AH Plus®
Scientific Compendium

With the compliments of

Dentsply DeTrey GmbH
Clinical Research
De-Trey-Str. 1 | 78467 Konstanz | Germany
Phone +49 (0)7531 583-0 | Fax +49 (0)7531 583-104

Dentsply Sirona

(For Individual Attention Only)
2005-04-01, updated 2024-02-26

AH Plus®
Scientific
Compendium

Table of contents

1 Introduction

The main clinical requirements of a root canal sealer presented in the literature are good tissue compatibility and a lasting tightness of the root canal. Tightness mainly depends on dimensional stability like shrinkage, expansion and solubility as well as adhesion to both dentin and applied cones. Additionally, good radio opacity and easy application of the material are expected.

With AH Plus®, Dentsply DeTrey sets a further milestone in more than 50 years of research in the area of endodontics. Maintaining the advantageous properties of the successful precursor product AH 26® such as high radio opacity, low solubility, little shrinkage, and good tissue compatibility, certain disadvantageous properties such as a tendency to discoloration and the release of formaldehyde have been eliminated with AH Plus®. The epoxide amine chemistry of AH 26® has been retained. However, newly developed amines which are protected by patents have been used. As a result of several innovations, with AH Plus® it has been possible for the first time to develop a thermoplastic root canal sealer which permits removal of the material, if necessary. Another advantage of AH Plus® is its application form: a paste-paste system, which ensures rapid and clean mixing.

	AH 26®	**AH Plus®**
Application form	powder/liquid	paste/paste
Radiopacity	very high	very high
Dimensional stability	very good	very good
Solubility	very slight	very slight
Discolorations	in part	none
Release of formaldehyde	yes	none
Tissue compatibility	very good	very good
Removability	only mechanically	yes

Table 1
Comparison of the products AH 26® and AH Plus® with regard to their essential properties.

2 Description of the AH Plus® System

2.1 Composition of AH Plus®

AH Plus® consists of a paste-paste system, which is delivered in two tubes and in a new double barrel syringe. The components of AH Plus® are given in Table 2.

In addition to the diepoxide, the epoxide paste contains radio opaque fillers and Aerosil. The amine paste consists of three different types of amines, radio opaque fillers and Aerosil.

AH Plus® is characterised by very good mechanical properties, high radio opacity, little polymerisation shrinkage, low solubility, and, not least, a high degree of stability on storage.

Epoxide paste	Amine paste
Diepoxide	1-adamantane amine
Calcium tungstate	N,N'-dibenzyl-5-oxa-nonandiamine-1,9
Zirconium oxide	TCD-Diamine
Aerosil	Calcium tungstate
Pigment	Zirconium oxide
	Aerosil
	Silicone oil

Table 2
Composition of AH Plus®.

The radio opaque fillers used in AH Plus® ensure an exceptionally good radio opacity of the material, even when applied in very thin layers.

Tightness and insolubility of the polymerised material are relevant for the function of a root canal sealer. These properties and the viscosity during application are directly dependent on the filler. Therefore, finely ground calcium tungstate with an average particle size of 8 µm and finely ground zirconium oxide of 1.5 µm average particle size are used.

The mixed and polymerised AH Plus® has a filler content of 76% in weight. The remaining constituents are polymers, Aerosil, and the pigment.

With regard to the epoxide components which are capable of polymerisation and the resulting addition cured polymers, the chemistry of AH Plus® is based on AH 26®, which has successfully been used for more than 50 years. Nevertheless, AH Plus® can rightly be described as an innovative material, since a completely new thermoplastic material was created on the basis of Dentsply's decades of experience in the field of epoxy amine research. With AH Plus®, the advantages of AH 26® are preserved, and further improvements have been achieved.

Both, an amine component and AH Plus® itself are protected by patent.

In the following chapter, the principles of the reaction mechanisms are described.

2.2 Reactions in AH Plus®

As already announced earlier, AH Plus® is a two-component system consisting of two pastes. The thermal polyaddition reaction starts immediately after the two components are mixed.

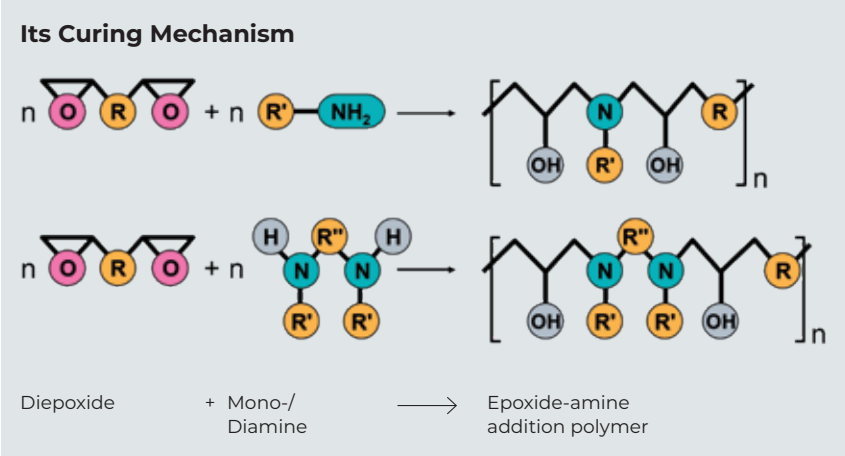

Figure 1
Polyaddition of diglycidyl ether of bisphenol-A, a primary monoamine and a disecondary diamine.

An essential feature of polyaddition is a step growth reaction. The monomers, diepoxides and amine, react to oligomers with epoxy - and amino- end groups, which for their part can add with remaining monomers or other oligomers[1]. As a result of this polyaddition, high-molecular weight addition polymers are formed. The monomers have been quantitatively converted; this means that almost no residual monomers remain and no molecules are released.

In Figure 1, the polyaddition reaction of the diepoxide, a diglycidyl ether of bisphenol-A, and 1- aminoadamantane, and also N,N'-dibenzyl-5-oxanonandiamine-1,9 is presented. The use of these special diamines for the first time guarantees the formation of a thermoplastic material of high dimensional stability, which further possesses inner flexibilisation and can therefore absorb tension, which might occur as a result of temperature change or mechanical stress.

The amines polymerise with the diepoxide to copolymers. Therefore, the polyaddition to the homopolymers shown in Figure 1 are a schematic simplification.

Polyaddition is dependent on temperature, and requires several hours. A relatively long working time of approx. 4 hours is thus also guaranteed. The polyaddition is only started in presence of the reaction partners and thermal energy. Initiators or catalysts are not necessary for this reaction. Therefore, the curing mechanism is fundamentally different from a radically-photo chemically initiated polymerisation, such as takes place in light-curing composite materials (Spectrum® TPH®) and compomer materials (Dyract®, Dyract® AP).

2.3 New Delivery system

In addition to the tubes delivery, the proven and unchanged AH Plus® sealer chemistry is now available as AH Plus Jet® Mixing Syringe. The new double-barrel syringe significantly improves working ergonomics.

