

Methacrylate Based Resin Sealers – A Paradigm Shift in Endodontics

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PREFACE

In recent years several methacrylate based resin root canal sealers (MBRS) have been introduced as an alternative to conventional gutta-percha in combination with zinc-oxide eugenol or epoxy-based sealers. Emphasis was directed towards introducing a simplified technique based on established dentin bonding principles. Favorable physical and biological properties coupled with a successful clinical performance, approximately 10 years since its inception, have contributed to an increase in interest using this approach. Currently various formulas are commercially available. While there is a wealth of anecdotal information as well as numerous reports on in vitro experiments, there are few long-term clinical studies. Due to a disparity in findings, the literature is far from conclusive if not to say confusing, and opposing views are rampant as to their performance, biocompatibility, toxicological reactions and clinical handling. Therefore practitioners have to rely mostly on anecdotal clinical information and the few clinical studies that have been published. A number of handling issues, while now commonly accepted by general practitioners doing restorative dentistry and having been taught for many years as routine procedures with the back-up of considerable scientific evidence, are new in endodontics. Therefore concepts such as moist versus dry dentin, the oxygen inhibited layer and the interaction of MBRS with irrigants, appear to have often been misunderstood and have frequently resulted in data that have cast doubt on their performance.

It is the intent of this text to critically review the published literature on in vitro and in vivo publications and to arrive at an opinion as to the validity of pertinent publications. The current status and future expectations of methacrylate based resin sealers will be presented in detail. Introduction of new endodontic sealers and or techniques requires extensive testing. In vitro cell culture tests to determine toxicological reactions, subcutaneous muscle and bone implantation tests in rats or rabbits provide useful information as to the need to conduct a next step, i.e. a efficacy and usage test. Only after favorable data from these tests has been obtained, can routine clinical use in humans be recommended.

It was the intent of the manufacturer of ER not only to introduce materials for obturation, but also to develop a system that would make it easier for practitioners doing root canal treatment. With that in mind a new system for preparing root canals for filling was introduced, the Anatomic Endodontic

Technology (AET). This system has been reviewed and analyzed as it is an integral part of the entire procedure when using ER.

OBJECTIVES

The objective of this monograph is to provide a comprehensive overview of the status and state of the art of Methacrylate Based Resin Sealers, thus providing a data base for practitioners, enabling them to make the decision whether to adhere to old techniques or to switch to newer methods and materials. Furthermore, principles of bonding to dentin, hydrophilicity of sealers, hybrid layer, and an oxygen inhibited layer will be highlighted, while in addition the importance of root canal conditions such as dry, moist and wet dentin are emphasized.

A critical analysis of the literature has been presented and the methodologies described in these publications have been carefully scrutinized. It is this database that practitioners should rely on and therefore a critical analysis is of great importance.

Furthermore a detailed presentation of the Anatomic Endodontic Technology should provide a better basis of understanding what this systems offers compared to conventional debridement armamentarium.

Furthermore an illustrated guide is presented presenting step-by-step the clinical handling of ER, placement of master cone and auxiliary cones.

The authors express their gratitude to the reader for having shown an interest in reading this monograph. They hope that it will answer their questions and will convince them one way or another what system is best for their patients.

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“ADHESIVE” ENDODONTICS – DEVELOPMENT AND INTRODUCTION OF METHACRYLATE BASED RESIN SEALERS

Oswaldo Zmener and Cornelis H. Pameijer

History of adhesion in Endodontics

The title “Adhesive” Endodontics – Development and Introduction of Methacrylate Based Resin sealers was carefully chosen and needs an explanation to emphasize that “adhesion” in endodontics has less to do with establishing high bond strength values than with providing a hermetic “seal”. Undoubtedly high bond strengths can be attained, which serve little purpose other than potentially complicating retreatment. For the root to benefit from structural reinforcement as afforded with a structurally strong adhesive, an extremely strong root canal filling material would be required. This should be avoided as much as possible, however, as the need for retreatment and/or potential post placement must be kept in mind. Furthermore, high bond strengths values are not necessarily synonymous with a better seal and the concept of bonding in endodontics should not be based on the parameters that are used in restorative dentistry. Even if an extremely strong root canal filling material were to be used, the small cross sectional dimensions of the root canal and its central location in the root make root reinforcement inconsequential. Foremost, long-term success in endodontics will depend on maintenance of the seal. There is a prevailing belief that an appropriate selection of a sealer and its clinical performance will influence, at least in part, the outcome of endodontic therapy (Ørstavik et al. 1987).

During the last four decades new materials have been introduced as alternatives to the most widely recommended root canal filling materials, gutta-percha cones and sealer cements (Taintor and Ross 1978). An established drawback is that gutta-percha does not bond to dentin or to any currently used sealer, such as ZOE-based cements and epoxy resins i.e. AH26 or AH-Plus. In addition gutta-percha does not bond to calcium hydroxide or glass ionomer-based sealers. While the foregoing materials have been successfully used for many years, ideally a root canal sealer should be capable of bonding to root canal walls and to gutta-percha, thus preventing microleakage.

Recent advances in adhesive technology have introduced a new generation of endodontic sealers and filling materials which are based on adhesion and polymer resin technology, enabling the formation of a hybrid layer and/or deep penetration into dentinal tubules by means the hydrophilic property of the resins. In a pertinent article, Mounce (2007) believed that the adhesive techniques that have been used for many years in restorative dentistry, have now definitively reached the root canal system. However, in 1978 Tidmarsh already suggested that low- viscosity resins could have the potential for use in root canal obturation. Of the bonding agents that were used in restorative dentistry, the earlier generations did not use an acid to remove the smear layer and therefore only bonded to the weak attached smear layer. This constituted a weak bond and a weak link and it did not prevent bacterial leakage. With subsequent generation dentin bonding agents, removal of the smear layer was accomplished through acid pretreatment with 35% phosphoric acid gels. Furthermore, the early resins were hydrophobic and therefore their action was adversely affected by moisture in the dentin. Conversely, the latest generation

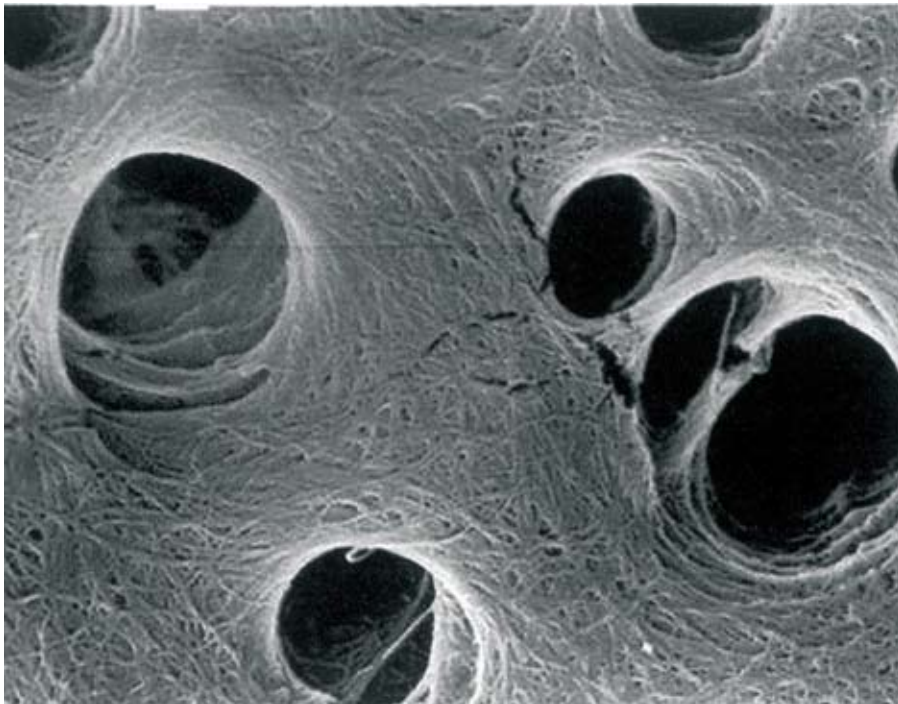


Fig. 1. Dentin exposed to 17% EDTA as a final rinse after instrumentation of the root canal. The smear layer was removed exposing the intertubular collagen and dentinal tubules that are free from smear plugs (Original magnification 8,500X). (Courtesy of Dr. Jorge Olmos.)

of bonding agents, all of which are hydrophilic, take advantage of micromechanical interlocking by penetrating into micro irregularities at the base of the decalcification zone after chelating or etching of peritubular and intertubular dentin, thus creating an attachment mechanism that is composed of both resin and collagen fibers, establishing ideally an intimate adaptation to the base of the decalcification zone. This resin/fibrillar zone has been referred to as the hybrid layer. This collagen network requires careful protection since unprotected collagen fibrils within the hybrid layer may compromise the longevity of the adhesion of the filling material to dentin walls. This can be avoided by the use of irrigating solutions other than strong acids. It has been demonstrated that the collagen network of dentin can be better preserved with the use of 17 – 19% EDTA (Osorio et al. 2005) or low concentrations of citric acid solutions (Olmos J 2006, personal communication) as the final rinse (Fig.1). Effective removal of the smear layer and dentin conditioning before filling the canals will enhance the ability of these bonding agents to enter the dentinal tubules and penetrate into the etched and chelated intertubular dentin. The presence of organic debris along with bacteria within the matrix of the smear layer represents an undesirable interface between filling material and dentin. Furthermore, the sequence of the irrigating solutions has been shown to be a factor. A 5% sodium hypochlorite solution followed by 17% EDTA or 50% citric acid appears to be the most effective irrigation protocol (Yamada et al. 1983; Baumgartner and Mader 1987). EDTA, albeit not effective for conditioning enamel, has shown to be optimal for removal of the smear layer and decalcification of the root canal dentin.

Zidan and ElDeeb (1985) were amongst the first to attempt to establish adhesion to dentin walls in vitro with the use of Scotch bond (3M/ESPE, St Paul, MN). After instrumentation of the root canals using freshly extracted human maxillary canines, the master cone and the canal walls were coated with the bonding agent and complemented with laterally condensed auxiliary cones coated with the bonding agent. Apical microleakage was evaluated with a dye penetration technique. Canals obturated with gutta-percha and the bonding agent leaked significantly less than root canals obturated with gutta-percha and Tubli Seal, a ZOE-based root canal sealer. However, the bonding agent tested presented problems with handling properties and radiopacity and was difficult to remove when retreatment was attempted.

Leonard et al. (1996) compared the effectiveness of a combination of a dentin bonding agent 4 – META and the resin C&B Metabond (Parkell, Farmingdale, NY), which was commercialized a few years later as MetaSeal (Parkell) as well as the glass ionomer cement Ketac – Endo (3M/ESPE) for sealing of the root canal system. The coronal and apical seal was tested by means of dye penetration which demonstrated that both materials showed some evidence of dye leakage. However, the sealing ability of the bonding agent and resin was significantly better. This was further supported by scanning electron microscopy of the interface sealer and dentin, demonstrating the presence of a hybrid layer and resin tags penetrating the dentinal tubules. In spite of these positive features, the materials appeared to be very technique sensitive. This was also shown by Erdemir et al. (2004), Nikaido et al. (1999) and Morris et al. (2001), who demonstrated that the use of sodium hypochlorite and hydrogen peroxide or a combination of both irrigants, decreased the bond strength to dentin by adversely affecting the tensile bond strength to bovine dentin. Hydrogen peroxide breaks down to water and oxygen, whereas the combination of sodium hypochlorite and hydrogen peroxide allows for the formation of oxygen, which in turn inhibits polymerization of the adhesive materials. Of significance here is that irrigation with chlorhexidine did not demonstrate these adverse effects. Chlorhexidine is an antimicrobial agent which does not dissolve soft tissues and has no effect on polymerization of MBRS. Sodium hypochlorite dissolves soft tissues and has an effect of the polymerization of resins. Therefore, the irrigation protocol with the use of MBRS is of critical importance and a separate chapter has been devoted to this topic (See: The effect of irrigation protocol on the polymerization of resin-based sealers – significance of oxygen inhibition).

In 1998, Mannocci and Ferrari tested the bonding agents All Bond 2 adhesive (Bisco, Itasca, IL) and Scotch bond Multi-purpose Plus adhesive (3M/ESPE) both in combination with gutta-percha and an epoxy resin-based root canal sealer AH26 (Maillefer, Switzerland). Leakage was tested using a 2% methylene blue solution. The results demonstrated that root canals in which a combination of bonding agents with gutta-percha and the epoxy-resin sealer leaked significantly less than the controls in which the root canals were obturated with gutta-percha and AH26. Scanning electron microscopy confirmed the presence of a hybrid layer. Although no problems were encountered regarding the working time of the bonding agents, the complexity of the technique requiring (too) many steps made the use of bonding agents not practi

cal for root canal obturation. Of additional concern is the use of HEMA containing bonding agents, which when extruded beyond the apex in bone, could sensitize patients, particularly if they are from Nordic countries or have genetic make-up that originates there.

In the same year, Ahlberg and Tay (1998) tested a methacrylate-based bone cement normally used in orthopedic surgery, in which the monomer from n-butyl methacrylate was changed to tetrahydrofurfuryl methacrylate with 1% N'N'dimethyl p-toluidine as the activator. The powder consisted of poly(ethyl methacrylate) with a molecular weight of 150,000 – 1,500 000 and a particle size of 15 – 100 μm . They used this formulation to obturate in vitro the root canals of human teeth in combination with gutta-percha while the control canals were filled with gutta-percha only. The root canals filled with the resin and gutta-percha leaked significantly less than the controls. Scanning electron microscope observation of the interface revealed a bond, not only between the resin-based sealer and the root canal walls, but also between the sealer and gutta-percha. With respect to their handling properties, it was found that the material was easy to place in the root canal and the working time was approximately 50 minutes. The authors postulated that, since the smear layer was not effectively removed, the bonding to the root canal walls may be attributed to the good flow of the resin itself, whereas the ability to bond to gutta-percha was probably due to dissolution of the gutta-percha surface.

Kataoka et al. (2000) analyzed the coronal and apical sealing properties of a newly developed resin-based root canal sealer composed of vinylidene fluoride/hexafluoropropylene copolymer, methyl methacrylate, zirconia and tributylborane as the catalyst, used in conjunction with gutta-percha in root canals, which were pre-treated with dentin conditioners and primers. They also analyzed the tensile bond strength and performed a scanning electron microscopy of the interfaces. The test material revealed a significantly higher sealing ability than Pulp Canal Sealer EWT (Sybron Kerr, Romulus, MI) and Sealapex (Sybron Kerr) which were used as controls. When the canal walls were pre treated with EDTA and further application of glutaraldehyde/2 – hydroxyethyl methacrylate primer, significantly higher bond strength values were recorded. SEM observation revealed the presence of a hybrid layer of approximately 2 μm thick formed by the penetration of the resin into the dentin with only a few gaps at the interface sealer/root canal walls. Based on

these observations, the authors suggested that the tested resin-based sealer has many useful properties for root canal obturation, such as adhesiveness to dentin and gutta-percha while exhibiting good sealing properties.

In 2004, four years after the Ultradent patent was granted, Gogos et al. described an injectable resin called Endoresin – 2 for root canal filling purposes. The material consisted of a powder of poly methylmethacrylate containing barium sulfate as the radiopacifier and a catalyst of methacrylate monomer. After mixing the components, the material was suitable for injecting in the root canal with a working time of approximately 6 minutes. According to the authors the physical properties of the sealer met the ISO 6876 standard requirements for root canal sealing materials.

According to the above information these experimental methacrylate-based formulations all had the potential to bond to the root canal walls providing the smear layer was removed. They can be safely used in endodontics and have shown promising results for root canal obturation (Leonard et al. 1996; Imai and Komabayashi, 2003; Gogos et al. 2004).

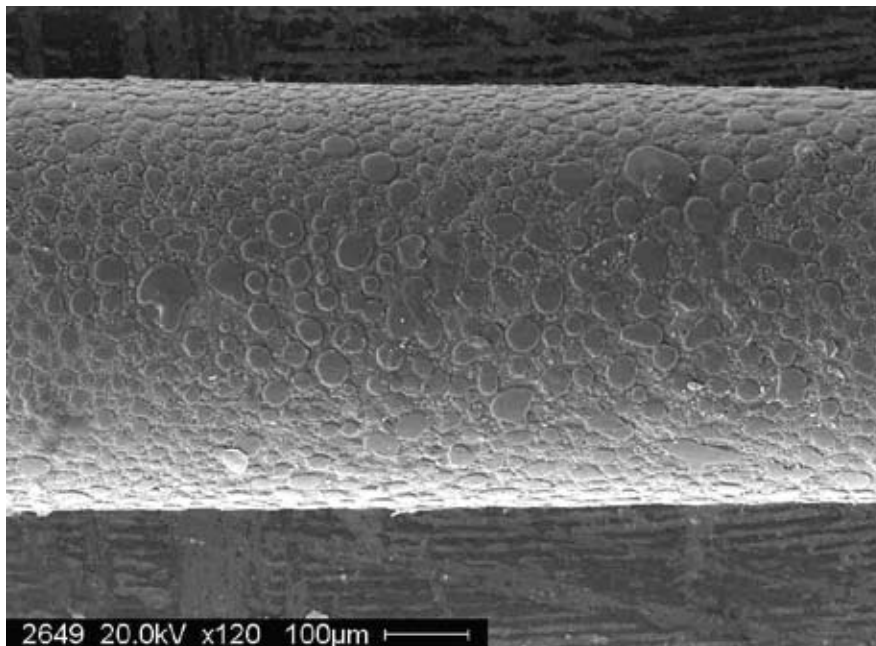


Fig. 2. Scanning electron micrograph of a resin coated gutta-percha cone. Note textured surface of resin coating, increasing surface area, thus adding to the retention for the bonding of EndoREZ.

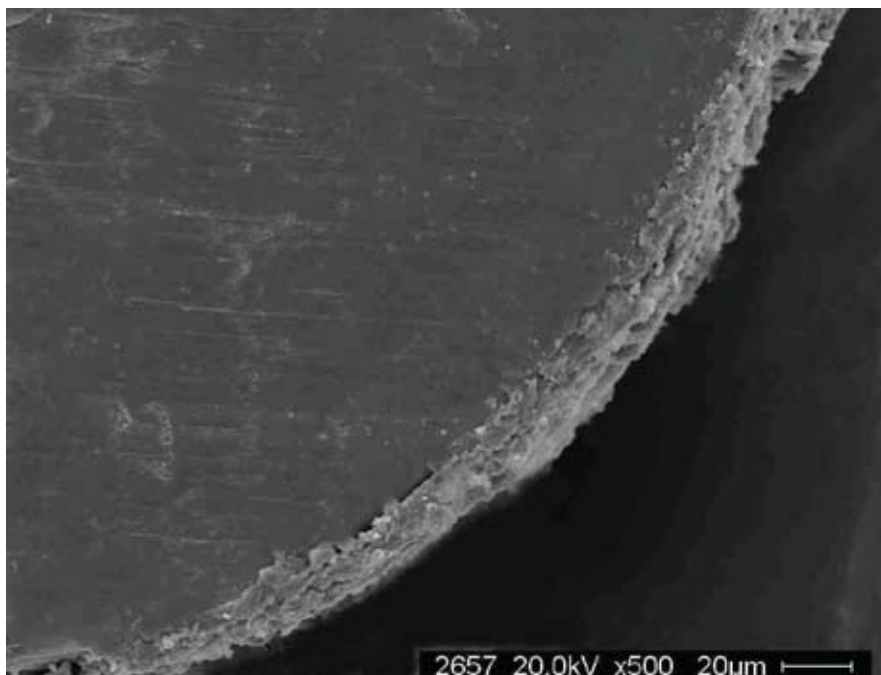


Fig. 3. Scanning electron micrograph of a cross section of a resin coated gutta-percha cone. Note resin surface lining the gutta-percha. The irregular resin surface promotes retention of the EndoREZ sealer. According to the bar the thickness of the resin coating measures approximately 20 microns. Some specimen preparation artifact at the gutta-percha resin interface can be seen.

Resin coated gutta-percha cones

To date, the use of gutta-percha in conjunction with a sealer is still considered to be one of the most reliable methods in root canal obturation (Taintor and Ross 1978). Its popularity exists in spite of the fact that coronal and apical leakage at the interface between the sealer and dentin and/or gutta-percha has frequently been demonstrated (Zmener and Pameijer, 2007c; Zmener et al. 2008). EndoRez and other methacrylate-based resin sealers have the capability to bond to the root canal dentin but not to conventional gutta-percha. Therefore leakage may occur at the interface sealer and gutta-percha. To resolve this problem and to obtain an effective bond between gutta-percha and resin-based sealers, a new brand of .02, .04 and .06 taper resin-coated gutta-percha (RCGP) cones (Ultradent Products Inc, South Jordan, UT, USA) have recently been introduced to the dental profession.

RCGP cones contain gutta-percha, zinc oxide, barium sulphate and coloring agents and are coated with a thin layer ($\pm 20 \mu\text{m}$) of polymerized urethane dimethacrylate resin (UDMA), which is similar in formulation to EndoREZ sealer. The resin coating bonds to the gutta-percha by a complex

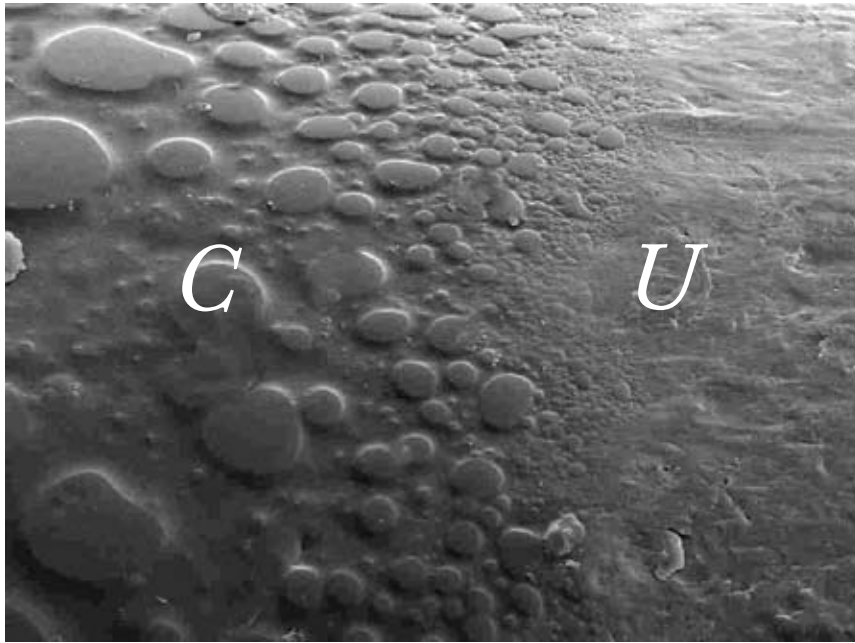


Fig. 4. Scanning electron micrograph of a resin coated gutta-percha cone, at the junction of uncoated (U) and coated gutta-percha (C). Not the entire length of the cone is coated, only 19mm, leaving the inconsequential coronal portion uncoated. (Bar = 20 μ m.)

chemical process in which an isocyanate group from a diisocyanate and a hydroxyl group of a hydroxyl-terminated polybutadiene react first and bonds to the polyisoprene component of the gutta-percha. This process is followed by grafting a hydrophilic methacrylate functional group to another isocyanate group of the diisocyanate (Tay et al. 2005). According to the manufacturer, the RCGP meets the requirements of the ANSI/ADA (1984) for root canal filling materials.

EndoRez bonds to the resin covering the gutta-percha surface and to dentin, thus creating a continuous layer (uniblock or monobloc) that completely fills the root canal space. In order to accomplish optimum adhesion when using EndoRez with RCGP, a clinical protocol of instrumentation and irrigation with 2.5% or 5.25% NaOCl solution, followed by removal of the smear layer and decalcification of the surface dentin with 17% EDTA (“conditioning”), and finally a rinse with copious amounts of saline is required. Morris et al. 2001; Ari et al. 2003, have reported that the final use of saline is necessary

to avoid the inhibitory effects of chemical remnants on free-radical polymerization. Although recommended by some, further tests have shown that a final rinse with saline is optional (See: The effect of irrigation protocol on the polymerization of resin-based sealers – significance of oxygen inhibition). In the instructions for use on EndoREZ, EDTA is recommended as the final step before obturation.

In a previous report by Tay et al. (2005), cleaned and shaped root canals were filled using an early generation passively fitted RCGP cones in conjunction with the dual cure EndoRez sealer. The authors found that the resin coating had peeled off in some areas and suggested that this feature may have occurred during the manufacturing and/or storage of the cones. A later generation RCGP underwent a revision of the manufacturing process and has produced cones that are free of defects with respect to the resin on the surface.

In a recent study by Zmener and Hilú (2006), RCGP of different sizes and tapers were randomly selected from fresh packages and analyzed in a scanning electron microscope (SEM). Surface morphology as well as thickness and continuity of the resin layer were examined. During removal from the packages as well as during preparation for SEM, care was taken to prevent any damage of the samples. In all samples the surfaces were rather uniform and smooth with only minor irregularities. Careful examination of serial cross-sections showed a continuous resin coating with an average thickness of 7 – 10 μm along the entire circumference of the RCGP while no separation between the resin coating and the gutta-percha was observed (Fig. 2, 3 and 4). These observations suggest that peeling of the RCGP surfaces as noted by Tay et al. (2005) could have been produced during the filling procedures or were inherently related to the early generation, now obsolete manufacturing method.

The goal of this feature, however, remained the same and that is to obtain an effective bond between gutta-percha and EndoRez, thus avoiding leakage at the interface between the cones and the sealer.

Since accidental overfilling with gutta-percha occurs with some frequency in Endodontic therapy (Augsburger and Peters 1990), the subcutaneous connective tissue and bone tissue response to resin-coated cones as well as con-

ventional gutta-percha cones used as controls was investigated in a rat model system by Zmener and Pameijer (2007a) and Zmener and Pameijer (2007b). Both experiments were conducted in conformity with Ethical Principles of Animal Experimentation and the Guidelines for the care and use of laboratory animals (Bayne 1998).

For the subcutaneous implantation test, silicone tubes measuring 8 mm in length were overfilled by 2 mm using a 10 mm length RCGP (size #35, taper .04). They were surgically implanted into the subcutaneous connective tissue of white male Wistar rats. Silicone rods of similar dimensions were also implanted and served as negative controls. Tissue reactions were evaluated histologically and analyzed under polarized light and by elemental electron microprobe analysis. The results showed that the tissues in contact with RCGP exhibited an initial inflammatory reaction which subsided over time. At the end of the experiment (90 days), some inflammatory cells and macrophages were still present in contact with the cones, suggesting that enzymatic degradation of the resin coat and/or phagocytosis of gutta-percha particles persisted even after 90 days post implantation. At this time interval an electron microprobe analysis identified the presence of zinc and barium in the gutta-percha cones. Control tissues demonstrated an initial low-grade inflammatory reaction, which subsided after 30 days. After 90 days, a well defined fibrous connective tissue, free of inflammatory cells, encapsulated the silicone rods.

For bone implantation, silicone tubes 1.5 mm long, with an outer diameter of 1.0 mm and a lumen of 0.5 mm were filled with the RCGP (size #35 .06 taper) or conventional GPC (Maillefer/Dentsply, Ballaigues, Switzerland) obtained from different unused packages. This experimental set-up meant to mimic root canals that had been overfilled with either RCGP or GP. GP were used as controls, since previous biocompatibility tests of gutta-percha (Spångberg and Langeland 1973; Wolfson and Seltzer 1975; Deemer and Tsaknis 1979; Tanzilli et al. 1983) revealed that, although not totally inert, gutta-percha was the least irritating root canal filling material. After sterilization, one end of the tubes was filled flush, while at the opposite end of the tubes the tip of the RCGP or GP extruded ± 5 mm. Samples were implanted in the tibias of white male Wistar rats weighing 350 to 400 g each. The implantation technique has been described elsewhere (Zmener et al. 2005). Briefly, after anesthetizing the animals through intraperitoneal administration of sodium pentobarbital (0.025 g/1000 g wt), the external surfaces of the

tibias were shaved and disinfected with 70% alcohol. A longitudinal incision of ± 16 mm was made at the lateral aspect of the anterior border of the tibia reaching the bone. After blunt dissection of the periosteum, a 2 mm deep cylindrical opening was prepared in the area of the diaphyseal bone (DB) approximately 8 mm from the lateral external side and perpendicular to the long axis of the tibia. The openings were prepared by manually rotating a 1 mm diameter end-cutting bur, thus preventing overheating. The silicone tubes were then placed in the openings with their overfilled sides extending into the marrow space while the opposite ends were level with the outer surface of the cortical bone. The material had to be placed in the marrow space since no reaction was to be expected from placement in cortical bone (Zmener et al. 2005). After implantation, the wounds were sutured and the animals maintained on a regular diet and water ad libitum. After 10 and 60 days they were killed in groups of 10 by ether suffocation, the tibias removed and fixed in 10% neutral buffered formalin. The short and long-term time intervals were used according to the recommended standard practices for biological evaluation of dental materials (Federation Dentaire Internationale 1980). Following decalcification in 10% formic acid, the specimens were processed for routine paraffin embedding. Longitudinal serial sections approximately 7 μ m thick were obtained from the center of the implants and stained with hematoxylin and eosin. To determine if components of the materials were present at the tissue/material interface, every third section remained unstained. These sections, were prepared for electron microprobe analysis according to a method described by Zmener (2004). The sections were also examined for birefringent properties using polarized light.

The reactionary trabecular bone density formation and the cell population were analyzed histometrically and histologically in the area that was in direct contact with the RCGP and the GP.

Although the RCGP and the GP appeared to be well tolerated by the surrounding tissues the results of subcutaneous and bone implantation deserves some discussion.

After a short evaluation period (10 days), the reactionary bone formation to RCGP and GP was significantly less than what was observed after 60 days. In an early pilot project evaluating bone activity (Zmener et al., unpublished data), 2 mm deep by 1 mm diameter cylindrical openings were prepared in the area of the diaphyseal bone in rat tibias. These osseous defects were left unfilled and the soft tissues sutured. After 4 days, there was evidence of

incipient new bone formation. An increased deposition of new bone trabeculae and complete repair of the bone defects was seen at the 15-day observation period. These results established a favorable criterion and can be used to compare the possible harmful effects of different materials when implanted in the rat tibias. In vitro investigations by Spångberg and Langeland (1973) have demonstrated that direct contact with different concentrations of gutta-percha eluates caused severe cell damage, whereas Sabino et al. (2004) and DeLaSalle et al. (2006) have shown that the release of uncured monomers from methacrylate-based materials affected the differentiation of osteoblasts and the process of mineralization. It is interesting to note, however, that when gutta-percha or methacrylate-based materials were implanted in the tibias of rats (Deemer and Tsaknis 1979) or rabbits (Goodman et al. 1988) these harmful effects were reversed over time. Based on these observations, it was hypothesized that the initial delay of reactionary bone formation could be due to an early inhibition of osteoblastic differentiation, which was caused by the release of components of the test materials into the surrounding tissues. After 60 days, however, the amount of BDF formation was significantly higher, indicating that the test materials did not interfere with normal (delayed) bone healing.

