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Materials used for root canal obturation: technical, biological and clinical testing

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Endodontic filling materials may be considered true implants as they touch and are based in vital tissues of the body, and protrude to meet the external surface directly or, more appropriately, indirectly via another surface restoration (Fig. 1). It follows that the materials must possess several different properties relative to their functions and location, ranging from biocompatibility to mechanical sealing ability.

The first 'root fillings' were probably items wedged and fixed in root canals exposed by trauma or wear and causing pain to the individual. He, she or a helping associate would poke and scratch into the root with whatever item available, e.g. the bronze pin found in an upper canine of a roman soldier, exhumed in the Israeli desert some 1800 years after his death (1).

The search for materials that would remedy the pains and problems associated with compromised pulps has been almost as haphazard up to this day. Most materials applied to other fields of dentistry have been tried also as endodontic filling materials, with variable, and at times disastrous, effects. Typically, focus has been on one particular property of the material advocated to be of primary significance for 'success', while disregarding other, in hindsight, more important aspects of the filling.

One component of the root filling, the gutta-percha core, has however remained dominant in the various techniques and material combinations advocated for endodontic obturation for the past century and more. Silver points have had and still have proponents as an alternative, but their suitability has been questioned with reference to corrosion and clinical failures. Only during the past few years has the gutta-percha been seriously challenged by other, synthetic materials in the production of root fillings.

Basic principles of root canal filling

The standard root filling is a combination of sealer cement with a central core material, which until now has been almost exclusively gutta-percha. The core acts as a piston on the flowable sealer, causing it to spread, fill voids and to wet and attach to the instrumented dentin wall. By design, it is the sealer that comes into contact with the tissues of the root canal and pulp stump; only occasionally does the gutta-percha protrude from the sealer and touch the dentin, pulp or periodontal tissues. It follows that the sealer should possess many of the critical properties of the root filling, e.g. biocompatibility and sealing ability.

Properties of an ideal root filling material

Textbooks usually provide a list of desirable properties of root filling materials, the classic being 'Grossman's criteria' (2). He listed 10 requirements for an ideal root filling material (Table 1). While each property may be desirable in itself, it must be clear that technical and practical, and even some of the biologically desirable properties must be subordinate to the primary functions of the root filling: filling and sealing. Sundqvist & Figdor (3) assigned three primary functions to the root filling: sealing against ingrowth of bacteria from the oral cavity; entombment of remaining microorganisms; and complete obturation at a microscopic level to

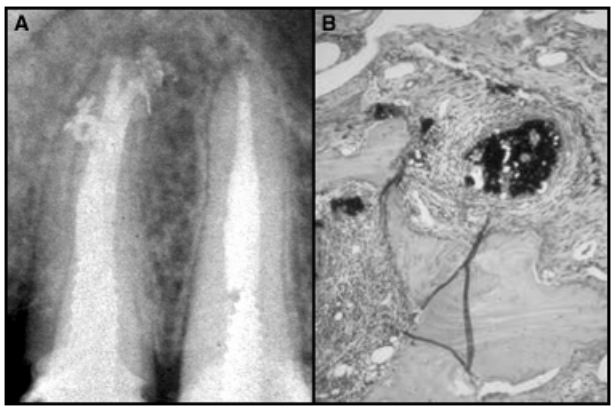

Fig. 1. Root filling material protrudes from the pulp space ramifications to meet vital tissues in the periodontal membrane and bone. (A) Radiograph of maxillary first premolar with numerous apical accessory foramina; (B) histological tissue response to material in periapical tissues of a *Macaca* monkey (D. Ørstavik & I.A. Mjor, unpublished).

Table 1. Requirements for an ideal root filling cement. From Grossman (2)

It should be easily introduced into the canal
It should seal the canal laterally as well as apically
It should not shrink after being inserted
It should be impervious to moisture
It should be bacteriostatic or at least not encourage bacterial growth
It should be radiopaque
It should not stain tooth structure
It should not irritate periapical tissue
It should be sterile, or quickly and easily sterilized before insertion
It should be easily removed from the root canal if necessary

prevent stagnant fluid from accumulating and serving as nutrients for bacteria from any source (Figs. 1 & 2).

A brief historical review

Root fillings in the true sense had to await the development of root canal instruments that could shape the root interior to receive a filling material. Traditional filling materials, cements, gold and amalgam, were first used mostly to extend the coronal restoration, rather than to truly seal off the root canal. The introduction of thermoplastic gutta-percha to dentistry in the mid-19th century was a turning point in endodontic treatment. Plasticity combined with physical durability made it possible for the material to move into the recesses of the root canal system and to adapt to the canal walls. Over the past 150 years, the only real challenge to gutta-percha has been silver points, but these have now been largely abandoned.