Figure 2
AH Plus Jet® Mixing Syringe – the new application device for AH Plus®.

AH Plus Jet® comes with a mixing tip, which automatically mixes the sealer components in ideal ratio. It is equipped with an intra-oral tip adjustable to individual anatomic conditions through rotation and angulation. Thus, AH Plus Jet® allows direct application of the sealer into the root canal orifices. The sealer can be clinically applied with a single hand. For infection control on direct intra-oral use, the AH Plus Jet® Mixing Syringe can be mantled with a hygienic single-use Disposa Shield® Sleeve.

3 Properties of the Material

3.1 Radio opacity

The radio opacity of root canal filling materials has established itself as one of the most important clinical criteria in the evaluation of successful dental care. The resulting contrast of the material in the root canal permits conclusions regarding the quality of the filling.

Depending on the condensation technique used, thicker layers (master point technique) down to very thin layers (lateral condensation technique) can be achieved. In order to ensure adequate visibility of the filling material even in these thin layers, the radio opacity has further been increased in AH Plus® compared to that of AH 26®. This was possible due to using new fillers with a greater absorption capacity.

Radio-opacity of Root Canal Sealers

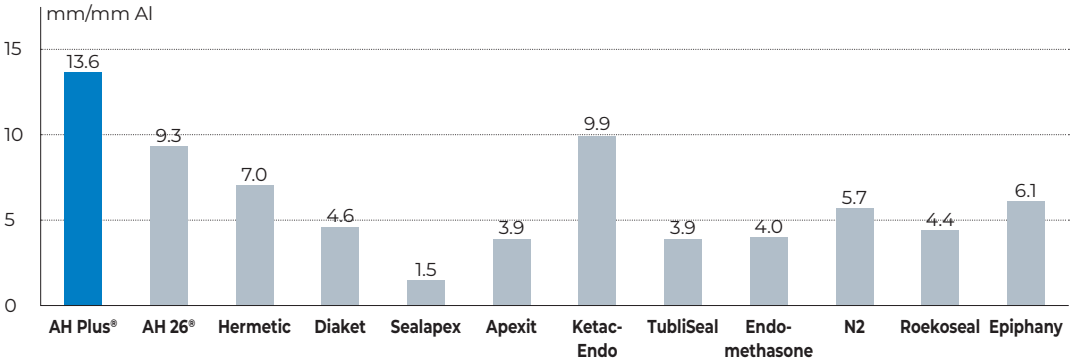

Figure 3
Radio-opacity of AH Plus®, AH 26® and other root canal filling materials.

As can be seen from Figure 3, all other root canal filling materials studied developed radio opacity which was clearly poorer than that of AH Plus®.

3.2 Shrinkage, Solubility and Expansion

The main objective of every root canal filling is to achieve a high degree of tightness. The quality of the root canal filling directly depends on the shrinkage upon setting and the solubility of the material used, as these properties are decisive for the impermeability of the treated root canal.

Polymerization Shrinkage of Root Canal Sealers

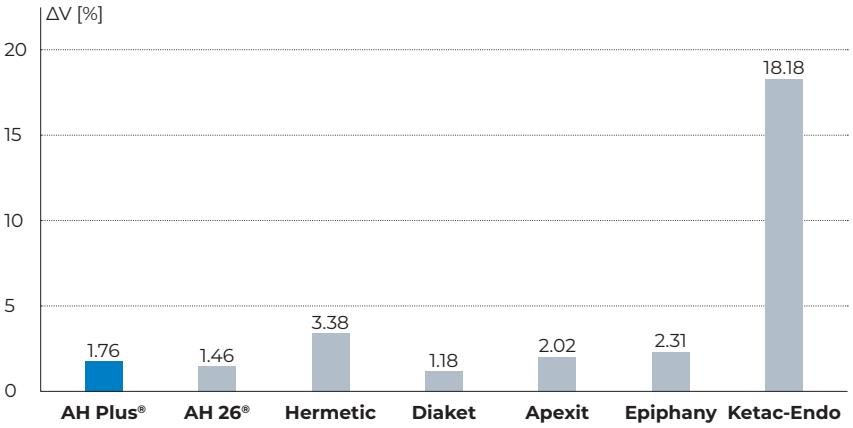

Figure 4
Shrinkage of AH Plus®, AH 26®, and other root canal filling materials.

With AH Plus®, a new material was created which, like AH 26®, is characterised by very low shrinkage or, in other words, by high dimensional stability. Some of the competitor materials which have been studied have considerably higher shrinkage values, while others show values which are low and similar to those of AH Plus® (cf. Figure 4).

Solubility of Root Canal Sealers

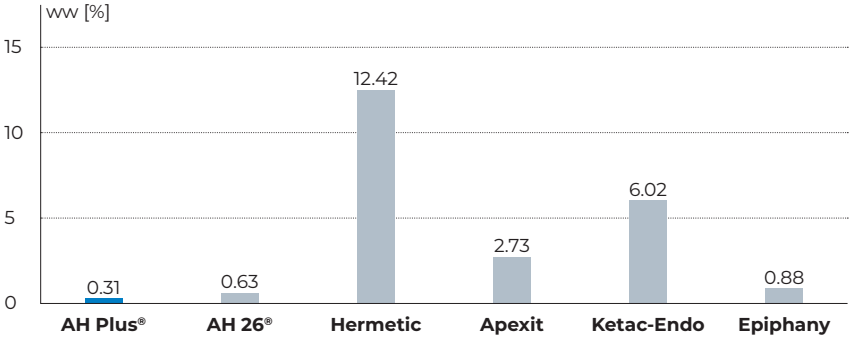

Figure 5
Solubility of AH Plus®, AH 26®, and other root canal filling materials.

However, the solubility of the reference products is considerably greater than that of AH Plus® or AH 26® (Figure 5).

AH Plus® showed the greatest stability in solution and Tubli-Seal EWT(R) performed well, but Apexit and Endion had higher solubility values[2]. Furthermore, AH Plus® showed the least weight loss of eight different root-canal sealers in water and in artificial saliva with different pH values, independent of the solubility medium used. Sealapex, Aptal-Harz and Ketac Endo had a marked weight loss in all liquids[3]. For example the solubility of AH Plus® is 0.11-0.19% and of RoekoSeal 0.85-1.01% measured according ISO 6876 (2001).
The linear expansion of AH Plus® is very low (0.129 ± 0.08) whereas a newer root sealing material Epiphany exhibits an linear expansion of 4.827 ± 0.183%.

3.3 Film Thickness

A further physical parameter which can also be decisive with regard to the tightness of the root canal filling is the particle size of the fillers used. Therefore, finely ground calcium tungstate with an average particle size of 8 mm (in relation to the mass) and finely ground zirconium oxide with an average particle size of 1.5 mm are used as fillers.