The histological findings revealed an initial inflammatory reaction of the tissues in direct contact with both RCGP and GP. However, the severity of this reaction decreased over time. After 60 days, the implants were walled off by fibrous connective tissue which was thickest at the areas in direct contact with the RCGP and GP. These observations agreed with those of previous reports (Deemer and Tsaknis 1979; Tanzilli et al. 1983; Goodman et al. 1988). Even though tissue reaction was markedly reduced, persistent inflammatory cells, as well as macrophages and occasional multinucleated foreign-body giant cells were observed in the tissues surrounding both materials. The persistence of some polymorphonuclear leukocytes surrounding the RCGP at the 60-day evaluation period was explained as follows. The outer surface of the cones is composed of a thin layer of polymerized UDMA and therefore the primary reaction of tissues in direct contact with RCGP is to UDMA resin and/or some of their additives. As has been demonstrated, a certain amount of unreacted monomer persists after polymerization of composite resins (Rueggeberg and Margeson 1990). As a result the components in adhesive resins are exposed to enzyme degradation (Hanks et al. 1991), leading to the formation of toxic by-products, which can leach into the surrounding environment. Previ

ous reports (Hanks et al. 1991; Nassiri et al. 1994) have shown that UDMA-based materials as well as other types of adhesive resins reacted cytotoxic in animal and human cell cultures. As has been speculated in a previous report by Zmener et al. (2007b), incomplete polymerization (Rueggeberg and Margeson 1990), may have resulted in a rapid elution and leaching of unreacted monomer and other components from the UDMA-based layer, thus causing the inflammatory reaction observed at the 10-day observation period. After initial rapid loss of components from the resin, further leaching may occur but at a considerably reduced rate (Ferracane and Condon 1990; Ferracane 1994), which explains the substantial reduction of the inflammatory reaction after 60 days. These findings are consistent with previous reports by Costa et al. (1997) and Costa et al. (2000), and are further supported by Ferracane and Condon (1990). In these areas, some chronic inflammatory cells and macrophages that had engulfed particles in their cytoplasm, were also observed. Some of these particles were birefringent to polarized light, a finding consistent with earlier reports by Spångberg (1968) and Holland et al. (1982). This can be explained in that the resin coating of RCGP is only 7 – 10 μm^* thick (Zmener and Hilú 2006) and therefore, the combined action of polymer degradation and/or possible damage of the coating and subsequent phagocytosis of UDMA and gutta-percha, may have caused the release of some of the gutta-percha components from the RCGP. In this respect similarities to GP were found. After 60 days of implantation, persistent chronic inflammatory cells and macrophages as well as occasional multinucleated giant cells with engulfed particles in their cytoplasm, (some of which were also birefringent under polarized light) were also detected in the tissues in contact with GPC. These observations are consistent with a previous report by Sjögren et al. (1995) in which gutta-percha specimens of various sizes were implanted subcutaneously in guinea pigs.

It could be demonstrated by means of elemental analysis that the areas adjacent to the RCGP and GP exhibited the presence of zinc and barium. Zinc and barium constitute a significant amount in gutta-percha. Leaching of zinc and barium has been shown to be a factor in the toxicity of gutta-percha and other zinc and barium containing materials (Moorer and Genet 1982; Cathers et al. 1984; Smith et al. 1984; Meryon and Jakeman, 1985; Pascon and Spångberg, 1990). Different time periods and animal models have been used to study tissue reactions to gutta-percha cones (Spångberg, 1968; Wolfson and Seltzer, 1975; Deemer and Tsaknis, 1979; Holland et al. 1982; Tanzilli et

**With the new technology the resin coating measures 15–20 μm .*

al. 1983; Sjögren et al. 1995), and most of them reported similar results. From the results of the above mentioned studies, the reaction to the resin-coated cones in subcutaneous and bone tissue of the rat is by and large comparable to conventional gutta-percha. In spite of the presence of some persistent inflammatory cells in contact with either material after 60 days, the fibroblastic proliferation that increased over time and the newly formed bone trabeculae indicate a favorable development of the repair process.

All the above discussed tests were done on the early generation RCGP cones, which have been supplanted by a next generation, which uses a tightly controlled new manufacturing of warm nitrogen purging and visible light curing process that has resulted in an improved monomer conversion as well as an absence of an oxygen inhibited layer. Figures 3, 4 and 5 are scanning electron micrographs of the surface of the RCGP cones. The surface appears “textured” and has layers that slightly differ in thickness. Yet an electron probe micro analysis confirmed that the different textures all consisted of resin. At lower magnification the border between coated and uncoated gutta-percha can be seen, as only the apical 19mm of the gutta-percha is covered with resin.

Finally it should be emphasized that it is universally advocated for all endodontic treatment, to make every effort to keep the RCGP or GP within the confines of the root canal at all times.

Leakage studies

The sealing properties of ER and an epoxy resin-based sealer AH Plus were investigated in vitro by Zmener and Banegas (2004). A further objective of the study was to investigate, under controlled conditions, the influence of possible oxygen contamination from the medium through the apical foramen on the sealing ability of the methacrylate-based sealer. This was an issue of concern when the sealing ability of a methacrylate-based material (ER) was tested in vitro. Oxygen inhibits free-radical polymerization of resin-based materials, yielding an uncured surface layer (Andrzejewska et al. 1998). Oxygen is consumed during curing while simultaneously oxygen diffusion from the air of the environment re-establishes the equilibrium. This is of particular concern when thin resin layers are to be cured (Ruyter 1984). This applies directly to ER, which, when used improperly during the clinical procedures, can result in the formation of an oxygen inhibited layer. ER does not polymerize when in contact with oxygen from the environment. The results of this study showed no statistically significant differences in apical leakage between

both sealers and suggest that the apical exposure of EndoRez to the oxygen from the medium does not appear to affect the behavior of the sealer negatively. However, this issue warrants further discussion. It is a recommended clinical practice to “trial mix” a material, especial a material a practitioner is unfamiliar with. In the case of EndoRez this presents a problem practitioners may not realize. After extrusion of the material on a mixing pad the material will not set as it is in contact with air, leading to the conclusion (and quite frequently a phone call to the manufacturer) that the material does not set and therefore is defective. This is the wrong test to do. The material should be back filled in a Skinny syringe followed by insertion of the plunger. After 24 hours, but probably much sooner, the material will have completely polymerized as in the absence of contact with oxygen complete polymerization will take place.

A subsequent in vitro dye leakage experiment was conducted by Zmener et al. (2005), in which the apical seal obtained in root canals obturated with either a single gutta-percha cone or lateral condensation of gutta-percha using EndoRez or Grossman's cement as sealers was compared. The least amount of leakage was observed in teeth filled with EndoRez, either with a single gutta-percha cone or with lateral condensation.

In another study, Zmener and Pameijer (2007c) analyzed the coronal bacterial leakage of *S. epidermidis* in root canals filled with resin-coated gutta-percha cones and EndoRez to which a catalyst (Ultradent Products Inc) was added. In another group ER had no catalyst. A dual-cure sealer has the advantage that after filling, light curing will polymerize the coronal surface of the material, allowing the practitioner to continue with the restoration of the tooth. Over time the deeper material not cured by the light will polymerize by means of a chemical set. In both groups, the dentin of the root canal walls was kept moist. Conventional gutta-percha cones and AH Plus in dry root canals were used as controls. The results suggested that root fillings in both EndoRez groups provided an acceptable coronal seal for up to 60 days. Root fillings performed with gutta-percha cones and AH Plus did not provide an efficient bacteria-tight seal as all of the samples showed leakage within a 21 – 40 day period.

It can be concluded that MBRS have undergone extensive in vivo and in vitro testing which has generated data that allows for a favorable comparison with

traditional sealers. MBRS have now been used for ± 10 years and its use is becoming increasingly more popular. This is based on favorable results from research data and clinical success. The ease of use of the materials and simplified technique are attractive to practitioners involved in endodontics.

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EVALUATION OF CYTOTOXICITY OF TWO ROOT CANAL SEALERS USING THE AGAR DIFFUSION METHOD

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RUNNING TITLE: CYTOTOXICITY OF ROOT CANAL SEALERS

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Introduction

The structure and morphology of root canals are known to be complex, with numerous lateral canals and fins (Hess, 1921; Davis et al., 1972; Vertucci, 1984). In addition, there are open dentinal tubules on the root canal surfaces. Consequently, when infected, bacteria can be found in the root canal system as well as in the dentinal tubules (Torabinejad et al., 2002).

The success in endodontic treatment depends on a number of factors. Studies have shown that pulpal and/or periradicular pathosis will occur only with the presence of bacteria (Takehashi et al., 1965; Möller et al., 1981; Bergenholtz, 1974). Traditional mechanical instrumentation and intracanal irrigation during root canal therapy can reduce but rarely eradicate the bacteria in the root canal system (Bergenholtz, 1974; Byström and Sundqvist, 1981; Pataky et al., 2002; Zhang et al., 2003).

Adequate root canal sealing has also been recognized as an important aspect for a successful outcome in endodontic treatments (Shipper et al., 2004; Barrieshi-Nusair and Hammad, 2005; Mavec et al., 2006; Jack and Goodell, 2008). Microleakage provides not only nutrients to residual bacteria in the

root canals and dentinal tubules but is also responsible for invasion of a oral microorganisms causing reinfection of root canals and dentinal tubules.

Consequently, efforts have been made to develop new root canal sealers that effectively seal the root canal. Since they are classified as medical devices, root canal sealers need to meet biocompatibility requirements, which includes the evaluation of cytotoxicity potential, in addition to exhibiting proper chemical, physical and mechanical properties. The purpose of this study was to evaluate the cytotoxicity of the two root canal filling materials using a standard agar diffusion method, and following the procedures specified in ISO 7405 (1997) and ISO 10993-5 (1999).

Materials and Methods

Cells were mouse fibroblasts, clone of strain L (NCTC clone 929, ATCC CCL 1) obtained from American Type Culture Collection (Manassas, VA). Eagle's minimum essential medium (MEM), L-glutamine, Penicillin-streptomycin-Fungizone solution, non-essential amino acids, neutral red solution, Hank's balanced salt solution (HBSS) and phenol (100%) were purchased from Sigma Chemical Company (St. Louis, MO). Fetal bovine serum (FBS) was obtained from HyClone Laboratories, Inc. (Logan, UT) and cottonseed oil from Acros Organics (Geel, Belgium). Agar was obtained from Difco Laboratories (Detroit, MI). Tissue culture flasks were purchased from Corning Costar Corporation (Cambridge, MA) and multiwell tissue culture plates (6-well Falcon 3046) were from Bacton Dickinson and Company (Franklin Lakes, NJ).

The two root canal filling materials evaluated for their cytotoxicity were EndoREZ UDMA Resin Root Canal Sealer and First Fill RCS (Table 1). Samples of 6 mm in diameter and 2 mm in height were prepared following the manufacturers' instructions. Both the set materials and their extracts in polar and non-polar solvents were examined for the cytotoxicity. The evaluation of extracts was to detect cytotoxicity, if any, associated with agents that may leach out from the material after its application. Two types of extracts were prepared by incubating the set materials in sterile culture medium without serum (polar solvent) or cottonseed oil (non-polar solvent) (0.2 g material per milliliter extractant) at 37°C for 72 hours, following the procedures described in ISO guidelines (ISO, 1997; 1999; 2002). Sterile culture media

without serum and cottonseed oil were included as the negative control, and phenol served as the positive control.

The agar diffusion method was used for the cytotoxicity evaluation, following pertinent ISO guidelines (ISO, 1997; 1999). L929 cells were cultured at 37°C in a humidified atmosphere of 5% CO₂. At confluence, cells were washed with HBSS and harvested in culture media. The cell density was determined using a hemocytometer and was adjusted to approximately 1.0×10^5 cells/mL. Cell suspensions were aliquotted into 6-well plates (5 mL/well) and cultured for 24 hours. The media was then withdrawn and an overlay agar (3% agar in 2x complete media at the ratio of 1:1), which was maintained at 45°C, was poured over the cell monolayer. The agar was allowed to solidify at room temperature for approximately 10 minutes, and 200 µL of neutral red solution (0.033%) was placed on the agar surface for approximately 20 minutes. The excess dye was then removed. The plates were shielded from light after the neutral red solution was added.

The test samples were placed at the center of each agar surface. Liquid samples (extracts, negative control and positive control, 50 µL per sample) were aliquotted onto sterile filter disks (6 mm in diameter, AP Prefilter Filter Paper, Lot No. H8KM39502, Millipore Corporation, Bedford, MA). The set samples and the filter disks with liquid samples were then placed at the center of the agar surfaces. Four samples were tested for each group, each in a separate 6-well plate to avoid cross contamination of test materials. Plates were then returned to the incubator. Cytotoxicity was examined by measuring the zones of cell decolorization and evaluating the extent cell lysis under an inverted microscope using the established criteria (ISO, 1997; 1999) after 24 and 48 hours (Tables 2 and 3).

Results

The results obtained from the 24- and 48-hour examination of the set EndoREZ UDMA Resin Root Canal Sealer and its extracts are presented in Tables 4 and 5, respectively. The positive control, phenol, caused significant cytotoxicity at both 24 and 48 hours, as evidenced by decolorization in the entire well (well diameter of 3.5 cm) and substantial cell lysis. No cell decolorization and lysis were observed in the negative controls. The results of the controls were consistent with requirements of the test and historical data of this laboratory, which thus validated the test system. EndoREZ UDMA

Resin Root Canal Sealer, either the set material or its two extracts, did not induce any cell decolorization and lysis. The observations were comparable to those obtained from the negative controls (Tables 4 and 5).

Tables 6 and 7 present the data for First Fill RCS. Again, the positive control, phenol, caused significant cytotoxicity at both 24 and 48 hours, while no evidence of cytotoxicity was observed in the negative controls. The results for First Fill RCS were comparable to those obtained from the negative controls, with no detection of any cell decolorization and lysis.

Discussion

For many years, the design of dental materials or biomaterials focused mainly on their mechanical, physical and chemical properties that would provide the ability to maintain structural integrity to perform intended functionality. Possible interactions between the material and tissues and any roles of such interactions in any physiological process generally were not within the consideration of designing the material. During the last three decades, biological properties, or biocompatibility, of a dental material have become increasingly important. Currently, there are mandatory regulatory requirements as well as voluntary standards at national and international levels (ISO, 1997; ANSI/ADA, 2005).

By medical definition, biocompatibility is the quality of not having toxic or injurious effects on biological systems (Dorland, 2007). David Williams (2008) offered a more precise description of the biocompatibility, which “refers to the ability of a biomaterial to perform its desired function with respect to a medical therapy, without eliciting any undesirable local or systemic effects in the recipient or beneficiary of that therapy, but generating the most appropriate beneficial cellular or tissue response in that specific situation, and optimizing the clinically relevant performance of that therapy.” Homsy and coworkers (1970) were among the first who used the term “biocompatibility”, which had not become generally known to medical and dental professionals until 1990s. However, nowadays there is no dispute on the integrated importance of adequate biocompatibility for a given dental material.

Various methods have been developed for evaluating the biocompatibility of dental materials (ANSI/ADA, 2005). The general approach is to conduct a battery of in vitro tests, which constitute an initial but important step towards animal studies and finally clinical trials that will eventually determine the biocompatibility of the material in the intended application. One of the initial

in vitro tests is the evaluation of cytotoxicity, which is the quality or state of a substance being toxic to cells.

The agar diffusion method used in the present study is one of the recommended procedures by ISO (1997; 1999) and U.S. National Standards (ANSI/ADA, 2005). It is simple, quick and repeatable. The two materials, EndoREZ UDMA Resin Root Canal Sealer and First Fill RCS, were examined for Cytotoxicity not only in their set form but also in extracts. The extractant of culture medium without serum is an aqueous, polar solvent, while the cottonseed oil is an organic, non-polar solvent; the combination of both extractants allows a wide spectrum of coverage of leachable agents from the set materials.

The results indicate no evidence of cytotoxicity induced by EndoREZ UDMA Resin Root Canal Sealer and First Fill RCS, regardless of in their set form or either types of their extracts. It is important to recognize that the cytotoxicity is an initial step in biocompatibility evaluation, and their biocompatibility needs to be determined using the overall data obtained from a battery of studies involving in vitro biological systems, animal models and clinical trials.

In conclusion, under conditions of the present study, EndoREZ UDMA Resin Root Canal Sealer and First Fill RCS are not cytotoxic as evaluated using the agar diffusion method.

(Note: First Fill RCS = Epiphany = RealSeal)

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Table 1

Test Materials

Test Material	Manufactures	Lot Number
EndoREZ UDMA Resin Root Canal Sealer	Ultradent Products Inc., South Jordan, Utah	C. Base: #0118012 D. Catalyst: #0118011
First Fill RCS	Pentron Clinical Technologies, Wallingford, CT	<ul style="list-style-type: none"> • Base Lot # 022301 • Catalyst Lot # 022301

Table 2

Evaluation Criteria for Agar Diffusion Test (ISO, 1997; 1999)

Score	Zone Index	Lysis Index
0	No detectable zone around or under sample	No observable lysis
1	Zone limited to area under sample	<20% of zone lysed
2	Zone <0.5 cm from sample	20 - 40% of zone lysed
3	Zone <1.0 cm from sample	41 - 59% of zone lysed
4	Zone >1.0 cm from sample but not entire plate	60 - 80% of zone lysed
5	Zone involves entire plate	>80% of zone lysed

Table 3

Cell Response Index for Interpretation of Cytotoxicity Results (ISO, 1997; 1999)

Cell Response ^a	Score	Interpretation
0/0 - 0.5/0.5	0	Nontoxic
1/1 - 1.5/1.5	1	Mildly toxic
2/2 - 3/3	2	Moderately toxic
4/4 - 5/5	3	Severely toxic

^a Cell Response = Decolorization Index / Lysis Index

Table 4

Evaluation of Cytotoxicity of Set EndoREZ UDMA Resin Root Canal Sealer and
Its Extracts Using the Agar Diffusion Method (24-hour Data)

Group ^a	Decolorization		Cell Lysis		Cell Response	Cytotoxicity
	cm ^b	Index	%	Index		
Culture Media	0	0	0	0	0/0	None
Cottonseed Oil	0	0	0	0	0/0	None
EndoREZ	0	0	0	0	0/0	None
Medium Extracts	0	0	0	0	0/0	None
CS Oil Extracts	0	0	0	0	0/0	None
Phenol	1.45 ± 0.00	5	80.0 ± 4.1	4	5/4	Severe

^a Culture media and cottonseed oil: 50 µL on filter disk to serve as Negative Controls; EndoREZ: Set EndoREZ UDMA Resin Root Canal Sealer; CS Oil: Cottonseed oil Extracts: filter disk with 50 µL extracts; Phenol: 50 µL on filter disk to serve as Positive Control.^b N=4. The distance from the sample (cm) = (Diameter of the Decolorization Zone - Diameter of the sample) / 2. The value of 1.45 cm indicates a decolorization of entire culture well (3.5 cm in diameter): 1.45 cm x 2 + 0.6 cm (diameter of the sample). Decolorization Index is 1 if the Decolorization Zone is limited to the area under the sample (Table 2).

Table 5

Evaluation of Cytotoxicity of Set EndoREZ UDMA Resin Root Canal Sealer and
Its Extracts Using the Agar Diffusion Method (48-hour Data)

Group ^a	Decolorization		Cell Lysis		Cell Response	Cytotoxicity
	cm ^b	Index	%	Index		
Culture Media	0	0	0	0	0/0	None
Cottonseed Oil	0	0	0	0	0/0	None
EndoREZ	0	0	0	0	0/0	None
Medium Extracts	0	0	0	0	0/0	None
CS Oil Extracts	0	0	0	0	0/0	None
Positive Control	1.45 ± 0.00	5	93.0 ± 2.5	5	5/5	Severe

^a Culture media and cottonseed oil: 50 µL on filter disk to serve as Negative Controls; EndoREZ: Set EndoREZ UDMA Resin Root Canal Sealer; CS Oil: Cottonseed oil Extracts: filter disk with 50 µL extracts; Phenol: 50 µL on filter disk to serve as Positive Control.

^b N=4. The distance from the sample (cm) = (Diameter of the Decolorization Zone - Diameter of the sample) / 2. The value of 1.45 cm indicates a decolorization of entire culture well (3.5 cm in diameter): 1.45 cm x 2 + 0.6 cm (diameter of the sample). Decolorization Index is 1 if the Decolorization Zone is limited to the area under the sample (Table 2).

Table 6

Evaluation of Cytotoxicity of Set First Fill RCS and Its Extracts

Using the Agar Diffusion Method (24-hour Data)

Group ^a	Decolorization		Cell Lysis		Cell Response	Cytotoxicity
	cm ^b	Index	%	Index		
Culture Media	0	0	0	0	0/0	None
Cottonseed Oil	0	0	0	0	0/0	None
First Fill RCS	0	0	0	0	0/0	None
Medium Extracts	0	0	0	0	0/0	None
CS Oil Extracts	0	0	0	0	0/0	None
Phenol	1.45 ± 0.00	5	81.3 ± 2.5	5	5/5	Severe

^a Culture media and cottonseed oil: 50 µL on filter disk to serve as Negative Control; CS Oil: Cottonseed oil Extracts: filter disk with 50 µL extracts; Phenol: 50 µL on filter disk to serve as Positive Control.

^b N=4. The distance from the sample (cm) = (Diameter of the Decolorization Zone - Diameter of the sample) / 2. The value of 1.45 cm indicates a decolorization of entire culture well (3.5 cm in diameter): 1.45 cm x 2 + 0.6 cm (diameter of the sample). Decolorization Index is 1 if the Decolorization Zone is limited to the area under the sample (Table 2).

Table 7

Evaluation of Cytotoxicity of Set First Fill RCS and Its Extracts

Using the Agar Diffusion Method (48-hour Data)

Group ^a	Decolorization		Cell Lysis		Cell Response	Cytotoxicity
	cm ^b	Index	%	Index		
Culture Media	0	0	0	0	0/0	None
Cottonseed Oil	0	0	0	0	0/0	None
First Fill RCS	0	0	0	0	0/0	None
Medium Extracts	0	0	0	0	0/0	None
CS Oil Extracts	0	0	0	0	0/0	None
Phenol	1.45 ± 0.00	5	86.3 ± 2.5	5	5/5	Severe

^a Culture media and cottonseed oil: 50 µL on filter disk to serve as Negative Control; CS Oil: Cottonseed oil Extracts: filter disk with 50 µL extracts; Phenol: 50 µL on filter disk to serve as Positive Control.

^b N=4. The distance from the sample (cm) = (Diameter of the Decolorization Zone - Diameter of the sample) / 2. The value of 1.45 cm indicates a decolorization of entire culture well (3.5 cm in diameter): 1.45 cm x 2 + 0.6 cm (diameter of the sample). Decolorization Index is 1 if the Decolorization Zone is limited to the area under the sample (Table 2).

RESEARCH AND DEVELOPMENT OF METHACRYLATE RESIN BASED ENDODONTIC SEALERS

Cornelis H. Pameijer

The advent of bonding in dentistry by means of an acid etch technique, was introduced in the mid 1950-ies by Buonocore and based on resin technology developed by Hagger (1954). Initial strong resistance slowly gave way to general acceptance and bonding materials and techniques completely changed the way dentistry is being practiced today. Initially only hydrophobic resins were available, however, over time these were supplanted by hydrophilic materials and about 30 years of research resulted in a change from using 85% phosphoric acid liquid for 60s to etch enamel to 35% phosphoric acid gels for 15s to etch both dentin and enamel. Therefore it was only a matter of time before other specialties looked into the possibilities of using adhesive materials, and after orthodontists embraced bonding, changing clinical techniques from “banding to bonding”, endodontics was introduced to resin-based sealers and new obturation materials. As is typical when new materials and techniques are introduced, reluctance on the part of the practitioner to embrace this new development needs to be overcome, a process that usually takes time. This cannot be accomplished by empirical data, but by presenting sound scientific evidence from in vitro and in vivo research. To allow for a comparison, gutta-percha and zinc oxide and eugenol and other conventional sealers, based on their successful long track record, have served as the “gold standard”.

Recommended pre-marketing tests

Before a new material designed to be placed provisionally or permanently in the oral cavity.

In an effort to facilitate the dental industry when testing experimental materials, a document entitled: “Recommended Standard Practices for Biological Evaluation of Dental Materials” (2005) describes in detail the tests that

are recommended to be carried out to determine whether a new material can safely be used in humans. Table 1 illustrates in greatly abbreviated format the minimum effort that should be made on the part of a company to establish a scientific basis for safety prior to marketing. It should be recognized, however, that the ultimate success can only be conclusively determined when a material or technique has demonstrated clinical success in humans. Usually passage of a test leads to the next until a clinical trial in humans has demonstrated a material to be safe. Unfortunately not all manufacturers adhere to these recommendations and frequently tests as outlined in the table below (Table 1) are not conducted. The fact that these materials are being marketed may imply to the practitioner that unrestricted use in humans is safe, while in reality insufficient data is available to back-up this claim. For all practical purposes the practitioner then becomes the researcher and the patient the guinea pig.

Recommended tests

- 1. In-vitro tests - cell and/or tissue cultures**
- 2. In-vivo tests**
 - Subcutaneous connective tissue implantation test**
 - Bone implantation test**
- 3. In-vivo usage test**
- 4. Clinical trial in humans**
- 5. Unrestricted human use**

Table 1. Recommended tests starting with in vitro tests using cell and tissue cultures, followed by in vivo, efficacy and biocompatibility tests and eventually a limited well controlled clinical trial are recommended before marketing a new material.

The author can state with certainty that the currently used methacrylate resin based sealers that will be discussed here have been tested rigorously following the above format of Table 1, with exception of the conduct of clinical prospective studies. They did undergo a "user evaluation" test, a clinical pilot study using a limited number of patients, however. There is a legitimate concern of the manufacturer, that a long term prospective study, and in endodontics one is ideally looking for at least 5-6 year post-operative follow-up data, the total time elapsed from initiation of the project until the final results are obtained, is counter productive. Frequently, improvements in materials and

changes in techniques are introduced after materials have appeared on the market and are based on clinical feedback from practitioners and data from researchers. So in reality useful data may become available when the profession uses these materials clinically and researchers conduct their tests and publish their findings, which ultimately may result in a better material and/or technique. Nevertheless the basic requirements for testing prior to marketing should be met first to exclude potential risks to patients.

Methacrylate resin based sealers

Methacrylate based resin sealers are relatively new in endodontics and are based on polymer chemistry technology, initially developed for adhesive restorative dentistry, albeit in modified formulations and viscosities as determined by the particular demands in endodontics. Attention will be focused on two systems:

1. EndoREZ (Ultradent Products Inc. South Jordan, UT) and
2. RealSeal (Sybron Dental Specialties, Orange CA),

Pentron Clinical Technologies (Wallingford, CT) was recently acquired by Sybron Dental Specialties, which includes the Resilon/Epiphany system which henceforth will now be marketed as RealSeal. As of this writing (August 2008), products such as SimpliFill (LightSpeed Technology Inc., San Antonio, TX), InnoEndo (Heraeus Kulzer, Armonk NJ), and Resinate (Obtura Spartan, Fenton MO) and Resilon/Epiphany are now all categorized under the name RealSeal.

EndoREZ

EndoREZ (ER) is a hydrophilic, two component (base and catalysts), dual curing self priming sealer. The formulation can be described as follows:

The EndoREZ Base contains:

- A bismuth compound as the radiopaque filler
- Small amount of other fillers
- Diurethane dimethacrylate
- Triethylene glycol dimethacrylate
- A peroxide initiator
- A photoinitiator (not CQ)

The EndoREZ Catalyst contains:

- A bismuth compound as the radiopaque filler
- Small amount of other fillers

Diurethane dimethacrylate
 Triethylene glycol dimethacrylate
 Tertiary amine

The sealer can be used with gutta-percha or with resin-coated gutta-percha, the latter with the objective to form a continuous adhesion (uniblock or monobloc) between all materials. Currently only the dual cure EndoREZ is being marketed.

The sealer is supplied in a double barrel auto mixing and delivery syringe and meets the basic requirements of an endodontic sealer (Pameijer and Zmener, 2006). The manufacturer recommends that after preparation the root canal walls should remain slightly moist to take maximum advantage of the hydrophilic properties of the sealer, thus allowing for resin tag penetration into the dentinal tubules and the formation of a hybrid layer with the collagen fiber network (Zmener et al 2008). However, too much water can cause water permeation during the polymerization process and results in the entrapment of water droplets in the sealer, which can result in bond disruption and an increase in leakage (Wong and Spencer 2005).

Delivery through the tiny opening and the hydraulics involved when using the NaviTips, produces a sealer free from air bubbles which coats the canal walls with an even layer.

The sealer is radiopaque and has favorable low viscosity properties. The latter plays a significant role in the handling properties and makes it very useful for placement in wide or narrow root canals, while it provides a good adaptation to the intricacies of the dentin walls (Tay et al 2005; Bergmans et al 2005). ER bonds well to root canal walls but not to gutta-percha, which constitutes a potential weakness, as a path for bacterial leakage may exist (Zmener and Pameijer 2007a). To address this issue and to establish a bond between the sealer and dentin as well as between the sealer and gutta-percha, the manufacturer recommend to use ER with a new brand of resin-coated gutta-percha cones (RCGP) cones (Ultradent Products Inc.). The combination of these materials establishes the so-called “monobloc” and is responsible for the superior sealing properties of the system.

It has been reported that the removal of the oxygen inhibition layer of the surface of the resin-coated gutta-percha (RCGP) cones during packaging may affect the bonding of methacrylate-based root sealers (Hiraishi N et al 2006).

The authors recorded a 5-fold increase in shear strength to RCGP cones when they were treated with Prime&Bond NT dual cure adhesive. As pointed out in a previous chapter (Zmener & Pameijer) the objective of the sealer is to establish a hermetic seal, rather than a high bond strength adhesion, i.e. optimum softness/hardness and a maximum seal.

However, an accelerator can be used for the RCGP cones, which serves a dual purpose. In the first place it accelerates the polymerization reaction of the ER (within 4-5 minutes) allowing for the immediate continuation of the restorative phase should the practitioner choose to do so, and secondly it promotes bonding of the ER to the RCGP cones, thus establishing a monobloc.

RealSeal (Resilon/Epiphany)

Resilon is composed of polymer based resin (Polycaprolactone), bioactive glass, bismuth oxide, barium sulfate and coloring agents. Epiphany contains a dual cure sealer, UDMA, PEGDMA, EBPADMA & BISGMA, barium-borosilicate, BaSO₄, Bi oxychloride, calcium hydroxide, photo initiators, and a thinning resin.

