**ENDODONTIC MATERIALS**

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**ABSTRACT**

Endodontic sealing materials for permanent obturation of root canals are highly variable both in chemistry of setting and in their additives. Conventional materials are based on zinc oxide-eugenol, rosin-chloroform, or synthetic resins. These have been extensively tested for biological and technical properties. Most materials are slightly or moderately cytotoxic, and some — notably paraformaldehyde-containing materials — have been associated with clinical complications such as paresthesia of the mental and/or inferior alveolar nerve. Recently, Ca(OH)$_2$-containing materials have been introduced with claims of improved clinical and biological performance. However, there is little documentation of the alleged benefits of new materials.

The virtual absence of comparative clinical studies on endodontic filling materials appears to be the major obstacle to critical assessment of old materials or to adequate documentation of new formulae. A recently introduced scoring system for the radiographic assessment of apical periodontitis may aid in the future testing of endodontic materials. Results with this scoring system on extensive clinical material indicate that it is possible to discriminate among endodontic materials with small differences in clinical performance.

**INTRODUCTION**

Endodontic materials are used for permanent obturation of root canals after cleansing, shaping, irrigation, and medication. Materials for obturation come either as (1) core and sealer combinations, (2) plasticized gutta percha, or (3) setting or non-setting pastes (Fig. 1). The most frequently used cores are made of gutta percha, an isoprene polymer, with additions of heavy metal oxides, primarily zinc oxide. Alternatively, metal points have been used. The sealers and pastes are of widely different compositions, but most of them fall into one of the four categories shown in Table 1.

Both the physical and biological properties of endodontic materials are dependent on their chemical composition. As an illustration of the great diversity in chemistry and composition of these materials, Table 2 lists the ingredients and mechanism of setting of some commonly used products. This diversity stems from the fact that several different properties have been considered important for the clinical performance of the materials. Thus, zinc oxide-eugenol sealers have been developed with emphasis on sealing qualities of this cement base, preventing ingress of saliva and bacteria through the root canal. Rosin-chloroform formulations were developed to soften the surface of the gutta-percha point, thereby improving the adaptation of the point to the root canal wall. Additions of paraformaldehyde or other antibacterial agents to zinc oxide-eugenol sealers were done by endodontists relying on antisepsis for treatment. In contrast, omission of such toxic substances is sought by researchers who emphasize the biocompatibility aspects of the materials. Synthetic resins have been introduced with minimal shrinkage, or slight expan-
TABLE 1
CATEGORIES OF ENDODONTIC SEALERS

<table>
<thead>
<tr>
<th>Type</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc oxide-eugenol</td>
<td>Rickert’s, Grossman’s, N2, Endomethasone, CRCS</td>
</tr>
</tbody>
</table>

Endodontic materials are intentionally applied directly on vital, soft tissues of the apical pulp or the periodontal ligament. In a sense, this makes them true implant materials and subject to the particularly complex requirements, both technical and biological, of this group of biomaterials.
al., 1981). The most commonly used synthetic resins behave differently: Initially marked cytotoxicity (Ols
son and Wennberg, 1985) diminishes when the ma
terial is cured, making this type of material one of
the least cytotoxic in the set state (Ørstavik et al., 1981). The mechanisms for cytotoxicity remain ob
scure, however.

It is fortunate for this group of materials that the
different biological tests tend to confirm each other.
Thus, the implantation tests applied on endodontic
materials (Brown and Friend, 1966; Ørstavik and Mjør,
1988) show cytotoxicity profiles similar to those of
the cell culture experiments (Spångberg, 1981; Ørstavik
et al., 1981). In short-term tests, rosin-chloroform, zinc
oxide-eugenol, chloropercha, and synthetic resin, in
that order; produce tissue reactions of increasing in
tensity. Longer-term implantation experiments (Fig.
3) show an almost dramatic resolution of the tissue
response to cured synthetic resins, whereas the chemically less stable zinc oxide-eugenol and chlo
ropercha are accompanied by persisting, though di
minishing, inflammation (Ørstavik and Mjør, 1988).