The particle size of the filler has a decisive effect on the film thickness of the mixed material. AH Plus® has a film thickness of 26 mm, which is clearly below the value of less than 50 mm required by the ISO standard for root canal sealing materials (ISO 6876).

3.4 Adhesion to dentin

The adhesion of five root-canal sealers (Grossman's sealer (GS), Apexit (AP), Ketac-Endo (KE), AH Plus® (AH), RoekoSeal Automix (RS)) to dentine and gutta-percha was studied. Mean tensile bond strengths (MPa ± SD) ranged from 0.07 ± 0.01 (Apexit) to 1.19 ± 0.47 (AH Plus®)[4]. Pecora[5] found an adhesion of AH Plus® to dentin of 4 MPa. After Er:YAG Laser treatment of the root canal the adhesion increases to about 7 MPa (Figure 6).
Recently, Gogos demonstrated that an identical product to AH Plus® exhibits a significant self- adhesion to dentin of 6.24 ± 1.43 MPa[6].

Adhesion after EDTAC or Er:YAG Laser treatment

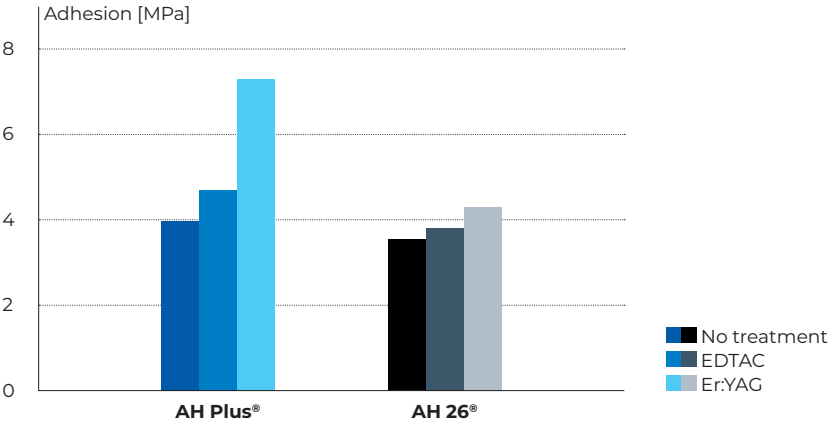

Figure 6
Adhesion to root canal dentine after various pre-treatment.

Pécora et al. Braz.Dent.J. 2001; 12(1):27-30

3.5 Flow Behaviour

The flow behaviour of a dental material is one of the most important handling properties. Firstly, favourable flow behaviour results in easy mixing. Secondly, the filling material must be able to be introduced easily into the root canal and exhibit a certain stability there. Therefore, AH Plus® has been designed to be slightly thixotropic. A flow of 36 mm also perfectly meets the requirements of the ISO standard (> 25 mm).

4 Sealing Abilities

As stated in the beginning, the ability of an endodontic material to seal root canals impermeably and lasting is of particular importance. Therefore, AH Plus® was tested at two universities before its market launch especially for this property. Consideration was given both to the filling techniques employed today and to a comparison to different reference materials.

Essential details of the test methods used and of the results obtained are presented in the sections below.

4.1 Study I

In the first study at the Charité University Hospital, Humboldt University, Berlin AH Plus® and the reference material AH 26® were tested by using a) Lateral condensation with gutta-percha points, b) Sealer plus Thermafil, c) Sealer plus Quick-Fil.

Details of the Method

- The procedure was published in the Journal of Dental Research 1992, 71 Spec. Iss.: Abstract #848
- Maxillary central incisors were instrumented according to the step-back technique for obturation.
- The teeth were randomly divided into groups and filled according to the filling techniques indicated under 4.1.3.
- The teeth were stored at 37 °C and 100% humidity for two days, followed by storage in water for three weeks at 37 °C.
- At the end of that period, the specimens were coated with nail varnish leaving the apical orifice open for possible further fluid exchange with the environment.
- After storage in a dye solution (fuchsine) for 48 hours, the roots were sectioned into discs (0.5 mm) perpendicular to the long axis of the root and examined for any penetration of the fuchsine solution.
- The results were evaluated under the stereo microscope in two ways:
  - In the first place, the depth of penetration of the dye solution was determined. Since both the coating thickness and the loss as a result of the sectioning process were known, the depth of penetration could be calculated for each tooth.
  - Secondly, the angle of penetrated dye along the filling material-dentine interface was also measured for each of the roots.

Results

In Figure 7, the penetration depths concerning AH Plus® and the reference material as a function of the filling technique employed are graphically presented. The good sealing properties of AH 26®, which are already well known, are maintained by AH Plus®. The new product has also proved to be suitable for use in connection with different filling techniques.

The same results for the depth of penetration were obtained for the values expressed as angle of penetration, which are not presented here. The results of the study were presented at the Conference of the American Association of Endodontics 1995.

Results from the Leakage Test at the University of Berlin

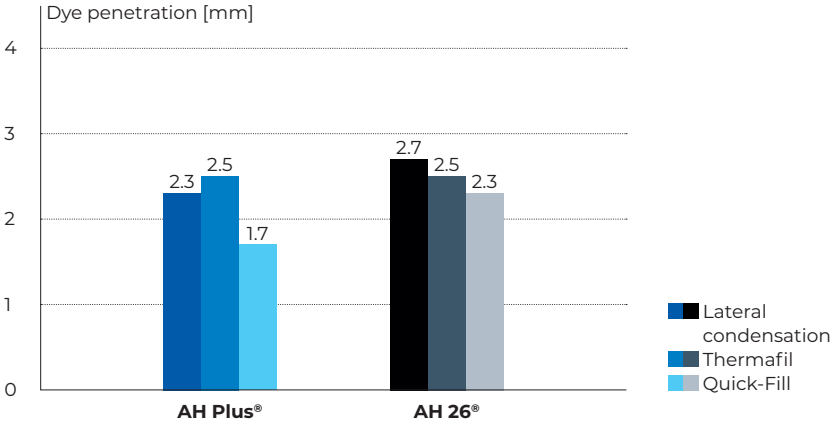

Figure 7
Penetration depths of AH Plus® and of reference material as a function of the filling technique employed.

4.2 Study II

In a further study the sealing ability of AH Plus® and three reference material (AH 26®, Diaket, Apexit) were investigated by using a) Lateral condensation and b) Master point technique with gutta percha points at the University of Munich (Figure 8).

Details of the Method

- Incisors from the upper and lower jaw as well as premolars were used.
- The teeth were prepared according to the step-back technique, as in Study I.
- After filling of the root canals as indicated under Point 4.2.3, the samples were kept at 100% humidity for two days. The specimens were subsequently stored in a saline solution for three weeks at 37 °C.
- At the end of that period, the tooth surfaces were coated with nail varnish except for the orifice of the apex.
- In order to test the impermeability, the prepared teeth were then immersed in a methylene blue solution for one hour.
- As described earlier, the whole root was then cut into segments of 0.6 mm in thickness.
- Each surface of the individual disc was examined for dye penetration. Since the loss of substance caused by the sawing process was known, the total penetration depth of the methylene blue solution for each root could be determined.