In addition the system comes with a self-etching primer. The premise behind the material is the formation of a “monobloc”, i.e. primer forms hybrid layer with dentin, which bonds to sealer, which in turn bonds to the Resilon core. As discussed previously for ER, the bondability of Resilon to methacrylate-based root canal sealers has also been questioned as the amount of dimethacrylate in the thermoplastic composite may not be optimum for chemical coupling (Tay et al 2006). When surface roughness was established, the micromechanical interlocking increased the mean bond strength significantly.

Several early publications reported on the biocompatibility and adhesiveness based on the hydrophilic properties of EndoREZ (Louw, Pameijer et al. 2001); (Becce and Pameijer 2001 & 2003). In the ensuing years a plethora of publications appeared, testing different MRBS and using a variety of techniques, which to a large extent have caused more controversy and confusion than that they helped answering the following basic questions:

1. Are resin-based sealers safe;
2. Can they be used successfully in patients;
3. Will they ultimately replace gutta-percha and conventional sealers and;
4. Will they last as long as conventional materials.

Leakage studies

Leakage of MRBS, whether coronal or apical, has been studied by numerous investigators, resulting in more contradictions and generating more questions than answers.

It is well established that selection of an appropriate sealer will influence the outcome of endodontic therapy (Spångberg 1981; Ørstavik et al 1987). For that reason many investigators have focused on this important aspect using techniques such as fluid filtration, dye penetration, and bacterial leakage tests. Frequently AH Plus or AH 26 are used as control materials. In one of the first published leakage tests using India ink, Zmener and Banegas (2004) reported no statistically significant difference between EndoREZ and AH Plus. Orucoglu et al (2005) using the fluid filtration method, reported that Diaket with cold lateral condensation leaked less apically than EndoREZ and AH Plus. However, da Silva Neto et al (2007) reported that AH Plus leaked less than EndoREZ and AH 26 when using a single cone technique. When compared to zinc oxide-eugenol, Adanir et al (2006) reported that methacrylate based resin sealers were found to be more effective in sealing root canals than zinc oxide-eugenol sealers. These authors also used the fluid filtration method. Using similar techniques Onay et al (2006) found that the apical seal of Epiphany and Resilon was not different from AH Plus and gutta-percha, AH Plus and Resilon and Epiphany and gutta-percha. In contrast Tunga and Bodrumlu (2006) concluded by means of a fluid-transport method that Epiphany and Resilon leaked significantly less ($p < 0.05$) than gutta-percha and AH 26. Stratton et al (2006) reached a similar conclusion comparing Resilon and gutta-percha and AH Plus. Furthermore, similar conclusions were drawn by Shipper et al (2004) and Maltezos et al (2006), by means of a bacterial leakage test; Epiphany and Resilon were superior to gutta-percha and various other sealers. On the other hand Pitout et al (2006) employing a bacterial leakage test, as well as a dye penetration method and Biggs et al (2006) did not observe a difference between Resilon and gutta-percha. Several authors have used the dye penetration technique to demonstrate that MRBS are superior to conventional materials. Gernhard et al (2007), Sevimay and Kalayci (2005), established more dye leakage for EndoREZ than for AH Plus and gutta-percha. Resilon as the main obturation material consistently resulted in less microleakage than gutta-percha at all 3 time intervals,

10 days, 1 and 3 month(s) (Aptekar and Ginnan 2006). An explanation for this difference between the two materials will be explained later and is based on the presence or absence of moisture of the root canal at the time of obturation.

To put leakage studies in context Oliver and Abbott (2001) conducted a study with the aim to determine if there was a correlation between apical dye penetration and clinical performance of root fillings. They tested the length of apical dye penetration using a vacuum technique in vitro in 116 human roots that had been root-filled at least 6 months prior to extraction. Endodontic treatment was classified as clinically successful or unsuccessful and results for these groups were compared using an analysis of variance and the Student's t-test. Positive and negative controls were also used to test the experimental system. The dye penetrated significantly further in unsuccessful cases although the raw data suggested little difference. Overall, dye penetrated in 99.5% of the specimens, which indicates that the presence of dye in a canal is a poor indicator as to whether a technique or material will succeed clinically. However, the extent of dye penetration may be related to the clinical outcome. The authors concluded that clinically placed root canal fillings do not provide an apical seal that prevents fluid penetration and therefore the outcome of treatment cannot be predicted based on the results of apical dye leakage studies. As early as 1993 Wu and Wesselink already reviewed the shortcomings of various tests that had been reported in the literature. However, dye leakage studies may be useful if one wants to determine the performance of a new material or technique by conducting comparative studies to existing systems.

As can be surmised from these publications, whether using a fluid filtration or bacterial leakage test or other tests, there is no general agreement as to whether there is reduced leakage or not when using methacrylate based resin sealers.

Toxicology studies - in vitro

One of the requirements of any dental material used in humans is that it has to be biocompatible. Cytotoxicity studies have been conducted in vitro by numerous investigators using cell cultures and in vivo in laboratory animals. As in the leakage studies, the results between investigators are contradictory. Huang et al (2001) showed that the elution compounds from methacrylate based resin sealers, zinc oxide-eugenol and calcium hydroxide-based sealers

were cytotoxic to primary human PDL cultures and V79 cells, with calcium hydroxide being the least toxic. Also according to Huang and co-workers (2002), the highest level of DNA damage was induced by epoxy resin-based sealers, in this case Topseal, AH 26 and AH Plus. In an independent study, Koulaouzidou et al (1998) demonstrated similar results, AH 26 had a severe cytotoxic effect, while Topseal and AH Plus were markedly lower. These findings are somewhat surprising as the basic formulation of AH 26 and Topseal are the same. This was further supported by Bouillaguet et al (2006), who reported that: "Most materials pose significant cytotoxic risks and that cytotoxicity generally decreased with time". At 72h, GuttaFlow became significantly less toxic than AH Plus, Epiphany sealer, and Resilon." Other authors, Key et al. (2006) determined Epiphany to be less toxic than Grossman's sealer while Epiphany was more cytotoxic than Sealapex after 1 hour, but less after 24 hours. Epiphany was more cytotoxic than conventional materials. In a more recent publication by Eldeniz et al (2007) similar findings were reported. According to Lodiene et al (2008) the multi-methacrylate resin-based (Epiphany) root canal sealer was significantly more toxic to L-929 cells than the silicone-based RoekoSeal and the single methacrylate-based EndoREZ root canal sealers. AH Plus showed intermediate toxicity.

Based on the findings of the above authors it appears that not one sealer is universally accepted as being non-toxic. Furthermore, there is a multitude of differences of opinion between the various authors. This makes selection of one particular sealer with favorable properties difficult, if not impossible. This also necessitates that a careful and critical analysis of the various in vitro research methodologies is in order. It is important that the results of the various techniques are correlated with the clinical performance of the same material(s). As previously mentioned, Oliver and Abbott (2001) concluded that clinical performance and in vitro data frequently contradict each other.

Toxicology studies in vivo

The early studies that supported the launch of EndoREZ were conducted by Louw et al (2001), and Becce and Pameijer (2003) who reported that EndoREZ was mildly irritating, yet within acceptable standards (1.5° is the acceptable limit). Further evidence of biocompatibility was published in by Zmener (2004a) and Zmener, Pameijer and Banegas (2005a).

In other related studies (Pameijer 2002), both ER and Epiphany/Resilon

reacted more favorable than the control AH Plus. Pre-operative and post-operative X-rays were made and root canal treatment was carried out according to a standardized protocol using rubber dam. The materials were inserted according to the manufacturer's instructions and histological observations were made at various time periods, 30 days to determine an early reaction and from 3 -6 months post-treatment for long-term reactions.

The results can be summarized as follows. Ten EndoREZ root canal treated teeth scored a mean inflammatory reaction after 26 days of 1.5°. After 90 days, out of 21 root fills, 4 had extruded sealer with an inflammatory mean of 0.8°. Good apical adaptation scored a lower mean inflammation of 0.4°. No roots in either time period demonstrated bone resorption. The control sealer (AH Plus) had a mean inflammatory reaction of 1.3° after 26 days and 1.0° after 90 days. Epiphany, tested according to the same protocol, scored after 120 days (13 teeth) a mean inflammatory reaction of all root fills of 1.2°, while the inflammation of bone was 0.4°. Control teeth (AH Plus) had a mean inflammatory reaction of 2°, and a bone inflammation of 1° (Pameijer 2002).

Both materials clearly reacted more favorable than the control AH Plus. A study by Zmener (2004a) confirmed an initial irritation reaction after 30 days, which subsided over time. Silicone tubes filled with the sealer were implanted in the subcutaneous connective tissue of rats and observed at 10, 30, 90 and 120 days. A granulomatous tissue containing numerous polymorphonuclear leukocytes, lymphocytes and plasmocytes as well as macrophages and multinucleated giant cells with engulfed material in their cytoplasm was initially observed in contact with the sealer. Some fibroblasts and newly formed vessels also were observed. The severity of the reaction decreased with time. Connective tissue healing was observed at the end of the experiment, even though some samples exhibited few persistent inflammatory cells. Elemental analysis of the surrounding tissues revealed the presence of heavy components of EndoREZ in all observation periods. The results of the study showed that the sealer seems to be well tolerated by the subcutaneous connective tissue of the rat.

In 2005(b), Zmener et al conducted a histologic and histometric study in which silicone tubes filled with EndoREZ were implanted in the tibias of rats during a period of 10 and 60 days. At the 10-day observation period, the number of inflammatory cells that was in contact with the sealer was signifi-

cantly higher. After 60 days, the initial inflammatory reaction was resolved and newly formed healthy bone was observed surrounding the implants. In contrast Sousa et al (2006) tested AH Plus, EndoREZ and Epiphany in guinea pigs over 4 and 12 weeks. They reported a severe reaction for EndoREZ, while AH Plus was also severe after 4 weeks and moderate after 12 weeks. Only Epiphany demonstrated intra-osseous biocompatibility.

Examples of sealer/point biocompatibility testing

The periapical tissues can react to the presence of a sealer and/or point in several ways:

1. It can cause an inflammatory reaction;
2. It can be regarded as a foreign body and be encapsulated;
3. A sealer can be present without causing inflammatory reactions and is not encapsulated;
4. The sealer can be resorbed over time, with or without an inflammatory reaction.

A material causing an inflammatory reaction is not necessarily bad and the outcome will depend on the intensity and duration of the inflammatory process. If over a relatively short period of time (up to 30 days) a mild inflammation is present and it has diminished over time, a material with otherwise favorable properties can be considered acceptable (Zmener 2004a). Elution of components has been recognized by Ferracane & Condon (1990) and the inflammatory process as a result of this is the body's response to irritation. Fibrous encapsulation is the body's response to isolate an otherwise biocompatible material. Furthermore, a material, usually small size particles, can be present in periapical tissues, cause no inflammation and be present without encapsulation.

Figure 1 is a representative radiograph of experimental sealers in the four central incisors after 83 days. After 113 days two reactions were observed for two different experimental sealers. Figure 2 is an example of extrusion of the sealer into periapical tissues. The sealer particles are not encapsulated and no inflammatory reaction was observed. The periapical tissues to the other sealer reacted very differently. Also after 113 days the histological features of the apical area (Figure. 3) showed slight extrusion into the periapical tissues. A fibrous encapsulation of the material can be observed, however, without the presence of inflammatory cells (Magnification 64x, H&E stain). Examples of resorption of a sealer (EndoREZ) are presented in the section "Clinical



Figure 1. 113 day postoperative endodontic radiograph of 4 central incisors. Some extrusion of sealer into the periapical tissues can be seen.



Figure 2. Histological reaction of an experimental sealer (black) extruded into periapical tissues. The white space was occupied by the Resilon point and disappeared during processing for histology. Ingrowth of connective tissue into apical root space adjacent to the point can be observed. In spite of the presence of numerous sealer particles beyond the apex, no inflammatory cells were present. (Magnification 64x, H&E stain).

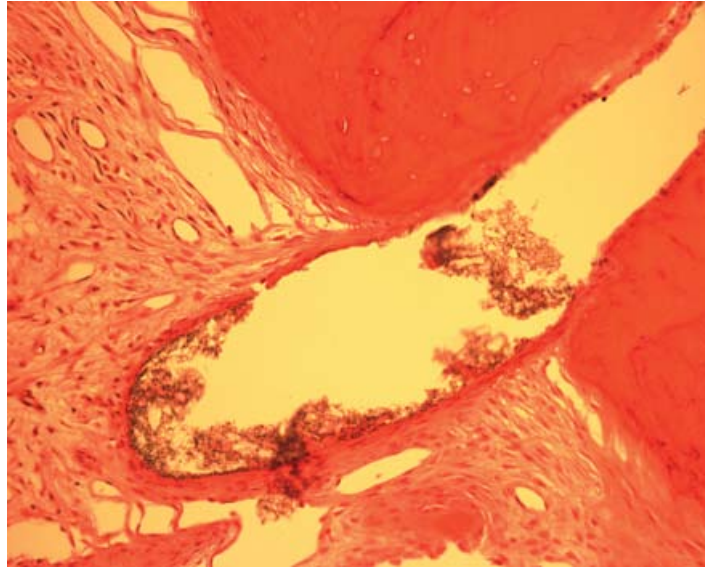


Figure 3. 113 days post-endodontic treatment. The sealer (dark brown) is surrounded by a fibrous capsule in the periodontal ligament space. No inflammatory reaction is present as a result of the extruded material, point and sealer. (H&E stain, magnification 200x).

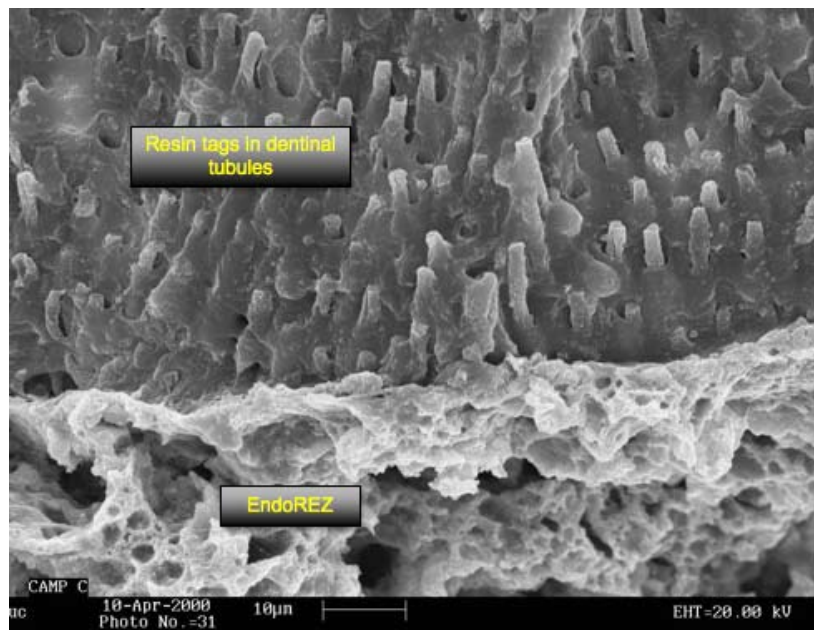


Figure 4. Moist condition of the dentin when using EndoREZ as a sealer allows the hydrophilic sealer to penetrate into the dentinal tubules to great length. The resin tags fractured at the interface of the fracture plane during specimen preparation for scanning electron microscopy. (From: Becce, C and Pameijer C.H. SEM study of a new Endodontic Root Canal Sealer. J Dent Res AADR Issue 79, Abstract #866, 2001).

Cases". Controversy regarding the reaction of materials exposed to certain test conditions is not new. With the introduction of glass ionomer cements, tissue culture tests reported toxicity when they were placed in direct contact with the medium (Hume and Mount 1988; Doherty 1991; Schedle et al 1998). However, after elution of irritating chemicals, for glass ionomer cements F, the reaction subsided over time. Correlating clinical performance to cell culture tests is not very reliable and frequently these tests have been contradicted by clinical success.

Based on in vitro and in vivo studies (Louw et al 2001; Becce and Pameijer 2003; Pameijer 2002), EndoREZ was determined to be biocompatible and introduced to the dental profession.

Discussion

The contradictory data of several of the leakage studies can be explained and are most likely the result of the ingrained belief in endodontics that root canals after a final rinse need to be dried thoroughly. Many articles that were reviewed stated in materials and methods: "the canals were dried", notably Biggs et al (2006) and Kardon et al (2003). Several articles did not specify in sufficient detail the condition of the root canal. Based on established endodontic techniques we can speculate with a fair amount of certainty that the canals were thoroughly dried. This thorough drying has created a hydrophobic environment while a hydrophilic material is being used. Field Emission Scanning Electron Microscopy (FESEM) and scanning electron microscopy (SEM), subsequently Figures 4 and 5, are excellent examples of the potential of EndoREZ when proper moist conditions are adhered to and the recommended insertion technique is followed (Figure 4) and what happens when the canal is dried according to well established endodontic techniques, using paper points until the canal is thoroughly dry (Figure 5). The concept of moist bonding, for many years and even today a difficult to explain condition in restorative dentistry, apparently has not exempted endodontics from the same misinterpretations and misconceptions. For methacrylate resin based sealers, whether EndoREZ or Epiphany, to establish a proper seal, the dentin needs to be moist to allow for the penetration of resin tags into the opened dentinal tubules, thus taking advantage of the hydrophilicity of these materials, whether bonding agent or sealer. In the case of EndoREZ this allows for deep penetration of resin tags, up to 500 - 1000 μm and more and for

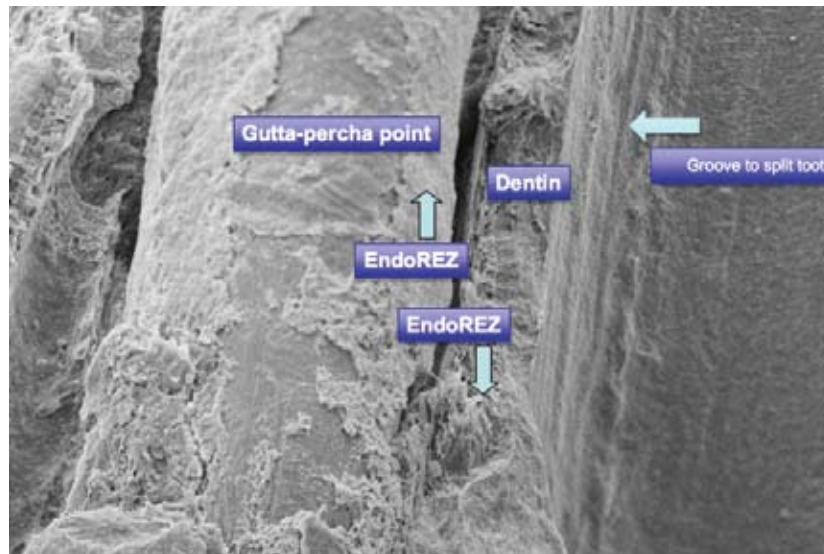


Figure 5. Scanning electron micrograph of a gutta-percha point partially covered with EndoREZ. The space between point and adjacent dentin wall is filled with EndoRez, however, no penetration into the dentinal tubules was observed. This is the result of over-drying. (From: Becce, C and Pameijer C.H. SEM study of a new Endodontic Root Canal Sealer. J Dent Res AADR Issue 79, Abstract #866, 2001).

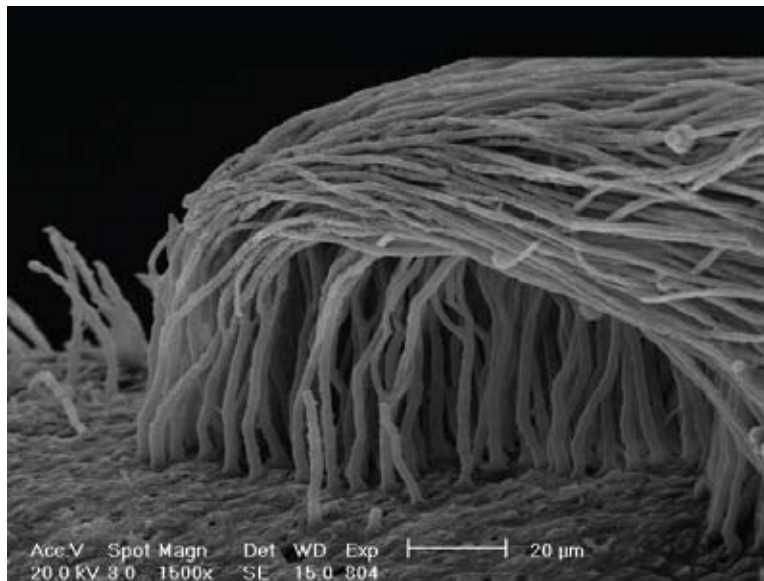


Figure 6. FESEM micrograph of EndoREZ tags extruding from the root filling material extending distances of at least 400–600 μm. The foreground shows fractured resin tags (due to polymerization shrinkage) or resin tags that have partially entered the dentinal tubules. (Courtesy Lambrechts et al.) (Reprinted with permission of www.incedce.com. Methacrylate Based resin Endodontic Sealers: A Paradigm Shift in Endodontics? ENDO0710DE;2008:1–11.)

Epiphany bonding of the adhesive by means of a hybrid layer and resin tags into the dentin. Unlike restorative dentistry, where a reflection of light from the moisture on the surface of a preparation can be visualized, in a root canal this is not possible, making clinical judgment more difficult.

In a study by Zmener et al (2008) four scenarios of dentin wetness/dryness were tested for apical and coronal dye leakage. In Group 1, 95% ethanol was used followed by paper points to dry the canals. In Group 2 the canals were blot dried with several paper points. In Group 3 a luer vacuum adaptor with low vacuum for 5 s followed by one paper point for only 1-2s was used. In Group 4 the root canal remained flooded and no effort was made to remove excess distilled water. It was theorized that perhaps the hydrophilic properties of EndoREZ with the scenario in Group 4 would displace excess water. Positive and negative controls were also tested. Dye leakage as determined by methylene blue demonstrated that EndoREZ and Epiphany/Resilon in Groups 2 and 3 exhibited significantly less coronal and apical leakage ($p < 0.05$) than Groups 1 and 4. The method with a low vacuum luer adaptor and 1-2s paper point drying (Group 3) scored the lowest leakage. There was no statistically significant difference between EndoREZ and Epiphany/Resilon. Another clinical technique to maintain moist dentin is to make sure, when excess water (or EDTA, Saline or Consepsis) is removed with paper points, that the last paper point shows a least 3 mm of moisture.

One of the reasons that Epiphany/ Resilon has perhaps scored better results in leakage studies is based on the fact that the Epiphany/Resilon system uses a self-etching dentin bonding agent which may make the moisture condition of root dentin less critical. This statement can be underscored by means of an analysis of a study that reported less leakage for EndoREZ when a dual-cured two-step self-etch adhesive was used in combination with EndoREZ. (Gillespie et al 2006). The authors reported statistically significant differences in filling techniques. EndoREZ alone exhibited significantly higher overall leakage, while no difference was found between AH Plus and the EndoREZ modified technique using a dentin bonding agent. The above findings and those in other studies that use fluid filtration, dye leakage or bacterial leakage methods that state in materials and methods: "The canals were dried with paper points", have generated data with questionable validity as the methodology did not allow for maximum efficacy of the hydrophilic properties of ER. Work by Lambrechts and co-workers (2006) using FESEM, demonstrated

convincingly that the hydrophilic penetration potential of EndoREZ when applied to moist dentin is exemplary. To demonstrate this they placed root canal treated teeth using the ER/gutta-percha technique in HCl for 30 hours followed by 2% NaOCl for 10 minutes and a distilled water rinse to dissolve the dentin. Figure 6 is a FESEM micrograph showing resin tag bundles protruding from the root canal filling surface and extending anywhere from 500-1000 μm or more. Due to their length and weight these bundles bent parallel to the root filling surface.

In view of the ability to penetrate the dentinal tubules to the extent as shown in the study by Lambrechts et al, a bonding agent in conjunction with EndoREZ does not seem to offer any benefits, after all, EndoREZ is a self priming sealer. It may actually make it worse as the sealer can only bond to the resin of the bonding agent without resin tag bundle formations as shown above. In addition several extra steps are required. In contrast, inserting EndoREZ with a gutta-percha point in a dried root canal produces the worst possible adaptation of the sealer to dentin (Fig. 5). The hydrophilic resin will simply not be able to penetrate the dried dentinal tubules, hence setting the stage for increased leakage which is operator induced and not related to the properties of the sealer itself.

Oxygen inhibited layer

When conducting biocompatibility studies by means of subcutaneous implantation or intra-osseous bone implants, specimen preparation of methacrylate based resin sealers may result in the formation of an "oxygen inhibited layer", and which will depend on the method of sample preparation. The presence of an oxygen inhibited layer plays a significant role in the outcome of tissue reactions, since resin, whether chemical, light or dual cured, when in contact with air does not polymerize on its surface. This surface layer contains unreacted monomers, which are highly toxic. (This is not to say that polymerized sealers cannot cause irritation.) Conversion of monomer in a typical polymerization reaction is at best less than 70% (Kidal and Ruyter 1994). As a consequence it is of importance to thoroughly flush the root canal with EDTA after the use of NaOCL followed by sterile saline or 2% chlorhexidine (Consepsis, Ultradent Products Inc.), as oxygen left behind from the NaOCL inhibits polymerization, thus forming an oxygen inhibited layer.

A final rinse in saline is optional and the manufacturer of EndoREZ in the

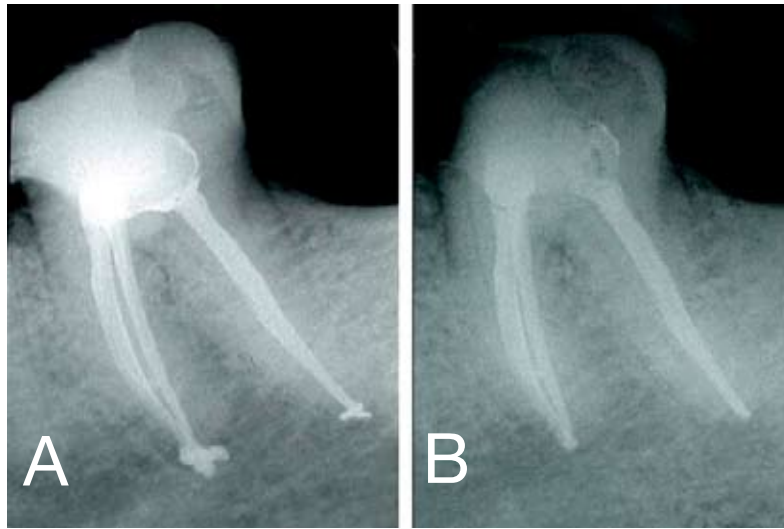


Figure 7. Immediate postoperative radiograph of root canal treated lower molar filled with EndoREZ and gutta-percha (left). Five year postoperative view (right). Note successful outcome in spite of the fact that no coronal restoration was present. (Reprinted with permission from Elsevier. Figure 1 from: Zmener O and Pameijer CH. Clinical and radiographical evaluation of a resin-based root canal sealer: A 5-year follow-up. *J Endod* 2007;33:676-679)

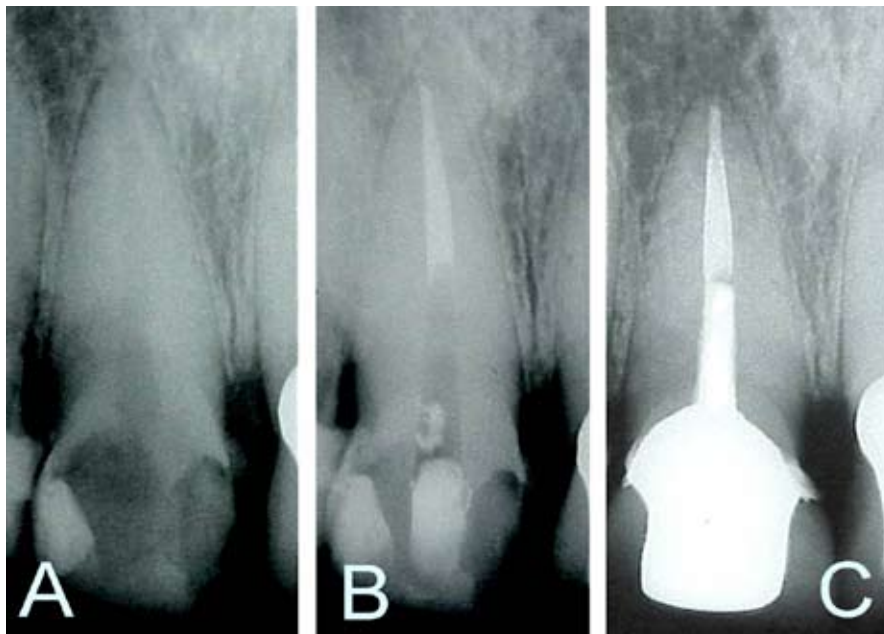


Figure 8A. Upper incisor with pulpal involvement due to leaking anterior restoration. B. Immediate postoperative view. C. After 5 years, the incisor, restored with a post and core and porcelain fused to metal is functional and completely asymptomatic. (Courtesy Dr. Osvaldo Zmener)

DFU, recommends EDTA as a final rinse. Secondly, further research has also shown that a thorough flushing with EDTA is apparently sufficient to neutralize the NaOCL and that as a result the polymerization of the resin is not affected. Therefore no oxygen layer is formed. Further research will be reported in a separate chapter by Pameijer and Zmener entitled: “The effect of irrigation protocol on the polymerization of resin-based sealers – significance of oxygen inhibition”.

Clinical evidence

Unfortunately a conclusive opinion derived from prospective or retrospective clinical studies is difficult to make as only a few long term clinical studies on EndoREZ have been reported (Zmener & Pameijer 2004b; Zmener & Pameijer 2007b) and one intermediate clinical study on Epiphany/Resilon (Debelian 2006). A long term clinical study on Resilon/Epiphany is reported in this monograph by Barnett and Debelian.

In a retrospective study on 180 patients (Zmener & Pameijer 2004), a total of 295 root canals were treated with laterally condensed gutta-percha cones in conjunction with EndoREZ. Root canal therapy was carried out in one visit using standardized techniques. The results were assessed clinically and radiographically 14 to 24 months postoperatively and a comparison to baseline radiographs was made. Parameters for success were based on absence of clinical symptoms, a normal or slightly widened periodontal ligament and reduction of periapical radiolucencies with an absence of pain in patients that had pre-existing lesions associated with pain. After 2 years the overall success rate was 91.03%. In a subsequent 5-year follow-up (Zmener & Pameijer 2007) using the same pool of patients, 129 responded to a recall request. Root canals had been adequately filled to the working length in 92 teeth (76.66%) and short in 13 (10.83%). Fifteen cases (12.50%), filled flush at the initiation of the experiment, showed slight resorption of the filling material at the apex within the lumen of the root canal. Of the 10 roots with extrusion, none had radiographic evidence of sealer in the periradicular tissues after 5 years. All patients were free of clinical symptoms. A life table analysis revealed a cumulative probability of success of 86.3% at the 5-year recall with a 95% confidence interval of 79.7 – 91.0. This percentage compares favorably with what has been reported in the literature (Ørstavik et al 1987; Friedman et al 1995; Huumonen et al 2003) using other sealers.