It would be reasonable to compare the results from
cell culture or implantation experiments with so-called
usage studies of endodontic materials, i.e., histologic
assessment of tissue reactions to root fillings in man
or experimental animals. A number of studies have
been carried out with endodontic treatment of mon
ey, dogs, cats, and rats, some of which also include
comparisons of different endodontic materials. One
major difficulty with the usage test is the frequently
uncontrolled influence of other (technical and biolog
ical) factors on the outcome of treatment. For in
stance, control of infection may be difficult, and the
filling material is often separated from the vital, re
acting tissue by a mass of dentin fillings. In general,
there seems to be a tendency for endodontic materials
to act less tissue-irritating in usage tests than might
be expected from the cell culture or implantation ex
periments.

**Physical Properties**

On the technological side, interest has focused on
the sealing properties of the root canal filling. Several
studies, mostly performed *in vitro*, have investigated
the leakage of dyes (Antoniazzi et al., 1968; Beyer
Olsen et al., 1983), radioisotopes (Higginbotham, 1967),
bacteria (Kos et al., 1982), or electrolytes (Mattison
and von Fraunhofer, 1983) at the dentin/endodontic
filling interface. Other parameters—*e.g.*, solubility,
flow, working and setting time, radiopacity, and ad
hesive properties—have also been assessed (Mc
Comb and Smith, 1976; Ørstavik, 1983 a, b; Beyer
Olsen and Ørstavik, 1981; Ørstavik et al., 1983a).

Although the results from different researchers are
somewhat variable, a pattern of the different material
types with respect to sealing properties is emerging.
Zinc oxide-eugenol preparations afford good seals
against leakage in most tests; resin-based sealers are
intermediate in sealing ability; chloropercha forma
tions show the most leakage (Table 4). On the other
hand, adhesion of the materials to dentin is achieved
only with synthetic resin (McComb and Smith, 1976;
Ørstavik et al., 1983a), and the solubility in water is
definitely lower for this type of material than for other
endodontic materials (Ørstavik, 1983b).

Whereas the flow properties and film thickness are
important characteristics for the distribution and spread
of the sealer inside the root canal and its ramifica-

### TABLE 3

**RESULTS OF ENDOodontIC THERAPY**

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Country</th>
<th>Operator</th>
<th>No. of Roots</th>
<th>Diagnosis*</th>
<th>Percent success</th>
<th>Obs. Period (years)</th>
<th>Sealer Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guignard and Holz</td>
<td>1985</td>
<td>S. Africa</td>
<td>Specialist</td>
<td>194</td>
<td>N</td>
<td>81</td>
<td>7</td>
<td>ZnO-eugenol</td>
</tr>
<tr>
<td>Swartz <em>et al.</em></td>
<td>1983</td>
<td>USA</td>
<td>Students</td>
<td>1770</td>
<td>M</td>
<td>90</td>
<td>1</td>
<td>?</td>
</tr>
<tr>
<td>Morse <em>et al.</em></td>
<td>1983</td>
<td>USA</td>
<td>Specialist</td>
<td>458</td>
<td>M</td>
<td>95</td>
<td>1</td>
<td>Eucalyptol-gutta percha</td>
</tr>
<tr>
<td>Barbakow <em>et al.</em></td>
<td>1981</td>
<td>Sweden</td>
<td>Students</td>
<td>124</td>
<td>N</td>
<td>89</td>
<td>1</td>
<td>ZnO-eugenol</td>
</tr>
<tr>
<td>Delessert <em>et al.</em></td>
<td>1980</td>
<td>Norway</td>
<td>Students</td>
<td>250</td>
<td>V</td>
<td>96</td>
<td>1.5</td>
<td>ZnO-eugenol</td>
</tr>
<tr>
<td>Bergenholtz <em>et al.</em></td>
<td>1979</td>
<td>Switzerland</td>
<td>Students</td>
<td>556</td>
<td>R</td>
<td>75</td>
<td>2</td>
<td>Rosin chloroform</td>
</tr>
<tr>
<td>Kerekes and Tronstad</td>
<td>1979</td>
<td>Belgium</td>
<td>Students</td>
<td>501</td>
<td>M</td>
<td>91</td>
<td>4</td>
<td>Chloropercha</td>
</tr>
<tr>
<td>Jokinen <em>et al.</em></td>
<td>1978</td>
<td>Finland</td>
<td>Students</td>
<td>2459</td>
<td>M</td>
<td>53</td>
<td>2-7</td>
<td>Chloropercha</td>
</tr>
<tr>
<td>Adenubi and Rule</td>
<td>1976</td>
<td>England</td>
<td>Specialists</td>
<td>870</td>
<td>M</td>
<td>88</td>
<td>?</td>
<td>ZnO-eugenol</td>
</tr>
<tr>
<td>Harty <em>et al.</em></td>
<td>1970</td>
<td>England</td>
<td>Specialists</td>
<td>1100</td>
<td>M</td>
<td>90</td>
<td>2</td>
<td>ZnO-eugenol</td>
</tr>
<tr>
<td>Grossman <em>et al.</em></td>
<td>1964</td>
<td>USA</td>
<td>Students</td>
<td>432</td>
<td>M</td>
<td>90</td>
<td>1-5</td>
<td>ZnO-eugenol</td>
</tr>
<tr>
<td>Strindberg</td>
<td>1956</td>
<td>Sweden</td>
<td>Specialists</td>
<td>775*</td>
<td>M</td>
<td>90</td>
<td>½-10</td>
<td>Rosin chloroform</td>
</tr>
</tbody>
</table>