Results from the Leakage Test at the University of Munich

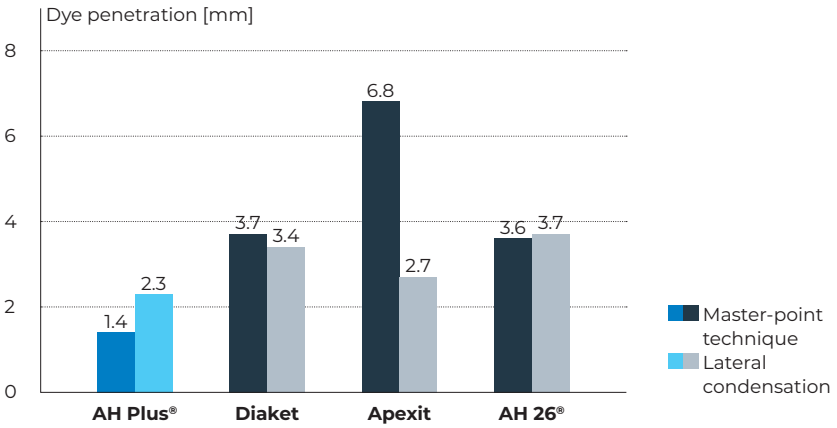

Figure 8
Penetration depth of AH Plus® and reference materials as a function of the filling technique employed.

Results

The results are summarised and graphically presented in Figure 8. It was definitely proven in the test that, compared to all reference materials used, AH Plus® clearly demonstrated its very good ability to seal the root canal in a lasting manner[7]. This applies both for the lateral condensation technique and for the master point technique.

4.3 Further investigations of sealing ability

Miletic et al.[8] investigated different root canal sealers and showed that the differences in leakage amongst Ketac-Endo (0.318 ± 0.084 µL), AH 26® (0.319 ± 0.075 µL), AH Plus® (0.330 ± 0.085 µL) Apexit (0.360 ± 0.127 µL) and Diaket (0.387 ± 0.140 µL) were not statistically significant ($P > 0.05$). Consequently, under the conditions of this study, all five sealers produced a satisfactory seal. Furthermore, it was found that AH Plus® (Topseal) and Sealapex showed similar leakage behaviour over time, with AH Plus® (Topseal) performing better[9].

Siqueira found, that there was no significant difference between ThermaSeal and AH Plus®. No significant differences were observed for Kerr Pulp Canal Sealer EWT when compared with either ThermaSeal or AH Plus®[10].

Furthermore, it was found that AH Plus® (Topseal) and Sealapex showed similar leakage behaviour over time, with AH Plus® (Topseal) performing better[11].

The bacterial leakage of root canals obturated with three root canal sealers, using Endodontalis faecalis as a microbial tracer to determine the length of time for bacteria to penetrate through the obturated root canal to the root apex were compared. There was no statistical difference between Ketac-Endo and AH-Plus ($p > 0.06$), but Apexit had significantly higher leakage ($p < 0.05$) at 30 days. After 60 days there was no statistical difference between Ketac-Endo and Apexit ($p > 0.05$), but Apexit leaked more than AH Plus®. The conclusion drawn from this experiment was that epoxy resin root canal sealer was found to be more adaptable to the root canal wall and filling material than a calcium hydroxide sealer when bacterial coronal leakage was studied[12].

In a in vitro study, gutta-percha and the sealers AH 26® and AH Plus® allowed leakage of bacteria and fungi. Samples with AH 26®, 45% leaked bacteria and 60% leaked fungi; whilst from the samples with AH Plus®, 50% leaked bacteria and 55% fungi. There was no statistically significant difference in penetration of bacteria and fungi between the sealers[13].

Overall AH Plus® demonstrated better diffusion into lateral accessory canals compared to Pulp Canal Sealer[14].

AH 26® and AH Plus® root canal sealers tightly adhered to the tube walls[15].

Lussi investigated the sealing quality of hand- or vacuum-obturated root canals after hand instrumentation or non-instrumentation cleansing[18]. A total of 60 single-rooted teeth were divided into six comparable groups. The root canals of three groups were instrumented with the balanced-force technique and obturated with gutta-percha condensation. The remaining teeth were cleansed and filled using non-instrumentation technology and the same sealers as with hand instrumentation (AH Plus®, Apexit, Pulp canal sealer EWT). After ageing the quality of coronal seal was assessed with a dye penetration method after perfusion with the dye under vacuum.

Leakage. Prof. Lussi. University Bern

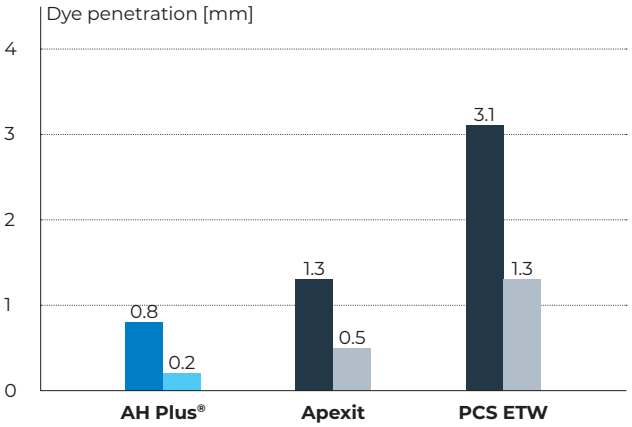

Figure 9
Comparison of Leakage of AH Plus®, Apexit and PCS ETW using lateral condensation and non-instrumentation technology.

J Endod 2000 Sep;26(9):491-3

The results of this study indicated superior sealing of the machine-filled roots (non-instrumentation technology), compared with laterally condensed conventionally filled root canals. AH Plus® results in the best leakage data compared to Apexit and PCS ETW in both techniques. (Figure 9).

Both AH 26® and AH Plus®, when used with an identical gutta-percha obturation technique, resulted in comparable sealability at all evaluation times and in comparable coronal sealability at 1 and 6 months[19].

4.4 Summary

The in-vitro studies described above clearly confirm the suitability of AH Plus® for the clinical obturation of prepared root canals. Moreover, it is irrelevant which of the acknowledged filling techniques is employed.

Due to its excellent properties, such as low solubility, small expansion, adhesion to dentin and its very good sealing ability AH Plus® is looked as a bench mark ("Gold Standard")[20].

5 Toxicological Studies

AH Plus® was tested for its biocompatibility in various toxicological studies. Both, the individual pastes (not cured), and also the polymerised material were tested. All studies were performed in accordance with the current international standards for biological evaluation of medical devices (ISO 10993, Parts 1-12) and the special procedures for preclinical evaluation of biocompatibility of medical devices used in dentistry (ISO CD/TR 7405).