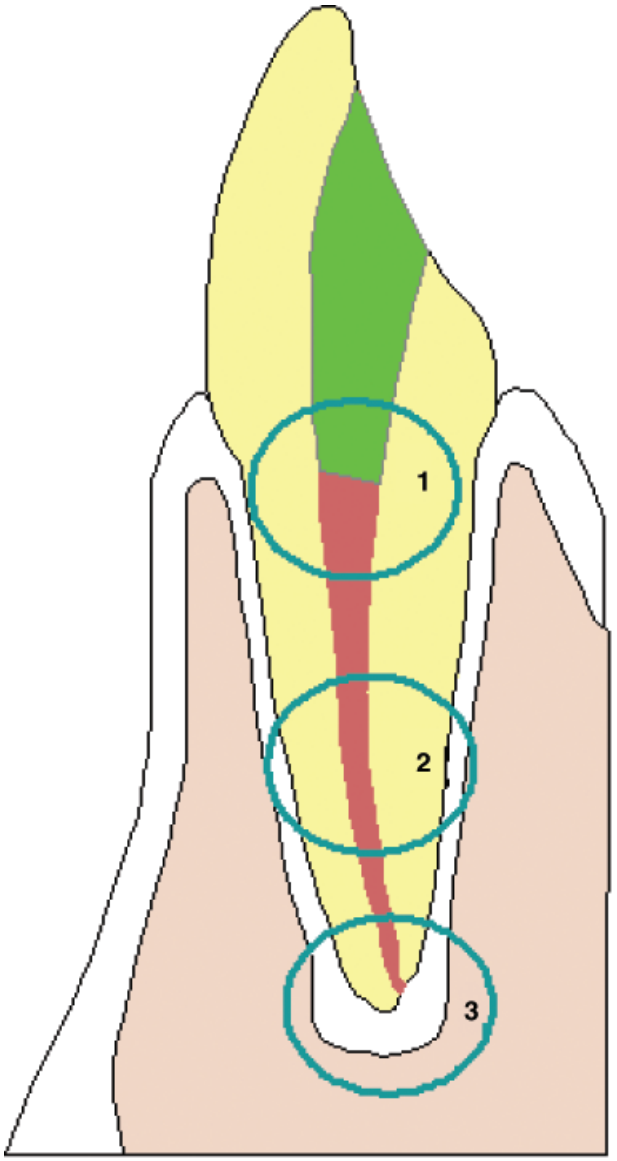

Fig. 2. Primary functions of a root canal filling. 1, stop coronal leakage; 2, entomb surviving microorganisms; 3, prevent accumulation of stagnant fluid. Modified from (3).

When further insight into the infectious aspects of dental caries and pulp exposure emerged, materials

possessing antimicrobial properties were also applied in the root canal. Paste techniques were introduced at the end of the 19th century, with strong antiseptics (phenol, camphor–phenol, creosote, and paraformaldehyde) added to e.g. zinc-oxide-eugenol cements. Shortly afterwards, calcium hydroxide was also added to the endodontic armamentarium.

While 'gutta-percha root fillings' remained the household term, it was realized that in the absence of a sealing cement, such root fillings were frequently associated with clinical and radiographic signs of apical periodontitis. Since the 1910's, therefore, developments in endodontic materials have been mainly on the chemistry and properties of the sealer as a technically and biologically important part of the root filling.

Basic composition of endodontic filling materials

Core materials

Gutta-percha

Gutta-percha is derived from dried juices from trees of the family *Sapotaceae*. It is an isomer of caoutchouc, but is harder, more brittle and less elastic (4). Crystalline gutta-percha may occur in α- or β-phase. There are only minor differences in chemical behavior and physical properties between the two. The α phase appears in nature; the β-phase occurs during refining and is dominant in the products used in endodontics. α-Gutta-percha is supposedly more fluid and softens at a lower temperature. Some sophisticated declarations describe a core of β- under a surface of α-gutta-percha. There is little if any documentation that this distinction is of importance (5).

In their final form, gutta-percha points consist of some 20 percent gutta-percha and up to 80 percent zinc oxide. A dye and metal salts are added for color and radiographic contrast. Some manufacturers add antimicrobials, e.g. calcium hydroxide (6), chlorhexidine (7) or iodoform (8), to impart some disinfectant properties to the materials.

Silver points

Formerly, instrumentation of the root canal aimed at preserving the narrow taper of the natural root canal. But the stiffness of stainless steel instruments made widening of curved canals a hazardous exercise with a great risk of canal transportation and strip perforation of gracile roots. Insertion of small size gutta-percha points in narrow, curved canals with small taper often led to buckling and bending of the point. Silver points, flexible but quite stiff, had an advantage in that they would not buckle and could more easily be inserted in these cases. Silver points were cemented with sealer, and lateral condensation could be applied using gutta-percha accessory points. Case reports and clinical experience with signs and symptoms of apical periodontitis associated with these fillings brought silver points into some discredit (9). Corrosion of the point with release of toxic products from the metal was believed to initiate or support inflammatory reactions, and the retrieval of silver points lost in the canal of teeth with post-treatment disease cast doubts on the sealing ability of these fillings.

Resin-based core filling materials

Synthetic resins have been discussed and tested as endodontic core filling materials for many decades (2). It is only with the introduction of the Resilon material points, however, that an apparently viable alternative to gutta-percha in clinical practice has emerged. Resilon is a polyester core material with bioactive glass, bismuth and barium salts as fillers (10). It is presented as cones for master point and accessory point placement with the lateral condensation technique, and as pellets designed for thermoplastic, vertical condensation techniques. With physical and handling characteristics similar to gutta-percha, the main advantage of thermoplastic resin as core material will be the extent to which it will bond to the sealer used.