* N = necrotic pulps; V = vital pulps; R = revisions; M = all diagnoses.
† Originally treated roots.
Clinical Tests of Endodontic Materials

In striking contrast to the numerous technological and biological studies is a virtually complete lack of comparative, clinical-radiographic studies on endodontic materials. This is remarkable, particularly in view of the many clinical-radiographic follow-up studies that have been published (Strindberg, 1956; Grossman et al., 1964; Harty et al., 1970; Adenubi and Rule, 1976; Jokinen et al., 1978; Kerekes and Tronstad, 1979; Bergenholtz et al., 1979; Delessert et al., 1980; Barbakow et al., 1980a, b; Morse et al., 1983; Swartz et al., 1983; Guignard and Holz, 1985). This lack of clinical correlates to laboratory assessments of endodontic materials is probably the major impediment to a scientific development of new and improved materials.

In consequence, most changes in the selection and application of endodontic materials over the past decades have been fads based on ingenuity in advertising rather than progress based on scientifically founded developments. Thus, no new material can present documented improved biocompatibility, improved healing properties, improved sealing properties, or improved clinical performance. Technological improvements in devices for application of gutta-percha — e.g., the various compactors (Kerekes and Rowe, 1982) and guns for mould injection (Marlin et al., 1981) — may offer advantages in the form of time-saving and ease of manipulation. However, there are no data to indicate that the use of these devices improves...
TABLE 4
RESULTS OF LEAKAGE TESTS

<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th>Technique</th>
<th>Material</th>
<th>Leakage*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Higginbotham</td>
<td>1967</td>
<td>Radioisotope</td>
<td>Kloroperka</td>
<td>++ +</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Diaket</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Procosol</td>
<td>+</td>
</tr>
<tr>
<td>Antoniazzi et al.</td>
<td>1968</td>
<td>Dye</td>
<td>Kloroperka</td>
<td>++ +</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Kerr (Rickert)</td>
<td>+ +</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>AH26</td>
<td>+</td>
</tr>
<tr>
<td>Mattison and von</td>
<td>1983</td>
<td>Electrochemical</td>
<td>Diaket</td>
<td>++ +</td>
</tr>
<tr>
<td>Fraunhofer</td>
<td></td>
<td></td>
<td>Procosol</td>
<td>+</td>
</tr>
<tr>
<td>Beyer-Olsen et al.</td>
<td>1983</td>
<td>Dye</td>
<td>Kloroperka</td>
<td>++ + + +</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>AH26</td>
<td>++ +</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Endomethasone</td>
<td>+ +</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Procosol</td>
<td>+/-</td>
</tr>
</tbody>
</table>

* Due to great variations among authors in experimental design and units of measurement, the results have been arbitrarily assigned values for leakage increasing with increasing number of +. 