The nature of the tests and their results are summarised in this section.

5.1 Individual Pastes

5.1.1 Mutagenicity

It is known from the literature that pure epoxy resins develop mutagenic activities under the conditions of the Ames test. Therefore, the epoxide paste (paste A) was also studied in the Ames test, in which the aqueous extracts did not induce any mutagenic effects.

In numerous in-vivo studies, the pure epoxy resins never showed any genotoxic effects[21].

The amines contained in the amine paste (paste B) were classified as non-mutagenic in the Ames test. Since the sum of the amines in paste B accounts for only a small proportion, the paste was not tested again for mutagenicity.

5.1.2 Systemic Toxicity

The pure resins contained in the epoxide paste were classified as non-toxic (LD_{50} > 5000 mg/kg). Therefore, a test of the epoxide paste itself was not performed. The amine paste was tested in rats for its systemic toxicity, and could also be classified as non-toxic (LD_{50} > 2000 mg/kg).

5.1.3 Cytotoxicity

The results of the studies of the cytotoxicity of the paste in the growth inhibition test (ISO 10993-5, 12) show that, as expected, the eluates of the non-polymerised pastes clearly induce cytotoxic effects on the cell cultures.

It is known that cyctotoxicity is responsible to attack bacteria. Saleh showed that root canal fillings with AH Plus® effectively kills enterococcus faecalis in dentin tubules[16]. On the other hand cytotoxicity of the AH Plus® is time limited and was no longer detectable after 4 hr of mixing[17] which corresponds to the working time of the material.

5.1.4 Antimicrobial effects

Recently, antimicrobial effects of six endodontic sealers (Apexit, Endion, AH 26®, AH Plus®, Procosol and Ketac Endo) were investigated[22] after 2, 20 and 40 days. It was found that Apexit, Endion and AH Plus® produced slight inhibition on Streptococcus mutants at 20 days and on Actinomyces israelii at every time interval. No effect was found on Candida albicans and Staphylococcus aureus. In conclusion, the sealers evaluated in this study showed different inhibitory effects depending on time span. Overall, sealers containing eugenol and formaldehyde proved to be most effective against the micro-organisms at the time intervals studied.

Siqueira[23] stated all of the investigated root canal sealers tested showed some antimicrobial activity against most of the micro organisms.

5.1.5 Formaldehyde Release

Two papers are dealt with formaldehyde release[24, 25]. These studies showed that AH 26® and Endomethasone sealers released formaldehyde after setting. Only a minimum release was observed for AH Plus® (3.9 ppm)[25]. This was followed by EZ-Fill (540 ppm) endodontic cement and AH 26® (1347 ppm) endodontic cement which yielded the greatest formaldehyde release[25]. According to the chemistry AH Plus® should not release formaldehyde. Consequently, the measured low concentration is within the margin of error of the method.

5.2 Polymerised Material

5.2.1 Mutagenicity

According to the studies available, the polymerised material is free of substances inducing mutagenic effects.

5.2.2 Cytotoxicity

In the presence of the eluates of the polymerised pastes, a clearly lower cytotoxic effect than with the individual pastes was found in the growth inhibition test (ISO 10993-5, 12). The second eluate no longer contained substances in cytotoxic concentrations.

Therefore, it can be expected that any local toxic effects would at most only temporarily occur directly after application of the material. Therefore, a continuous and prolonged migration of components from AH Plus® is not to be expected.

Recently, AH Plus® and Fill Canal were investigated with regard to inflammatory response. Inflammatory cells or areas of necrosis were not associated with AH Plus®. Hard tissue formation apical to the material was observed in 14 specimens. The Fill Canal sealer presented an inflammatory response of moderate intensity in the periapical region, mainly adjacent to the material[26].

In a further study[27] was determined the cytotoxic and genotoxic effects of AH Plus® by means of the growth inhibition test with primary human periodontal ligament fibroblasts and permanent 3T3 monolayers, the prokaryotic umu test, the eucaryotic DNA synthesis inhibition test, and the in vivo alkaline filter elution test. In addition, Ames tests were performed with extracts from AH Plus®. AH Plus® caused only slight or no cellular injuries. Furthermore, no genotoxicity and mutagenicity were revealed by AH Plus®. These data should be taken into consideration when deciding about a root canal sealer.

Furthermore, the cytotoxicity of resin-based root canal sealers (AH 26® and AH Plus®) was evaluated in vitro[28]. The experiments included two cell lines, L929 mouse skin fibroblasts and RPC-C2A rat pulp cells. AH 26® had a severe cytotoxic effect whilst AH Plus® showed a markedly lower toxic influence on the cells during the experimental period.

5.2.3 Sensitisation

Polymerised AH Plus® was tested for its sensitisation property on guinea pigs (ISO 10993-10 and ISO CD/TR 7405). No release of sensitising substances was observed. Therefore, according to the OECD Guidelines for Testing Chemicals (OECD 406 dated 17 July 1992), AH Plus® can be classified as “non-sensitiser”.

Since sensitisation cannot be excluded in very susceptible persons, AH Plus® must nevertheless be classified as a “weak sensitiser” according to the requirements of ISO 10993-10 of August 1993 on the performance of irritation and sensitisation tests for medical devices.

5.2.4 Implantation Studies

5.2.4.1 Subcutaneous Implantation

In order to test the compatibility of AH Plus® in direct contact with tissue in accordance with ISO 10993-6, freshly mixed material (filled into polyethylene test-tubes) and pre-hardened material was subcutaneously implanted in rabbits. After 7 days and 90 days post-implantation, no persistent tissue reactions were detected neither macroscopically nor histologically. Rather, a complication- free incorporation of the material into a connective tissue capsule was observed.

5.2.4.2 Implantation in Bone

Pre-hardened samples of AH Plus® were intraosseously implanted into the tibiae of rabbits. Compared to the control materials, no macroscopically visible reactions of the bone tissue at the implantation sites were found four months after implantation.

5.3 Summary

AH Plus® was tested in numerous tests for possible interactions with living tissue. Therefore, according to the present level of knowledge, AH Plus® can be classified as harmless and safe.

6 Clinical Investigations

AH Plus® was investigated in two clinical studies at the University of Bristol and the University of Munich. Short summaries of both studies are given below.

6.1 Results

6.1.1 Results from the University of Munich, Germany

In this study, conducted by Investigators KHATAR, HICKEL and KREMERS[29-31], University of Munich, 105 teeth in 82 patients were filled with gutta-percha and sealer in cold lateral condensation technique. A distance of up to 2 mm between endodontic restoration and apex was considered adequate. The treated teeth respectively patients were divided into two groups: a test group (group A, AH Plus®, 58 teeth in 53 patients) and a control group (group B, Sealapex (Kerr), 47 teeth in 44 patients).

