Healing of Periapical Lesions after Endodontic Treatment with the GentleWave Procedure: A Prospective Multicenter Clinical Study

Asgeir Sigurdsson, DDS, MS,[*] Randy W. Garland, DDS,[†] Khang T. Le, DDS,[‡] and Shahriar A. Rassoulian, DMD[§]

Abstract

Introduction: This report includes outcomes for a group of patients with significant periapical lesions who were treated and evaluated in two single-arm, multicenter, prospective, nonsignificant risk clinical studies. **Methods:** Forty-five teeth were from 45 patients who met the inclusion criteria and consented for the clinical studies and were diagnosed with periapical lesions with periapical index score ≥3. Patients were treated with a standardized treatment protocol including instrumentation to an apical diameter of #20 without orifice enlargement, the GentleWave Procedure, and warm vertical obturation. Clinical signs and radiographic assessments were evaluated at 12 months to assess healing. Success was classified as healing or healed and accounted for the cumulative success rate of healing. Statistical analyses were performed by using Fisher exact test, Pearson correlation, and multivariate logistic regression analyses. **Results:** At 12 months, 44 of 45 teeth (97.8%) were evaluated. The cumulative success rate for the GentleWave Procedure was 97.7%. Forty-three of 44 teeth were completely functional; all teeth had complete resolution for measured indices of mobility, soft tissue lesions, sinus tract, and furcation involvement. No patients experienced moderate or severe pain at 2, 7, and 14 days after procedure. Although only 1 patient was unsuccessful and the presence of clinical symptoms and type of periradicular diagnosis at 12 months were correlated with an unsuccessful outcome, the analyses were limited by the sample size. **Conclusions:** In this case series analysis, treatment of sizable periapical lesions with the GentleWave Procedure resulted in a success rate of 97.7% at 12-month re-evaluation. *(J Endod 2017;■:1–8)*

Key Words

GentleWave procedure, healing, molar, Multisonic, periapical index score, periapical lesion, root canal therapy, Ultracleaning

Significance

Teeth with necrotic pulps and large periapical lesions treated with GentleWave procedure had high healing rate at 1-year re-evaluation. Postoperative pain associated with the treatment was mild for all patients.

Apical periodontitis is an inflammatory reaction of the immune system to the presence of infection in or around the root canal system (1). This inflammation is associated with ongoing alterations in the periapical bone, changes that can be identified on periapical radiographs (2).

Past research has shown that root canal infections must be resolved for the associated inflammatory processes to abate and the periapical lesion to heal (3, 4). However, it is well-accepted that standard therapy does not consistently completely eradicate biofilm, smear layer, and/or the microorganisms present within the complexities of the root canal system (4). They may remain within the dentinal tubules, affixed within the apical region, or are challenged by patient-specific morphologic factors such as lateral canals, ramifications, and isthmi (5, 6). In addition, past research has shown that standard instruments and rotary files may not completely debride the canals and leave up to 57% of the root canal system untouched (7).

Limitations with standard endodontic therapy have prompted the development of root canal therapies such as ultrasonic irrigation, negative pressure irrigation, and laser technologies among others. By using therapies that include irrigants with potent antimicrobial agents, there have been some improvements in cleaning, yet each of these therapies has their own challenges (8). There have been few reported results that predictably show root canals free of debris and biofilm after treatment with these therapies, and some reports express safety concerns for a portion of these therapies (9–11). These systems typically require enlargement of the apical third for adequate depth penetration of irrigants, with studies reporting canal instrumentation to at least size #35 (8, 12, 13). This apical enlargement is known to potentially cause various complications including apical transportation, ledge formation, perforation, and instrument separation while also removing greater amounts of natural tooth structure that could weaken the root and may lead to fractures or affect long-term healing rates (14).

The GentleWave System (Sonendo, Inc, Laguna Hills, CA) was developed as an innovative way to clean and disinfect the root canal system without the need for over-enlarging the root canals. The GentleWave Procedure uses Multisonic Ultracleaning technology in which advanced fluid dynamics, acoustics, and tissue dissolution chemistry are applied to clean and disinfect the entire root canal system, regardless

From the *Department of Endodontics, New York University College of Dentistry, New York, New York; †Garland Endodontics, Encinitas, California; ‡SC Endodontics, Santa Ana, California; and §Private practice, Aliso Viejo, California

Address requests for reprints to Dr Asgeir Sigurdsson, Department of Endodontics, New York University College of Dentistry, 345 East 24th Street, New York, NY 10010. E-mail address: endo@simnet.is or asgeir.sigurdsson@nyu.edu

