Periapical Inflammation and Bacterial Penetration After Coronal Inoculation of Dog Roots Filled With RealSeal 1 or Thermafil

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Abstract

Introduction: The purpose of this study was to subject 2 carrier-based root filling products to a 4-month microbial challenge in a dog model with histologic markers to assess periapical inflammation and bacterial penetration of the 2 filling materials. Histologic evidence of bacterial penetration and periapical inflammation were the outcome parameters used to compare the products. **Methods:** Teeth were aseptically prepared and then filled with carrier-based Resilon (RealSeal 1 [RS-1], n = 25) or with carrier-based gutta-percha (Thermafil, n = 25) and were left exposed for 4 months. The first control group received a coronal seal over either RS-1 or Thermafil root fillings (n = 8). A second control group was instrumented and left completely empty (n = 8). **Results:** Histologic evidence of periapical inflammation was observed in 29% of the Thermafil group and in 9% of the RS-1 group. This difference was only significant when controlling for a possible tooth position effect on inflammation presence ($P < .05$). Histologic evidence of bacterial penetration was present in 9% of the RS-1 group and in 70% of the Thermafil group. The difference in penetration rates between RS-1 and Thermafil was statistically significant when controlling for any dog or tooth position effects on bacterial penetration ($P < .001$). Furthermore, there was a statistically significant correlation between histologic evidence of inflammation and histologic evidence of infection ($P = .002$). **Conclusions:** RS-1 appeared to resist bacterial penetration more effectively than Thermafil under the conditions of this study. *(J Endod 2009;35:852–857)*

Key Words

Coronal, gutta-percha, *in vivo*, leakage, Resilon

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The aim of endodontics is to preserve apical health or to permit healing of pre-existing apical pathosis. Infection of the root canal system is a prerequisite for the development of periapical disease (1, 2). A recent review of outcome studies for teeth with no evidence of periapical disease reported success rates of up to 95% (3). When teeth develop apical periodontitis, the prognosis can fall below 80% (4). After optimal microbial control in the first phase of root canal treatment, the function of the root filling is to seal the canal to maintain an environment conducive to the prevention or elimination of apical periodontitis over time. If a root canal filling material can consistently resist coronal microleakage in teeth that have been rendered free of cultivable bacteria, optimal success rates can be anticipated (1, 2, 5–7).

Previous studies suggested that coronal leakage might be more critical in predicting the development of periapical disease than apical leakage (8, 9). The leakage resistance of root filling products has been assessed by using both *in vitro* and *in vivo* models. *In vitro* studies have assessed the passage of markers such as dyes (10), bacteria (11), saline (12) and endotoxins (13) through root-filled teeth to estimate the ability of the test specimens to resist the coronal leakage of pathogens. Although *in vitro* studies have the advantages of low cost and the ability to limit the variables to one, they cannot be considered of a similar caliber to usage studies when evaluating whether a technique or material shows enough promise to warrant *in vivo* testing.

Noyes (14) describes a Dr E. L. Clark in 1865 filling root canals with plasticized gutta-percha, heating the filling material until it became "as hot and fluid as possible without burning it and churning it into the pulp canals with a hot instrument." More than one century later, Schilder (15) introduced a more standardized warm gutta-percha technique known as warm vertical compaction. In 1978, Johnson (16) discussed the concept of placing a stainless steel file coated with heated gutta-percha in the root canal. Thermafil (Tulsa Dental, Tulsa, OK), a commercial product based on this technique, was introduced in 1989. Two years later, the stainless steel carriers were replaced with a resin-based polymer. Thermafil Plus is a root filling product based on Johnson's original concept that consists of a plastic carrier coated with gutta-percha. The product is heated in a ThermaPrep Plus Oven (Dentsply, Melbourne, Australia), and the manufacturer recommends using this product in conjunction with an epoxy-resin sealer (Thermaseal Plus; Tulsa Dental). Resilon (Pentron Clinical Technologies, Wallingford, CT) is a synthetic polymer-based root filling material designed to be used with a dual-cured polymer-based composite sealer containing a mixture of dimethacrylate, urethane dimethacrylate, ethoxylated dimethacrylate, hydrophilic difunctional dimethacrylates and several fillers. A primary objective of this system is to establish bonded interfaces between the Resilon core, the sealer and the prepared root canal wall. A carrier-based version of the Resilon filling material has recently been developed. The RealSeal 1 Bonded Obturation System (SybronEndo Corp, Orange, CA) is Resilon-based. The carrier-based root filling is used in conjunction with RealSeal SE Self-Etch sealer. The carrier is a polysulfone-containing polymer with radiopaque filler, and the surrounding Resilon-based filling contains polycaprolactone and polyolefin polymers loaded with fillers. This product combines adhesive bonding technology with a carrier product and aims to provide the benefits of an efficient obturation technique combined with optimal leakage resistance.