Immediate and 5-year post-operative radiographs of a molar treated in one

visit using EndoREZ and gutta-percha is presented in Figure 7A & B. In spite of the fact that the tooth had not been restored the endodontic outcome was evaluated as successful after 5 years. A further example, also from the 5-year study is shown in the following three radiographs. Pre-operative (Figure 8A) and immediate post-operative view (8B), and a 5 year follow-up (8C) on tooth #8 filled with EndoREZ and gutta-percha. Extruded sealer has been resorbed during the interim and new bone deposited. The patient has been free of symptoms since completion of treatment.

The results of the use of Resilon/Epiphany in a 2-year prospective study have been reported by Debelian (2006). A total of 67 vital teeth were treated in one visit and 53 necrotic pulps in 2 visits (n=120). After 2 years 108 cases were evaluated by 3 evaluators and the mean of the Periapical Index Scores (PAI) was calculated. When the PAI 1 and 2 were combined (PAI1=healed; PAI2=in the process of healing) success after 24 months was 91.6%. It is of interest to note that the results reported by Zmener and Pameijer (2004) after 24 months using EndoREZ were essentially the same, i.e. 91.3%. It appears that after 2 years the materials performed similarly in spite of different clinical protocols and different operators.

Radiographic follow-up of examples of Epiphany/Resilon, with evaluations after 12 and 24 months can be seen in Figure 9. Radiographs were scored by independent evaluators using a PAI score. Both cases had a PAI of 1, were completely healed and symptom free.

Regardless, more clinical studies are needed. One prospective study using ER and resin coated gutta-percha points on a population of 100-150 patients, including controls, is in its early stages and it will be many years before data is generated and then several more years before it is published.



Figure 9A. Preoperative radiograph of a periapical lesion on lower molar. 2B. Immediately postoperative view after filling with Epiphany and Resilon. 2C. Six months postoperative X-ray. The lesion has healed and the periapical area appears normal. (Courtesy of Dr. Fred Barnett)

Although only a few clinical studies are available reporting data up to 5 year postoperatively, in reality MRBS have been used much longer, perhaps for as long as 10 years. Empirical feed back and positive data from retrospective studies support the use of MRBS in endodontics and success has reached a 10 year mark.

Do resin based sealers reinforce roots?

A comparison of intraradicular dentin bond strength by means of a push-out test between Epiphany/Resilon and gutta-percha/Kerr Pulp canal Sealer EWT demonstrated that the mean bond strength of the Epiphany/Resilon group was significantly higher ($p < 0.05$) (Skidmore et al 2006). Teixeira et al (2004) also reported higher fracture loads for a resin based sealer than gutta-percha filled teeth, however, no statistically significant difference was established. The lack of reinforcement was further refuted by Ungor et al (2006) testing dentin root cylinders with AH Plus + gutta-percha, AH Plus + Resilon, Epiphany + Resilon, Epiphany + gutta-percha and gutta-percha alone. They concluded that the Epiphany-Resilon combination was not superior to that of the AH Plus-gutta-percha. Using a similar dentin cylinder protocol to optimize standardization Grande et al (2007) arrived at a similar conclusion; the currently available endodontic filling materials and their recommended adhesive procedures are not able to influence the mechanical properties of root canal dentin. The flexural properties of Resilon and gutta-percha are too low to reinforce roots. Although supportive of the Grande et al (2007) results, the data of Gesi et al (2005) cannot be accepted as entirely valid since they described in their materials and methods, as was mentioned before about the authors of leakage studies: "The debrided root canals were dried with multiple paper points". Also for Epiphany/Resilon the manufacturer's instructions for use clearly recommend the dentin to be moist. Additional critique has been levelled at the choice of the push-through test, variation in specimen thickness, analysis of the data, etc. (Leinfelder 2007).

Summary.

The consensus in the literature is that MRBS and gutta-percha and/or Resilon do not reinforce the root.

Retreatment of methacrylate based resin sealers

The possibility in case of a failure to be able to retreat root canals filled with methacrylate based resin sealers, or with any other sealer for that matter, is one of the requirements of a root canal sealer.

According to de Oliveira et al (2006) and Ezzie and co-workers (2006) Epiphany/Resilon could be removed faster and demonstrated less residual filling material when K3 files (de Oliveira et al 2006), or ProFile 0.06 combined with heat and chloroform (Ezzie et al 2006) was used compared to gutta-percha and AH Plus. Zmener et al (2005a) investigated the efficacy of automated instrumentation in removing resin based and zinc-oxide and eugenol endodontic sealers when retreating root canals. This study demonstrated that straight canals obturated with gutta-percha/sealer may be negotiated with engine driven stainless steel AET instruments and their efficacy may be attributed to the cutting efficiency and stiffness of the shaping and apical files. The engine-driven shaping files have a flute design with sharp cutting edges, resulting in efficient cutting of the gutta-percha, aided by the softening of the material caused by frictional heat.

However, as per design of the study, each individual instrument was discarded after instrumentation of two teeth, thus reducing the possibility of instrument breakage substantially. This recommendation had been reported by Tronstad and Niemczyc (1986), who emphasized that the use of new instruments is strongly recommended when retreating teeth. It should be emphasized, however, that only teeth with straight canals were used and consequently no conclusions can be drawn about the retreatment efficacy of AET instruments in curved root canals. Another limitation of this study was that the amount of apically extruded debris was not measured. Extrusion of debris may result in a post-operative flare-up, as well as periapical failure. The biological implications of retreatment of a tooth warrant further clinical studies. To test the in vitro results in clinical practice a 4-year retrospective study in 67 patients was conducted and the outcome of non-surgical endodontic retreatment was studied clinically and radiographically (Zmener and Pameijer 2008, unpublished data). After removal of the original obturating material, the root canals were re-instrumented and filled with gutta-percha with EndoREZ as the sealer. Of the 67 patients who were initially seen for retreatment, 52 (77.61%) responded to the request for a recall. Retreatment was judged successful when no clinical symptoms were present, when preexist-

ing periradicular radiolucent areas were reduced or had been totally resolved, and when a normal or slightly widened periodontal ligament was observed. Tabulation of the data showed that the overall success rate was 84.61%. Of 28 teeth with preoperative periapical pathosis, healing was observed in twenty two cases (78.57%) whereas six (21.42%) were judged failures. Twenty two teeth of 24 (91.66%) with no preoperative periapical radiolucencies were successful. Nineteen of these (79.16%) revealed no radiographic changes whereas in three cases (12.5%) the PDL showed a slight widening. The remaining two cases (8.33%) were judged failures. It was concluded that while clinical success of endodontic retreatments depends in part on the total elimination of factors that caused the failure of the primary endodontic therapy, the data suggested that the use of AET instruments for gutta-percha/sealer removal, followed by root canal obturation with gutta-percha and a methacrylate-based sealer can be regarded as an acceptable endodontic regimen for retreatment based to the results after 4 years.

These results after 4-years exhibit a strong correlation with data of the 5-year follow-up study reported by Zmener and Pameijer in 2007b, in which ER was used for the first time.

Summary

Based on the limited data available in the literature and the studies reported above, MRBS appear an appropriate choice when retreatment of failed endodontic treatment is indicated.

Discussion and Future expectations

Is it possible to make an assessment of the current status of methacrylate based resin sealers through interpretation of the available literature and can it be done with reasonable confidence? If we were to depend singly on in vitro tests, such as leakage tests, then the contradictory reports would make it very difficult to come up with a strong recommendation one way or another. However, if we exclude all experiments that have a flawed specimen preparation technique, in particular the drying of dentin, then methacrylate based resin sealers appear to perform as conventional root canal sealers.

Obturation techniques and choice of endodontic sealer are determining factors. De Moor and Hommez (2002) reported that coronal leakage with AH 26 was significantly greater during the first 4 months for the Thermafil sys-

tem as compared to the three other obturation techniques; coronal leakage was significantly greater at all time periods for the Soft-Core system.

In general the biocompatibility studies on methacrylate based resin sealers are favorable and have demonstrated that after an initial elution of chemical components that cause irritation (inflammation), a reduction over time reaches acceptable levels. Acceptable levels can be interpreted as levels the body's defense mechanisms can cope with, without causing adverse effects.

The percentages of clinical success that have been reported for both EndoREZ and Epiphany/Resilon are in agreement with previous reports in which conventional sealers and gutta-percha were used (Ørstavik et al (1987); Ausburger and Peters 1990; Friedman et al 1995).

In vitro and in vivo tests are helpful and point us in the right direction. Tests in sub human primates and the results from histological analysis provide us with in depth knowledge concerning the biological behavior of materials. The reliability of these tests and attempts to correlate their data with reactions in humans has been questioned by some authors (Costa et al 2000; Park and Kim 1997). However, a most relevant study by Murray and Garcia-Godoy (2007) established a very strong correlation. The authors tested the accuracy of pre-clinical screening with respect to predicting human clinical response according to the following protocol. One hundred and six class V cavities were prepared in human and non-human primate teeth. The teeth were restored with calcium hydroxide and amalgam, zinc oxide –eugenol or a resin modified glass ionomer. The teeth were extracted after 10-163 days and processed for histological analysis. Reactionary dentin formation was measured and pulp inflammation scored according to the ISO 10993 and 7405 guidelines (International Standards Organization 1993). No statistical differences were observed between human and sub- human primates for amount of reactionary dentin and inflammatory cells. One can therefore extrapolate from the data of the sub-human primate studies reported earlier (Louw et al 2001; Becce and Pameijer 2001; Pameijer 2002) that, since EndoREZ and Epiphany are well tolerated by periapical tissues in sub human primates, they therefore by extension, can be accepted as biocompatible in humans. Extensive use by the dental profession (for almost 10 years now) has proven this to be true.

Future expectations

It is anticipated that the methacrylate based resin sealers will continue to improve their appeal to the dental profession. Technique modifications and new techniques will continue to be developed and new sealers, currently under development, will appear on the market within a few years. A recently developed technique recommends harpooning of catalyst coated accessory cones after placement of the master cone into the sealer, offers several advantages. It accelerates the setting reaction and reduces the amount of sealer, thus reducing the polymerization shrinkage; consequently a reduction of leakage can be accomplished. Since the accessory cones are placed after the master cone has been seated, there is no risk pushing catalyst beyond the apex potentially causing damage to the periradicular tissues. (See: Step-by-step clinical technique using the EndoREZ system). That bonding in endodontics is gaining recognition is reflected in the following statement by Mounce (2007): "Given the long-term trends in dentistry there can be little, if any, doubt that the future of endodontics is bonded. The goal of being able to bond a canal from the minor constriction to the canal orifice to the occlusal surface is a desirable one."

On the challenging side of the positive in vitro and in vivo studies and clinical successes are publications that cannot be ignored and which underscore the complexity of chemical compositions and their biological interaction of currently available dental materials. Material composition appears to be a critical factor (Schweikl et al 2006; Schweikl et al 2007). "It has been established that the comonomer triethylene glycol dimethacrylate (TEGDMA) causes gene mutations in vitro. Formation of micronuclei is indicative of chromosomal damage and the induction of DNA strand breaks detected with monomers like TEGDMA and 2-hydroxyethyl methacrylate (HEMA). New findings indicate that increased oxidative stress results in an impairment of the cellular pro- and anti-oxidant redox balance caused by monomers. Monomers reduced the levels of the natural radical scavenger glutathione (GSH), which protects cell structures from damage caused by reactive oxygen species (ROS). Depletion of the intracellular GSH pool may then significantly contribute to cytotoxicity, because a related increase in ROS levels can activate pathways leading to apoptosis." It should be noted that neither EndoREZ nor Epiphany contain the above mentioned components.

It appears after a thorough review of the available data that methacrylate based resin sealers are here to stay. More long-term data are needed, however, to determine whether they eventually will replace conventional sealers or will be used in parallel as an alternative choice when filling root canals.

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THE ENDO - EZE AET SYSTEM - ROOT CANAL PREPARATION USING ANATOMIC ENDODONTIC TECHNOLOGY

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INTRODUCTION

The main objective of root canal therapy is thorough shaping and cleaning of all pulp spaces and its complete obturation with an inert filling material (European Society of Endodontology 2006). Although successful endodontic therapy depends on many factors, one of the most important steps in any root canal treatment is canal preparation. This is an essential step because proper preparation determines the efficacy of all subsequent procedures. Root preparation includes mechanical debridement, creation of space for delivery of medicaments, and the creation of optimal canal geometries for adequate obturation (Peters 2004). The thorough removal of debris by means of mechanical instrumentation is one of the primary objectives in endodontics and aimed at accomplishing the total elimination of remaining pulp tissue and microorganisms from the root canal system (European Society of Endodontology 2006). A major cause of endodontic failure is the inability to locate, debride, or obturate properly all canals of the root canals (Vertucci 2005). Together with diagnosis and treatment planning, a better knowledge of the root canal system and its frequent variations is an absolute necessity for a successful root canal treatment (Friedman 2002, Plotino 2008, Somma 2008). A further aim of root canal preparation is to achieve a progressive and uniform conical shape within the canal. However, this may not always be possible in canals that do not have a circular morphology. A cone-shape with a circular base is not the most common anatomical configuration in radicular canals, which are more laminar than circular, especially in the coronal and

middle third (Kerekes & Tronstad 1977a, 1977b, 1977c, Wu et al. 2000, Bellucci & Perrini 2002, Plotino et al. 2008c). On the basis of early studies (Hess 1921, Hess 1925 and Kraus 1969), Latrou (1980) classified root canals based on their cross-sectional shape as: laminar or tubular. Laminar canals can be further divided into semilunar, or straight, while tubular canals may be circular, triangular or oval. Recently, the cross-sectional shape of a root canal has been classified as round, oval, long oval, flattened or irregular (Jou et al. 2004). The authors defined oval as a canal having a maximum diameter of up to two times greater than the minimum diameter and long oval as a canal having a maximum diameter of two to four times greater than the minimum diameter. Recent studies reported a high prevalence of oval and long oval root canals in human teeth, even at an apical level (Mauger et al. 1998, Gani & Visvisian 1999, Wu et al. 2000, Plotino et al. 2008c). The basic concepts of the Anatomic Endodontic Technology (AET) are founded on the aforementioned anatomical observations (Riitano 2005). Since its first description by Talbot (1880), and subsequent '3-tempi' (three-step) technique (Riitano 1976), crown-down shaping with tapered instruments has become an accepted and rational norm in endodontic practice (Marshall & Pappin 1980, Scianamblo 1993). In recent years, the interest in NiTi rotary instruments has grown, representing a revolution in endodontic therapy (Thompson 2000). The rotating movement of these instruments, their super-elasticity and self-centering properties result in a non-selective circular cutting action along the walls of the root canal (Peters 2004). Therefore, rather than creating an anatomical enlargement, the increased taper realizes a canal that has the same shape as the instrument, resulting in a cone-shaped enlargement with a circular base (Wu & Wesselink 2001, Barbizam et al. 2002, Rodig et al. 2002, Weiger et al. 2002, Wu et al. 2003, Grande et al. 2007a). This shape, however, is not the most common in radicular canals, which are more laminar rather than circular, while the area where canals tend to be more circular is the apical third, that is the last 3-4 mm before the CD-junction (Kerekes & Tronstad 1977a, 1977b, 1977c, Wu et al. 2000, Bellucci & Perrini 2002, Plotino et al. 2008c). For this reason, the concept of producing predetermined, conical preparations in oval canals is flawed, with areas of the canal being at risk of over-enlargement and others sites being untouched (Wu & Wesselink 2001, Baroni Barbizam et al. 2002, Rodig et al. 2002, Weiger et al. 2002, Wu et al. 2003, Grande et al. 2007a). Incomplete cleaning, shaping and obturation of the entire root canal space may be a reason of treatment failure. Anatomical

variability of the teeth is often a complicating factor in root canal treatment. The buccal and lingual extensions of the irregular oval root canals represent difficult areas for instrumentation and obturation (Wu & Wesselink 2001, Wu et al. 2001). It seems questionable whether flexible NiTi instruments allow controlled and complete preparation of such extensions (Hulsmann et al. 2005). In fact, in comparative studies of preparation of oval root canals, the middle and coronal cross-sections frequently showed circular bulges, whereas the buccal and lingual extensions of the oval root canals often remained unprepared (Wu & Wesselink 2001, Baroni Barbizam et al. 2002, Rodig et al. 2002, Weiger et al. 2002, Wu et al. 2003, Grande et al. 2007a). Furthermore, the use with a light pressure/withdraw motion (pecking) of nickel-titanium, rotary instruments maintain centered in the root canal during rotation and generally tend to form round preparations in most oval-shaped canals (Short et al. 1997, Weiger et al. 2002). This would explain that the polar recesses located at the coronal and middle thirds of oval canals are more prone to be out of reach of Ni-Ti rotary instruments. The great disparity between bucco-lingual and mesio-distal dimensions and taper determines that many canals are of an oval shape (Kerekes & Tronstad 1977a, 1977b, 1977c, Wu et al. 2000, Bellucci & Perrini 2002, Plotino et al. 2008c), and it may be difficult to enlarge them in all dimensions by traditional methods. After preparation, uninstrumented recesses may be left in many oval canals, regardless of the instrumentation technique, thus leaving a smear layer, debris and unprepared root canal walls behind (Wu & Wesselink 2001, Baroni Barbizam et al. 2002, Rodig et al. 2002, Weiger et al. 2002, Wu et al. 2003, Grande et al. 2007a). In teeth with non-circular anatomy it is preferable to use an instrument that is able to maintain the original anatomical shape of the root canal, in order to effectively enlarge it and to enhance cleaning of buccal and lingual recesses (Hulsmann et al. 2005), with the objective to remove its organic and inorganic contents (Bartha et al. 2006, Weiger et al. 2006). Zmener et al. (2005a) compared by means of scanning electron microscopy, the presence of smear layer and remnants of debris on the walls of oval-shaped root canals after preparation with AET, ProFile .04 and .06 taper rotary instruments and manual instrumentation. Overall, the canals prepared with AET appeared to have less surface contamination compared to using ProFile or manual instrumentation. There are several reasons that may explain why AET-shaped root canals have lower debris and smear layer scores than canals shaped by means of ProFile or manual instrumentation. The

AET technique was performed with stainless steel instruments used in a 30° reciprocating side-to-side and up-and-down motion. These instruments are stiffer than nickel-titanium rotary instruments and can be easier and with less risk forced towards the root canal walls and the polar recesses during the side-to-side lifting motion. The use of stainless steel instruments in this motion was probably more efficient in following the natural shape of the oval-shaped canals and in removing tooth structure. In contrast, nickel-titanium instruments used only in a rotary motion and without lingual and buccal pressure, tend to partially remove tooth structure leaving untouched areas on the opposing walls. Furthermore, the authors had the impression that the AET technique was easier to use and less time-consuming, followed by ProFile and manual instrumentation, although the time required to prepare the root canals in each group was not recorded. They concluded that the use of AET was promising. In another study, Grande et al. (2007a) compared the morphological changes in the coronal, mid-root and apical portions of oval-shaped root canals prepared using the AET and ProTaper system. Forty freshly extracted human single-rooted lower premolars were used for this study. Selection of teeth was based on specimens that had a ratio between the bucco-lingual to mesio-distal dimension of at least 3:1 at the cervical and mid-root level. Occlusal access preparations were prepared, patency of the root canal was established, working length of the canal was determined and all instrumentation procedures were performed using 2.5x magnification. The teeth were then embedded in stainless steel muffles as described by Kuttler et al. (2001) using an auto curing acrylic resin (Ortho Jet, Lang Dental MFG, Wheeling, Illinois, USA). The resin blocks were cut in three locations, 3, 7 and 11 mm from the apex, resulting in 4 blocks representing subsequently the apical, mid, and coronal third of the root and the crown of the tooth. The sections were scanned using a template as a guide, which maintained the same spatial position of the samples on the scanner surface. The apical sections (3 mm from the apex), mid-level sections (7 mm from the apex) and coronal sections (11 mm from the apex) were then measured at a magnification of 24x in a mesio-distal (MD) and bucco-lingual (BL) direction and the MD/BL ratios calculated as described by Wu & Wesselink (2001). On the basis of the BL and MD diameter ratio the 34 remaining specimens were sequenced according to decreasing values and alternating samples were allocated to subsequently Group A and Group B, each consisting of 17 specimens (n=17). The specimens of Group A were prepared using the AET system and the

Endo-Eze hand piece (Ultradent Products Inc., South Jordan, Utah, USA), which is a 30° reciprocating 4:1 low-speed hand piece. The canals were instrumented at a speed of approximately 1500 rpm, using a side-to-side/up-and-down motion as guided by the natural shape of the canal. The ProTaper procedure technique was carried out for Group B using only the ProTaper Sx in a brushing action as recommended by the manufacturer (Ruddle 2001). Both techniques adhered strictly to the instructions provided by the inventors (Ruddle 2001, Riitano 2005). The AET technique required an apical preparation using 2° taper. The apical diameter of the preparation was 0.40 mm for Group A, which was obtained with Apical Files used to full length with a quarter turn and withdrawal movements. In Group B the apical diameter of the preparation was 0.30 mm, which was obtained with F3, the largest ProTaper available. Canals of both groups were irrigated with 1 mL, 5% NaOCL followed by 0.5 mL of 17% EDTA after each change of instrument. After canal preparation a final 5 mL of 17% EDTA solution was left in situ for 2 min. and replaced by 5 mL of saline solution. All irrigation procedures were delivered with a 30-gauge needle (Navi Tips, Ultradent Products Inc.). After mechanical preparation the sections were removed from the muffle and again scanned using the above-described technique. Thus it was possible to evaluate for each specimen, at three levels of the root canal, three parameters: 1) Changes in root canal diameters (ΔD) in Bucco-Lingual (BL ΔD) and Mesio-Distal (MD ΔD) dimensions after instrumentation. Calculations were made using the following formulas: BL ΔD = BL diameter post – BL diameter pre and MD ΔD = MD diameter post – MD diameter pre, in which BL ΔD represents the change as a result of instrumentation, BL diameter post, the diameter after instrumentation, and BL diameter pre, the measurement before instrumentation, both in a bucco-lingual direction. The same applied to the mesio-distal measurements 2) The areas (A) of the surface of the canal lumen in a horizontal plane, before (Apre) and after (Apost) instrumentation, using the formula $\Delta A = A_{\text{post}} - A_{\text{pre}}$. 3) Changes in BL to MD diameter ratio (ΔR) after instrumentation. ΔR = BL-MD Ratio pre – BL-MD Ratio post. PC software AutoCad 2000 (Autodesk Inc., San Rafael, California, USA) was used to calculate these parameters. Means and standard deviations were calculated for the three parameters and a Student t-test applied to determine if there were statistically significant differences between the two groups with respect to variations of root canal diameters (ΔD) in both BL and MD dimensions, ΔA values and BL-MD diameter ratios variations (ΔR) at a signifi-

cance level of $P < 0.05$. Figures 1 and 2 are representative of subsequently Group A (AET) and Group B (ProTaper). The design of this study was such that an analysis of areas before and after root canal preparation would furnish data concerning the total quantity of dentin removed, while an analysis of BL and MD diameters would show from what location the dentin had been removed (qualitative assessment). An analysis of the diameter ratio permitted an evaluation of the modification of the shape of the root canal as a result of instrumentation. The data obtained in this study indicate that there was an increase in the MD and BL diameters of the coronal, mid, and apical sections for both groups, however, statistically significant differences were found between the two groups with respect to the changes in the BL diameter at a coronal level ($P < 0.001$); BL ΔD being greater in Group A (AET). A statistically significant difference was also found for the MD diameter at mid level ($P < 0.001$); MD ΔD was greater in Group B (ProTaper). No statistically significant differences were demonstrated between the two groups for BL ΔD at mid and apical levels and for MD ΔD at the coronal and apical levels. An analysis of the areas (ΔA) established statistically significant differences only at the coronal level ($P < 0.001$), in which in Group A (AET) more dentin had been removed. For the mid and apical levels there were no statistically significant differences. Comparison between coronal sections of Group A (AET) and Group B (ProTaper), demonstrated a greater enlargement for the samples in Group A. This may be explained in that all the AET Shaping files are manually pushed against all dentinal walls, while the ProTaper Sx only was used with a brushing action. All the other ProTaper files, remain self-centered, thus making little or no contact with some portions of the dentinal walls. Therefore, at least at a coronal level, the NiTi rotary instruments only partially instrumented the dentinal walls in a BL direction (mean variation of BL diameter was 0 in this group), while at a mid level the NiTi rotary instruments increased the MD diameter more than reciprocating stainless steel files. In the midsections the AET system had a much lower BL to MD ratio variation compared to the NiTi rotary instrument samples. The MD-BL diameter ratio (ΔR) exhibited statistically significant differences after instrumentation at the mid level ($P = 0.03$). This means that the shape of the canals for Group A remained almost unaltered in contrast to Group B. The ratio for Group B changed at a coronal level, since at this level there was a greater increase in MD diameter compared to the BL diameter. This was not observed in Group A. The apical third was instrumented using .02 tapered

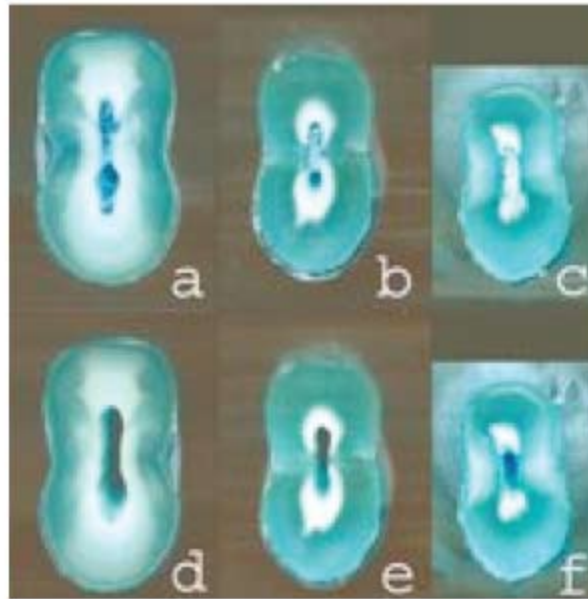


Fig. 1. Representative samples of Group A (AET), in which a, b and c are subsequently the coronal, middle and apical sections before instrumentation; d, e and f represent the cross sectional configuration after instrumentation. Note the visible change in the coronal section while the apical portion has been minimally altered.

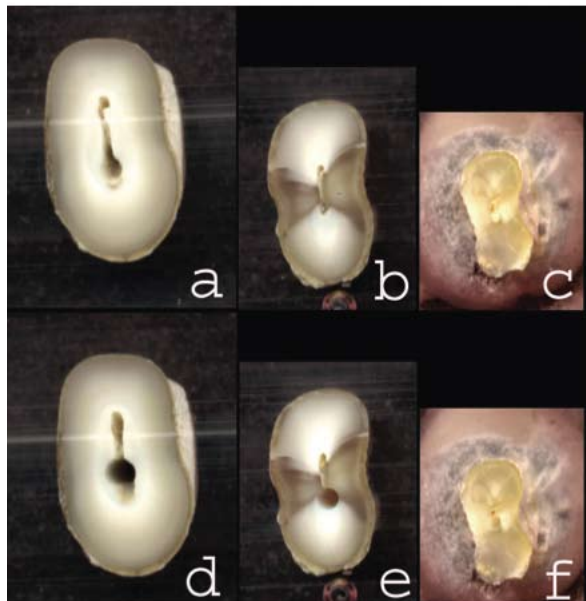


Fig. 2. Representative samples of Group B (ProTaper), in which a, b and c are subsequently the coronal, middle and apical sections before shaping; d, e and f represent the after instrumentation root canal configuration. The difference between instrumentation comparing Figs 1 and 2 are obvious.

instruments for AET and .09 for ProTaper, with a final diameter of preparation of 0.40 mm for Group A and 0.30 mm for Group B. The shape obtained with these preparations was circular, which is desirable for obturation of a canal (Tan & Messer 2002). In fact, the apical post-operative Diameter Ratio appeared to be close to 1 for both Groups (1.36 ± 0.63 for Group A and 1.03 ± 0.40 for Group B).

The data of Group B suggested that NiTi rotary instruments do not come in close contact with all the dentinal walls in the canal. In particular, the data show that in the middle third, especially in oval canals, which is not an uncommon feature, the NiTi instruments do not alter the BL diameter, while the MD diameter underwent a considerable change. This is due to the inherent self-centering action of NiTi instruments (Ponti et al. 2002). These findings have been corroborated by other studies (Wu & Wesselink 2001, Baroni Barbizam et al. 2002, Rodig et al. 2002, Weiger et al. 2002, Wu et al. 2003). With the use of the AET system the ratio between BL and MD diameters remained almost the same. This points towards a more uniform three-dimensional removal of dentin, which can be attributed to the metallurgical properties of the stainless steel files and the ability to selectively guide the instrument against the dentinal walls. These findings are corroborated by another study, in which it was reported that better cleanliness was achieved in oval root canals that were prepared with AET (Zmener et al. 2005a). Root canals treated with the AET system end up with an anatomy that is not too different from what was present before instrumentation (Figure 1). An analysis of the canals in different sections orthogonal to the long axis of the tooth showed a smooth appearance of the surface after the action of the AET Shaping files. Furthermore the ratio between the diameters remained almost unchanged before and after instrumentation. There were no particular differences between the sections at a coronal, mid and apical level. In contrast, with the use of NiTi ProTapers a clearly distinguishable modification of the anatomy had taken place, with some areas showing the shape of the instrument on the dentinal wall (Figure 2). It was also observed that the ability to selectively guide the AET Shaping files towards the canal walls permitted the removal of more hard tissues in areas where the wall was thicker. This is advantageous since it reduces the risk of weakening the tooth (Sorensen & Martinoff 1984, Katz & Tamse 2003). The non-reciprocating movement of the NiTi instruments tends to maintain the instrument in the center of the canal with the result that not all areas are being instrumented.

