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

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## 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 tender 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 tender 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;40:465–470)*

## Key Words

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

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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 impairs 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. 13/2007) 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

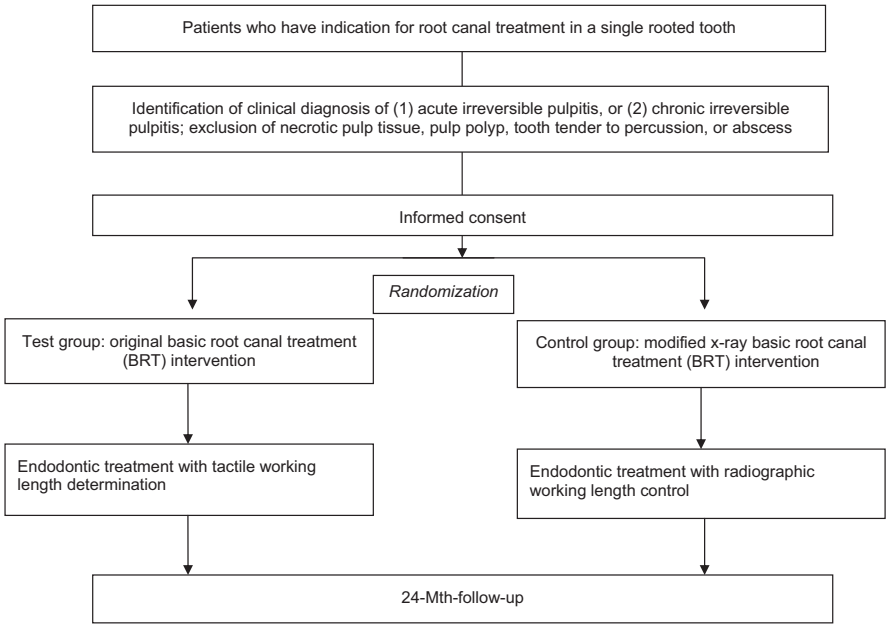


**Figure 1.** The design of the study.

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. A 6-point ordinal scale for measuring radiographic status to determine the extent of healing periapically after 24 months (see Table 3 for category description)
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 (10).

## 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 Specialities, 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