The restorations were reevaluated after 12 months, considering clinical symptoms and radiographic changes. For both groups, the following outcome levels were determined:
a) "Success"
b) "Success" with incomplete (periapical) healing
c) "Failure"

Results:
At the 12-month recall, equal success rates were found for both test and control group (91.3% and 91.7%). In cases affected by changes in periapical tissues, healing was found in 78% of of cases treated with AH Plus®, and 60% of cases treated with Sealapex.

6.1.2 Results from the University of Bristol, UK

In this trial, conducted by Main Investigator Sir R. J. Elderton, former Professor and Head of Operative Dentistry at Bristol (UK), 110 endodontic fillings were placed with half test (AH Plus®) and half control (Sealapex, Kerr) material. All restorations were placed under anesthesia and rubberdam. Furthermore, step-back preparation, mastercone technique and cold lateral condensation of gutta-percha were applied and pre-op and follow up radiographs (Digora) were taken. 78% of included teeth had a history of pain prior to treatment, 22% a history of swelling. The variable "complaint free restoration" served as a success criteria throughout the recalls periods of up to 4 years.

Results:
Within the recall periods, the success rates (criteria: "complaint free restorations") for AH Plus® and Sealapex vary between 84.6% and 95.2% (AH Plus®) and 90.2% and 100% (Sealapex) for the recalled restorations.

	1 week	6 months	1 year	2 years	3 years	4 years
AH Plus®	90.4	95.2	94.1	84.6	92.7	90.7
Sealapex	95.5	92.7	100	90.2	90.5	100

From the results of this study, no significant differences in terms of signs and symptoms, safety or efficacy could be identified between both materials. No adverse handling properties of AH Plus® had been reported. Concerning the clinical assessment, up to date no detrimental effects have been observed with either AH Plus® or the control sealer material.

7 Instructions for Use

CAUTION: For dental use only.
USA: Rx only.

1 Product description

The intended purpose of **AH Plus®** root canal sealing material and **AH Plus Jet®** root canal sealing material is to be used as permanent root canal sealer.

AH Plus® root canal sealing material and **AH Plus Jet®** root canal sealing material are based on epoxy-amine resin, offering the following features:
- Long-term sealing properties.
- Outstanding dimensional stability.
- Self-adhesive properties.
- Very high radiopacity.

AH Plus® root canal sealing material and **AH Plus Jet®** root canal sealing material do not stain teeth.

1.1 Indications
- Permanent obturation of root canals of teeth of the secondary dentition in combination with root canal points.

1.2 Contraindications
- Use with patients who have a history of allergic reaction to epoxy resins or amines or any of the other components (see Composition and Warnings for further details).

1.3 Delivery forms
- AH Plus® in tubes for manual mixing of paste A and paste B.
- AH Plus Jet® mixing syringe offering a more precise, convenient and faster procedure.

1.4 Composition

Paste A (amber color)
- Calcium tungstate
- Araldite GY 250 epoxy resin
- Zirconium oxide
- Araldite GY 285 epoxy resin
- Highly dispersed silicon dioxide
- Iron oxide pigments

Paste B (white color)
- Calcium tungstate
- Zirconium oxide
- Dibenzyldiamine
- Amantadine
- Highly dispersed silicon dioxide
- Polydimethylsiloxane
- Tricyclodecane-diamine

2 Safety notes

Be aware of the following general safety notes and the special safety notes in other chapters of these Instructions for Use.

Safety alert symbol.

- This is the safety alert symbol. It is used to alert you to potential personal injury hazards.
- Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

The material contains epoxy resins Araldite GY 250 epoxy resin (Bisphenol-A epoxy resin; 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane; CAS No. 25068-38-6) and Araldite GY 285 epoxy resin (formaldehyde, oligomeric reaction products with 1-chloro-2,3-epoxypropane and phenol; CAS No. 9003-36-5) and amines Amantadine (1-Amino adamantane; CAS No. 768-94-5) and Tricyclodecane-diamine (Octahydro-4,7-methano-1H-indenedimethylamine; CAS No. 68889-71-4) which may be irritating to skin, eyes, and oral mucosa and may cause allergic contact dermatitis, allergic sensitization, or systemic allergic reactions in susceptible persons.

- **Avoid eye contact** to prevent irritation and possible corneal damage. In case of contact with eyes rinse immediately with plenty of water and seek medical attention.
- **Avoid skin contact** to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs, remove material with cotton and alcohol and wash thoroughly with soap and water. In case of skin sensitization or rash, discontinue use and seek medical attention.
- **Avoid contact with oral soft tissues/mucosa** to prevent inflammation. If accidental contact occurs, remove material from the tissues. Flush mucosa with plenty of water and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.
- **Do not re-use contaminated tubes or syringes** to avoid cross-contamination.
- **Do not use improperly mixed material** as wrong mix ratio or inhomogeneous mixing may lead to inadequate curing of the material and leaching of monomers or oligomers.
- **Prevent ingestion.** If accidental **swallowing** occurs, have patient drink plenty of water. If nausea or illness develops, seek medical attention.
- **Do not place too much sealer** to prevent overfilling of the root canal, damage of periapical tissue, and acute inflammation of periapical tissues resulting in (temporary) post-operative pain or extrusion into the mandibular nerve canal.

2.2 Precautions

This product is intended to be used only as specifically outlined in these Instructions for Use.

Any use of this product inconsistent with these Instructions for Use is at the discretion and sole responsibility of the dental practitioner.

- Use protective measures for the dental team and patients such as glasses and rubber dam in accordance with local best practice.
- Contact with saliva, blood and sulcus fluid during application may cause failure of the root canal filling. Use adequate isolation such as rubber dam.
- The syringes cannot be reprocessed. To prevent from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringes are handled with clean/disinfected gloves. Discard syringes if contaminated.
- As additional precautionary measure, the syringe may be protected from gross contamination but not from all contamination by applying the single use Disposa-Shield® protective barrier[1].
- AH Plus Jet® root canal sealing material mixing tips and Disposa-Shield® protective barrier are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination or malfunction.
- Make sure that AH Plus Jet® root canal sealing material mixing tips are correctly and firmly attached to the syringe and the intraoral tip to the mixing tip.
- Interactions:
  – If refrigerated, allow material to reach room temperature prior to use.

[1] Disposa-Shield® Infection Control Barrier for low speed, long handpiece, REF A88006.

2.3 Adverse reactions

Following adverse reactions or undesirable side-effects might occur. See chapter Warnings and referenced chapters for details how to prevent or react.

- Acute inflammation of periapical tissues resulting in (temporary) post-operative pain (see Step-by-Step chapter 3.3).
- Irritation and possible corneal damage.
- Irritation of skin or possible allergic contact dermatitis.
- Inflammation of mucous membranes.
- Nausea or illness.
- Dys- or anaesthesia could occur if material is overfilled and extruded into the nerve canal (see Warnings).
- Ingestion or aspiration of mixing or intraoral tip (see Precautions and Step-by-Step chapter 3.2.2).