It can be concluded from the above that the ability of selectively guiding the AET Shaping files towards the walls of oval canals permits the removal of more hard tissues in areas where the wall is thicker. The non-reciprocating movement of the NiTi instruments appear to maintain the instrument more in the center of the canal, which may result in not all areas are being instrumented. The two instrumentation techniques produced a significant difference in the ultimate shape in the coronal and medium third of oval-shaped root canals. Whether, once obturated, these differences affect the final clinical success cannot be determined and will need to be investigated in long-term clinical studies. It is also recommended to further investigate the effect of NiTi rotary instruments when used in a milling brushing action when instrumenting root canals. The Bramante technique (Bramante 1987) modified by Kuttler et al. (2001) offers a method that is relatively easy and economic and provides information of the three-dimensional action of an instrument in the canal space. This information can also be obtained with more accuracy using computed tomography (Bergmans et al. 2001, Peters et al. 2001), however, the much higher expense and more involved procedures, which, especially when a large number of specimens needs to be analyzed, makes it less practical and affordable. A further study that aimed to evaluate root canal preparation in oval root canals performed by two nickel-titanium rotary systems and the AET system used micro-computed tomography as a method of investigation (Butti et al. 2005). This study confirmed the results of the above described study performed on serial histological sections (Grande et al. 2007a), showing a perimetral anatomic root canal preparation with the AET system (Figures 3a, b and 4a, b), while nickel-titanium rotary instruments, used passively to prepare oval root canals, frequently showed circular bulges, and the buccal and lingual extensions of the oval root canals often remained unprepared (Figures 5a, b). Attention must be paid when selecting endodontic instrumentation, so that they are compatible with the anatomic shape of the root canal (Bellucci & Perrini 2002) to preserve maximum dentin thickness. This also reduces the risk of perforating a root. The survival of root filled teeth may depend on the amount of residual dentin (Plotino et al. 2008a). Many studies demonstrate a direct relationship between the loss of tooth structure and the possibility of fracture of the crown or root (Trabert et al. 1978, Sorensen & Martinoff 1984, Assif & Gorfil 1994). Since there is an appreciable loss of dentin during root canal preparation (Montgomery 1985, McCann et al. 1990, Pilo et al. 1998, Garala et al. 2003, Weller et al. 2005),



Fig. 3a. Representative section of a root prepared using the AET system before instrumentation obtained by micro-computed tomography (μ CT).

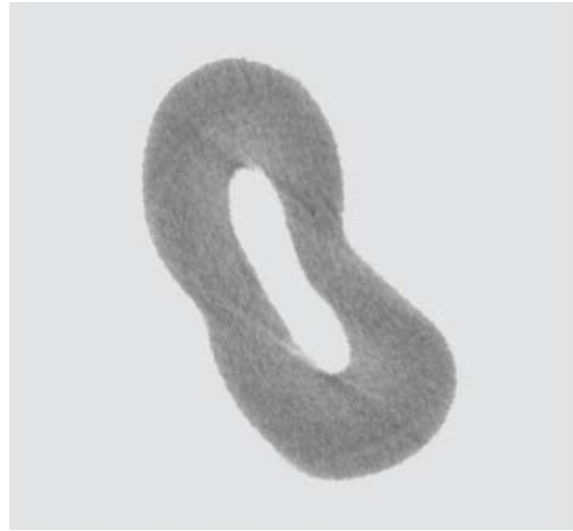


Fig. 3b. An adjacent section of the same tooth as shown in Fig. 3a but now after preparation using the AET system. Note the maintenance of the original oval anatomy, which now appears slightly oversized.



Fig. 4a. Representative μ CT section from another sample before preparation with the AET system.



Fig. 4b. An adjacent section of the tooth of Figure 4a after instrumentation. Also here the original oval anatomy was maintained showing a slightly enlarged peripheral anatomy (perimetric).

attention must be directed to roots with a minimum diameter (Plotino et al. 2007). The measurements of the narrowest mesio-distal root canal width reported in a morphometric study (Plotino et al. 2008c), are in accordance with those of a previous study that reported measurements at a cervical, middle and apical level (Tilk et al. 1979). They are also similar or slightly larger than those reported by Kerekes & Tronstad (1977b) at 1, 2, 3 and 5 mm from the root apex. Furthermore, a mostly flat medio-distal root shape has also been previously reported (Bjorndal et al. 1999, Bellucci & Perrini 2002, Plotino et al. 2006a). The results of this morphometric study demonstrated that at all levels the mesial and distal wall thickness was less than the buccal and lingual walls. In many sections, the dentin was very thin. This observation is in accordance with Pilo et al. (1998), Pilo & Tamse (2000) and Bellucci & Perrini (2002), who reported wall thickness values in mesio-distal and bucco-lingual direction corresponding to those reported in the present investigation. It is important to realize that periapical radiographic images overestimate mesial and distal root canal wall thickness by approximately 25%, regardless of the clinical stage evaluated (Souza et al. 2008).

Based on data reported by Plotino et al. (2008c), that for part of the root the wall thickness increases towards the coronal aspect, it is preferable in teeth with non-circular anatomy, to use an instrument that can maintain the original anatomy of the root canal, thus removing as little dentin as possible (Grande et al. 2007a). The dentin should be removed from the buccal and lingual walls where the thickness is greater (Bellucci & Perrini 2002, Plotino et al. 2008c). This also reduces the risk of weakening or perforating a root (Tilk et al. 1979, Pilo et al. 1998, Pilo & Tamse 2000, Tamse et al. 2000, Raiden et al. 2001). Therefore a treatment that aims to prevent indiscriminate removal of tooth structure from the canal walls during endodontic treatment or during restorative procedures should be always considered, since conservation of dentin is mandatory, and techniques that support this concept are preferable (Assif & Gorfil 1994, Grande et al. 2006b, Plotino et al. 2008b). Furthermore, the data from Plotino et al. (2008c) show that the mean Bucco-Lingual root canal taper was greater than in a Mesio-Distal direction; subsequently 0.18 and 0.03 mm/mm. These values demonstrate that the mean Mesio-Distal root canal taper matches the taper commonly found in NiTi rotary systems (.06), while the taper in a Bucco-Lingual direction differs, especially for the medium and coronal portion of the root canal. This implies that, if one is to

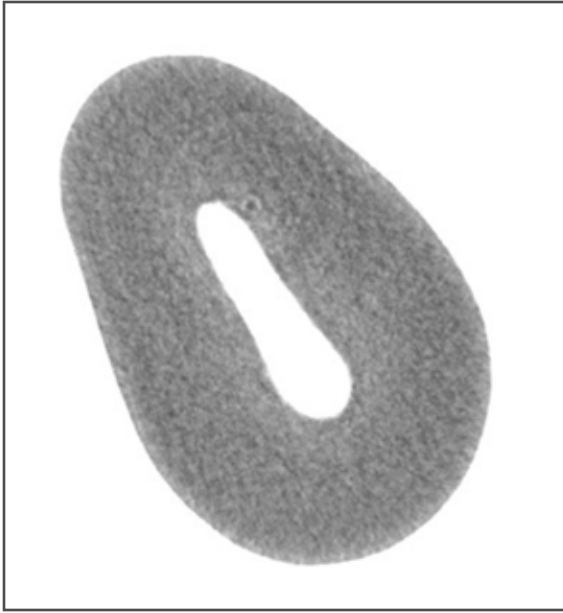


Fig. 5a. Representative μ CT section of a tooth at the coronal one third before NiTi rotary system instrumentation.



Fig. 5b. Adjacent section of Fig. 5a after instrumentation. Note the round widening in the center of the canal, which is characteristic of NiTi preparations in oval root canals.

obtain a circumferential root canal preparation, instruments should be used with specific instrumentation motions such as a lateral brushing action, thus optimizing the efficacy of the preparation even in oval anatomy while preserving maximum dentin thickness and enhancing cleaning and shaping of buccal and lingual recesses (Hulsmann et al. 2005, Grande et al. 2007a).

Anatomical Endodontic Technology

The following section is devoted to the Anatomical Endodontic Technology (AET), (Ultradent Products Inc., South Jordan, Utah, USA) which was introduced following a publication by Riitano (2005). This system consists of a new generation of flexible stainless-steel files for shaping the coronal and middle third of the root canal (Shaping Files), disposable syringes with 30-gauge needle tips and File-Eze™ (FE), a 19% EDTA chelating gel and filing lubricant. The Shaping files are designed such so as to maintain the natural shape of the root canal during instrumentation and are used to prepare the bulk of the root canal to within 3-4 mm of the working length. The files, rather than rotating, have a reciprocating motion when used in a reduction gear of 4 to 1 with an oscillation of 30° degrees (Fig. 6). They have almost the same diameter at the tip (#10 for AET Shaping 1, #13 for AET Shaping 2, AET Shaping 3 and AET Shaping C) and a slight increase in taper (from .02 to .06 taper) (Fig. 7). The AET technique permits a perimetric or circumferential preparation of the coronal and middle canal thirds (Grande et al. 2007a). Stainless steel mechanical instruments, specifically designed for this technique, (Shapings, Ultradent Products Inc.) are designed to be guided by the anatomical shape of the canal cutting with their fins in a milling-type action. In fact, they are selectively guided by the operator against every portion of each wall with a brush-like action, which is intended to eliminate interferences. The AET instruments, consistent with the crown-down technique, have been designed with a stronger and sharper bulk in the upper half (extended over the 16 mm ISO standard), which engages the coronal and middle thirds and are employed for circumferential and anatomical enlargement. The rounded and narrow tip is more flexible and practically inactive, serving principally to guide the instrument within the canal towards the apex. The dentin is selectively removed and weakening of the walls of the canal or perforation in areas where the wall is thin is avoided, as previously described by others (Abou-Rass et al. 1980). The system is complemented by a set of hand instruments with a .025 taper for apical preparation (Apical Files), to

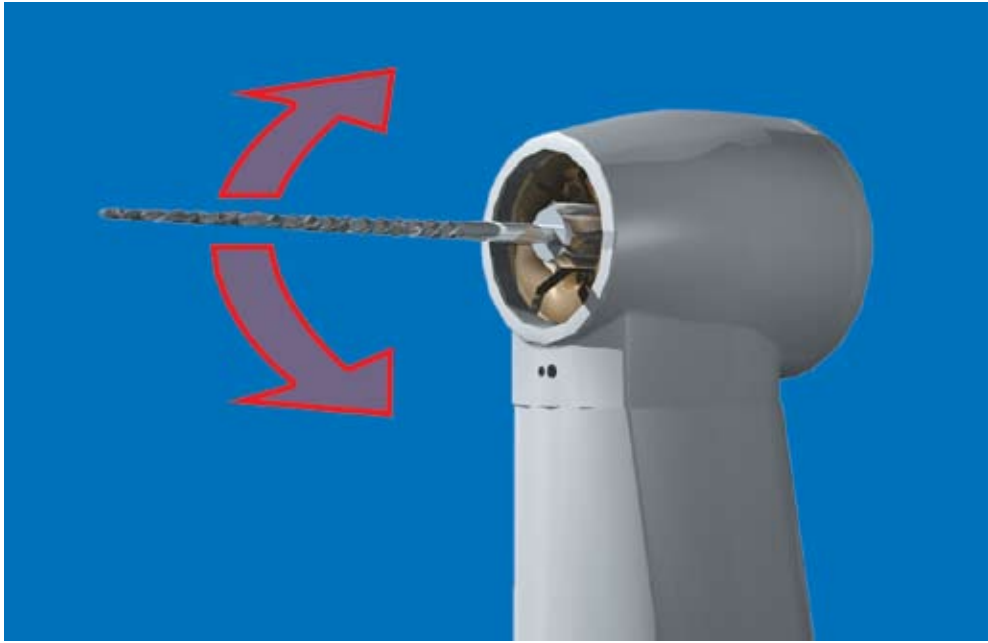


Fig. 6. The Endo-Eze hand piece operates the files in a reciprocating motion of 30° degree.



Fig. 7. The four Shaping Files: S1 (yellow), SC (red), S2 (blue), S3 (green).



Fig. 8. Apical hand files 25 (red), 30 (blue), 35 (green) and 40 (black).

assure tug-back at the apical portion using 2° tapered cones. Apical Files are available in sizes #08 up to #50 (Fig. 8). The Apical Files, which cut only at the tips, are designed to be used manually.

Concepts of the ‘operative canal’ and straight line access refinement

When using the AET technique the preparation includes the pulp chamber walls, and the root canal is conceptualized from the occlusal surface of the tooth to the root apex. Fig. 9 illustrates the division of a tooth into thirds in classical anatomical and AET ‘operative canal’ terms (Laurichesse 1986, Scianamblo 1993, Riitano 1980). The latter described the anatomical division as follows:

1. a coronal ‘third’ extending from the occlusal surface to floor of the pulp chamber in multirooted teeth and to the neck of the tooth in single rooted teeth,
2. a middle ‘third’ extending from the end of the coronal third to 3–4 mm from the apex,
3. an apical ‘third’ corresponding to the final 3–4 mm of the canal, ending at the apical foramen.

The AET preparation technique comprises three phases:

1. coronal access using the Access Bur Kit,
2. coronal-middle preparation using Shaping files TM, and
3. apical preparation using Apical files.

Operative procedure

Preoperative radiographs are essential to facilitate the procedure. The following sequence is recommended.

A. Coronal Phase

Aims. To open and clean the pulp chamber and identify canal orifices. The instruments and methods that are used are possible with the ‘Access bur kit’ (Fig. 10) comprising of:

1. Round and tapered diamond burs to prepare the access cavity.
2. Non end-cutting burs to remove the roof of the pulp chamber in multi-rooted teeth without damaging the floor and to remove dentin overhangs and residual enamel interferences.

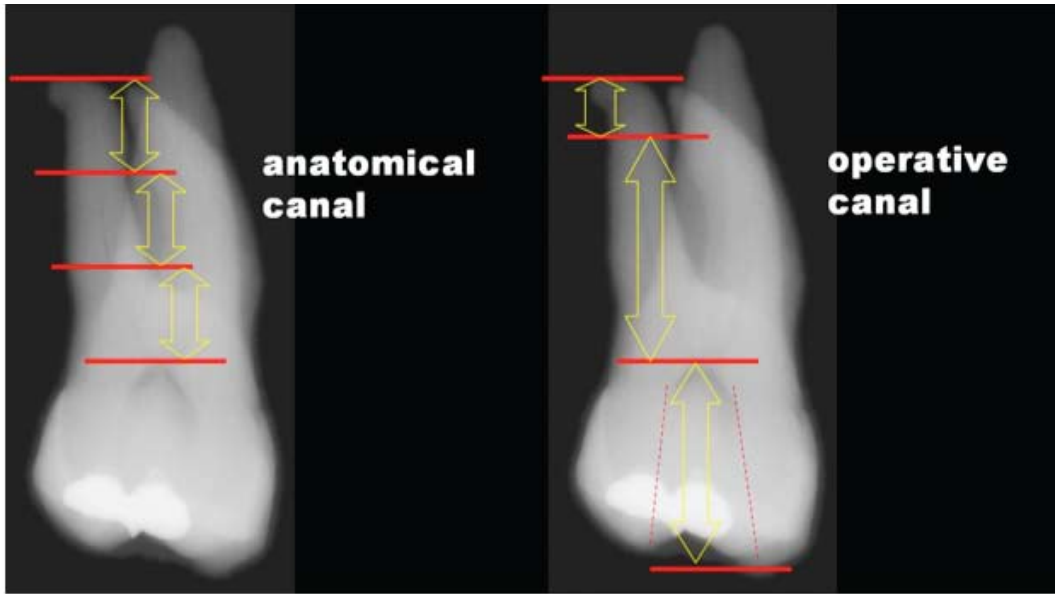


Fig. 9. This figure clearly demonstrates the difference between the classical anatomical canal and the AET “operative” canal.



Fig. 10. The access bur kit consisting of 5 diamonds. Each diamond has a particular shape for a specific procedure in the preparation of the access opening.

3. Safe-point diamond bur to prepare axial line access by removing dentin interferences.

B. Coronal-middle Phase

Aims. Circumferential shaping following the anatomic contour and eliminating interferences in the middle section of the canal in order to obtain the straightest possible access towards the apical region. The second phase is termed coronal-middle since the instruments used in this phase are designed to prepare not only the middle third of the 'operative canal' (OC) but also to refine the preparation of the coronal third that has been initiated during the first phase.

Instruments

Shaping files. Four stainless steel (S1, SC, S2, S3) instruments with a square cross-section. The blades of the instrument extend from the tip almost to the handle, thus also covering the coronal section of the OC. The flexible tip of the instrument is rounded. Shaping files are available in lengths of 16 mm (X-short), 20 mm (short), 24 mm (medium) and 27 mm (long) (Fig. 11 and 12). The Endo-Eze hand piece (Ultradent Products Inc.) (Fig. 13) is a dedicated hand piece designed for the Shaping files with a 30° right/30° left reciprocating action (Fig. 6). It is possible to vary the insertion depth of the instrument within the head of the hand piece, via a push button collet (Fig. 14a, b, c). This permits four different working lengths for each instrument length, as follows:

- 13, 14, 15 and 16 mm for the 16 mm length;
- 17, 18, 19 and 20 mm for the 20 mm length;
- 21, 22, 23 and 24 mm for the 24 mm length;
- 24, 25, 26 and 27 mm for the 27 mm length;

In this way, the head of the hand piece works as a stop for the file at the working length and provides continuous internal spray irrigation. Internal irrigation is supplied by a unit containing water (a disinfection solution can also be used) and its aim is to remove gross debris created from the action of the Shaping instruments.

Method

1. The coronal-middle working length for the Shaping files is determined as follows:
 - in teeth with vital non-infected pulps the canal length (CL) is deter-

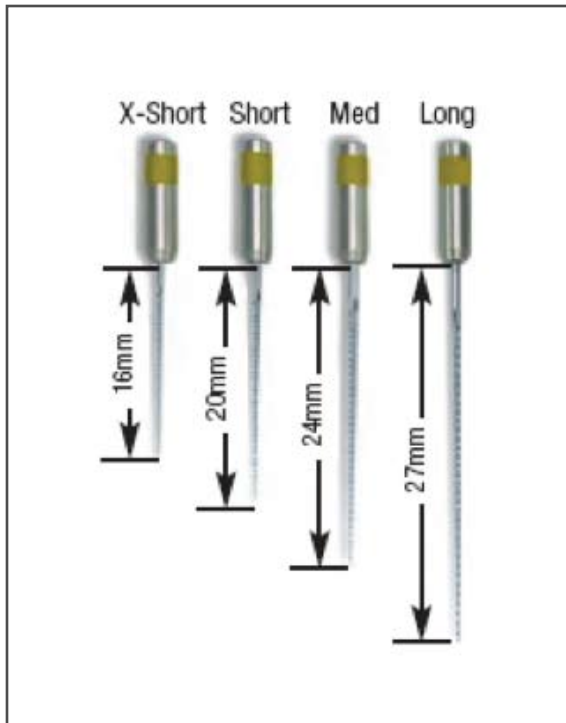


Fig. 11. The shaping files of the AET instrument armamentarium designed for the different lengths of a canal.



Fig. 12. The complete kit is available in four lengths, X-Short, Short, Medium and Long.



Fig. 13. The Endo-Eze hand piece.

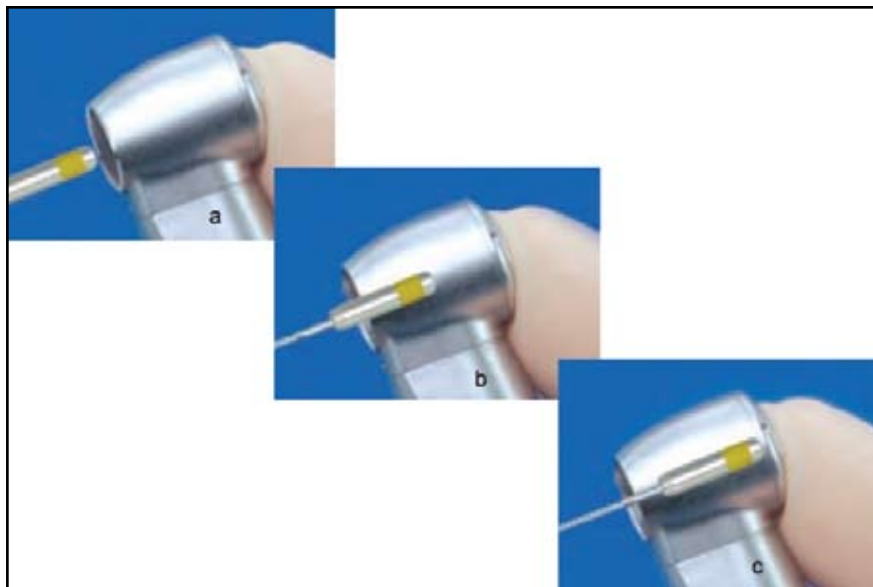


Fig. 14a-c. It is possible to vary the insertion depth of the instrument within the head of the hand piece, via a push button collet.

mined with an apex locator and small K-files and confirmed radiographically. Coronal-middle length is obtained by subtracting 3 mm from the recorded length;

- in infected canals the coronal-middle length is obtained by subtracting 3–4 mm from the estimated tooth length on the pre-operative radiograph, to prevent the transport of bacteria and debris into the apical region of the canal.

As modern electronic apex locators are quite reliable in the determination of the working length both in vitro and in vivo (Plotino et al. 2006b, Plotino et al. 2008d, Grande et al. 2008), the coronal and middle third working length can be obtained in all cases with the use of an electronic apex locator as described above, paying attention to avoid over-instrumentation.

2. Complete the manual glide path and canal negotiation using the first Shaping file (yellow) before starting mechanical preparation.

3. Use Shaping files in the Endo-Eze hand piece and insert into the coronal-middle length that has been established. Direct the instrument with its reciprocating action circumferentially, brushing the canal walls in order to remove interferences (Fig. 15). The objective is to obtain a straight-line coronal-radicular access. Active brushing should be performed only when the Shaping instruments are withdrawn from the canal. They should be pushed mainly laterally, using the upper half of the instruments. The four shaping instruments are used for approximately 1 minute each in the following sequence: shaping 1 (yellow-S1), shaping 'C' (red-SC), shaping 2 (light blue-S2) and shaping 3 (green-S3).

C. Apical Phase

Aims. To shape and clean the apical third of the canals taking into consideration the electronically determined apical limit and maintaining the original apical foramen diameter as narrow as possible. In the apical few millimeters the canals tend to be circular (Wu et al. 2000, Plotino et al. 2008c). Thus, the preparation of the apical region is completed by means of a cutting rotary movement. NiTi hand instruments are safe to use and achieve the goal of preserving apical curvature.

Instruments

Apical files in lengths of 19, 23, 27 and 30 mm (Fig. 16).

- manual stainless steel files with tip diameters ranging from 0.08 mm up to 0.20 mm;

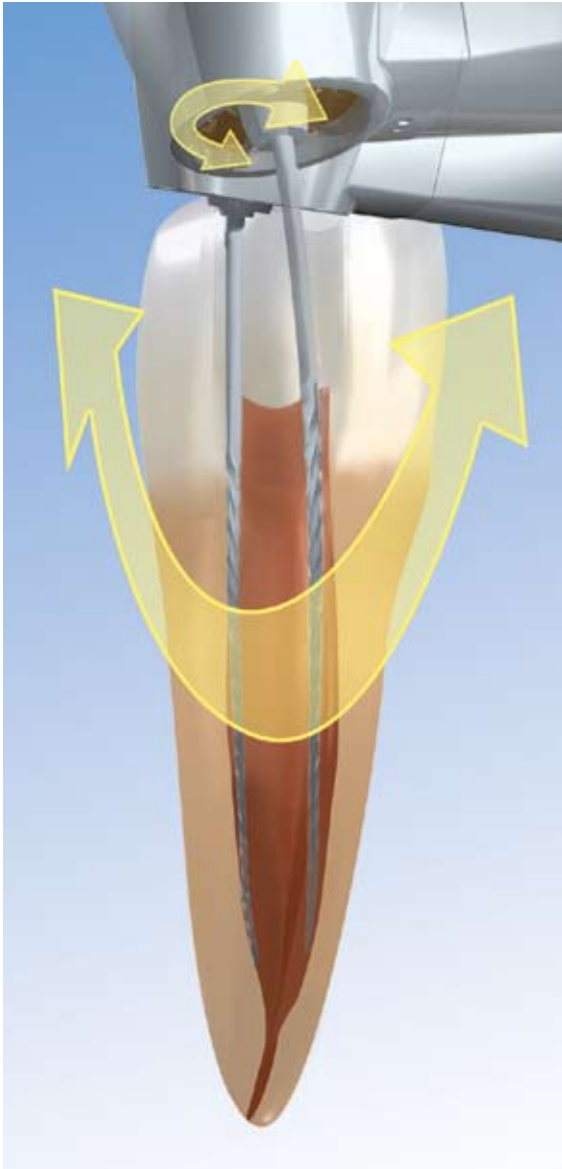


Fig. 15. The circumferential movement of the AET instruments, brushing the canal walls during the exit movement in order to obtain an anatomical enlargement.

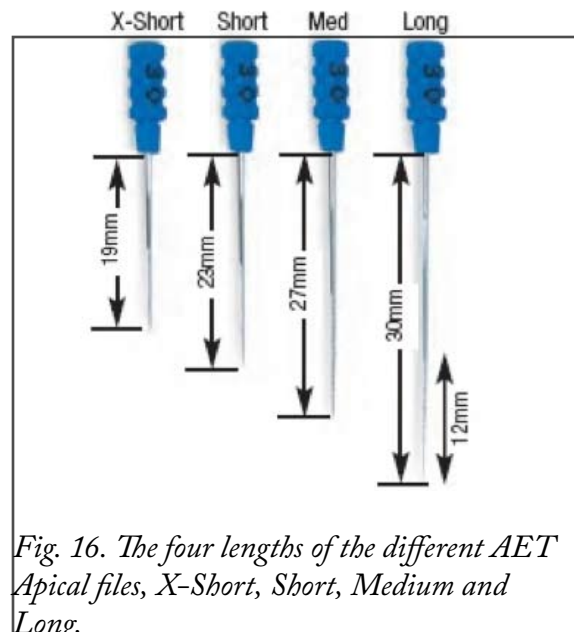


Fig. 16. The four lengths of the different AET Apical files, X-Short, Short, Medium and Long.

- manual NiTi files with tip diameters ranging from 0.25 to 0.50 mm that are round and non-cutting. Apical files have a 2° taper in sizes 0.8–20 and a 2.25° taper in sizes 25–50. Their active cutting action extends over a length of 12 mm.

Method

Re-evaluate the canal length (CL) and establish the Apical Limit in order to obtain the Apical Working Length (AWL). The AWL is determined by the electronically established CL. In most canals, having completed preparation with Shaping files, the size 25 hand Apical NiTi used in manual rotary motion will easily reach the AWL. If this is not possible, use stainless steel Apical files with diameters ranging from size 08 up to size 20 and with 1/4 turn and withdrawal movements until reaching the AWL with the size 25 Apical NiTi. Continue with the Apical NiTi (size 30, 35, 40, etc.) until reaching the final Diameter of Apical Preparation (DAP). The DAP is to be established on the basis of the morphometric data of the tooth which is being treated (Kerekes & Tronstad 1977a, 1977b, 1977c, Wu et al. 2000, Tan & Messer 2002, Marroquin et al. 2004, Plotino et al. 2008c). However, apical enlargement should only be considered as complete when the Apical files are extracted from the canal filled with clean dentinal debris. It should be noted that many studies have demonstrated that widely accepted endodontic cleaning and shaping techniques are inadequate (Wu & Wesselink 1995, Tan & Messer 2002, Weiger et al. 2002, Baugh & Wallace 2005). This can be attributed to the fact that root canal diameters are larger than the instrument used (Kerekes & Tronstad 1977a, 1977b, 1977c, Wu et al. 2000, Bellucci & Perrini 2002, Plotino et al. 2008c). The results of the above referenced studies show that in the apical third, root canals have a minimum diameter greater than 0.30 mm, and a maximum diameter larger than 0.45 mm, even at a distance of 1 mm from the apex. These results are confirmed by morphometric anatomical studies on root canal dimension that have reported a high prevalence of oval canals in the apical third (Kerekes & Tronstad 1977b, Wu et al. 2000, Plotino et al. 2008c). One of the primary goals of root canal treatment is to completely clean and shape the root canal system by cutting the dentin on the root canal wall circumferentially. While in the coronal and medium third of the root canal the objective is to remove the inner layer of dentin so that the outline of the prepared root canal wall reflects the original outline (Wu et al. 2003), in the apical few millimeters the objective must be to enlarge the canal to a suitable size permitting adequate debridement. It should

also obtain a circular shape that permits manipulation and control over filling materials and instruments, in order that the tightest seal can be achieved with current root canal filling techniques (Bartha et al. 2006, Weiger et al. 2006). These objectives are more difficult to achieve in complex anatomical spaces, such as oval canals, in which the apical portion should be enlarged to at least the maximum canal diameter, which normally is the bucco-lingual diameter. However, this will also increase the diameter of the canal in the mesio-distal direction, thereby reducing wall thickness (Wu et al. 2000, Plotino et al. 2008c). A circular preparation would require instruments of a size that may significantly weaken the root or even perforate it. Nevertheless, larger apical shaping, as has been frequently demonstrated, promote cleaner apical preparations and a reduction in bacteria count (Bystrom & Sundqvist 1981, Orstavik et al. 1991, Wu & Wesselink 1995, Siqueira et al. 1997, Dalton et al. 1998, Siqueira et al. 1999, Shuping et al. 2000, Card et al. 2002, Rollison et al. 2002, Tan & Messer 2002, Albrecht et al. 2004, Usman et al. 2004, Baugh & Wallace 2005, Falk & Sedgley 2005, McGurkin-Smith et al. 2005, Bartha et al. 2006, Khademi et al. 2006, Weiger et al. 2006, Mickel et al. 2007). A recent publication (Paqu  et al. 2005) reported on a study conducted on curved root canals in molars using the AET technique, and recommended against its use in curved canals. Unfortunately the authors tested an early and no longer available version of the AET system. Significant changes had been made more than three years prior to their publication. The rigid stainless steel transition files that were used after shaping the middle third were eliminated as they transported too much. The shaping files originally taken to full length are now used to within 3 mm of the apex. Additionally, a change in apical shaping files to a triangular cross-section, to be used to working length, considerably reduced the early transportation problems. As a result of these changes the validity of their data and conclusions are no longer valid. In fact, further research conducted with the same methodology demonstrated that AET instruments were able to prepare both maxillary and mandibular molars with optimal results and low risk of procedural errors (Grande et al. 2007b) (Fig. 17a, b and 18a, b). The authors evaluated root canal morphology in maxillary and mandibular molars after instrumentation with Endo-Eze AET stainless-steel instruments (Ultradent Products Inc.) and ProFile Ni-Ti rotary instruments (Dentsply Maillefer, Baillagues, Switzerland) and assessed the results by means of micro-computed tomography. A micro-computed tomography scanner (SkyScan 1072, Assing SPA, Belgium) was used to ana-

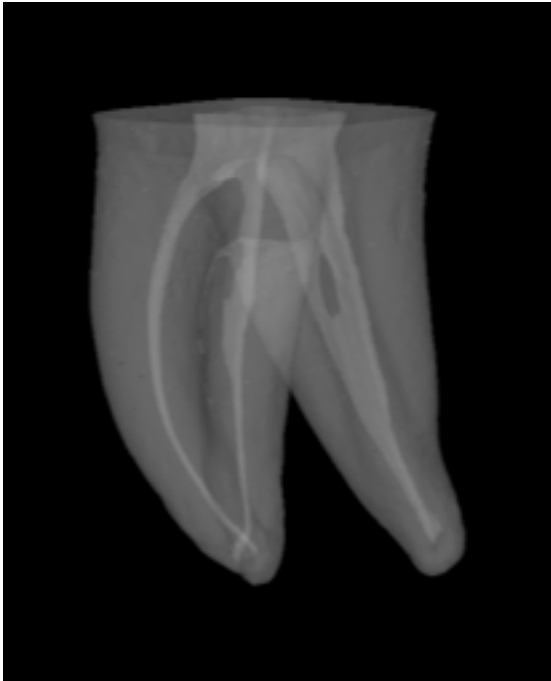


Fig. 17a. Pre-instrumentation μ CT image of a mandibular molar tooth.