Sealers

The sealers are responsible for the principal functions of the final root filling: sealing off of the root canal system, entombment of remaining bacteria and the filling of irregularities in the prepared canal. For that reason, and for reasons of space constraints, this review will concentrate on the properties of this group of materials. Several, quite different chemical formulations have served as bases for root canal sealers (Table 2).

Table 2. Overview of sealers: chemical types and examples

Type	Brand	Principle components	Manufacturer
ZnO-eugenol	Roth	ZnO-eugenol, colophony, Bi- and Ba salts	Roth Inc., Chicago, IL, USA
	Kerr PCS	ZnO-eugenol, thymol, silver	Kerr, Romulus, MI, USA
	ProcoSol	ZnO-eugenol, colophony, Bi- and Ba salts	Den-tal-ez, Lancaster, PA, USA
	Endome-thasone	ZnO-eugenol, paraformaldehyde	Septodont, Saint-Maur des Fossés, France
Resin	AH Plus	Epoxy-bis-phenol resin, adamantine	Dentsply Maillefer, Ballaigues, Switzerland
	Epiphany	BisGMA, UDMA and hydrophilic methacrylates	Pentron, Wallingford, CT, USA
	EndoRez	UDMA	Ultradent, South Jordan, UT, USA
	Acroseal	Epoxy-bis-phenol resin, metheneamine, enoxolone, calcium hydroxide	Septodont, Saint-Maur des Fossés, France
Glass ionomer	Ketac-Endo	Polyalkenoate cement	3 M ESPE, St. Paul, MN, USA
Silicone	RoekoSeal	Polydimethylsiloxane, silicone oil, zirconium oxide	Roeko/Coltène/Whaledent, Langenau, Germany
	GuttaFlow	Polydimethylsiloxane, silicone oil, zirconium oxide, gutta-percha	Roeko/Coltène/Whaledent, Langenau, Germany
Calcium hydroxide	Sealapex	Toluene salicylate, calcium oxide	Kerr, Romulus, MI, USA
	Apexit	Salicylates, calcium hydroxide	Ivoclar Vivadent, Schaan, Liechtenstein

Solvent-based sealers

The Johnston–Callahan technique (11) of conditioning the dentin surface and softening and churning the gutta-percha into the root canal has been applied in variations until today. Rosin-chloroform as a sealer/softener may be used, and 'chloropercha,'formulations with dissolved or milled gutta-percha in the chloroform have added body to the dentin–gutta-percha interface. Zinc oxide may be added to the mix for even more substance and to reduce shrinkage. Leakage because of shrinkage remains a problem with these methods, however (12), and these materials are hardly taught at dental schools any more, and, apparently, not much used in practice.

Zinc-oxide-eugenol-based sealers

Zinc-oxide-eugenol materials have dominated the past 70 to 80 years. Prototypes are Rickert's sealer, commercial in the form of Kerr Pulp Canal Sealer, and Grossman's sealer, which has several commercial variants, among them Roth sealer and ProcoSol. Rickert added silver powder for X-ray contrast, whereas Grossman used bismuth and barium salts. On the European scene, paraformaldehyde was added for antibacterial activity, as in the controversial N2 paste and in Endométhasone. Zinc-oxide-eugenol-based sealers have some antibacterial activity of their own, but will also exhibit some toxicity when placed directly on vital tissues.

Glass-ionomer-based sealers

No longer marketed, these were considered to be biocompatible and to show some adhesion to dentin, both of which are seen as desirable properties in a root filling. Since their introduction some 20 years ago, they have been used widely despite laboratory findings of leakage and disintegration (13, 14).

Resin-based sealers

By far the most successful of the resin-based sealers has been the AH series. The prototype was developed more than 50 years ago by Andre Schroeder in Switzerland (15), and is a bis-phenol resin using methenamine for polymerization. As methenamine (also known as urotropin) gives off some formaldehyde during the setting reaction (16), substitutes were sought and found in a mixture of amines that could effect polymerization without the formation of formaldehyde. AH Plus is the result of this product development.

Another resin formulation, until recently widely used in many parts of the world, is the resorcin-formaldehyde type (17). A variant of the phenol–formaldehyde or Bakelite resin, this sealer is strongly antibacterial, but shrinks and leaves a reddish hue on the surrounding tooth structure (hence the nickname 'Russian Red'). As it is advocated for use without the necessity for a gutta-percha central cone, and as it sets to a very hard and insoluble mass, retreatment of root fillings with this material may become a very frustrating experience. Forfénan and Traitement SPAD are Western European examples.

Simple methyl-methacrylate as a combined pulp fixative and root filling has also been reported, designed for young permanent molars with carious pulp exposure without total necrosis and infection. Shrinkage, poor biocompatibility during setting and water immiscibility are concerns with this type of material. A possible improvement was hoped for with the application of hydroxyethyl-methacrylate (Hydron), but case reports, clinical experience and biocompatibility concerns (18) quickly dampened the enthusiasm for this material as a root filling material.

Diaket (3 M ESPE) is a sealer that sets by chelation, but it contains polyvinyl chloride in polymer form as a main ingredient. It has attracted modest attention in the literature, but appears to be performing well in *in vitro* tests, including biocompatibility (19).