In general, root canal treatment and obturation might be associated with discharging sinus, intermittent dull ache, and intermittent discomfort of biting and, therefore, could occur when this material is used, too.

2.4 Storage conditions

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

- Store at temperatures from 10 °C to 24 °C (50 °F-75 °F). Use the product at room temperature.
- Do not use after expiration date.

3 Step-by-step instructions

3.1 Preparation

1. Prior to the application of the material prepare, clean, and dry the root canals to be filled using state-of-the-art endodontic techniques.

3.2 Dosage and mixing

3.2.1 AH Plus® root canal sealing material (tubes)

Appropriate paste condition.

For Paste B slight separation may occur. This condition does not negatively affect the setting time of the mixed product. If the dispensed material is solely of clear color, discard the dispensed material, to ensure convenient handling of the mixed paste.

1. Using a metal spatula[2], mix equal volume units (1:1) of paste A (amber color) and paste B (white color) of AH Plus® root canal sealing material on a glass slab or the mixing pad supplied with the package. Mix to a homogeneous consistency.
2. Tightly close tubes after use.
3. Do not exchange caps of tubes. The white cap belongs to paste A; the colored cap belongs to paste B.

3.2.2 AH Plus Jet® root canal sealing material (mixing syringe)

Appropriate mixing ratios.

The syringe filling volumes of pastes A (amber color) and B (white color) vary slightly. To ensure appropriate mixing, bleed the syringe prior to the first use.

The AH Plus Jet® syringe cannot be reprocessed. To prevent the AH Plus Jet® syringe from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringe are handled with clean/disinfected gloves.

[2] Mixing ratio by weight is 1 g of paste A to 1.18 g of paste B.

1. Remove the cap by turning it 90° counter-clockwise and pulling it.
2. Attach the mixing tip[3] to the syringe, aligning the notch.
3. Turn the tip 90° clockwise and secure the mixing tip in place.
4. Rotate and adjust the tip in angle in order to meet treatment requirements.
5. Use Disposa-Shield® protective barrier when cross-contamination cannot be avoided.
6. Carefully apply steady pressure onto the plunger. The two pastes are automatically mixed in equal volume units.
7. After having finished remove mixing tip by turning it 90° counter-clockwise and pulling it off (together with protective barrier if any).
8. Replace the cap on the syringe head, aligning the notch, then turn it 90° clockwise.

3.3 Application

Overfilling.

Damage of periapical tissue and acute inflammation of periapical tissues resulting in (temporary) post-operative pain.

1. Do not place too much sealer to prevent overfilling of the root canal. For condensation and warm gutta-percha obturation techniques apply only a light coating of sealer onto the canal walls.
2. If overfilling occurs the material is usually tolerated very well by the surrounding tissue. If however material is pressed into the mandibular canal, immediately apply state of care measures.

Clogging.

Separation of mixing tip from syringe.

1. Do not allow material to dry inside.
2. Do not reuse mixing tip.
3. Always make sure mixing tip is properly connected to syringe before application. The material should extrude easily.

3.3.1 Condensation and warm gutta-percha techniques

1. As a standard technique, the material is used in combination with gutta-percha or other root canal points.
2. For these filling techniques where most of the canal is obturated by endodontic point material, apply a light coating of sealer with a paper point or file onto the canal walls to the working length and/or apply a light coating of sealer onto the surface(s) of the root canal filling point(s).
3. Insert root canal filling point(s) into the canal according to standard procedure.

3.3.2 Master-Point-Technique

1. Select a gutta-percha point (or alternatively a paper point or a reamer) of the size of the last instrument used during apical preparation.
2. Wet the canal walls with the material through a pumping or simultaneously rotating movement in a counter-clockwise direction of the point/reamer. Alternatively, apply the material onto the tip of a Lentulo spiral.
3. Advance the Lentulo spiral slowly to the apex running at very low speed. Avoid the formation of air bubbles in the material and overfilling of the canal.
4. Withdraw Lentulo very slowly still running at low speed.
5. Dip disinfected and dry master point into the material and insert it into the canal with a slow pumping motion.

3.3.3 Working and setting time

- Working time is 4 hours at 23 °C[4].
- Setting time is 24 hours at 37 °C[5].

3.4 Removal of root canal filling

1. If the material is used in combination with (gutta-percha) points, root canal fillings can best be removed using thermo-mechanical techniques.

[3] AH Plus Jet® Mixing Tips, EU REF 60620116, US REF 667006.
[4] Internal test method.
[5] Measured according to ISO 6876:2012 (E). The complete polymerization needs 7 days at 37 °C.

4 Hygiene

4.1 AH Plus Jet® syringe

Cross-contamination.

Infection.

1. The syringe cannnot be reprocessed.
2. To prevent the syringe from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringe and finger grip are handled with clean/disinfected gloves. Do not reuse syringe if contaminated.
3. Dispose of contaminated syringe in accordance with local regulations.

4.2 AH Plus Jet® mixing tips and Disposa-Shield® protective barrier

The use of protective barriers is an additional precautionary measure against gross contamination but not against all contamination.

1. Right after use, carefully remove protective barrier together with mixing tip without contaminating the device.

Cross-contamination.

Infection.

1. Disposa-Shield® protective barrier and AH Plus Jet® root canal sealing material mixing tips are intended for single use only. Do not reuse in order to prevent cross-contamination or malfunction.
2. Discard in accdordance with local regulations.

4.3 Cleaning

1. Clean spatulas, mixing slabs and instruments immediately after use with alcohol or acetone.

4.4 Diposal

Dispose of in accordance with local regulations.

5 Lot number (LOT), expiration date (⌛) and correspondence

1. Do not use after expiration date.
   ISO standard is used: “YYYY-MM” or “YYYY-MM-DD”
2. The following numbers should be quoted in all correspondence:
   - Reorder number (REF)
   - Lot number
   - Expiration date
3. Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.
4. Device Identification (Basic UDI-DI): ++D010EFM02PZ

A summary of the safety and clinical performance (SSCP) for this product can be found (upon activation) at https://ec.europa.eu/tools/eudamed by searching using the Basic UDI-DI number listed above and at https://www.dentsplysirona.com/ifu using the reference number (REF).