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the success rate or increases the number of teeth that may be conserved by endodontic treatment. Moreover, the current, ardent marketing of sealers containing calcium hydroxide appears to have very few, if any, comparative studies to back up the claims of biocompatibility and healing properties.

It would seem evident from the above that research and development of endodontic materials are hindered by the lack of acceptable procedures for the testing of their clinical performance. Therefore, new materials are marketed which may or may not comply with some of the currently recognized laboratory requirements, but which rely on unsubstantiated claims of superior clinical performance as a competing edge in comparison with traditional products.

The lack of clinical correlates also reflects on the "accepted" properties tested in the laboratory. Requirements for sealing properties, physical stability and biocompatibility, for example, may be well-
founded on thorough considerations of what are desirable properties. However, it should be kept in mind that they are based on just that: considerations, and not on clinically proven relevance. Therefore, with the coming of clinical testing of endodontic materials, the so-called “ideal” physical and biological properties of these materials may have to be revised. Moreover, with an increased knowledge of clinical performance, new in vitro designs may be applied which more accurately assess particular clinical complications. Thus, the guinea pig maximization test has been applied and the test results related to the clinical occurrence of an allergic reaction to endodontic materials (Hensten-Pettersen et al., 1985), and a neurotoxicity model has been adapted for the testing of endodontic sealers (Brodin et al., 1982; Brodin and Ørstavik, 1982) implicated in paresthetic reactions of the inferior alveolar nerve to endodontic treatment (Ørstavik et al., 1983b; Rowe, 1983).

Finally, the clinical assessment of the materials must take into account the level, i.e., the frequency and severity, of the problems. Fig. 6 is an illustration of some examples of clinical complications with endodontic materials occurring at various levels. It should be remembered that the more severe complications may occur with extremely low frequency. Therefore, in a clinical trial the number of subjects required for the assessment of these complications may be prohibitively large, and we may also have to rely on enlightened inferences in the future.

Another factor which may have influenced the development of endodontic materials is the comparatively small market from the point of view of manufacturers. Endodontic materials are a low-cost area with little chance of research and development revenue in the form of high-priced new products, and new endodontic materials have usually been spin-offs from other areas of research. Moreover, the endodontic establishment may have been overzealous in its skepticism of new products. This traditionalism also tends to become cemented by the divergent techniques and materials taught in different dental schools and in the post-graduate programs.

### Current Developments

#### General

Pulp biology and endodontics as areas of scientific research have prospered in recent years. Pulpal and periodontal reactions to trauma (Hammarström et al., 1986) and to infections (Fabricius et al., 1982a) are under study, with application of clinical research strategies as well as the tools of the basic sciences: pulpal physiology and the immunology and bacteriology of infections of the pulp and periapex.

In endodontic practice, the improvements in the standardized technique have been disseminated to many practicing dentists and specialists, who feel that their performance has thereby improved. Reciprocating angle pieces and, more recently, the introduction of sonic and ultrasonic devices for instrumentation may ease and improve canal preparation (Klayman and Brilliant, 1975; Stamos et al., 1985).

#### Bacterial Studies

The current activity in endodontic microbiology may be of greater significance for endodontic materials. Improved methods of bacteriologic sampling from root canals and periapical tissues (Tronstad et al., 1987) have led to better characterization of the infecting bacteria, which turn out to be a lower number of genera than previously believed (Table 5). A strategy of selective antibacterial treatment may therefore be envisaged, and controlled-release delivery systems for antibiotics or other antibacterial components, also involving filling materials, are conceivable. Moreover, with improved possibilities for bacteriological diagnosis, selection among materials with different activ-