EndoREZ™ is based on urethane dimethacrylate (UDMA)(20). It has some hydrophilic properties assumed to improve performance even if moisture is present. Recently, EndoRez has been marketed in conjunction with resin-coated gutta-percha points (21), which through bonding to the sealer supposedly gives better adhesion and seal throughout the filling mass.

This concept is taken to its full distance in the Epiphany/Resilon or RealSeal (Kerr) product (22). Here, a primer is applied to the dentin surface after a chelator has worked to remove the smear layer. Then a dual-curing sealer based on BisGMA, UDMA and hydrophilic methacrylates with radiopaque fillers coats the primed dentin wall. Completion of the filling is by the insertion of cones or thermally plasticized pieces of Resilon core material. The sealer may bond effectively to dentin *via* the primer, and with the chemical integration of the sealer with the core, this has given rise to a concept of a homogeneous, 'monoblock' root filling with little or no voids. Tests *in vitro* and *in vivo* also show impressive performance by this material (10, 23).

Materials with calcium hydroxide

The success of calcium hydroxide as a pulp protecting and capping agent and as an interappointment dressing prompted its use also in sealer cement formulations. Sealapex and Apexit are well known brand names of this type of material. The setting reaction of these materials is complex and quite inhomogenous; through contact with moisture, a hard surface is produced, but the deeper part of the mix may remain in a dough-like consistency. Products of this kind stand up remarkably well in laboratory leakage, biological, animal as well as clinical tests in humans (24), but their lack of physical sturdiness has given rise to concern. Thorough condensation of gutta-percha is especially important to minimize the risk of the root filling loosening during post space preparation.

Calcium hydroxide is also added to cements of other chemical compositions, such as resins and zinc-oxide-eugenol-based sealers (25–28), but there is limited evidence for any benefit derived from its inclusion in these formulations.

Silicone-based sealers

Silicones dominate as sealants in kitchens, bathrooms and as joining material in construction work. Lee Endo-Fill, Lee Pharmaceuticals, El Monte, CA, USA (28, 29) was an early attempt at utilizing the water-repellant, chemical stability and adhesive properties of silicone materials in endodontics. More recent formulations (Roeko-Seal) polymerize without shrinkage, with platinum as a catalyzing agent. They show impressive biological performance (30), also as documented by testing according to international standards,

including clinical follow-up studies (31). With Gutta-Flow, an attempt has been made to incorporate the filling qualities of gutta-percha in the sealer: gutta-percha milled to a low grain size is mixed into components of the silicone sealer. In the paste fill technique advocated, the gutta-percha is then carried with the sealer to fill the entire root canal system. Additional gutta-percha cones are placed *ad libitum*.

Technological tests

A number of tests have been developed to assess the physical and technological properties of endodontic filling materials. Such tests serve a number of purposes: They ensure that the materials are presented in a consistency and workability so that they are practical to use in a clinical situation; they provide a physical characterization of the materials when mixed and set; and they may in some instances be helpful in anticipating how the material will perform clinically. It must be recognized, however, that these tests do not unequivocally provide assurance that the material is suitable for its purpose; more tests on biological and clinical performance are necessary for a total assessment.

Technological tests have been systematized by the standards organizations, the ADA/ANSI in the US and by the ISO internationally. While there may be minor differences in detail between these two standards, they are now well harmonized. For the sake of simplicity, the following is based on the ISO standard 6876-2001(32).

Flow

Flow is traditionally measured by having a fixed amount (0.05 mL) of ready-mixed material placed between two glass plates and subjected to a total load of 120 g. After 10 min, the diameter of the material between the plates is measured: the lower the diameter, the thicker the mix (Fig. 3). Twenty mm diameter is the acceptable minimum. Other studies have made use of more sophisticated methodologies, such as rheometers (33, 34). Rheometers must be used judiciously, however, as the continuous movement of the material may interfere unduly with the initiation of setting. It has been found that the flow depends on particle size (35), rate of shear (36), temperature and time (37, 38) and on the internal diameter of the tubes and the rate of insertion, and that this effect varies with different materials (34).

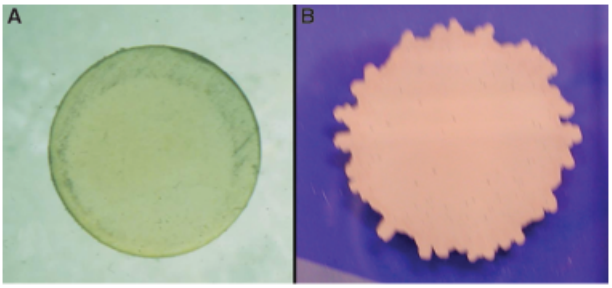

Fig. 3. The diameter of the disk in (A) is easily measured, whereas an experimental sealer in (B) shows an inhomogenous material with subcomponents of varying flow properties. A side finding is separation of subcomponents also in A with a central mass of a mix with different color characteristics than the peripheral part.

Working time

The working time is an extension of the flow test, in that it is repeated at time intervals relevant to the manufacturer's stated working time. This is essentially a control of the product's stability in use, and it is relevant only for products with working times shorter than an extended filling session.