Fig. 17b. Post-instrumentation μ CT image of a mandibular molar of Fig. 17a prepared using the AET system.

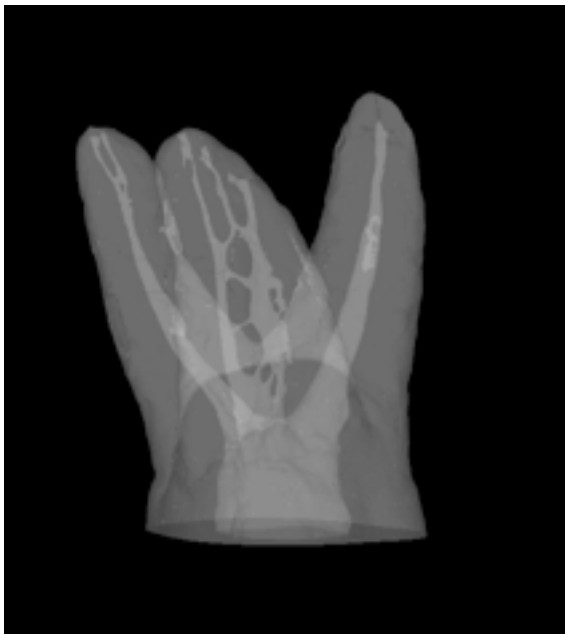


Fig. 18a. Pre-instrumentation μ CT image of a maxillary molar tooth.



Fig. 18b. Post-instrumentation μ CT image of a maxillary molar tooth prepared using AET system.

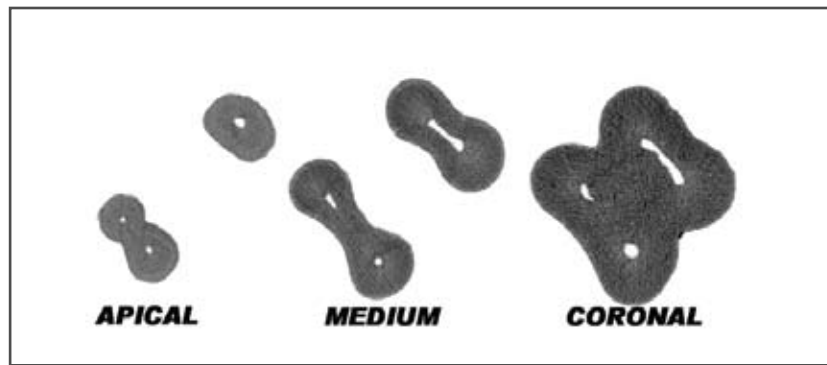


Fig. 19a. Pre-instrumentation cross-sections at the apical, medium and coronal level from a representative lower first molar specimen from Group 1 obtained by means of μ CT scanning and reconstruction.

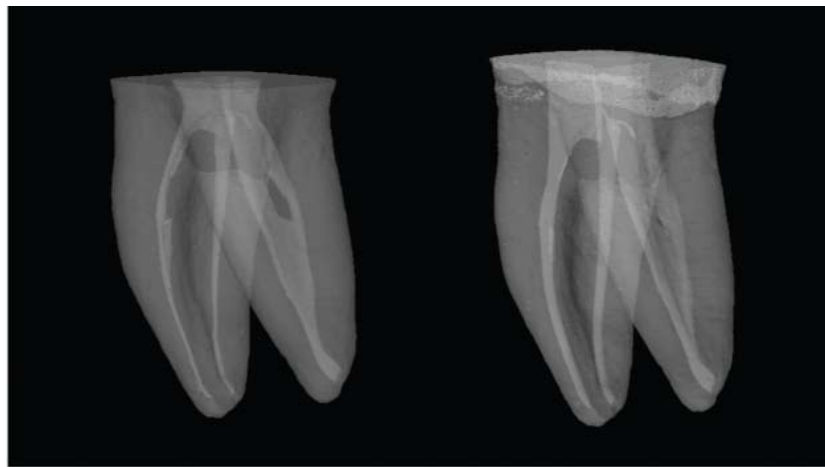


Fig. 19b. An example of an image from the first lower molar of Fig. 19a. obtained by μ CT imaging. On the left the pre-instrumentation three-dimensional view is depicted, while the right scan shows the Endo Eze AET post-instrumentation view. A coronal access widening can be seen with a slight widening of the root canal space tapering off to the apex.

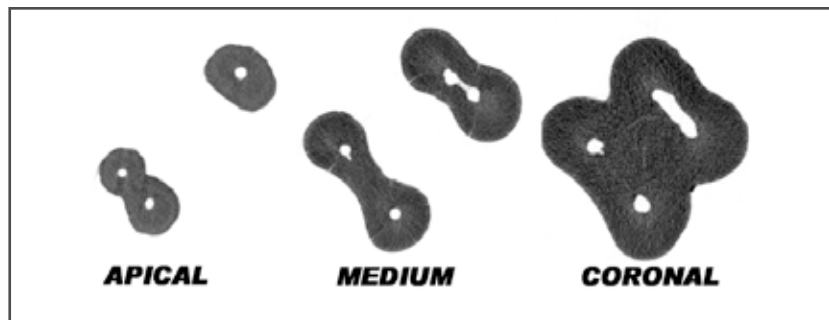


Fig. 19c. Post-instrumentation cross-sections at the same apical, medium and coronal level of the first lower molar specimen from Group 1 obtained by means of μ CT scanning and reconstruction. The AET system has generated a perimetric anatomical enlargement.

lyze 10 maxillary and 10 mandibular first molars. Specimens were scanned before and after root canal preparation using Endo-Eze AET and ProFile. Each system was used to prepare 5 maxillary and 5 mandibular molars. The scanning procedure was completed using 10W, 100 kV, 98 μ A, a 1 mm-thick aluminum plate and 15X magnification with 5.9 s exposure time and 0.45° rotation step, resulting in a pixel size of 19.1 μ m x 19.1 μ m. The acquisition procedures consisted of the realization of several two-dimensional (2D) lateral projections of the specimens during the 180° rotation around the vertical axis. This digital data were further elaborated by reconstruction software that obtained new axial cross sections with a pixel size of 19.1 μ m x 19.1 μ m. The distance between each cross-section was 38.0 μ m. Three-dimensional root canal models were reconstructed and evaluated for volume. The total volume of dentine removed and the volume of the coronal, middle and apical third of each root canal were calculated. The mean volume change before and after instrumentation was determined for the entire root canal as well as each section for both systems. A qualitative evaluation of root canal preparation was performed on the three-dimensional models. Student t-test was used to determine the difference between the two groups ($P < 0.05$). Instrument fracture and deformation was part of the observations that were recorded. No instruments fractured, while deformation occurred in one ProFile size 30, .04 taper instrument. No statistically significant differences were noted between the groups in the volume of dentin removed after canal preparation for all mandibular and maxillary molars, except for the total volume ($P = 0.04$) and the volume of the apical third ($P = 0.03$) of the disto-buccal canal of maxillary molars, where ProFile instruments produced significantly less enlarged canal volume than the Endo-Eze AET. Qualitative evaluation of the preparations showed that both ProFile and Endo-Eze AET were able to prepare root canals in mandibular and maxillary molars with little or no procedural error (Fig. 19-22). In summarizing the data of this study it can be concluded that both systems (EndoREZ AET and Profile) were able to prepare molar teeth with removal of similar amounts of dentin and having a low risk of procedural errors [Fig. 23-27 (Endo-Eze/AET) and 28-31 (Profile)].

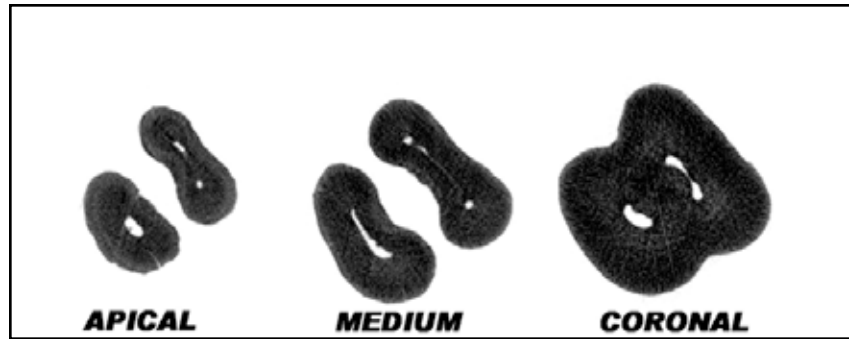


Fig. 20a. Pre-instrumentation cross-sections at the apical, medium and coronal level of a representative lower first molar from Group 2 obtained by means of μ CT scanning and reconstruction.

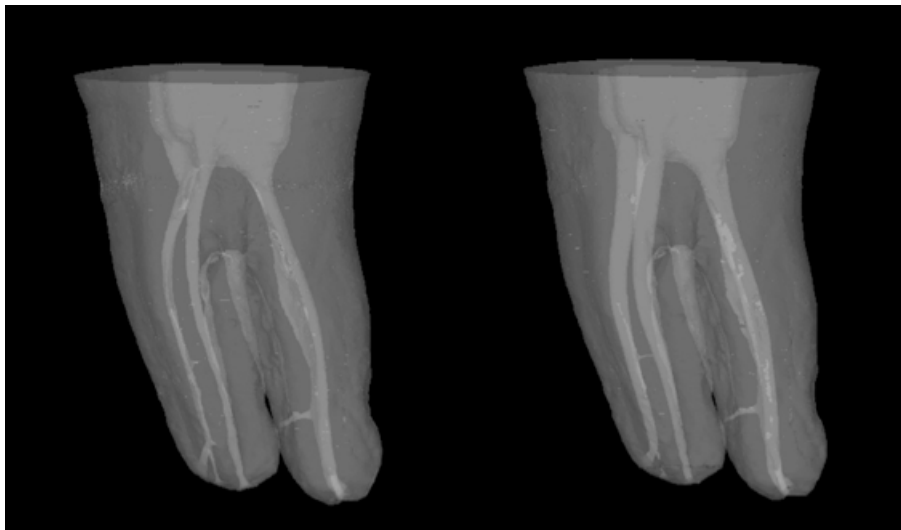


Fig. 20b. A representative example of a μ CT image of the lower first molar.

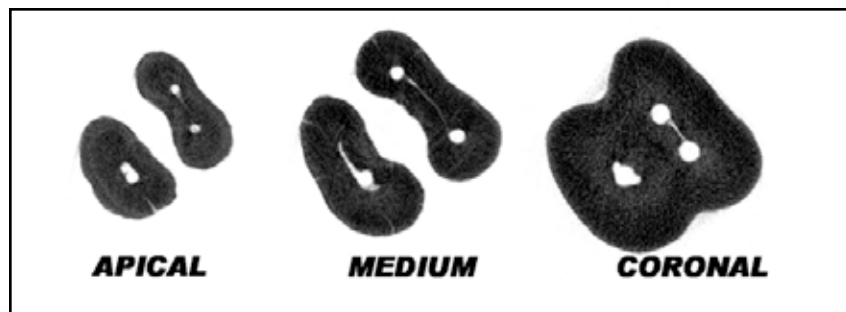


Fig. 20c. Post-instrumentation cross-sections at the same apical, medium and coronal level of Fig. 20a of the lower first molar specimen from Group 2 obtained by means of μ CT scanning and reconstruction. In cross section the observation that the Endo-Eze AET system causes minimum transportation can be confirmed.

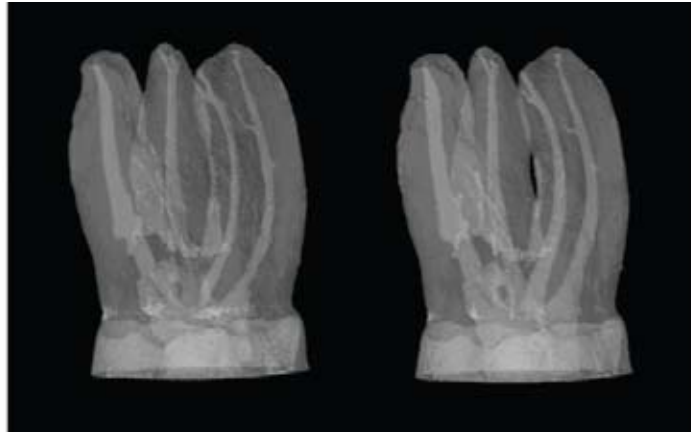


Fig. 21. A representative sample of a μ CT image of a maxillary first molar specimen from Group 1 . On the left the pre-instrumentation three-dimensional view, while on the right the Endo-Eze AET post-instrumentation view can be seen.

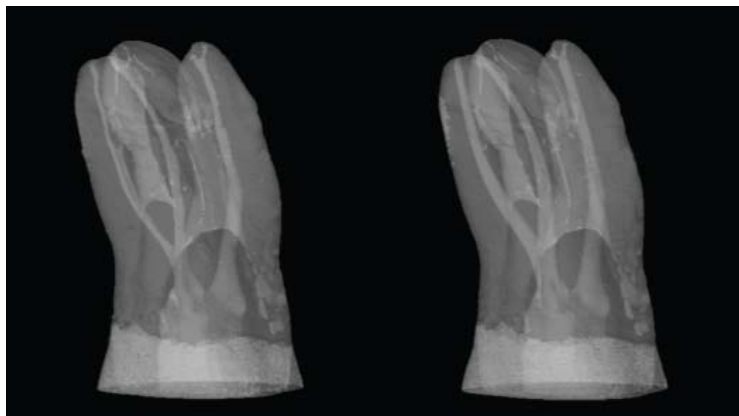


Fig. 22. A μ CT image of a representative maxillary first molar specimen from Group 2 . On the left the pre-instrumentation three-dimensional view can be seen; the right shows the Endo-Eze AET post-instrumentation view.

Fig. 23-27. Examples of mandibular and maxillary molars prepared using the Endo-Eze AET system obtained by μ CT imaging: a. pre-instrumentation three-dimensional view; b. post-instrumentation three-dimensional view.



Fig. 23a. Endo-Eze/AET



Fig. 23b. Endo-Eze/AET

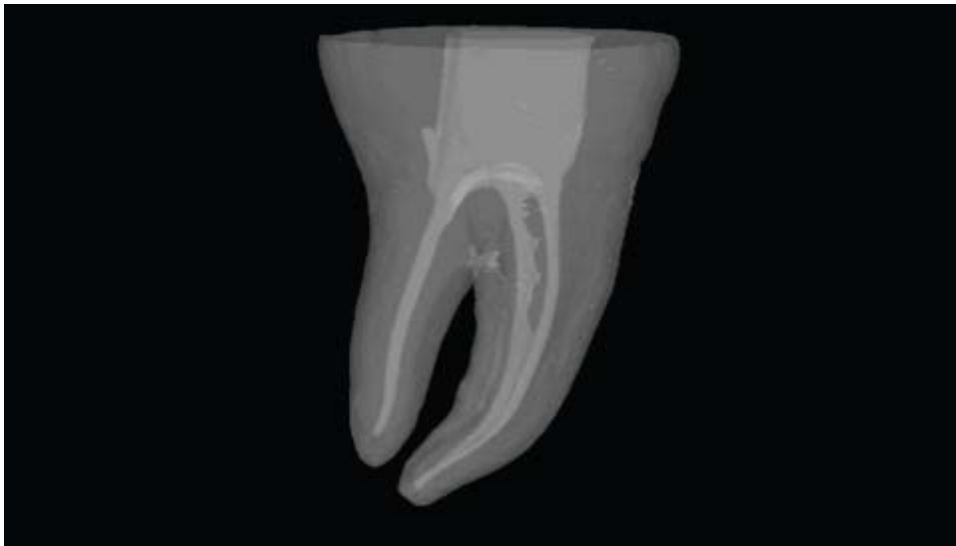


Fig. 24a. Endo-Eze/AET

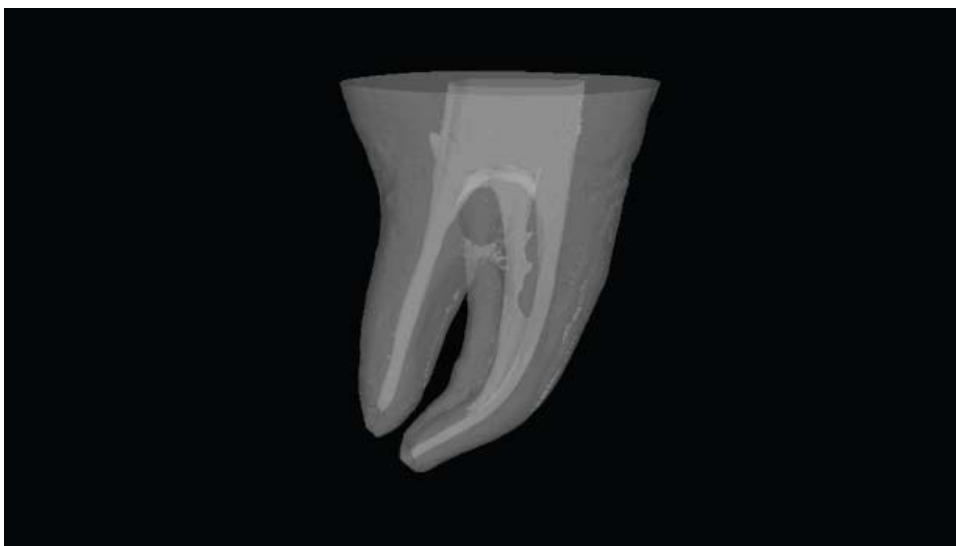


Fig. 24b. Endo-Eze/AET



Fig. 25a. Endo-Eze/AET



Fig. 25b. Endo-Eze/AET



Fig. 26a. Endo-Eze/AET



Fig. 26b. Endo-Eze/AET

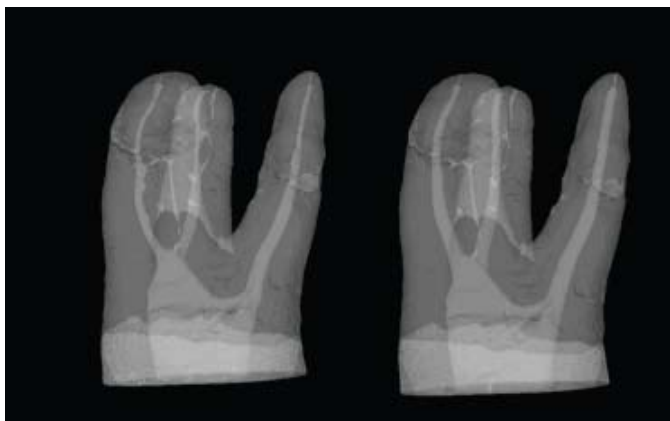


Fig. 27. Endo-Eze/AET

Fig. 28–31. Examples of mandibular and maxillary molars prepared using the ProFile system and obtained by means of μ CT imaging: a. pre-instrumentation three-dimensional view; b. post-instrumentation three-dimensional view.



Fig. 28a. Profile



Fig. 28b. Profile

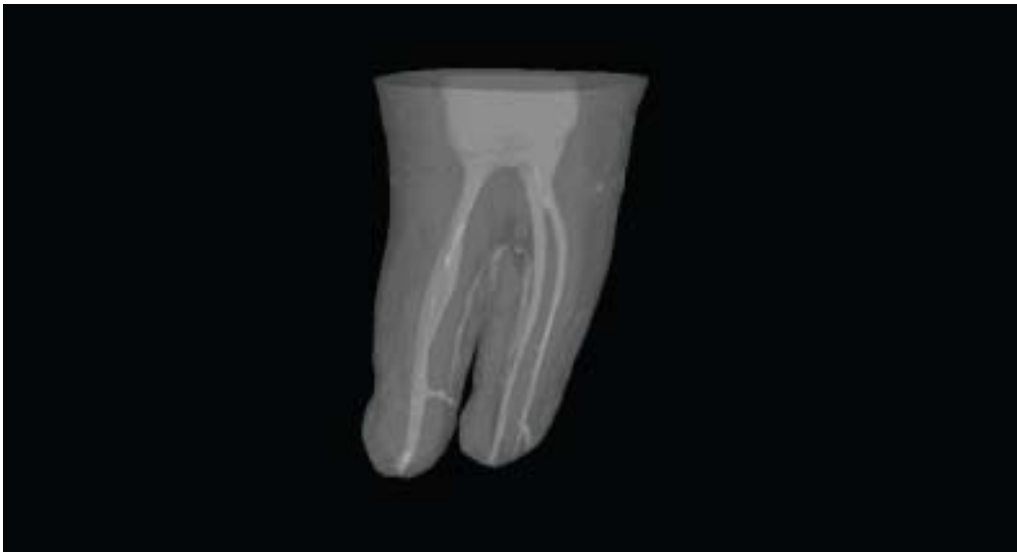


Fig. 29a. Profile

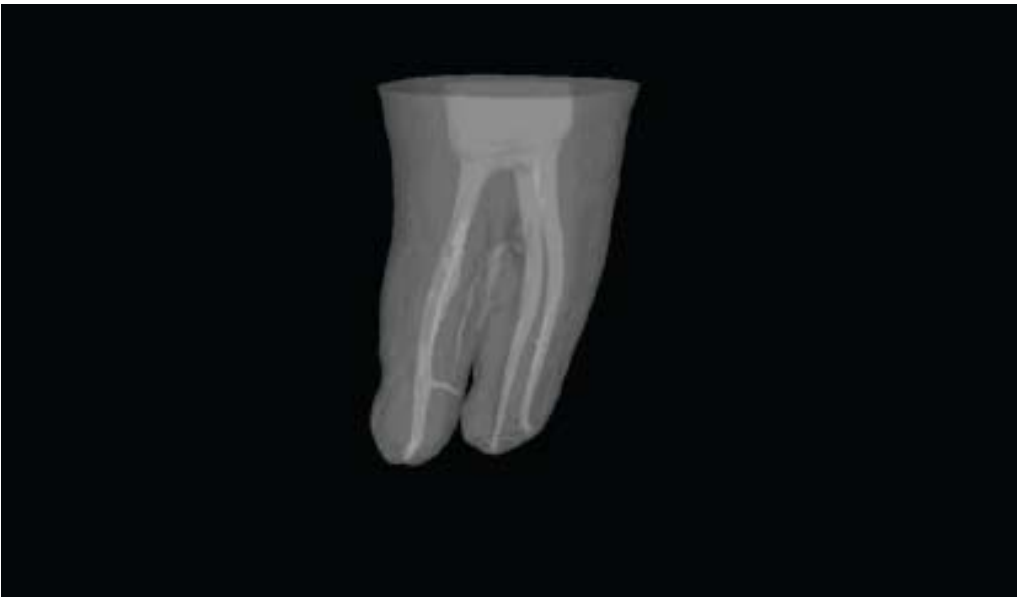


Fig. 29a. Profile



Fig. 30a. Profile

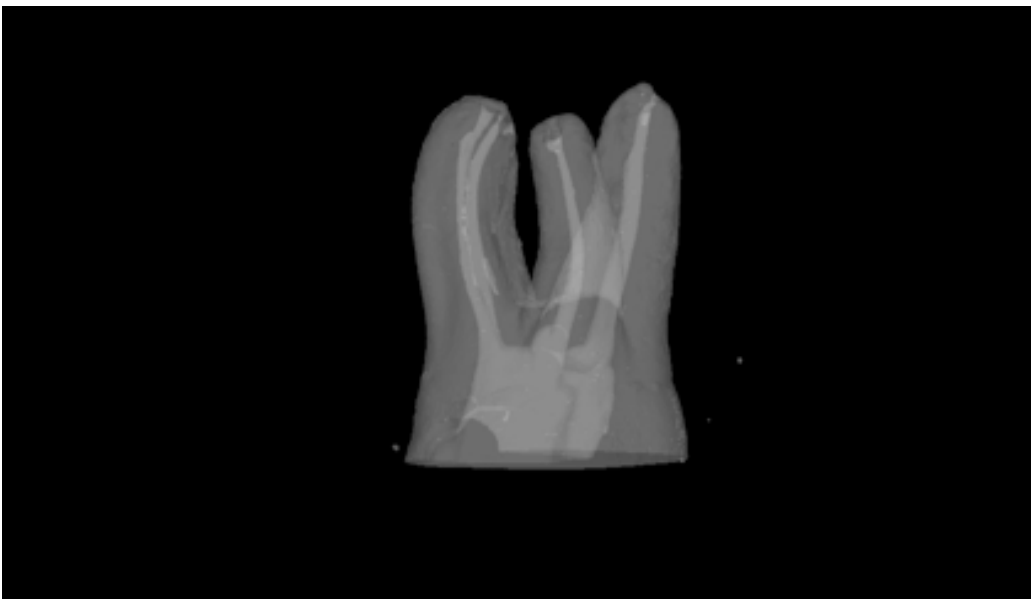


Fig. 30b. Profile

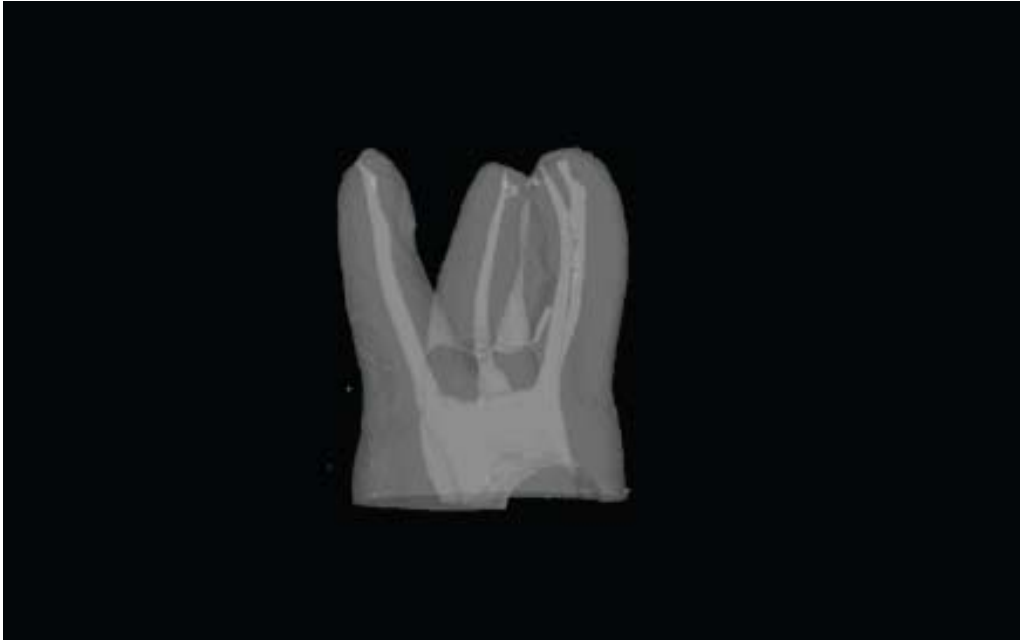


Fig. 31a. Profile



Fig. 31b. Profile

Hybrid technique

Despite variations in dental anatomy, the outcome of shaping using nickel-titanium rotary instruments is mostly predictable (Peters 2004) and result in centered apical preparations (Bergmans et al. 2003, Leoni et al. 2007). The rotating movement of the NiTi instruments tends to give the canal a definitive shape, with a known minimum diameter and taper at all levels of the root. This will promote a predictable obturation with hot gutta-percha, where it is necessary to bring tapered pluggers or carriers deep into the canal (Buchanan 2000). In reference to the aforementioned, it has been reported that a better root fill was obtained when obturating oval-shaped root canals with the use of hot gutta-percha (Wu et al. 2001). Compared to the NiTi system the stainless steel system does not offer this definitive shape. However, it has been demonstrated that the apical third of premolars, after instrumentation with a .02 tapered AET instrument resulted in a final diameter of 0.40 mm with a circular shape (Grande et al. 2007a), which is desirable for obturation of a canal (Tan & Messer 2002). In order to obtain an apical preparation with a known diameter and a known taper that promote predictable obturation with vertical condensation of hot gutta-percha, nickel-titanium rotary instruments may be used to prepare the apical third after preparation of the coronal and middle third with the AET Shaping Files (Grande et al. 2007c). Combining these two techniques was coined a “Hybrid Technique” by Walsh (2004). The hybrid concept is to combine instruments of different file systems and use different instrumentation techniques to manage individual clinical situations so as to achieve the best biomechanical cleaning and shaping results and the least procedural errors (Grande et al. 2007d). The hybrid concept combines the best features of different systems for safe, quick and predictable results. When combined in a hybrid technique, the strengths of both systems are put to good use. The high flexibility of nickel-titanium rotary instruments, even in the largest sizes (Grande et al. 2006a), permits adequately preparation of the apical portion of root canals, even in the presence of significant curvatures. Furthermore, Riitano had suggested NiTi for apical files, which will be introduced in 2009. Enlargement of the coronal and middle third established with the use of the AET Shaping Files, permits the Ni-Ti rotary instruments to reach the apical portion of the root canal in a straight path without coronal interferences and without binding in the coronal and middle portion of the root canal, thus reducing stress on the instrument and consequently reducing the risk of fracture. With the Shaping instruments in the AET technique it

is possible to simultaneously complete the initial negotiation, the circumferential canal enlargement, the elimination of all interferences, while creating straight line access of the first '2/3' of any canal regardless of its diameter, morphology and length. The AET Shaping Files are instruments that realize an effective pre-flaring of the coronal and middle third, substituting the instruments used as "opener" in the nickel-titanium crown-down technique. The use of the AET Shaping Files will create an anatomical enlargement of the coronal and middle third rather than creating the shape of Ni-Ti rotary instruments with big tip sizes and big tapers that are used for the (indiscriminate) coronal enlargement until the first steps in the crown-down technique start. The hybrid technique will also permit to the Ni-Ti rotary instruments to be used in a safer way to treat the apical portion of the root canal, with less risk to bind the tip of the instrument. The hybrid technique also reduces the risk of torsional fracture and allows maintaining a straight-line access to the apical third, thus reducing the risk of fatigue fracture in more abrupt curvatures. The use of flexible Ni-Ti instruments to prepare the apical third will permit the use of a file that is large enough to ensure cleaner canals that after instrumentation result in a circumferential enlargement in the apical 3-4 mm. This will make cone fitting much easier and can promote a more predictable root canal filling. Independent reports on the use of AET instruments for root canal retreatment have appeared. Zmener et al. (2005b), Zmener et al. (2006) compared the efficacy of ProFile .04 taper nickel-titanium rotary instruments, AET and manual instrumentation with Hedstrom files for the removal of gutta-percha/sealer from oval-shaped root canals. Their findings demonstrated that the use of AET and manual instrumentation was significantly more effective than ProFile with respect to cleanliness of the entire canal. AET Shaping Files have sharp cutting edges, which may account for a more effective cutting of the gutta-percha. AET was as fast as ProFile and significantly faster than manual instrumentation in the removal of gutta-percha/sealer and deformation of AET instruments was significantly less than ProFile. The authors also pointed out that completely clean canals were not obtained with any of the techniques that were tested. The more effective removal of debris in the coronal and middle thirds by AET may be explained on the basis that the stainless steel instruments are stiffer than nickel-titanium rotary instruments and can be safely directed towards the root canal walls allowing for a better performance in polar recesses of oval canals. The use of flexible stainless steel instruments was probably more

efficient in following the natural shape of the oval-shaped canals than Ni-Ti instruments.