<table>
<thead>
<tr>
<th>TABLE 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>MICRO-ORGANISMS MOST COMMONLY ASSOCIATED WITH PULPOPERIAPICAL INFECTIONS</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genus</th>
<th>Characterization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacteroides</td>
<td>G⁻, anaerobic, pleomorphic rods</td>
</tr>
<tr>
<td>Eubacterium</td>
<td>G⁺, anaerobic rods</td>
</tr>
<tr>
<td>Bifidobacterium</td>
<td>G⁻, anaerobic rods</td>
</tr>
<tr>
<td>Fusobacterium</td>
<td>G⁺, anaerobic cocci</td>
</tr>
<tr>
<td>Peptostreptococci</td>
<td>G⁺, anaerobic cocci</td>
</tr>
<tr>
<td>Peptococci</td>
<td>G⁺, anaerobic cocci</td>
</tr>
<tr>
<td>Wolinella</td>
<td>G⁻, anaerobic, mobile rods</td>
</tr>
<tr>
<td>Selenomonas</td>
<td>G⁻, anaerobic, mobile rods</td>
</tr>
<tr>
<td>Streptococci</td>
<td>G⁺, facultative cocci</td>
</tr>
<tr>
<td>Enterococci</td>
<td>G⁺, facultative cocci</td>
</tr>
<tr>
<td>Lactobacillus</td>
<td>G⁺, facultative rods</td>
</tr>
</tbody>
</table>

Based on Sundquist, 1976; Möller et al., 1981; Fabricius et al., 1982b; Byström et al., 1985; Haapasalo et al., 1985; Haapasalo et al., 1986.
itivity toward different bacterial species (Cox et al., 1978; Ørstavik, 1981) becomes feasible. Work is in progress on the controlled delivery of drugs into root canals; however, at this point in time, activity is mainly focused on temporary dressing medicaments (Barnett et al., 1986).

**Tissue Reactions to Endodontic Materials**

In contrast, the philosophy on endodontic filling materials has considered release of material components to be undesirable, indeed associated with inflammatory reactions to the materials. Whereas this concept could change if bacteriostatic or bactericidal agents with no or few tissue-irritating properties could be controllably and selectively leached from the material, current research is concerned with the identification and localization of material components in the tissues. Moreover, the analysis of vascular and cellular reactions to the endodontic material is still of primary interest in endodontic research.

This interest is based on the supposition that toxic components of the material may initiate or perpetuate periapical inflammation (Fig. 7), which in turn may necessitate the removal of the tooth. While it has long been recognized that unset endodontic sealers are irritating to tissue (Keresztesi and Kellner, 1966; Langeland, 1974), only recently have the mechanisms for this irritation been subjected to a more detailed study.

One of the advances in microscopic diagnosis is the application of element analysis to tissue sections and cell culture preparations. At our laboratory, we have applied this technique to implantation studies with endodontic sealers and to clinical biopsies from cases of endodontic failures with the material as suggested etiology. Fig. 8 is a brief outline of the methodology, and shows the use of the scanning electron microscope on paraffin-embedded tissue sections. Fig. 9 illustrates the results obtained for a clinical specimen analyzed microscopically, by back-scattered scanning electron microscopy (BSEI) and by energy-dispersive micro-analysis of particles identified by BSEI. While the analysis is less efficient for elements of atomic weights below 20, precise, qualitative or semi-quantitative, measurements may be made of microscopic and submicroscopic (<1 μm) particles released from the endodontic materials. The information obtained is easily related to inflammatory reactions observed in neighboring sections by light microscopy (Ørstavik and Mjör, 1988). Moreover, insight into the mechanism of tissue damage may be obtained through correlation with more basic studies on cytotoxicity of endodontic material components. Thus, the recent documentation of the toxic properties of zinc (Helgeland, 1977; Meryon and Jakeman, 1985), combined with the demonstration of zinc in particles associated with inflammatory reactions to endodontic sealers (Table 6), may indicate that the zinc oxide so commonly used in endodontic materials may exert a negative influence on the tissues.