[These Instructions for Use are based on Master Version 13]

Manufactured by
Dentsply DeTrey GmbH
De-Trey-Str. 1
78467 Konstanz
Germany
www.dentsplysirona.com

CE 0123

8 Literature Reviews

Literature referring to the AH sealer family has been analysed by Rödig and Attin from the University of Göttingen in Germany. They reviewed more than 190 literature sources and advocate the use of the material in conclusion.[32)]

Schäfer, Senior Lecturer at The University of Münster and Endodontic Board Member of The German Society of Conservative Dentistry, concludes that epoxy-based root canal obturation sealers are the most established and best investigated sealers worldwide, and can be recommended for clinical application without limitation.[33)]

9 References

1. J.E. Klee, H.-H. Hörhold, "Linear Epoxide-Amine Addition Polymers“ in Polymeric Materials Encyclopaedia, Ed. J.C. Salomone, Boca Raton 1996, p. 2182 - 2192
2. McMichen FR, Pearson G, Rahbaran S, Gulabivala K., A comparative study of selected physical properties of five root-canal sealers. Int Endod J. 2003 Sep;36(9):629-35
3. Schafer E, Zandbiglari T. Solubility of root-canal sealers in water and artificial saliva. Int Endod J. 2003 Oct;36(10):660-9
4. Saleh IM, Ruyter IE, Haapasalo M, Orstavik D. The effects of dentine pretreatment on the adhesion of root-canal sealers. Int Endod J 2002 Oct;35(10):859-66
5. J.D. Pecora, A.L. Cussioli, D.M.Z. Guerisoli, M.a. Marchesan, M.D. Sousa-Neto, A. Brugnera-Junior. Evaluation of Er:YAG Laser and EDTAC on dentin adhesion of six endodontic sealer. Braz. Dent. J. 2001 (12), 27-30
6. Gogos, C, Economides, N, Stavrianos, C, Kolkouris, I, Kokorikos, I, Adhesion of a new methacrylate resin-based sealer to human dentin. J. Endodont. 2004, 30, 238
7. Al-Khatar N, Kunzelmann K-H, Hickel R, Apical leakage of new root canal sealers. J. Dent. Res. 74 (3), 1995, 945, Abstract #273
8. Miletic I, Anic I, Pezelj-Ribaric S, Jukic S, Leakage of five root canal sealers. Int Endod J 1999 Sep;32(5): 415-8
9. Haikel Y, Wittenmeyer W, Bateman G, Bentaleb A, Allemann C. A new method for the quantitative analysis of endodontic microleakage. J Endod 1999 Mar; 25(3): 172-7
10. Siqueira JF Jr, Rocas IN, Valois CR. Apical sealing ability of five endodontic sealers. Aust Endod J 2001 Apr;27(1):33-5
11. Haikel Y, Wittenmeyer W, Bateman G, Bentaleb A, Allemann C. A new method for the quantitative analysis of endodontic microleakage. J Endod 1999 Mar;25(3):172-7
12. Haikel Y, Freymann M, Fanti V, Claisse A, Poumier F, Watson M. Apical microleakage of radiolabeled lysozyme over time in three techniques of root canal obturation. J Endod 2000 Mar;26(3):148-52
13. Miletic I, Prpic-Mehicic G, Marsan T, Tambic-Andrasevic A, Plesko S, Karlovic Z, Anic I. Bacterial and fungal microleakage of AH 26® and AH Plus® root canal sealers. Int Endod J 2002 May;35(5):428-32
14. Venturi M, Prati C, Capelli G, Falconi M, Breschi L., A preliminary analysis of the morphology of lateral canals after root canal filling using a tooth-clearing technique. Int Endod J 2003 Jan;36(1):54-63
15. Erdemir A, Adanir N, Belli S. In vitro evaluation of the dissolving effect of solvents on root canal sealers. J Oral Sci. 2003 Sep;45(3):123-6
16. I.M. Saleh, I.E. Ruyter, M. Haapasalo, D. Orstavik. Survival of Enterococcus faecalis in infected dentinal tubules after root canal filling with different root canal sealers in vitro. Int Endod J. 2004 Mar;37(3):193-8
17. Azar NG, Heidari M, Bahrami ZS, Shokri F. In vitro cytotoxicity of a new epoxy resin root canal sealer. J Endod 2000 Aug;26(8):462-5
18. Lussi A, Imwinkelried S, Hotz P, Grosrey J. Long-term obturation quality using noninstrumentation technology. J Endod 2000 Sep;26(9):491-3
19. De Moor RJ, De Bruyne MA. The long-term sealing ability of AH 26® and AH Plus® used with three gutta-percha obturation techniques Quintessence Int. 2004 Apr;35(4):326-31
20. Roggendorf, M, Bayerisches Zahnärzteblatt Sept. 2004, 32-34

21. Opinion of the Scientific Panel on Food Additives, Flavouring, Processing, Aids and Materials in Contact with Food (AFC) on a request from Commission related to 2,2-bis-(4- hydroxyphenyl) propane bis (2,3-epoxypropoxyl) ether (BADGE), The EFSA Journal (2004) 86, 1-40

22. Kaplan AE, Picca M, Gonzalez MI, Macchi RL, Molgatini SL. Antimicrobial effect of six endodontic sealers: an in vitro evaluation. Endod Dent Traumatol 1999 Feb;15(1): 42-5

23. Siqueira Junior JF, Favieri A, Gahyva SM, Moraes SR, Lima KC, Lopes HP. Antimicrobial activity and flow rate of newer and established root canal sealers. J Endod 2000 May;26(5):274-7

24. Leonardo MR, Bezerra da Silva LA, Filho MT. Santana da Silva R, Release of formaldehyde by 4 endodontic sealers. Oral Surg Oral Med Oral Pathol Oral Radiol Endod 1999 Aug;88(2): 221-5

25. Cohen BI, Pagnillo MK, Musikant BL, Deutsch AS. Formaldehyde evaluation from endodontic materials. Oral Health 1998 Dec;88(12): 37-9

26. Leonardo MR, da Silva LA, Almeida WA, Utrilla LS. Tissue response to an epoxy resin-based root canal sealer. Endod Dent Traumatol 1999 Feb;15(1): 28-32

27. Leyhausen G, Heil J, Reifferscheid G, Waldmann P, Geurtsen W. Genotoxicity and cytotoxicity of the epoxy resin-based root canal sealer AH Plus®. J Endod 1999 Feb;25(2): 109-13

28. Koulaouzidou EA, Papazisis KT, Beltes P, Geromichalos GD, Kortsaris AH. Cytotoxicity of three resin-based root canal sealers: an in vitro evaluation. Endod Dent Traumatol 1998 Aug;14(4): 182-5

29. AL-KHATAR, N, KREMERS, L, HICKEL, R. Re-evaluation of Endodontic Treatment using two different Root-Canal Sealers – a one year follow up study., Dept. of Operative Dentistry and Periodontology, University of Munich, Internal Report

30. Al-Khatar N, Kunzelmann KH, Hickel R (1995). Dichtigkeit und Wandständigkeit verschiedener Wurzelkanalfüllmaterialien in schmierschichtfreien Wurzelkanälen. Autorenreferat DGZMK-Tagung Wiesbaden; 52.

31. Al-Khatar N, Kunzelmann KH, Hickel R (1995). Apical leakage of new root canal sealers. J. Dent. Res. 74:3;945/273.

32. Rödig T, Attin Th (2005). The root canal sealers AH 26® and AH Plus® - an overview. (article in German, to be published)

33. Schäfer E (2003). Evaluation of current root canal filling materials, ZM 93:1, 24-28, article in German.