Setting time

This is measured by lowering an indenter of 100 g mass and a circular tip of 2 mm onto the flat surface of the mixed material as the setting time approaches. The time when no mark is left by the indenter on the material's surface is recorded as the setting time. Again, this is primarily a control test on the stable behavior of a product. It should be realized that the development of compressive strength, a parameter of greater consequence for clinical performance, is not necessarily complete when the setting time is recorded (33, 39).

Radiopacity

A degree of radiopacity is indispensable for control of root filling placement. While standards specify only a lower limit to this property, it should be realized that extreme contrast in a material may mask voids and slits where the material has not penetrated. An eye-pleasing, bold filling with strong contrast may thus lead to the false impression of a dense and homogenous fill. The technical procedure for the assessment of root canal filling materials' radiopacity is very simple. A washer of 10 mm internal diameter and 1 mm height is filled with the mixed material and radiographed together with an

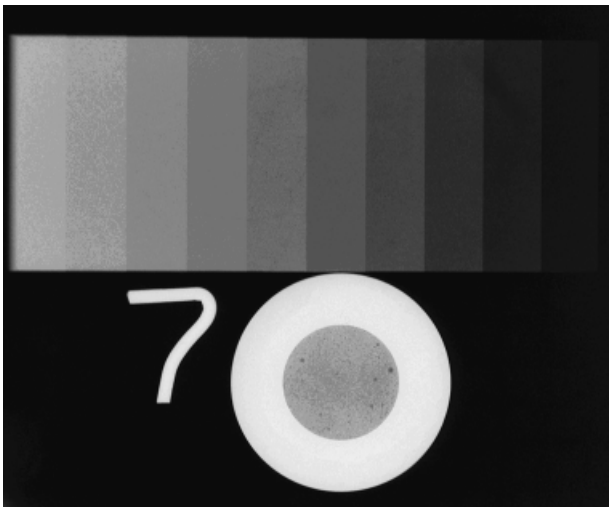

Fig. 4. The radiopacity of the material in the washer is measured in relation to the aluminum step wedge, which has steps from 1 to 10 mm.

aluminum step wedge on occlusal films (Fig. 4). The radiopacity of the specimen is compared with that of the step wedge by means of a densitometer. The minimum requirement is 3 mm Al-equivalents, which may be on the low side considering that conventional gutta-percha points are about 6 mm Al-equivalents. Most materials are in the range 4–9 (40,41)

Solubility and disintegration

This test measures the stability of the set materials. Disk-shaped specimens of 20 mm width and 1.5 mm height are produced and eluted in 50 mL water for 24 h. After removal of the specimen, the water is inspected for particulate matter indicating disintegration, and residual material is weighed after evaporation to produce a measure of the amount of material solubilized. Three percent of the disk mass is accepted. While this may be seen as a slack requirement, many materials approach or exceed this limit (42, 43)

Dimensional change following setting

Neither shrinkage nor expansion is considered desirable for a root canal filling material. Shrinkage produces slits and passageways for bacteria and their products; expansion may create forces threatening to cause infractions in and fracture of dentin. The apparatus for dimensional change registers minor vertical movements (1 μm) of a cylindrical test specimen during a 30-day test period.

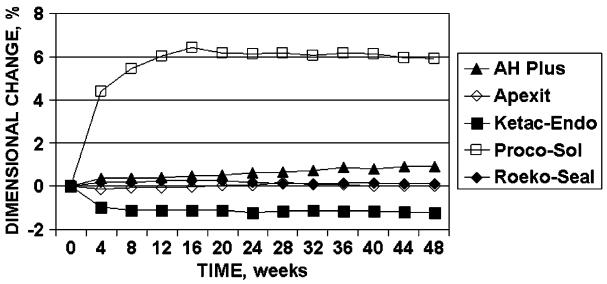

Fig. 5. Dimensional changes in five endodontic sealer over a 4-year period. One material shows a strong expansion initially; one shrinks below the requirements of the standard; the other three are stable and with little dimensional changes (D. Ørstavik & I. Nordahl, unpublished).

While it has been assumed, also in the design of the test specifications, that dimensional changes cease after 30 days, continued measurements have revealed that some materials have an expansion that continues for months and years after initial setting (Fig. 5)(44).

Over the past few decades, the impact of the standards has gradually increased. While several products failed to comply with the relevant documents some 30 years ago, it seems that most commercially available products today have technological properties that pass these tests. This is a basic prerequisite for adequate clinical performance of the materials' properties, and form an important foundation for certification procedures.

Biological tests

Sealers are designed for direct contact with vital tissues. Although the area of contact is small, there is always concern about untoward reactions by the tissue to the filling material. In the more extreme situations, accidents may occur that cause major and permanent damage to the tissues (Gluskin, this issue). Biologically unfavorable materials, while not necessarily causing overt clinical symptoms, may affect the healing processes in the periapical tissues and delay or prevent resolution of lesions (Dahl, this issue).