Conclusions

The AET EndoEze system appears to be a safe and effective system for instrumentation of root canals. I thorough understanding of the technique and the philosophy behind the concept is important for any practitioner using this system or the “hybrid” system. Properly used, the system establishes a basis for predictable mechanical debridement and prepares the root canal for optimum obturation.

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CLINICAL OUTCOMES OF ENDODONTICALLY TREATED TEETH ROOT FILLED WITH RESILON

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INTRODUCTION

The role of bacteria and their byproducts in the development of pulp and periapical disease has been well established (Kakehashi et al. 1965). Therefore, the main goal of clinical endodontic treatment is to prevent the ingress of or the elimination of microorganisms from the root canal system (Sundqvist and Figdor 1998). This goal may be achieved by thorough debridement and disinfection of the root canal system, followed by the placement of a root filling and coronal restoration to prevent recontamination of the root canal system. Complete periradicular healing after endodontic treatment may be influenced not only by the effectiveness of the microbial control procedures, but also the apical extent of the root filling materials, the composition, biocompatibility and performance of these materials, the quality of the coronal restoration and host response (Ray and Trope, 1995; Chugal et al. 2001; Walton and Torabinejad 2002).

The main functions of root filling materials are to prevent the coronal ingress of oral fluids and bacteria, 'entomb' the bacteria that persist after the debridement and disinfection procedures and to prevent the apical penetration of tissue fluids into the canal space that may serve as a source of substrate (Sundqvist and Figdor 1998). Gutta-percha with various sealers has been the standard against which other materials are compared (Walton and Torabinejad 2002). However, despite the high clinical success rates demonstrated by University and specialty-based outcome studies, traditional root filling materials have been shown to be less than ideal (Madison and Wilcox 1988; Khayat et al. 1993, Trope et al. 1995). As such, research to find better mate-

rials that may provide an increase in favorable clinical outcome is mandatory.

Recently a thermoplastic synthetic polymer-based root canal filling material has been developed that might be used as an alternative core obturation material. This material Resilon originally developed by Resilon Research LLC (Madison, CT), is made of polycaprolactone, and contains bioactive glass, bismuth oxychloride, and barium sulfate. The corresponding sealer, Epiphany Root Canal Sealant (Pentron Clinical Technologies, Wallingford, CT), is a dual-cure dental resin composite sealer (Shipper et al. 2004). These obturation materials have been compared with gutta-percha and various sealers in preclinical studies evaluating microleakage (Shipper et al. 2004), fluid filtration leakage (Biggs et al. 2006), cytotoxicity (Key et al. 2006), surface characteristics after exposure to enzymes (Tay et al. 2005), and differences in periapical inflammation in dogs with apical periodontitis (Shipper et al 2005; Leonardo et al. 2007).

The endodontic literature that evaluates success and failure is diverse (Brynnolf 1967; Kerekes and Tronstad 1979; Hoskinson et al. 2002; Field et al. 2004; Kojima et al. 2004; Conner et al. 2007; Cotton et al. 2008). The parameters and methods of evaluation for determining the outcome of treatment vary among studies. In addition, the factors evaluated for prognostic purposes also vary among studies, as does the statistical method for evaluation. This makes assessment of the literature difficult in regards to what is deemed success and what factors might influence the outcome of treatment. Comparing the clinical outcomes between Resilon and Epiphany sealer and gutta-percha and Kerr Pulp Canal Sealer is important from a treatment perspective. Regardless of the reported outcomes from multiple in vitro studies evaluating Resilon, clinical decision-making should be based on the outcomes of clinical research (Cotton et al. 2008).

Clinical outcomes (healed versus non-healed) have been assessed by using the Periapical Index determination and clinical evaluation at recall appointments (Orstavik et al. 1986). The Periapical Index (PAI), a scoring index based on histological analysis by Brynnolf (1967) assigned a rating on a 5-point scale, in which score 1 represented teeth with normal apical periodontium, and score 5 denoted the presence of a radiolucency and radiating expansion of bony structural change. Periapical tissues were classified as Healed (PAI scores of 1 or 2

and the absence of clinical signs or symptoms of disease), Healing (PAI scores that have improved but not reached a score of 2) or Non-healed/Diseased (PAI scores above 2 that have remained unchanged or have increased, and cases with clinical signs or symptoms of disease (Orstavik et al. 1986).

Figure 1 is an example of an upper bicuspid with a PAI score of 5 at the start of the treatment. Resilon/Epiphany was placed and by means of periodic recalls the success/failure of the treatment was evaluated. After 4 years a PAI score of 1 was given, complete healing, filling of the defect and no symptoms.



Fig. 1. Periapical lesion with significant bone loss. A Resilon/Epiphany root canal filling was done. Note slight extrusion of Resilon point through the apex with significant extrusion of sealer. After 4 years the periapical bone has completely filled the original defect, however, excess sealer is still present. Here is a clinical example that demonstrates the biocompatibility of the sealer.

Clinical studies

The following 3 studies represent the currently available human clinical trials.

Study 1: Retrospective outcome of endodontic treatment performed in private practice by several clinicians using a non-standardized protocol with Resilon as the filling material; 1-year follow-up results (Conner et al. 2007).

This study compared immediate postoperative (IPO) radiographs with short-term (1 year) post-treatment, follow-up (F) radiographs from endodontic cases treated in private practice with the Resilon system root filling. These findings were then compared with gutta-percha-treated teeth reported in the endodontic literature.

Approval for the project was obtained from the UNC School of Dentistry Committee on Investigation Involving Human Subjects. A total of 16 dentists provided the investigators in this study with the IPO and F radiographs of 82 teeth that had been root-filled with Resilon. Participating private practitioners were from the continental U.S. and Western Europe. Teeth were randomly selected by the practices office managers, without input from the practitioners, with the agreement that patients and doctors would remain confidential. The study accepted radiographs of teeth with and without pretreatment apical periodontitis but did not collect diagnostic information or patient-related variables. The patient was required to be asymptomatic when the postoperative radiograph was taken. Beyond the use of Resilon root filling, there was no standardization regarding endodontic treatment protocol or technique used by practitioners. Radiographic guidelines were required to have similar projection angles between IPO and F films, demonstrate the entire apex and lesion, and have at least 1-year follow-up. Besides the PAI evaluation, the Clinical Impression of Healing (CIH) was used to assess the 1-year outcome. Three examiners were used for this evaluation. In this approach, there was no evaluation reliability requirement; clinical observers viewed the IPO-F pairs with a known restoration status, and the observed teeth received 1 of 3 ratings: healed, healing, or not healed/not healing. Also, average proportions were calculated for the healed/healing and not healed/not healing categories. After these calculations for PAI and CIH, comparisons were made with gutta-percha-based results reported in the endodontic literature.

Results from PAI: Fifty-two of 82 teeth started healthy (PAI 1, 2). Of these, 47 (90.4%) remained healthy. Five of the 52 teeth (9.6%) started healthy and ended unhealthy (PAI 3-5). Thus, the success rate (PAI 1,2) for teeth without pre-operative apical periodontitis was 90.4%.

Thirty of the 82 teeth started unhealthy (PAI 3-5). 15 (50%) finished healthy (PAI 1, 2), seven (23.3%) were improved, but not yet healed (PAI >2). Thus, the healed and healing rate for the unhealthy teeth was 73.3%.

Results from the CIH analysis were dichotomized into favorable (healed or healing teeth) and unfavorable healing (not healed/healing). There was an average of 90.9% favorable healing. The CIH classification did not permit analysis of a starting condition of the teeth; teeth in the process of healing were subsumed under the category of favorable healing. One evaluator, who was also calibrated according to the PAI protocol, gave the most favorable ratings for the 82 experimental teeth.

This study was unique in that it evaluated randomly selected cases from private dental offices. The results were obtained from practitioners using various treatment and restorative protocols, however, the one commonality was the use of Resilon as the root filling material. As these practitioners had no prior knowledge that in the future their cases would be used for outcome assessment, it was assumed that the results represent the outcomes expectations from private practice (Conner et al. 2008).

In conclusion, both the PAI and CIH results of this study were comparable to University-based outcome studies when gutta-percha and sealer were used. As such, the cases root filled with Resilon were as successful as those filled with gutta-percha and sealer. Figure 2 is an example of a case that started out unhealthy and had a PAI score of 5. After 3 years, healed and symptom free, a score of 1 was assigned



Figure 2. A periapical lesion under an existing bridge with a score of PAI=5. After 3 years the lesion had completely healed. PAI=1

Study 2: Retrospective outcome of endodontic treatment performed in private practice by a single clinician using a standardized protocol with Resilon as the filling material; up to 25 months follow-up results (Cotton et al. 2008).

The purpose of this retrospective study was to evaluate the treatment outcome of root canal systems obturated with gutta-percha and Kerr Pulp Canal Sealer compared with Resilon and Epiphany sealer. One hundred three teeth treated in a private endodontic practice by a single endodontist were included in the

study. Clinical outcomes (healed versus non-healed) were assessed by using the Periapical Index (PAI) and clinical evaluation at recall appointments. The magnitude of the association between obturation materials used and outcome measured was evaluated with univariate and multivariate logistic regression analysis.

This study was approved by the Institutional Review Board of the University of Texas Health Science Center at San Antonio. The sample population was initially composed of 276 endodontically treated teeth of patients who were referred by general practitioners to a single practitioner endodontic practice located in Wichita, KS. The patients were treated between August 2003 and May 2004. The endodontic office in this study provided 2 fully equipped rooms for treatment. One room was equipped for obturation with gutta-percha and Kerr Pulp Canal Sealer and the other with Resilon and Epiphany sealer. All other equipment and instruments were the same in each treatment room. Patient assessment, treatment data, and radiographs were obtained by both the practitioner and his staff, while the diagnosis and treatment was being provided by a single endodontist with 18 years of private practice experience. Digital radiographs were taken with variable exposure times, and Schick sensors and software (Schick Technologies, Inc, Long Island City, NY) were used to capture the radiographic images. At each appointment, patients were seated in the first available treatment room. This patient allocation method did not take into account any demographic or preoperative variables at the time of treatment room assignment. Canals were obturated with the material assigned to the treatment room that the patient was in at the time of obturation, independent of the treatment room occupied at any previous visit. Every patient was anesthetized, and a rubber dam was placed. Access was made, canals were located, and coronal flare was obtained with a rotary ProFile GT size 20, 0.06 taper (Dentsply Tulsa Dental, Tulsa, OK). Stainless steel FlexoFile (Dentsply Maillefer, Tulsa, OK) hand files and an Elements Apex Locator (Sybron Endo, Orange, CA) were used to determine working length (WL) as the point at which the apex locator read 0.0. Then rotary K3 size 15–25 with a 0.02 taper (Sybron Endo) and rotary ProTaper S1, S2, and F1 (Dentsply Tulsa Dental) nickel-titanium (NiTi) files were used to initially clean and shape the canals to WL. Light-Speed NiTi rotary instruments (LightSpeed Technology, Inc, San Antonio, TX) were then used without rotary power to determine the largest size that

would go past WL. This size was recorded, and the canal was then prepared with a K3 0.04 or 0.06 taper to the previously determined LightSpeed size. After canal preparation to the size of the largest LightSpeed that would go past WL, larger LightSpeed instruments were inserted. If a LightSpeed of 2 sizes or greater easily fit to within 1 mm of the WL, the canal would then be prepped with a K3 0.04 or 0.06 taper to match the larger size at the shorter length determined by the LightSpeed instrument.

Throughout treatment the canals were irrigated with 5.25% NaOCl warmed in a beaker on a warming device. A final flush of hydrogen peroxide followed by a rinse of 17% ethylenediaminetetraacetic acid (EDTA) to remove the smear layer completed the irrigation. All irrigants were dispensed with a Monojet syringe through a 30-gauge Max-i-Probe (Dentsply Rinn, Elgin, IL) needle. The volume of irrigants was not recorded. Canals were then dried with sterile paper points. For multiple visit appointments, UltraCal XS (Ultradent Products, Inc, South Jordan, UT) calcium hydroxide was dispensed into the canal by using a 30-gauge needle followed by a sterile cotton pellet and a temporary restoration of Cavit or intermediate restorative material (IRM).

Before obturation, WL length was confirmed with the Elements Apex Locator. A master cone of the obturation material to be used was selected to match the final size and taper of the canal preparation to WL, placed to length for assessment, and then removed. For canals that were prepared to a larger size within 1 mm short of WL, a cone of corresponding size and taper was selected, and the apical 3 mm of the cone was softened with chloroform. The cone was then fit to WL and removed. For canals obturated with gutta-percha, Kerr Pulp Canal Sealer was mixed, and the gutta-percha master cone was coated and placed back to WL. For canals obturated with Resilon, a sterile paper point was used to apply the Epiphany primer to the walls of the canal. A dry paper point was then placed to length and used to absorb excess primer inside the root canal. The Resilon master cone was coated with Epiphany sealer and placed to length. Both obturation materials were then incrementally down-packed by using a System B (Sybron Endo) and condensers. The goal was to down-pack and condense to within 3 mm of WL or as close to that as possible. After the down-pack, the canals were backfilled by using an Obtura II gun (Obtura Spartan, Fenton, MO) with

the same obturation material as the master cone. The material was finally condensed at the orifice(s), with the Resilon and Epiphany sealer obturated canals being light-cured for 40 seconds. After obturation, the chambers were closed with composite, amalgam, or a sterile cotton pellet followed by Cavit or IRM. The post-obturation restoration was determined on the basis of the referring dentist's preference and the endodontist's judgment of maintaining a coronal seal.

After treatment, patients were mailed postcards and telephoned to set up a recall appointment. A total of 117 treated teeth from 110 patients were recalled, with recall times ranging from 2–25 months. At the recall appointment, patients were seated, and a radiographic image was acquired. The treated tooth was tested with percussion, the area was visually inspected and palpated, and any complaints by the patient were recorded. Asymptomatic/within normal limits (WNL) was recorded if no clinical symptoms were present. The type of restoration present at the time of recall was also recorded. Treatment and recall data were recorded and stored in the endodontic practice's TDO (Dog Breath Software, Inc, San Diego, CA) software. The data from the patients' charts were assessed retrospectively by independent observers consisting of a board-certified endodontist and an endodontic resident and analyzed by a statistician. None of the observers were involved in treatment of the teeth. The data from 117 recalled teeth were subjected to various exclusion criteria without consideration as to the type of obturation material used. Initially, 3 teeth were eliminated from the study for various reasons. One tooth obturated with gutta-percha Kerr sealer was extracted by a general dentist without being evaluated by the endodontist, another tooth obturated by gutta-percha Kerr sealer was extracted as a result of a vertical root fracture confirmed on extraction, and a third tooth obturated with Resilon/Epiphany was re-treated as a result of an initial procedural error. Nine teeth (5 obturated with gutta-percha Kerr sealer, 4 obturated with Resilon/Epiphany) were eliminated because either the immediate postoperative or the recall radiograph did not adequately show the apices and surrounding bone of the tooth being evaluated. In addition, 3 adjacent teeth in 1 patient had confluent periradicular radiolucencies, and all were obturated with Resilon/Epiphany at the same appointment. One tooth was selected randomly to be included in the study, and the other 2 were eliminated. After the exclusion criteria were applied, 103 endodontically treated teeth (50 obturated with gutta-percha

Kerr sealer, 53 obturated with Resilon/Epiphany) from 98 patients remained to be evaluated in the study. All teeth presented with permanent restorations at the time of recall. Eighty-three teeth (41 obturated with gutta-percha Kerr sealer, 42 obturated with Resilon/Epiphany) were recalled at 12–25 months. The 12–25-month group was further divided into an intermediate recall group of 12–18 months having 15 teeth (8 obturated with gutta-percha Kerr sealer, 7 obturated with Resilon/Epiphany) and a long recall group of more than 18 months having 68 teeth (33 obturated with gutta-percha Kerr sealer, 35 obturated with Resilon/Epiphany). Twenty teeth (9 obturated with gutta-percha Kerr sealer, 11 obturated with Resilon/Epiphany) were recalled in less than 12 months. The data were evaluated for all 103 teeth (entire population), regardless of recall time, and then for the subset of 83 teeth (12–25-month recall group) with a recall of 12 months or greater. Finally, subsets of patients with preoperative lesions in the above 2 groups were analyzed.

Results: The overall healed rates (PAI 1, 2) for the entire population (2–25 months follow-up) and the 12–25 month recall group were 78.6% and 85.5%, respectively. Overall, the success rates were similar to other outcome assessment studies (Kerekes and Tronstad 1979; Hoskinson et al. 2002; Field et al. 2004; Kojima et al. 2004).

This study found through univariate and multivariate analysis that the type of obturation material, either gutta-percha and Kerr Pulp Canal Sealer or Resilon and Epiphany sealer, had no detectable difference in the outcome of endodontic treatment as assessed by means of PAI radiographic scoring and based on clinical symptoms.

Study 3: Prospective outcome of endodontic treatment performed in private practice by a single clinician using a standardized protocol with Resilon as the filling material; 2 and 4 year follow-up results (Debelian, Manuscript in preparation).

The endodontic treatment was performed on patients referred to a private endodontic practice in Bekkestua, Norway, between October 2003 and February 2004. One hundred-twenty teeth were included in this study and were comprised of 67 teeth diagnosed with ‘vital’ pulps and 53 teeth with ‘non-vital’ pulps with apical periodontitis. All treatments were performed by one endodontist. After a thorough medical and dental history, routine endodontic

testing was performed to establish both a pulpal and periapical pre-operative diagnosis. Teeth were excluded from this study if they had any of the following criteria: periodontal probing defects >4mm, crown or root fractures, canals not negotiable to within 3mm of the radiographic apex on teeth with apical periodontitis, obliterated canals and previous endodontic treatment.

Two procedural protocols were strictly adhered to based upon the pre-operative pulpal and periapical diagnosis. Local anesthesia was administered and a rubber dam was placed. All endodontic treatment was aseptically performed under 5-8x magnification using a dental operating microscope. An apical-box preparation was made using handfiles and RaCe NiTi rotary instruments, to a minimum apical size of #35/.02 taper (Kerekes et al. 1979). 1% NaOCl was used for irrigation throughout the procedure and 17% EDTA was used as a final rinse. Both irrigants were ultrasonically activated for at least 10 seconds per canal. Coronal restorations were placed prior to the removal of the rubber dam.

1. Treatment protocol of teeth with 'vital' pulps:

The working length was established at 1.0mm short of the apical foramen as determined by an electronic apex locator. The root filling was completed at this visit, using lateral condensation. A coronal restoration was then placed.

2. Treatment protocol of teeth with 'non-vital' pulps with apical periodontitis (2-visit procedure):

1st visit: The working length was established at 0.5-1.0mm short of the apical foramen as determined by an electronic apex locator. The instrumentation and irrigation protocols were the same as described above. However, in this group, the canals were filled with 2% chlorhexidine for 5 minutes as a final soak. After the canals were dried with sterile paper points, an inter-appointment medication of Ca(OH)₂ paste was placed with a lentulo spiral. The patient was scheduled for the second visit at 3-4 weeks.

2nd visit: The Ca(OH)₂ paste was removed with 17% EDTA with ultrasonic activation. If the patient was asymptomatic and all canals could be dried, the Resilon root filling was placed using lateral condensation. If however, the patient was still symptomatic at the second visit, or if the canals could not be dried due to persisting exudation, a paste of Ca(OH)₂ was again placed to the WL, but this time for a period of 3 months. If, at 3 months, the patient was

free of symptoms and the canals could be dried, the tooth was completed as above. However, if symptoms and exudation persisted, systemic antibiotics were prescribed and/or apical surgery was performed.

Post-treatment radiographs were taken and all patients were put on a recall schedule of 6 months, 1, 2, 3 and 4 years. At recall visits, the patient was clinically and radiographically assessed for signs and symptoms of post-treatment disease. The PAI scoring system (Orstavik et al. 1986) was used to evaluate the periapical conditions. The operator and 2 additional endodontists scored the recall radiographs, and an average of the three scores were used as the final PAI score. 108 of 120 treated teeth were available at the 2-year recall, which represents a 90% recall rate. At the 4 year recall, 102 cases were available for examination; an 85% recall rate. A PAI score of 1 or 2 was considered to be Successful, whereas a PAI score >2 was deemed a Failure.

Results at 2 years:

101/108 teeth (93.5%) were scored as successful (PAI 1,2). 57/60 teeth (95%) that were without pre-operative apical periodontitis were scored as successful. 44/48 teeth (91.6%) that were diagnosed as 'non-vital' pulps with apical periodontitis were scored as successful.

Results at 4 years:

86/102 teeth (93.1%) were scored as successful (PAI 1,2). 53/56 teeth (94.6%) that were without pre-operative apical periodontitis were scored as successful. 42/46 teeth (91.3%) that were diagnosed as 'non-vital' pulps with apical periodontitis were scored as successful.

These results are similar to other outcome studies for the treatment of 'vital' teeth without apical periodontitis (Kerekes and Tronstad 1979; Hoskinson et al. 2002; Field et al. 2004; Kojima et al. 2004). However, for teeth with pre-operative apical periodontitis, the treatment protocol used in this study appears to yield the same success rate as 'vital' teeth without pre-treatment apical disease. This finding is quite interesting, because this outcome is better than those seen in previous studies for teeth with pre-operative apical periodontitis (Kerekes and Tronstad 1979; Hoskinson et al. 2002; Field et al. 2004; Kojima et al. 2004). It is unknown if the use of Resilon as the root filling material in this study was responsible for the higher success rate of teeth with apical periodontitis than what has been previously shown, or the strict

adherence to a Ca(OH)₂-based two-visit protocol, or the use of 2% chlorhexidine or the combination of all of the factors. Until further clinical trials can be performed, the strict 'biologically-based' protocol used in this study should be considered.

CONCLUSION

In conclusion, these three human clinical trials clearly demonstrate that the use of the Resilon system for root filling allows for the same high degree of clinical and radiographic success as University-based clinical studies with gutta-percha and sealer (Kerekes and Tronstad 1979; Hoskinson et al. 2002; Field et al. 2004; Kojima et al. 2004). Additionally, the strict adherence to a two-visit Ca(OH)₂-based approach may offer a higher success rate for teeth with pre-operative apical periodontitis. Further longer-term recall evaluations are recommended and will be reported on in due time.

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THE EFFECT OF IRRIGATION PROTOCOL ON THE POLYMERIZATION OF RESIN-BASED SEALERS – SIGNIFICANCE OF OXYGEN INHIBITION

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Osvaldo Zmener

INTRODUCTION

During the last 10 years Methacrylate-Based Resin Sealers (MBRS) have gained popularity for root canal obturation and have been accepted by the ADA Council on Scientific Affairs (1998). It has been well established that many factors may affect the setting properties of methacrylate-based resin endodontic sealers. One of these factors is the choice of irrigating solutions used throughout the biomechanical preparation of the root canal. NaOCl and EDTA are commonly being used as chemically active irrigants (Baumgartner and Mader, 1987; Spanó et al. 2002; Hülsmann et al. 2003). NaOCl breaks down to sodium chloride and oxygen, of which the latter has a strong inhibiting effect on the polymerization of methacrylate-based resin materials (Nikaido and Nakabayashi, 1998; Nikaido et al. 1999; Rueggeberg and Margeson, 1990; Franco et al. 2002). Therefore, it has been recommended to remove all traces of NaOCl by gently flushing the root canal with EDTA. It should be further noted that some authors (Morris et al. 2001; Bergmans et al. 2005; Nagas et al. 2007; Zmener et al. 2008) suggest using an additional flush with saline or sterile distilled water before obturation. This is recommended to minimize the adverse effect of possible NaOCl remnants on free-radical polymerization. In a pilot experiment (Zmener and Pameijer, 2009; unpublished data) the authors used a Gilmore needle and adhering to a slightly modified ANSI/ADA specification No. 57 (ANSI/ADA 2000), analyzed the effect of different irrigants on the bulk setting of EndoREZ (ER) (Ultradent Prod-

ucts Inc, South Jordan, UT). Tests were performed at the center and adjacent sites of the specimens, however the borders contacting dentin were not tested. Remnants of NaOCl may be present in the dentinal tubules and the intertubular dentin and is at this interface and the dentinal tubules that an oxygen inhibited layer will be formed. Since the hydrophilicity of the sealer promotes penetration into the dentinal tubules (Bergmans et al. 2005), any contamination with NaOCl will have an inhibiting effect on the polymerization of MBRS. Viewed in cross-section, MBRS may have fully set away from the canal walls, but not at the interface. Unpolymerized resin at this interface is undesirable as it is a methacrylate-based resin sealer's prime objective to prevent microleakage; unpolymerized resin offers a pathway for leakage. It has been reported in the literature that the sealing ability of an endodontic sealer and the correlation it has to bond strength to dentin, has not been clearly determined (Huffman et al. 2009). Resistance to dislocation from the dentinal walls should not be adversely affected by possible remnants of irrigating solutions. In order to evaluate the dislocation resistance of root canal filling materials, a thin-slice push-out test has been used as the method of choice (Sousa Neto et al. 2005; Skidmore et al. 2006 Bouillaguet et al. 2007; Fisher et al. 2007; Nagas et al. 2007; Lawson et al. 2008). Of interest here, as well as in additional studies is the diversity of the experimental design of the studies and the methodology used.

Jainaen et al (2007) evaluated the push-out bond strength of three endodontic sealers, AHPlus, EndoRez and Epiphany with and without a single master cone. After completion of canal preparation, a final rinse with 5 mL 15% EDTA was followed by 5 mL distilled water with the objective to minimize the effect of NaOCl on free radical polymerization. The canals were dried with paper points. Subsequently a 1 mm thick section of mid-root dentin was prepared and tested for bond strength. The results showed that AHPlus generated the highest push-out bond strength. Values were higher when the canals were filled in bulk using only the sealers. The authors recorded: AH-Plus 6.6 Mpa, Epiphany 3.4 Mpa, EnodREZ 0.9 MPa. Nagas et al. (2007) employed a push-out bond strength test and evaluated microleakage of the Epiphany/Resilon obturation system using different polymerization photo activation methods (QTH, LED, PAC) on human maxillary central incisors. The irrigation protocol during canal preparation consisted of RC-Prep and 5% NaOCl. After canal preparation a final rinse with 5 mL NaOCl was followed by 5 mL 17% EDTA and 10 mL of distilled water. Canals were dried with

paper points. They tested 2 mm thick horizontal slices. The maximum push-out bond strength was obtained when the quartz-tungsten halogen was used for polymerization (3.9 MPa).

Fisher et al. (2007) compared the bond strength to root canal dentin of single gutta-percha cones + Pulp Canal Sealer (Kerr Corp. Romulus, MI), which is a ZOE-based sealer; single gutta-percha cones + AHPlus; single Resilon cone + Epiphany; Activ obturation system (Brasseler, Savannah, GA) and single g-p cone + EndoREZ. During preparation, the canals were irrigated with 5.25% NaOCl and a final rinse with 17% EDTA. After preparation, the canals were dried with paper points. They tested 1 mm thick slices obtained at the coronal, middle and apical thirds. The coronal sections scored higher push-out strengths. AH Plus showed the highest values (2.0 MPa), The ZOE-based sealer was 0.79 MPa, Activ GP 1.10 MPa, Resilon/Epiphany 0.32 MPa and EndoREZ 0.09 MPa.

Using similar tests Lawson et al. (2008) evaluated MetaSeal (Parkell Inc, Farmington, NY) a methacrylate-based endodontic sealer and compared it with AHPlus with either a single g-p cone or warm vertical compaction. Human mandibular incisors were irrigated with 6.15% NaOCl with a final rinse of 17% EDTA. The canals were then dried with paper points. These authors tested 1.5 mm thick slices from the coronal and middle thirds. The push-out bond strength of AHPlus was significantly higher ($p < 0.05$) than MetaSeal irrespective of the obturation technique. Resin tags were an inconsistent presence in the MetaSeal Group. The authors concluded that the use of self-adhesive bonding materials to create continuous bonds within root canals is not appropriate.

And in yet another push-out test Bouillaguet et al. (2007) used single rooted human teeth and analyzed the bond strengths of EndoRez, Epiphany, and an acrylic cone bonded with SE Bond to radicular dentine. Irrigation consisted of 3% NaOCl and a final rinse with 17% EDTA followed by distilled water. The canals were then dried with 95% ethanol and multiple paper points. They tested 0.7 mm thick slices for the push-out strength. EndoREZ and Epiphany exhibited the lowest bond strengths (subsequently 2.5 and 5.0 MPa) but not significantly different from each other ($p > 0.05$). The highest bond strength was achieved with the Clearfil SE bond.

Objectives

The aim of this experiment was to evaluate the bond strength values of ER using different intracanal irrigation scenarios. A modification of the thin-slice push-out test design was used in an effort to standardize the experiment. The null hypothesis in this study was that after the use of NaOCl and EDTA as irrigants, a final flush with saline or sterile distilled water is always necessary in order to remove all traces of these chemicals as they may negatively affect the complete polymerizations of the resin at the interface with dentin. An additional objective was to determine that bulk setting of EndoREZ was not subject to the irrigation protocol.