Thermafil has been compared with cold and warm gutta-percha techniques by using a variety of leakage models. These have included dye leakage (17–20), fluid filtration (21, 22) and bacteria leakage (23, 24) techniques among others. When Thermafil has been compared with both cold and warm gutta-percha filling techniques, no consensus has been reached regarding the relative superiority of one product in spite of the leakage model used (17–24). Although a number of *in vitro* studies have demonstrated improved leakage resistance of gutta-percha compared with Resilon, the majority of such leakage studies to date have shown that Resilon provides a similar, and in many cases, an improved resistance to leakage compared with that of gutta-percha. The number of *in vivo* usage studies of both traditional and contemporary root filling materials is limited, but it would appear that filling the root canal with Resilon results in less periapical inflammation than gutta-percha techniques when the filling material is maximally challenged by coronal infection. If one considers periapical inflammation to be a reliable surrogate marker for microbial penetration of the root canal system (coronal leakage combined with any antimicrobial effects of the obturating material), then it can be argued that Resilon provides better results more consistently than gutta-percha products (25–28). Human outcome studies of Resilon show promising results but are not directly compared with gutta-percha techniques or have relatively short follow-up periods (29, 30). The purpose of this usage study was to compare periapical inflammation and intracanal bacterial penetration of two contemporary carrier-based root filling products, RealSeal 1 (RS-1; SybronEndo Corp) and Thermafil.

Materials and Methods

The protocol followed was approved by the University of North Carolina Institutional Animal Care and Use Committee (IACUC). Eight beagle dogs approximately 3 years old were used. Treatment was performed on 8 premolars per dog (dog 5 received treatment on 10 lower premolars). A total of 66 premolars were treated. Both RS-1 and Thermafil products were used according to the manufacturer's instructions. Within each dog, 3 teeth were filled with RS-1 (RealSeal 1 group), 3 teeth were filled with Thermafil (Thermafil group), 1 tooth received both a root filling and a coronal seal (sealed control group), and 1 tooth was left completely empty (empty control group). The teeth in each dog were randomized.

Treatment was performed under general anesthesia. Induction was achieved with intravenous Pentothal 13.5 mg/kg (Abbott Laboratories, North Chicago, IL). Up to 2% isoflurane (Halocarbon Laboratories, River Edge, NJ) was used for maintenance of anesthesia supplemented with 0.5 mL per quadrant of plain 0.5% bupivacaine (Abbott Laboratories) to achieve local anesthesia of the teeth undergoing treatment. To minimize postoperative pain, tramadol 3 mg/kg was administered orally to each dog every 12 hours for 2 days before treatment. This was complemented with a postoperative subcutaneous injection containing 0.2 mg/kg of butorphanol (Fort Dodge, IA). To reduce the chance of postoperative infection, an intramuscular injection of 20,000 U/kg of penicillin G was administered after treatment. Staff in the Department of Laboratory Animal Medicine monitored the postoperative recovery of each dog. The dogs were monitored daily for the duration of the study to ensure that they were consuming their normal diet and that no clinical signs of infection were evident.