0099-2399/$ - see front matter

https://doi.org/10.1016/j.joen.2017.12.004

of any anatomic complexities (15). Once the GentleWave Procedure has begun, a stream of optimized fluid is generated that enters the root canal system, creating a powerful shear force. This causes hydrodynamic cavitation in the form of a cavitation cloud. The implosion of thousands of microbubbles creates an acoustic field of broadband frequencies that travels through the procedure fluid into the entire root canal system. A gentle vortical flow is induced in such a way that it creates a slight negative pressure inside the root canals. Vapor lock is addressed by reducing the gas content of the procedure fluids and creating a sealed platform during the GentleWave Procedure (16–18). A broad spectrum of acoustic energy is delivered to all anatomic features, with various lengths ranging from tubules to anastomoses to main canals. Haapasalo et al (19) reported 7 times faster tissue dissolution with the GentleWave System than with standard root canal systems, including sonic and ultrasonic devices. Past studies have provided evidence of superior debris, smear layer, and bacterial removal after the GentleWave Procedure as compared with standard endodontic therapy (20–22). In addition, the GentleWave Procedure was shown to cause minimal dentin erosion (23). Separated hand files within the apical and middle thirds of root canals have been reported to be removed with the GentleWave System without the need for increased dentin removal (24). Clinical studies evaluating the GentleWave Procedure have demonstrated success rates of 97% at 6 and 12 months after GentleWave Procedure (15, 25). In those 2 studies the preoperative endodontic diagnosis was a mixture of vital and non-vital pulps, where only 14 of the total sample were diagnosed as being necrotic, and the periapical lesions associated with those cases varied in size (15, 25).

This report of 2 single-arm, multicenter, prospective, nonsignificant risk clinical studies evaluated the outcomes for a group of patients with large periapical lesions (periapical index [PAI] score $\geq$3) who received the GentleWave Procedure. The current studies were designed to evaluate the rates of healing in a population of patients requiring initial molar root canal therapy. Consecutive patients who consented for participation in the study were treated with the GentleWave Procedure, and outcomes were evaluated at 12 months after procedure by using a composite end point that included both clinical and radiographic outcomes to assess healing. Demographic, clinical, and procedure characteristics were also examined to assess their associations with clinical outcomes.

Materials and Methods

This analysis was derived from 2 single-arm, multicenter, prospective, nonsignificant risk clinical studies that were initiated in 2013 and 2014, respectfully. The study protocols were approved by Aspire institutional review board (Santee, CA), and the study was performed in accordance with all applicable laws and regulations including the Declaration of Helsinki.

Study Subjects

Study subjects were referred for root canal therapy to 4 private endodontic clinics in Southern California. Forty-five patients were enrolled after study procedures were explained and informed consent was obtained. All subjects adhered to the study inclusion and exclusion criteria as shown in Table 1. All subject teeth included in the analysis were determined as having the presence of a baseline periapical lesion (PAI score $\geq$3), as determined by 2 blinded, independent evaluators.

Data Collection

Four endodontists participated as investigators and were trained to use the GentleWave System and follow the clinical study procedures and standardized treatment protocol. Clinical data were collected by using standardized coded data sheets. The redacted clinical and radiographic data were directly transferred to a database.

The standard coded data sheets used subject initials and corresponding subject identification numbers. The investigators ensured that subject names and data were kept confidential.

Baseline Patient and Clinical Characteristics

Demographics and medical and dental history were collected for all subjects. The clinical examination involved an intraoral evaluation that included measurement of periodontal pocket depths, mobility testing, the presence and extent of swelling and soft tissue lesions, percussion, and palpation.

Radiographic Assessments

A standardized, parallel periapical radiograph was taken for each study tooth before procedure, after procedure, and at the 12-month reevaluation visit. These radiographs were used to assess the periapical lesion at each time point and were used for independent radiographic analysis by 2 blinded, independent evaluators. Before evaluation and scoring of the study radiographic images, the 2 independent and blinded examiners evaluated a series of radiographs outside of the study sample that represented a wide range of periapical lesions. This served as a standardization exercise for using the PAI scoring system. The

TABLE 1. Clinical Study Inclusion and Exclusion Criteria

Inclusion criteria	Exclusion criteria
1. The study subject is 18–75 years of age. 2. The subject tooth is indicated for root canal treatment. 3. The subject tooth is a first or second molar. 4. The subject signed an informed consent form.	1. Subject tooth had previous or attempted pulpotomy, pulpectomy, or root canal therapy. 2. Patients reported taking corticosteroids. 3. Any known infectious diseases (eg, human immunodeficiency virus, hepatitis B, hepatitis C, tuberculosis, bovine spongiform encephalopathy, or prion). 4. History of cancer within the oral-maxillofacial region. 5. History of cancer within the last 2 years. 6. History of head and/or neck radiation therapy. 7. Subject tooth with mobility score $\geq$2. 8. Subject tooth with periodontal pocket depth $\geq$6 mm. 9. Subject tooth with open or incompletely formed root apices. 10. Subject tooth that requires a post. 11. Subject tooth with vertical fracture or horizontal fracture extending below the cementoenamel junction of the tooth. 12. The 2 adjacent teeth in direct contact with the subject tooth require root canal therapy. 13. Subject has non-odontogenic facial pain.