Usage testing

Usage tests are tests of materials or procedures under clinical conditions, but in experimental animals. For root filling materials, such tests have been performed in dogs and monkeys, mostly on uninfected teeth without apical periodontitis (Fig. 6)(45–47). While there may

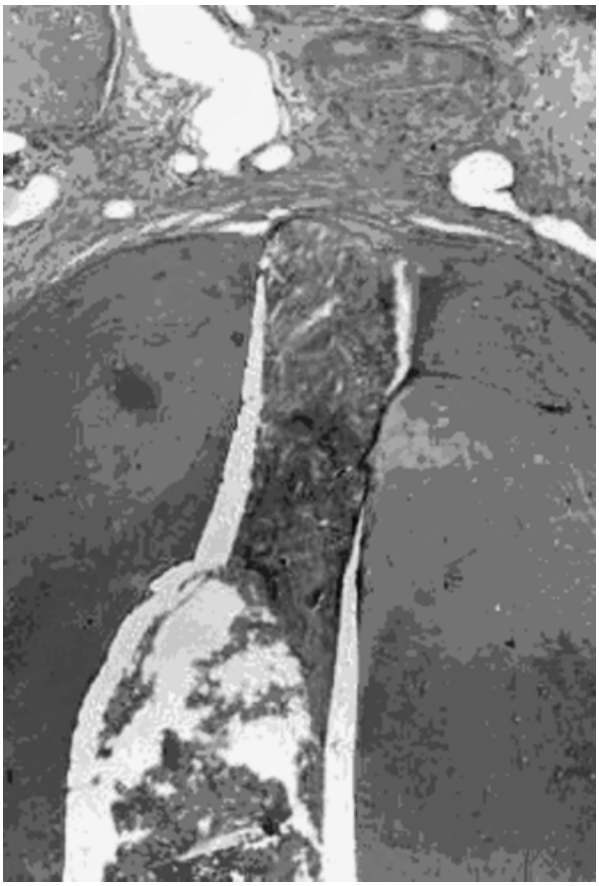

Fig. 6. Histological section of apex of a *Macaca* monkey root filled with gutta-percha and sealer. A dentin plug is interspersed between the filling and the periodontal tissues, which apparently are not adversely affected by the materials.

be clear differences among materials in their ability to cause an inflammatory reaction in the periapical tissues, such inflammation appears limited for most brands, and it is often difficult to distinguish the material source from other influences, e.g. infection.

The reverse clinical situation may offer a better clinical assessment of the materials for obturation. Katebzadeh et al (48) induced apical periodontitis in dogs and then tested the effect of calcium hydroxide dressing in comparison with immediate filling with a zinc-oxide-eugenol sealer on the healing of the lesions. While theirs was a study on the effect of medication on healing, the model should be highly applicable also for comparative studies of root filling materials.

Antibacterial testing

Current concepts of root canal filling functions do not include antimicrobial activity as an important or necessary property, but it is well recognized that most materials in current use exhibit some such properties (49–52). With increased emphasis on improving procedures for disinfecting the root canal system, this particular property may be more appreciated in the future.

Functional laboratory models

Neurotoxicity

This test was designed for evaluation of sealers focusing on their potential to cause nerve damage, especially of the inferior alveolar nerve after overfilling and placement of material in the mandibular canal (Gluskin, this issue). While there are other mechanisms that potentially may cause nerve paresthesia, such as compression of the nerve or damage to it by the needle for placement of anesthesia, chemical toxicity on the part of the material may be the most likely cause.

The model utilizes the phrenic nerve in the rat, which is dissected free, cut out and mounted in a bath between electrodes that permit the transmission of an electric pulse through the nerve *ex vivo* (53). Following the application of freshly mixed sealer, the transmission of pulses can be monitored and inhibition of conductance by the material assessed. The findings confirmed that the materials themselves, without mechanical pressure, can cause inhibition of nerve transmission. Moreover, the neurotoxicity of the materials *ex vivo* corresponds well with their association with clinical cases of paresthesia, further strengthening the assumption that the chemical nature of the material is important for the clinical reaction.

Leakage

The leakage tests have become some of the most popular, but at the same time most controversial, among the attempts to find 'clinically relevant' laboratory tests for the clinical performance of root filling materials.

The classical leakage test was with radioisotopes attached to soluble markers that were given time to seep into the root canal system of root filled teeth *in vitro.* (54) Later, isotopes have been substituted with dyes, India ink particles, bacteria, ions, and air, pressure has been applied to speed up the process, vacuum has

been introduced to prevent entrapped air from blocking penetration by the marker,and focus has shifted from 'apical leakage' or 'percolation' occurring at the apex to 'coronal leakage', where marker penetration is monitored from the oral cavity aspect through the root canal to the apical target area for external irritants and infectious agents.

The first leakage test experiments were based on the assumption that apical disease or endodontic failure was associated with stagnant or percolating tissue fluid at the apical part of the root filling, not necessarily associated with through-and-through passage of toxins or microbes. As the hypothesis that stagnant tissue fluid or necrotic tissue was responsible for apical pathosis was effectively disproven in the 1960's (55–57), emphasis gradually but slowly shifted to studies on the penetration of bacteria and their products from the coronal part to the apical end (58–60). Up till 2005, however, research was still conducted and published on leakage with testing of the apical area only (61). This is a testimony to the simplicity and appeal of the dye leakage test rather than a tribute to its relevance in light of current concepts of endodontic pathology.

