of infrastructure in low-income countries must be considered as a limiting factor in general for clinical studies.

<table>
<thead>
<tr>
<th>TABLE 2. Primary End Point at 24 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ideal standard achieved</strong></td>
</tr>
<tr>
<td>Apical extension</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Filling 0.5–1.5 mm from the apex</td>
</tr>
<tr>
<td>Ideal standard not achieved</td>
</tr>
<tr>
<td>Apical extension</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>Total</td>
</tr>
<tr>
<td>Filling at apex</td>
</tr>
<tr>
<td>Over-/underfilling &gt;1 mm</td>
</tr>
</tbody>
</table>

BRT, basic root canal treatment; CI, confidence interval.
The primary end point apical extension was extracted from the radiographic quality parameter of root canal fillings as defined by Santos et al (9).

Variables were analyzed using the Fisher exact test.

This was the primary end point of the study.
On the other hand, the organization and management of a randomized controlled trial observing several end points even under very difficult circumstances of health services research conditions was successfully completed. Nixdorf et al (16) also showed that it is possible to recruit a sufficient number of patients as participants for a large-scale prospective endodontic study; however, their study was performed under different study settings. This might be acknowledged as a strength of our study. Different radiographic parameters, such as apical changes and root canal filling quality, and clinical parameters, such as tooth tender to percussion and tooth preservation, could be analyzed successfully although there are various suggestions concerning endodontic survival analyses calculation reported in endodontic research (17). A BRT instrument kit was easy to arrange and work with. An ART kit can easily be extended and completed for BRT. Therefore, the number of instruments and materials was kept low.

**Interpretation and Implications**

There is 1 other study but no systematic review concerning the BRT approach in low-income countries (6). Therefore, further contributions and results from other research groups in different oral health care settings are eligible. Our actual study with its randomized clinical trial design was intended to corroborate and substantiate scientific evidence of BRT.

Although the number of participants in our study is limited, the external validity of our study was considered robust because recruited patients were not highly selected, thus representing an unexceptional part of the Gambian population visiting primary oral health care facilities where ART and BRT are developed. Patients’ postoperative behavior played a small part in any source of error in the present study. Detection bias was not expected in our study because the same study end points for each patient and treatment evaluation were adopted. On the other hand, attrition bias cannot be completely excluded because of a loss to follow-up that was unbalanced in both study arms.

**Patient Care and Health Policy**

ART is still used for early dental caries intervention, mainly in class 1 dental cavities (18); therefore, ART does not reflect dental caries epidemiology in many low-income countries. Few studies also showed the effectiveness of ART in later disease stages (5). Therefore, BRT might be seen as a treatment proposal in addition to ART in infrastructural, more distinguished primary oral health care settings to avoid early tooth extractions.

**Controversies**

According to the World Health Organization, about 90% of all carious lesions in Africa remain untreated (1, 2). Even though global strategies have slowly improved dental treatment in Africa and other low-income countries over the last decades, dentistry plays a minor role in developing primary health care because of the other health problems facing these countries (19). Against this background, BRT might appear to be a time- and cost-consuming and complex treatment approach. Tooth extraction is usually performed faster and easier and is also an accepted dental treatment. However, in many clinical cases, endodontic treatment would be indicated and would be performed under standard operating conditions. It is our belief that closing the gap between ART and early tooth extraction as a succeeding or even alternative treatment to further restorative procedures in low-income countries should be a scientific and ethical goal to overcome global oral health inequalities. In this respect, BRT is intended to be a proposal and contribution to this discussion (1).

**Future Research Directions**

In order to promote the future of BRT for countries with a developing oral health care infrastructure, the proposal is to continue the validation procedure according to Food and Drug Administration recommendations for pharmacologic drug admission. As a next clinical step, a phase 3 clinical study in terms of a pivotal study should be initiated. Because this kind of study includes between several hundreds and thousands of participants, this phase would be preferable in an organized, multicentered, international setting. Furthermore, evidence on patients’ acceptance, use, and oral health–related quality of life is necessary to complete the picture of a new treatment concept.
determination. Tactile working length determination turned out to be an accurate method in BRT.

Acknowledgments

We would like to thank Igor Zibold and Daniel Hesse for their organizational and operative contribution to the study.

The basic root canal treatment program was supported by Voco (Cuxhaven, Germany). Voco had no bearing on the conduct of this study and was excluded from other matters, including analyzing the data and reporting the results.

The authors deny any conflicts of interest related to this study.

Supplementary Material

Supplementary material associated with this article can be found in the online version at www.jendodon.com (http://dx.doi.org/10.1016/j.joen.2013.11.028).

References