Preoperative radiographs were taken of the teeth to be treated to confirm that no periapical pathology was present. A strict aseptic protocol was followed before all treatment procedures. Lower premolars were cleaned of debris by using moist gray pumice. Rubber dam isolation with sterile rubber dam clamps was carried out, and Cavit (3M ESPE, St Paul, MN) was used to optimize the marginal seal around individual teeth as required. Ten percent povidone-iodine (Medical Supply Co Inc, New York, NY) was applied generously to the teeth and to the surrounding area to optimize aseptic conditions. The occlusal surface was reduced by approximately 2 mm, and access cavities were prepared by using a sterile round carbide bur (SS White Burs Inc, Lakewood, NJ) in an air-turbine dental handpiece under constant sterile saline irrigation. On accessing the pulp chamber, access cavities were completed by using a sterile Endo-Z bur (Dentsply Maillefer, Tulsa, OK). The presence of vital pulp tissue in all 66 teeth confirmed that none of the teeth were infected before treatment. Because beagle dog premolar roots have closed apices, working lengths were established by using tactile sense supported by information obtained from the preoperative radiographs. After confirmation of a glide path, each root canal was instrumented in a crown-down fashion by using sterile K3 nickel-titanium rotary files (SybronEndo Corp), terminating in a final apical size of ISO 45 (.04 apical taper). Each root was irrigated with 1 mL of 1.25% sodium hypochlorite (Clorox Company, Oakland, CA) between files by using a 10-mL syringe and a 30-gauge nickel-titanium irrigating needle (Vista Dental Products, Racine, WI). When instrumentation was complete, canals were irrigated with 2 mL of 17% ethylenediaminetetraacetic acid (Vista Dental Products) applied over a period of 1 minute. Each canal was then flushed with 2 mL of sterile water followed by a 2-mL final rinse of 2% chlorhexidine (Vista Dental Products). Sterile paper points (Dentsply Maillefer) were used to dry each canal. A separate set of instruments was used for each of the experimental root filling materials to avoid cross-contamination of the different root filling products.

Group 1: RealSeal 1 (n = 25)

A size verifier was used to determine that the obturator size to be used was appropriate. RS-1 self-etching sealer was removed from refrigeration and allowed to reach room temperature before use. The sealer was placed in each root canal by using a lentulo spiral rotating at 300 rpm as per the manufacturer's instructions. RS-1 obturators were disinfected for 1 minute in 2% chlorhexidine, rinsed with sterile water, and dried with sterile gauze. Each obturator was heated in a ThermaPrep Plus Oven and inserted into the prepared canal at the end of a full heating cycle in accordance with manufacturer's instructions. The handle of each obturator was stabilized while the carrier was sectioned at the orifice level. Excess filling material surrounding the carrier was compacted apically by using Buchanan pluggers (SybronEndo Corp). Excess sealer was removed from the pulp chamber by using alcohol and sterile cotton pellets. The coronal surface of the root filling was light-cured for 40 seconds with a portable curing light (DENTSPLY Caulk, Milford DE) to create an immediate coronal seal, as recommended by the manufacturer. After preparing the dentin in the access cavity with GC dentin conditioner (GC America Inc, Alsip, IL), a small sterile cotton pellet was carefully placed on the floor of the pulp chamber. The access cavity was sealed with Fuji IX GP FAST (GC America Inc). The coronal seal was removed after 1 week, having allowed time for the sealer to set before the microbial challenge.

Group 2: Thermafil (n = 25)

A size verifier was used to determine that the obturator size to be used was appropriate. Thermaseal Plus sealer was sparingly placed in each root canal by using a sterile paper point (Dentsply Maillefer) as per the manufacturer's instructions. Thermafil obturators were disinfected for 1 minute in 2% chlorhexidine, rinsed with sterile water, and dried with sterile gauze. Each obturator was heated in a ThermaPrep Plus Oven until an audible signal indicated that the obturator was ready for placement. It was then inserted into the prepared root canal. The