The coronal leakage concept has a number of supporting findings from clinical, radiographic and epidemiologic studies. The general association of apical pathosis with the presence of a technically deficient root filling is well established (62). Animal experiments with root fillings exposed to the oral environment show that apical periodontitis develops after a time sufficient for bacteria to penetrate along the filling (63). Observations on root fillings *ex vivo* and in laboratory experiments routinely show lack of adaptation of the root filling to dentin (Fig. 7) and the presence of voids or bubbles in the sealer (64).

There are two methods that are in frequent use currently: The fluid filtration model (65) was designed for tooth restorative fillings, but the elegant design and intuitive relevance in comparative studies have made it increasingly popular also in other contexts, not least in the testing of endodontic filling materials (66). This method will find any passageway that will allow water to pass along, and measures the volume of water that passes through the filling as a function of time and experimental variables.

The other method is the bacterial penetration setup (60), where a filled root or root section is mounted between an upper chamber containing a test bacterium, typically *Enterococcus faecalis*, and a lower chamber,

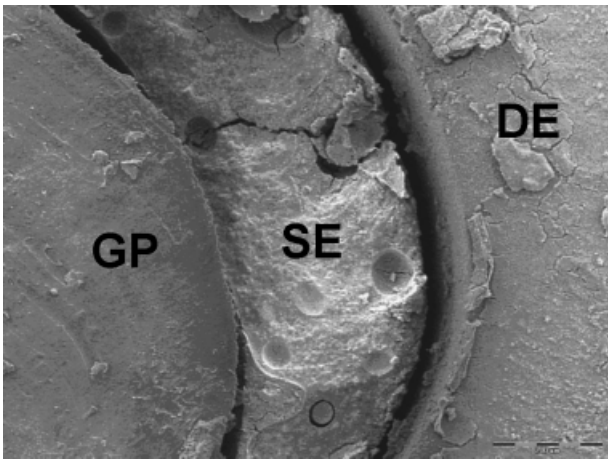

Fig. 7. Sealer material (SE) interspersed between gutta-percha cone (GP) and dentin (DE), suggesting lack of adaptation and passageway for microorganisms (Eldeniz et al., in preparation).

which at the start contains sterile medium. Again, with time and dependent on the quality and type of root filling, bacterial growth may occur in the lower chamber, indicating that the test organism has passed along the entire filling. The method does not permit a quantitative assessment of the voids and passageways (except that they must be large enough and continuous for a bacterium to move alongside), but this is partly overcome by applying survival statistics in comparisons among experimental variables, *in casu* root canal filling material.

An innovative animal model was proposed by Friedman et al (63, 67). Periapically healthy dog's teeth are root filled with different filling materials and then exposed to the oral environment. The incidence and time of development of apical periodontitis is then monitored and the performance of the materials compared.

Stiffness of root

Root filled immature roots or roots that are otherwise weakened internally run a greater risk of fracture. With the introduction of adhesive filling techniques, attempts have been made to strengthen such teeth through reinforcement of the coronal part of the root by composite cements and fillings (68–70). More recently, this concept has been taken further by attempting to reinforce the whole root canal system via an adhesive filling and integrated resin core (Resilon)(71). Such effects have been tested in

standard mechanical testing machines, with varying degrees of specimen standardization and experimental procedure.

These tests have shown that there may be a significant improvement in physical resistance to fracture of such teeth *in vitro*. As the bond strength of sealers to dentin and gutta-percha is comparably low, concerns have been raised about the clinical efficacy of the root-strengthening concept (72). However, clinical follow-up of individual cases *in vivo* have shown that teeth thus treated may survive for a long time (73–75), but comparative clinical studies are lacking.

As strengthening is dependent on the setting of the sealer cement binding both to a mechanically strong root filling core and to the dentin wall, the forces of contraction or expansion during setting may have unwanted consequences. These forces induce tension or compression on the surroundings, the dentin wall and/or the filling core. If they exceed the ability of dentin or the central core to absorb the strain generated, they may, at least in theory, induce crack formation with the possibility of fracture (44).

Clinical testing

There are several levels of clinical testing that may be applied, each exploring different properties and characteristics of the filling material. The ultimate test would be survival of the tooth or root in the absence of pathological signs or symptoms. But clinical testing also includes very simple parameters, such as ease of handling and insertion. Published information on clinical experiences with different materials' handling characteristics is limited. Some studies have assessed the time spent during the filling procedure, but this is more related to the method employed than to the materials as such (Withworth, this issue). Also, there are reports on mishaps during root filling (Gluskin, this issue) that are often associated with poor handling characteristics.

Traditionally, clinical-radiographic follow-up studies have been used as a yard-stick for testing root filling materials. Furthermore, these have been conducted for several years in order to assess late healing or disease development, particularly to ensure that when healing is slow, it is followed until completion.

Lack of standardization or harmonization of such studies has been a major obstacle to progress in the clinical assessment of filling materials as well as other aspects of treatment procedures in endodontics. Criteria for success or failure may be agreed on in principle, but calibration of operators and evaluators is seldom performed, and inter-study standardization even less commonly. If one applies current criteria of how clinical studies should be designed and performed to produce optimum levels of clinical evidence, then a very limited number of endodontic studies on treatment outcome meet such criteria (76).