Recent research into the cell and tissue reactions to endodontic materials and their components also sheds new light on the influence of these materials on cellular functions. Particularly, studies on macrophage function (Biggs et al., 1985; Syrjänen et al., 1985) in the presence of material components may indicate that inflammatory cells attack and dispose of different endodontic materials with different mechanisms and efficacy. Improved knowledge of the host's ability to deal with elements and particulate matter from en-

![Fig. 7 — Adverse tissue reactions to endodontic filling material displaced periapically. M: Material particles. I: Inflammatory reaction. Zinc oxide-eugenol cement with paraformaldehyde addition (N2). Original magnification 40x.](image)
Electron beam of SEM

EDXA

BSEI

SEI

SPECIMEN

Fig. 8—Element analysis of tissue sections in the scanning electron microscope (SEM). SEI: Secondary electron image (regular SEM). BSEI: Back-scattered electron image displaying components with elements of high atomic weights. EDXA: Energy-dispersive spectrum of elements detected.

dodontic materials may aid in the selection among existing products and in the manufacture of new products.

Case Reports of Adverse Reactions to Endodontic Materials

The literature is replete with case reports of atypical reactions to and mishaps during endodontic treatment. As a whole, endodontic materials are fortunately relatively innocuous, and adverse reactions are few and therefore not easily compiled and analyzed with respect to incidence and severity. Case reports therefore remain an important source of information on the clinical qualities of endodontic materials. Recently, damage to the inferior alveolar nerve subsequent to endodontic treatment of posterior teeth of the lower jaw has been the subject of several reports and literature surveys (Ørstavik et al., 1983b; Rowe, 1983). In laboratory testing, a modified neurotoxicity assay to endodontic filling materials has demonstrated that the part played by the material may be important in this clinical state. The pattern of neurotoxicity in vitro correlates well with the association of the material with clinical paresthesia (Fig. 10), and this model may be advantageous in the testing of newly-developed products (Brodin et al., 1982; Brodin and Ørstavik, 1982; Schippers et al., 1986).

Allergic reactions to endodontic materials may occur, and reports of clinical cases have surfaced in the literature (Horsted and Søholm, 1976; Barkin et al., 1984). Also for this clinical condition there are accepted laboratory methodologies which may be used to screen materials for allergenic properties (Hensten-Pettersen et al., 1985). Particularly with regard to the sensitizing properties of many synthetic polymer systems and antibacterial agents, it would seem proper to suggest that new materials should be subjected to a sensitization test. The fairly high sensitizing potential of commonly used sealers (Table 7) may actually point to the desirability of improving some of the most commonly used materials in just this respect.

Clinical Studies

Being engaged in standardization work on both technological and biological aspects of endodontic materials, NIOM launched a research program with these materials which also included a clinical study. As indicated previously, few if any comparative clin-

Fig. 9—Tissue reaction to subcutaneous implant of AH 26. A: Section stained with hematoxylin and eosin displays intense inflammation.
B: BSEI image for orientation in the scanning electron microscope showing tissue-associated bright particles of high atomic weights (arrows).
C: Identification of bismuth in EDXA spectrum from area encircled in B. Original magnification of micrographs 40 x.
denounce x-ray analyses of root-filled teeth as an adequate basis for scientific research. To overcome this difficulty, we investigated the possibility of making the radiographic diagnosis more objective and reproducible by applying a scoring system. As a basis for the clinical studies on endodontic materials, therefore, a periapical index termed the PAI was developed (Fig. 11) (Orstavik et al., 1986). Similar in concept to the successful indices now so familiar in periodontal, caries, and plaque research, this index is based on a delineation of steps on a progressive disease scale. The steps on PAI are represented by reference radiographs of teeth with various degrees of apical periodontitis verified histologically in a necropsy study of 299 root-filled teeth, including successes as well as failures by conventional criteria (Brynolf, 1967). This index allows for a possible blind score of experimental teeth in coded radiographs and permits unbiased assessment of the radiographic appearance. Extensive analyses of parameters for reproducibility and accuracy indicate that the PAI may be used with clinical and statistical confidence in clinical experiments, allowing for comparisons between subgroups of teeth with systematic or randomized differences (Orstavik et al., 1986; Orstavik, 1988).