Material and Methods

Specimen preparation

Intact extracted human maxillary central incisors and canines, stored in de-ionized water with a few crystals of thymol, were used to fabricate customized dentin tubes that simulated prepared root canals. To meet the inclusion criteria, the teeth had to be without root caries, had to have wide non-calcified single straight root canals and the total external diameter at the coronal third of the roots had to measure at least 6mm. The teeth were decoronated with a water-cooled diamond-impregnated low-speed saw (Isomet, Buehler, Lake Bluff, IL), by cross sectioning at the cemento-enamel junction (CEJ) and at 8mm apical to the CEJ. After the removal of gross pulp tissue, the root canal space was progressively prepared/flared with #2 to #5 Gates Glidden drills (Dentsply/Maillefer, Ballaigues, Switzerland) until a depth of 6 mm was reached. Each root was centered in a lubricated aluminium ring (12mm internal diameter and 8mm high) and embedded in clear acrylic resin. After polymerization the sample was removed from the ring and placed on a fixed jig mounted on the base of a mini drill press. The canals were then progressively enlarged to the predetermined 6mm depth with #1.0 to #3.0-mm diameter parallel-side precision drills mounted in a low speed motor. Distilled water was used as a coolant to negate the effect of heat generation. The depth was standardized with a rubber stopper set at 6mm length. Each drill was used with light apical pressure with in and out movements. Improperly prepared samples were replaced with new ones. Subsequently the samples were sectioned horizontally at 3mm below the upper surface with the water-cooled low-speed saw (Isomet). This method produced 18 standardized cylindrical

dentin tubes, 3mm thick with a 3mm internal diameter. The tubes were then randomly assigned to three groups (n=6). Each section was placed on a glass histology slide and fixed with wax. The exposed lumen was then flushed with the following irrigation protocol:

Group 1 (n=6): Irrigation for 1 minute with 10 mL of 17% EDTA to remove the smear layer followed by a continuous flow of 10 mL of 5.25% NaOCl. The canal was then dried with a luer low vacuum tip for 2s followed by sterile cotton pellets leaving the dentin slightly moist with NaOCl.

Group 2 (n=6): Irrigation with a continuous flow of 10 mL of 5.25% NaOCl followed by 10 mL 17% EDTA (1 minute each) followed by drying with a luer low vacuum tip for 2s followed by sterile cotton pellets leaving the dentinal walls slightly moist with EDTA.

Group 3 (n=6): Irrigation with a continuous flow of 10 mL of 5.25% NaOCl followed by 10 mL 17% EDTA (1 minute each) and a final 2-minute rinse with 10 mL sterile distilled water. The canals were dried with a luer low vacuum tip during 2s followed by sterile cotton pellets leaving the dentinal walls slightly moist with distilled water.

All samples were then obturated with EndoREZ as follows.

The specimen was placed on a histology glass slide separated by a celluloid matrix strip. EndoREZ was then mixed according to the manufacturer's instructions and the mixed sealer was injected from the double-barrel syringe through the auto-mixing tip in the tubes with slight excess. The top surface was then immediately covered with a matrix strip covered by a glass slide, allowing excess material to be squeezed out by pressing the glass slide down. After 30 minutes bench setting all samples were kept at 37°C and 100% relative humidity in an incubator for 7 days to allow complete setting of the sealer. After the storage period, the matrix strip was removed from the top surface of the material and a Gilmore-type needle with a mass of 400 ± 0.5 g and a flat point of 1.0-mm in diameter was used at the center and adjacent sites of the specimens but at some distance of the borders contacting dentin to ensure that the sealer had set. The final thickness of the filled tubes was measured with a digital caliper (Mitutoyo Corp. Tokyo, Japan) to the nearest 0.01 mm. If a sample did not meet both aforementioned requirements it was excluded from the experiment and a replacement sample prepared.

Push-out test

For the push-out tests the tubes were fixed with sticky-wax to the upper

surface of a custom-made metal jig (which served as the support for the tubes) and additionally by two screws (Fig.1). The metal jig had a central opening over which the samples were centered. A stainless steel cylindrical plunger with a flat surface of 1.5mm in diameter was placed over the center of the sample and used to shear the sealer from the dentin walls. The plunger had a clearance of 0.75mm from the borders of the dentin walls and was attached to a load cell connected to a Universal Testing Machine (Instron Corp. Canton, MA USA). The samples were subjected to a compressive load with a cross-head speed of 0.5 mm/min until failure. The maximum force at failure was recorded in Newtons by using a data-analysis software, which plotted a load/

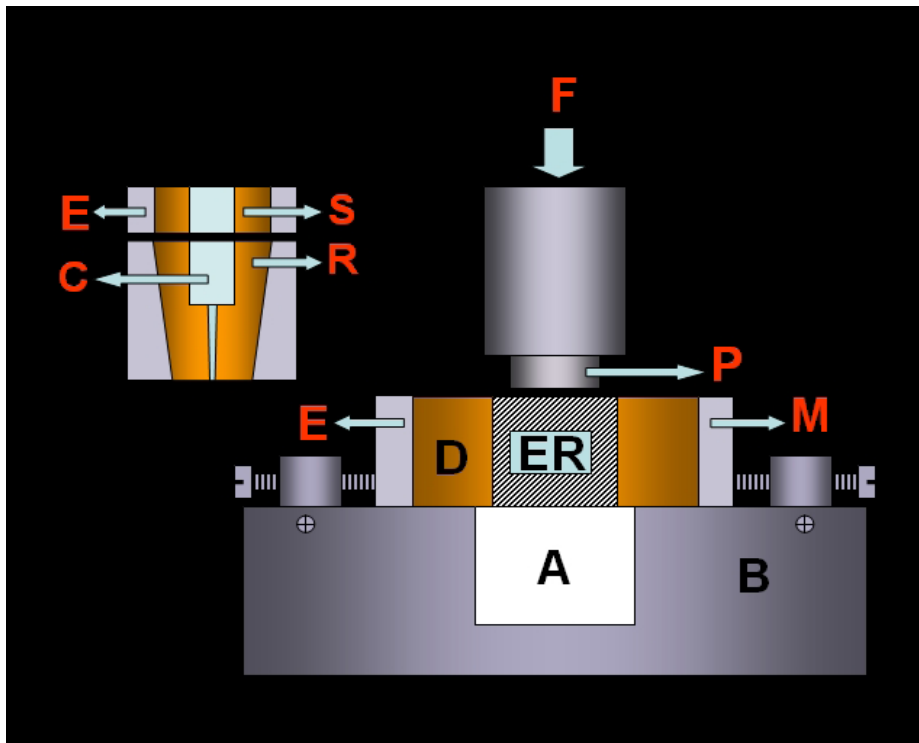


Fig.1. Schematic representation of the push-out test setup. A: Space for displaced sealer; B: Metal base of apparatus for sample fixation; F: Direction of force; P: Cylindrical plunger; D: 3 mm high root dentin cylinder; ER: EndoRez sealer; E and M: Lateral sides of acrylic resin; R: Remaining root; C: Cylindrical preparation of the root canal (6 mm long with a 3 mm internal diameter); S: 3 mm high root section embedded in acrylic resin. The black line below E and S represent the cut through the samples perpendicular to the long axis of the tooth.

time curve during compression testing. In each group, the push-out strength at failure was calculated by dividing the load by the total area of the bonded interface and expressed in MPa. Means were then calculated for each group and the data analyzed statistically by one-way ANOVA and Tukey's tests. A level of significance was set at $p < 0.05$.

After the push-out test, both sides of the dentin tubes were examined with a stereomicroscope at 40X magnification to determine the mode of failure. These were classified as described by Huffman et al (2009): 1. Adhesive failure along the sealer/dentin interface; 2. Mixed failure (partial adhesive failure along the dentinal walls and partial cohesive failure within the sealer) and 3. Cohesive failure within the sealer. In addition the samples were immersed in 0.5% methylene blue for 2 minutes, rinsed and photographed with the objective to visualize the dentin/ER interface.

Results

The test with the Gilmore-type needle demonstrated that the sealer in all samples had completely set. Two samples out of 18 did not meet the required thickness parameter and were rejected. They were replaced with new specimens. After replacement, the final 18 samples that were tested all had standardized dimensions and had no statistically significant differences ($p > 0.05$). The mean push-out bond strength results for the three groups are shown in Table 1. Specimens of Group 1 exhibited the lowest mean bond strengths (1.33 MPa), whereas Group 2 and 3 showed the highest, subsequently 7.95 MPa and 8.09 MPa, which were not statistically significant different from each other ($p > 0.05$). Groups 2 and 3 were statistically significantly different from Group 1 ($p < 0.05$).

Table 1. Mean push-out bond strength value in MPa (SD)

Group	n	Mean bond strength	range
1	6	1.33 (0.45)	0.69 – 1.73
2	6	7.95 (0.60)	8.67 – 7.11
3	6	8.09 (0.49)	8.67 – 7.28

The failure modes of the samples at the dentin/sealer interface revealed that in Group 1, samples showed mostly adhesive failure (5 samples). One sample

showed adhesive failure but in some areas of the canal wall, a few particles of the sealer were still present. In Group 2 and 3, the failure mode of the samples was cohesive within the mass of the sealer.

Discussion

An issue of confusion but of great significance with the use of Methacrylate-based resin sealers, is the irrigation protocol during and after instrumentation. What irrigation protocol requires a final rinse of sterile saline or distilled water after the use of NaOCl or EDTA? In particular, the effects of NaOCl have been thoroughly discussed but not sufficiently clarified (Ishizuka et al. 2001). The collagen of dentin is degenerated by the action of NaOCl by dissolving it, thus, residual NaOCl may still be present and interfere with polymerization due to oxygen generation of the resin-based materials in direct contact with dentin walls. In this study a modified push-out test design was used to analyze the effect of three different irrigating protocols on the bond strength of ER sealer to radicular dentin. In previous experiments, different areas from endodontically prepared roots (Bouillaguet et al. 2007; Faría e Silva et al. 2007; Fisher et al, 2007; Lawson et al. 2008) or conical cavities drilled into thin dentin slices (Patierno et al, 1996; Nagas et al, 2007; Alfredo et al. 2008) were used. In the present study, however, straight-walled standardized dentin cylinders simulating prepared root canals were tested. Although this experimental model does not correlate directly with the clinical reality, it provided a better standardized and more reliable and measurable dentin surface for a push-out test, since it is very difficult to get equal cleaning and shaping conditions along the full length of a natural tapered root canal preparation with the use of standard instrumentation procedures. As demonstrated by Peters (2004) and Zmener and Pameijer (2005), after canal preparation many non-instrumented areas are frequently present, especially in oval shaped root canals. As a result microorganisms may remain trapped in the dentinal tubulas as illustrated by Figure 1. Comparing the results from a natural root canal space in which probably 50% or more non-instrumented areas are present, to a simulated standardized cylindrical canal with almost 100% of instrumented and cleaned canal walls (Zmener et al, 2008; unpublished data), will no doubt result in a misleading interpretation of the push-out bond strength values.

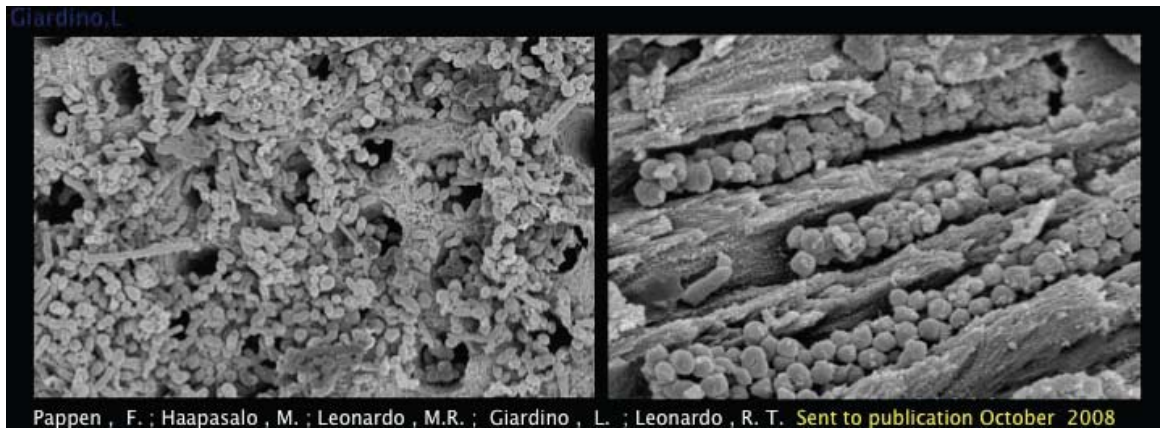


Figure 1. Scanning Electron Micrograph of microorganisms in dentinal tubules, in cross section (left) and longitudinally (right). (Courtesy; Pappen, F; Haapasalo, M; Leonardo, M.R.; Giardino, L.; Leonardo R.T.)

The results of the push-out tests revealed that all groups had measurable adhesive properties. Group 1 showed the lowest bond strength values, whereas Groups 2 and 3 were much higher. Although the results in Group 3 were slightly better, no statistically significant differences were demonstrated when compared to Group 2. Therefore based on these observations the null hypothesis was rejected. Our results are in agreement with those of Nikaido et al (1999), Erdemir et al (2004) and Osorio et al (2005), who showed a significant decrease in bond strength after NaOCl treatment. On the contrary, specimens treated with EDTA to remove the smear layer and being the final rinse showed no significant decrease in bond strength. Osorio et al (2005) speculated that the higher bond strength exhibited by these specimens may be due to an improved resin infiltration into the EDTA-demineralized collagen matrix. The bond strengths for ER reported in this study were higher than those reported by Fisher et al. 2007 and Bouillaguet et al. 2007, which can be based on the differences in testing methodology. The straight-walled cylindrical preparations used in the current study were drilled into 3.0 mm high dentin slices rather than the diverging wall preparation of 1.0 mm (Fisher et al, 2007) or 0.7 mm thick dentin slices (Bouillaguet et al, 2007). Obviously a 3.0 mm high straight-walled cylindrical preparation offers more frictional resistance to dislodgement than a thin-sliced tapered preparation (Patierno et al.1996). In addition, the use of different drying techniques with paper points (Fisher et al. 2007) or ethanol (Bouillaguet et al. 2007) may also account for these differences. In the current study, the dentin surfaces of the

samples were left slightly moist which had a positive effect and contributed to a superior bond strength. A moist dentin surfaces take advantage of the hydrophilic properties of ER sealer to develop long resin tags within the root dentinal tubules (Bergmans et al. 2005; Sevimay and Kalaicy, 2005). Another important factor to be considered is the elastic deformation modulus of the set sealer, a physical property that was not analyzed in this study. In this respect, all filling materials suffer deformation during loading, which in turn may interfere with the push-out from the cavity (Ishizuka et al. 2001). In order to minimize the adverse effect of material deformation, a plunger of 1.5 mm in diameter with an all around clearance of only 0.75 mm was used for ER sealer displacement.

The possible adverse effect of the cavity configuration factor (C-factor), which is considered extremely high in long and narrow root canals (Tay et al. 2005), was not analyzed in this study. Previous reports by Fisher et al. (2007), Bouil-laguet et al. (2007) and Lawson et al. (2008), suggested that the location of the dentin specimens (coronal, middle or apical, all with different diameters) may have influenced their results. It was the intention of the experimental design of this study to minimize, if not eliminate, the C-factor.

Visualization of the presence or absence of an oxygen inhibited layer at the interface dentin and ER sealer was demonstrated and are depicted in Figures 2 and 3. Figure 2 is a photograph of a sample of Group 1. The light blue color represent dentin, the narrow gold colored band is the oxygen inhibited layer, while the dark blue color represent fully polymerized EndoREZ. A photograph of Group 2 is significant for the absence of a halo of unpolymerized resin. The dentin has a light blue color, while the dark blue is fully polymerized EndoREZ. Figure 3. When EDTA (or distilled water) was used as a final rinse, only polymerized (dark blue) EndoREZ was present at the dentin (light blue).

The extensive review of the literature that was presented in the Introduction uncovers a disturbing fact about the experimental design of these experiments. "After irrigation the canals were dried with paper points" is the standard text reported by the authors. Therefore it should not come as a surprise that either more leakage or lower adhesive values were reported. Drying the dentin disadvantages the outstanding hydrophilic properties of MBRS causing compromised penetration into dentinal tubules and less than optimum adaptation in general. Therefore the reported data is suspect.

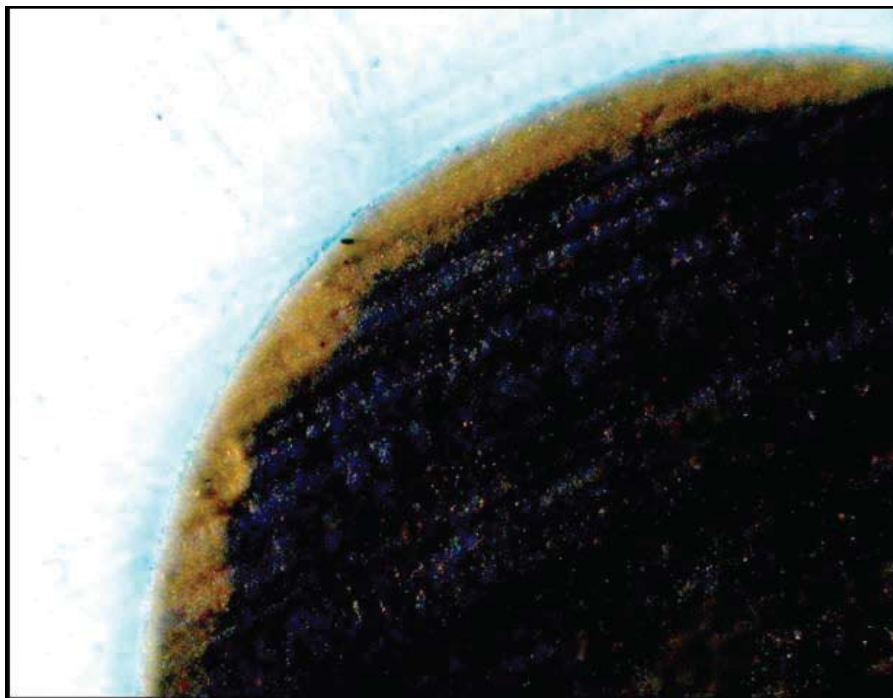


Figure 2. Photograph of Group 1, showing a cross section of dentin (light blue), an oxygen inhibited layer (gold colored band) and polymerized EndoREZ (dark blue).

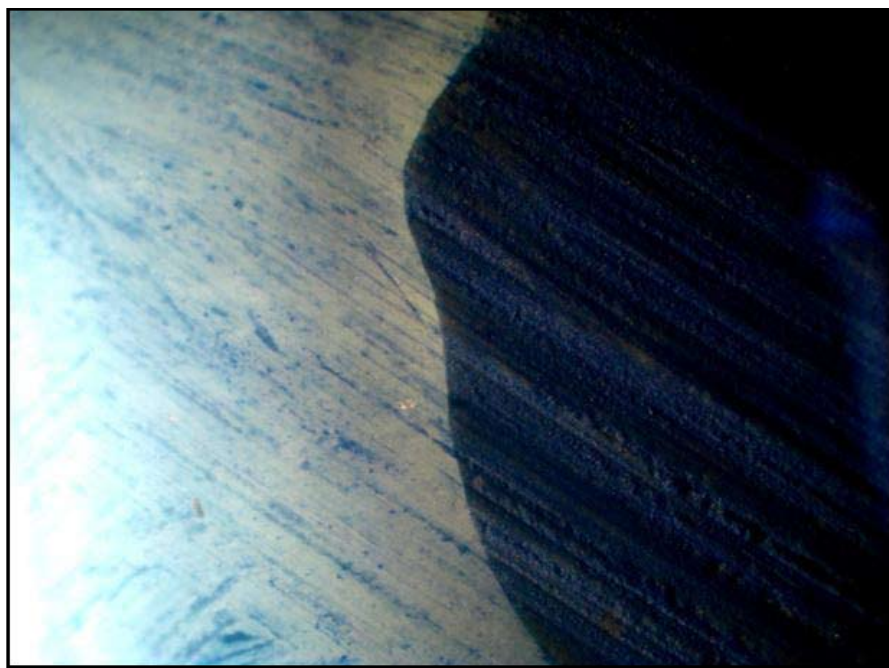


Figure 3. Photograph, showing dentin (light blue), adjacent to fully polymerized EndoREZ (dark blue).

Another issue of concern is the belief that higher bond strengths provide a better seal. Endodontic sealers should establish the best possible seal independent of adhesive bond strength values. The need for higher bond strength should not be regarded as bonding agents for restorative dentistry. Extra coronal and interradicular forces are totally different and cannot be compared.

Conclusions

Specimens treated with a final rinse of EDTA or distilled water did not show a decrease in bond strength of ER sealer to root canal dentin, whereas samples treated with a final rinse of NaOCl showed a significant decrease in bond strength due to the presence of an oxygen inhibited layer.

In a review of the literature it was noted that almost all authors dry the root canals after irrigation prior to obturation with resin-based sealers. This step is contra-indicated when methacrylate-based resin sealers are used.

Finally the notion that endodontic sealers with higher bond strengths correlate with better sealing is a fallacy. The capacity of an endodontic sealer to provide a hermetic seal is not necessarily related to higher bond strengths.

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STEP-BY-STEP CLINICAL ILLUSTRATIONS USING THE ENDOREZ SYSTEM

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Cornelis H. Pameijer

The development and tests that have led to the introduction of EndoREZ have been presented elsewhere. It is the objective of this chapter to illustrate a step-by-step technique for the insertion of EndoREZ, placement of the resin coated gutta-percha master cone and finally placement of the auxiliary cones. EndoREZ is a chemical setting self-priming methacrylate resin-based sealer, which is marketed in a double barrel syringe, containing a base and a catalyst. The kit comes with assorted NaviTips, mixing tips, Skini syringes and EndoREZ points (resin coated gutta-percha points) (Fig. 1). It has the same radiopacity as gutta-percha. After set it is still soft enough to facilitate removal for post space preparation. When using EndoREZ for the first time, extrude a small amount of base and catalyst on a mixing pad. This ensures that the subsequent flow will generate even amounts. Take care not to cross-contaminate the openings of the syringe. After bleeding the EndoREZ, attach an auto mixing tip. Once more a small amount of mixed material should be extruded on a mixing pad. Please note that these amounts are small and that the waste of material in the auto mixing tip is negligible. The EndoREZ can now be back-filled in a Skiny syringe (Fig. 2). After filling, a NaviTip of choice is attached. To ensure that no air bubbles are trapped and that there is an even flow, a small amount is extruded first (Fig.3). The NaviTip is then inserted into the root canal 2-3 mm short of the apex (Fig 4). The reader is referred to Zmener and Pameijer (2008) with respect to filling the root space while the dentin is moist. This can best be accomplished by evaluating the last paper point used for drying and making sure that the last 3 mm appear wet after removal. The presence of moist root canal dentin is extremely important to take advantage of the hydrophilicity of EndoREZ, which is important

to accomplish the best possible seal. After proper placement of the NaviTip continue to slowly inject the EndoREZ into the root canal space while slowly moving the syringe coronally. The tip should remain buried in the sealer, otherwise air bubbles can be trapped. When the sealer level reaches the coronal aspect, the NaviTip is removed (Fig. 5) and the selected resin coated gutta-percha cone is placed to length (Fig. 6). No condensation is necessary, however, lateral condensation or other warm gutta-percha techniques may be used. Please note that the master cone should not be dipped in the accelerator. This precaution should be followed to prevent a possible adverse reaction of the periapical tissues to the accelerator should sealant or the cone be extruded through the apex. EndoREZ sealer chemical bonds to the resin coated gutta-percha points. This entire system establishes a “Uniblock”, sometimes also referred to as “Monobloc”. Placement of as many accessory cones as the tooth allows, reduces the amount of sealer, resulting in less polymerization shrinkage, thus promoting a better seal (Fig. 7). The accessory cones should be dipped in the accelerator if the operator wants to accelerate setting of the sealer (Fig. 8)*. Without accelerator EndoREZ will polymerize in about 20 - 30 minutes, with the accelerator final set is reached in about + 5 minutes. Whether to use the accelerator or not is the decision of the operator. If an immediate completion of the restorative phase is the objective, then the accelerator should be used. The restorative phase may be the preparation of a post space, or completion of the final restoration using an acid-etch/dentin bonding agent/composite resin. Even as a temporary restoration an acid etch/bonding agent/composite resin or glass ionomer restoration is recommended to prevent coronal leakage.



Fig. 1. The EndoREZ system is composed of the sealer in a double barrel syringe, an automixing tip, a skinny syringe, Navi-tips, resin coated gutta-percha points and accelerator.

** One can dip the mastercone in the accelerator for certain clinical indications. In that case the apical 3 mm of the cone should be wiped before placement in the EndoREZ.*



Fig. 2. EndoREZ root canal sealer is mixed by means of an automix tip, which is used to back fill a skinny syringe. Note: It is advisable to first extrude a small portion of base and catalyst on a mixing pad before attaching the automix tip. The same caution should be exercised when the first mix appears at the tip of the automix syringe. Extrude a small amount on a mixing pad. Following these precautions ensures a well-mixed sealer.



Fig. 3. An EndoREZ loaded skinny syringe with a Navitip. The rubber stopper determines the depth of placement of the Navitip (2–3 mm short of the apex). Also here a small amount should be extruded first to establish an even flow of the sealer.

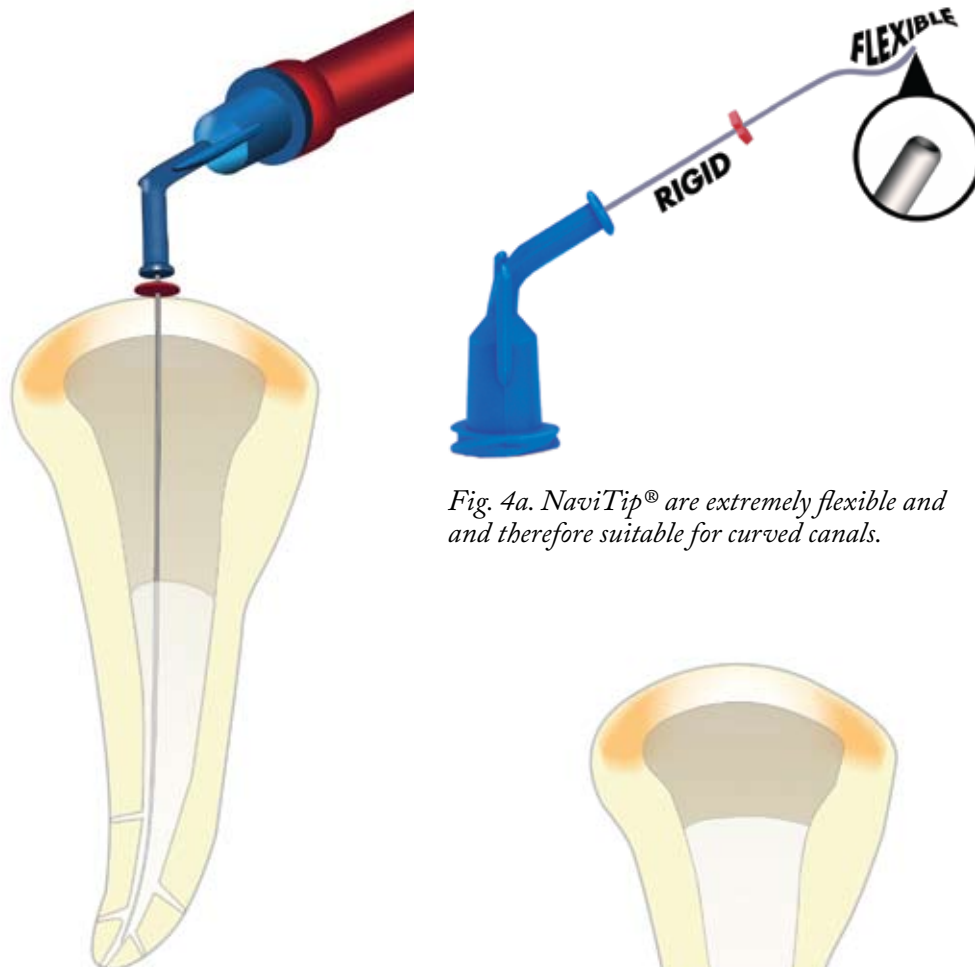


Fig. 4a. NaviTip® are extremely flexible and therefore suitable for curved canals.

Fig. 4. Placement of the sealer using a Navi -tip placed 2-3mm short of the apex. While extruding the EndoREZ sealer the Navi-tip should be moved coronally, taking care not to move it out of the EndoREZ. (Navi-tips are extremely flexible and therefore suitable in curved root canals.)



Fig. 5. Root canal space filled with EndoREZ reaching the coronal aspect.



Fig. 6. Placement of the master cone (resin coated gutta-percha cone), approximately 1mm short of the apex. Note: The master cone should not be dipped in the accelerator.



Fig. 7. Accessory cones may be dipped in the accelerator and should then be placed passively into the root canal. They should fill up as much space as the root canal allows, thus reducing polymerization shrinkage of the sealer. The accelerator causes rapid polymerization of the EndoREZ sealer (± 5 minutes at body temperature). This will allow removal of the excess resin coated gutta-percha cones, which may be followed by an immediate completion of the restorative phase.

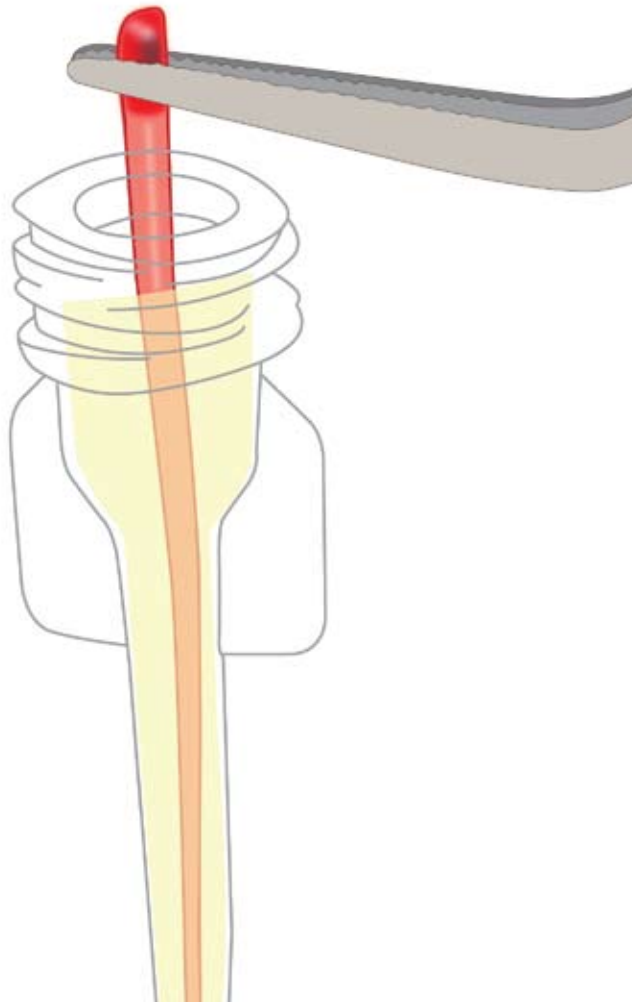


Fig. 8. An accessory cone dipped in accelerator. This technique has several advantages. It allows the operator to finish a restoration that same session. In addition placement of accessory cones also reduces the total volume of the sealer thus reducing polymerization shrinkage resulting in an improved seal.

Clinical Cases with EndoREZ and Resilon/Epiphany

Images courtesy of:

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