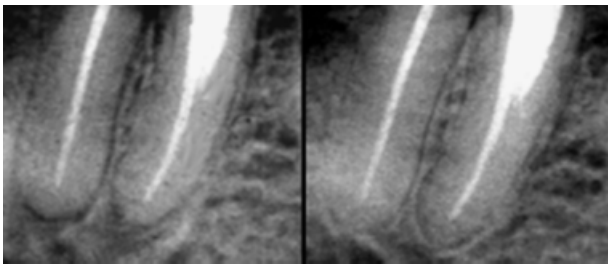

Fig. 8. Chronic apical periodontitis healed one year after endodontic treatment; 'success'.

Observation criteria

Treatment outcome in endodontics is traditionally registered as clinically and radiographically successful cases (Fig. 8).

Clinical signs and symptoms being usually few and small, most outcome studies rely heavily on radiographic criteria. A commonly used reference for radiographic success/failure analyses is the criteria defined by Strindberg (77) (Table 3). Alternative approaches have been assessments of the likelihood of disease assessed by radiography (78) and the Periapical Index (PAI) scoring system relating radiographic signs to histological disease scores (79). In addition, partly to overcome the practical obstacles associated with the frequently long time required for complete restoration of periapical tissues, categorization into 'healed', 'healing' and 'persistent disease' has been proposed (62). Attempts have also been made to apply automated procedures on digitized images (80–82), and treatment procedures, if not materials, have been assessed with such methodology (83).

Direct clinical comparisons of root filling materials' clinical performance are only recently emerging. Most studies are case series of one particular method/material combination, often designed to assess the influence on treatment outcome by other pre-, per- and postoperative factors. The first large case series with

Table 3. Success/failure criteria. Modified from (77)

Success when
The contours, width and structure of the periodontal margin are normal
The periodontal contours are widened mainly around the excess filling
Failure when there is
A decrease in the periradicular rarefaction
An unchanged periradicular rarefaction
An appearance of new rarefaction or an increase in the initial
Uncertain when
There are ambiguous or technically unsatisfactory control radiographs which could not for some reason be repeated
The tooth is extracted prior to the 3-year follow-up owing to the unsuccessful treatment of another root of the tooth

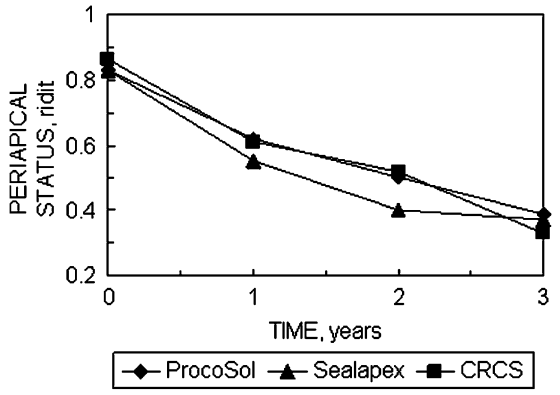

Fig. 9. Clinical performance of three endodontic sealers, ProcoSol, Sealapex, and CRCS (a zinc-oxide-eugenol sealer with calcium hydroxide) in the treatment of apical periodontitis. Modified from (26).

follow-up of a certain root filling material may have been Castagnola's (84) report on treatment outcome with Walkhoff's Paste, an iodine-containing paste. Typically, such studies report success rates in the order of 80–95%; however, comparisons across studies cannot be done in the absence of observer calibration.

Using the PAI scoring system with calibrated observers, we have performed a number of studies comparing different root canal sealers (23, 26, 31, 85–88). With the multitude of factors known to influence treatment outcome, it is no surprise that the effect of the sealer per se is moderate. However, a traditional material such as Kloroperka (Chloropercha) was found to be inferior in comparative studies to a zinc-oxide-eugenol-based sealer and to an epoxy resin (85), and the $Ca(OH)_2$-containing material, Sealapex, was at least not inferior to a conventional zinc-oxide-eugenol-based sealer (Fig. 9)(26). Moreover, it was reassuring to find that the clinical performance of the new silicone-based sealer, RoekoSeal, was indistinguishable from that of the traditional zinc-oxide-eugenol-based sealer (31). Preliminary data on the treatment results obtained with the Resilon–Epiphany material in comparison with a resin sealer and gutta-percha are also quite favorable (23).

Concluding remarks

Primary infection or infection secondary to root filling procedures is the principle cause of apical periodontitis and endodontic failure. It follows that the root filling functions, entombment and prevention of bacterial penetration, are paramount. Traditional, zinc-oxide-eugenol and epoxy resin sealers have stood the test of time and perform well clinically and in laboratory tests. It is exciting to see new formulas and concepts for root filling emerge with an obvious potential for improvement. It must be remembered that clinical studies have a high degree of variability because of the multitude of factors affecting outcome. Therefore, it may be difficult to document improved treatment results that are statistically significant in comparison with conventional materials of reference. However, with judicious extrapolations from animal experiments and laboratory tests, we should expect clinical outcomes with new materials that are at least as good as those obtained with the old. Moreover, refining case selection and limiting the variables in clinical study designs may provide relevant clinical data with better discriminatory power in the future.

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