The PAI scoring system has been applied in a controlled study on the clinical performance of three endodontic sealers used in combination with a standardized gutta-percha/sealer technique (Orstavik et al., 1987). The choice of sealer was randomized by the throwing of a die when the tooth was ready for filling. A total of 810 roots were filled with either AH 26, a synthetic polymer, ProcoSol, a zinc oxide-eugenol cement, or Kloroperka NO, a rosin-gutta-percha-zinc oxide-balsam-chloroform mixture, in conjunction with a master cone of gutta-percha. At the three- and four-year follow-up, 451 and 289 roots, respectively, were available for clinical and radiographic re-examination. Computer analysis permitted stratification of the material to correct for the influence of clinical and radiographic characteristics of known influence on the prognosis, other than the sealers used.

Tables 8 and 9 and Fig. 12 show some salient results from this study. The results document that the PAI scoring system is suitable for follow-up examinations and for experimental, prospective clinical studies in endodontics. Apparently, the PAI scores are highly discriminatory and may be subjected to powerful statistical tests; the possibility for unbiased recording of the periapical situation makes the results "true" in a numerical or statistical sense; and the histological verification (Brynolf, 1967) of the reference radiographs lends credence to the supposition that the results are also "true" in a biological sense.

The use of the PAI made possible a discrimination of the results obtained with different sealers. Although the conventional failure rate was low and did not permit discrimination between the sealers, the distribution of scores in the "doubtful" categories 2
and 3 of the PAI clearly documented that Kloroperka N0 performed less well than did AH 26 and ProcoSol. This rating persisted through all stratifications of the total material, which resulted in a sufficient number of teeth in each subgroup for adequate statistical (RIDIT) analysis.

The PAI scoring system, with its possibilities for unbiased scoring and intra- and interobserver harmonization, applied in clinical studies where the endodontic material is the only randomized variable, forms a sound basis for clinical testing and comparisons of endodontic materials. Combined with a judicious selection of physical and biological tests, such clinical testing may ultimately determine the suitability or advantages claimed for new products.

**New Materials**

**Regulatory Action**

There is a framework, however frail, which should be reinforced for the development and approval of new materials. Within the US, ADA Specifications No. 56, Endodontic Filling Materials, and No. 41, Recommended Standard Practices for Biological Eval-
not documented compliance with any of the existing standards or specifications. Indeed, for some of them it is apparent that they do not comply with important parts of some specifications. This must be considered a most unfortunate situation: The painstaking work of the endodontists/material scientists leading up to complete specifications and standards is put aside, and new materials are marketed with claims of, but without documentation of, superior new qualities but
technology seeks new applications, one of which is the surface glazing of root canal walls. The concept would be to seal off the dentinal tubules, apical foramen, and accessory canal openings with sintered masses of dentin or enamel powder (Zakariasen et al., 1986). Another approach to the problem of dentin tubule plugging is impregnation of tubules with synthetic resin. Research activity in this area may be tempered by the lessons of history: Riebler’s paste and conventional or e.g., dentin chips or calcium hydroxide. B: “Mechanical” plug, e.g., conventional or improved sealing materials.

CONCLUSIONS

Endodontic treatment is reported to succeed in from 80 to 95% of the cases treated. Failures are mostly associated with the occurrence or persistence of infection, to a lesser extent with adverse tissue reactions to the root-filling materials. Whereas root-filling materials and techniques display widely different sealing qualities, their clinical performance is not similarly divergent. Although improved sealing properties may be desirable, great improvements in success rates are unlikely. Moreover, although the materials vary greatly in biocompatibility, there are few data to indicate that superior biocompatibility is essential for endodontic treatment success. Endodontic problem cases are usually successfully treated when the anti-infective measures have been effective. Significant improvement in endodontic therapy may be expected when control of infection can be achieved regularly and predictably. To the extent that new materials, material combinations, or techniques can contribute to this end, real improvements in endodontic materials may be feasible.

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