DENTSPLY
DETREY

AH Plus®

Root Canal Sealer

With the compliments of

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

SCIENTIFIC COMPENDIUM

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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.

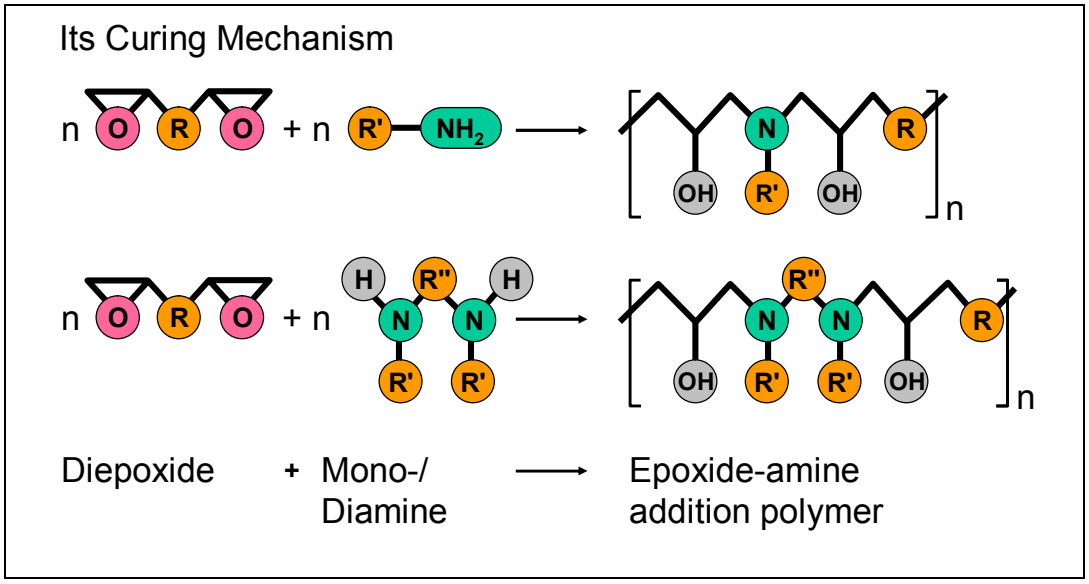

Figure 1 Polyaddition of diglycidyl ether of bisphenol-A, a primary monoamine and a disecondary diamine

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.

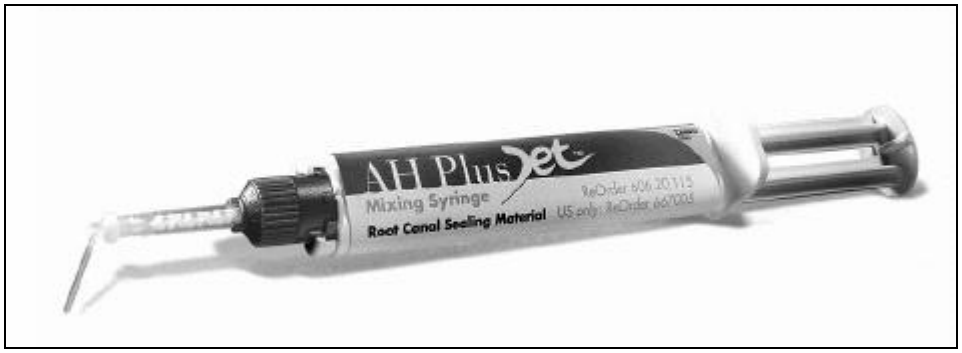

Figure 2 AH Plus Jet™ Mixing Syringe – the new application device for AH Plus

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.

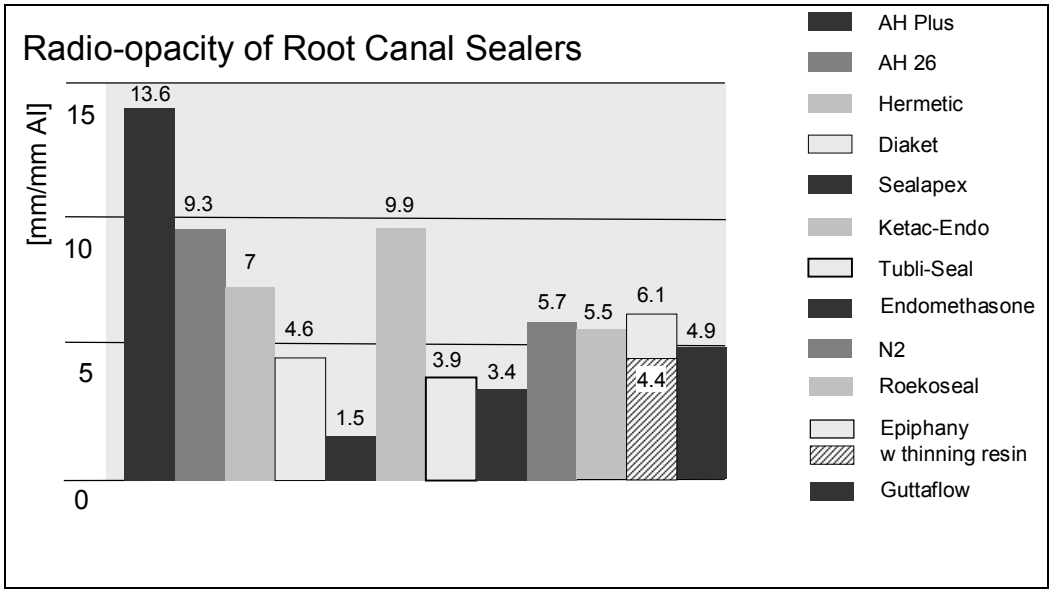

Figure 3 Radio-opacity of AH Plus, AH 26 and other root canal filling materials

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.

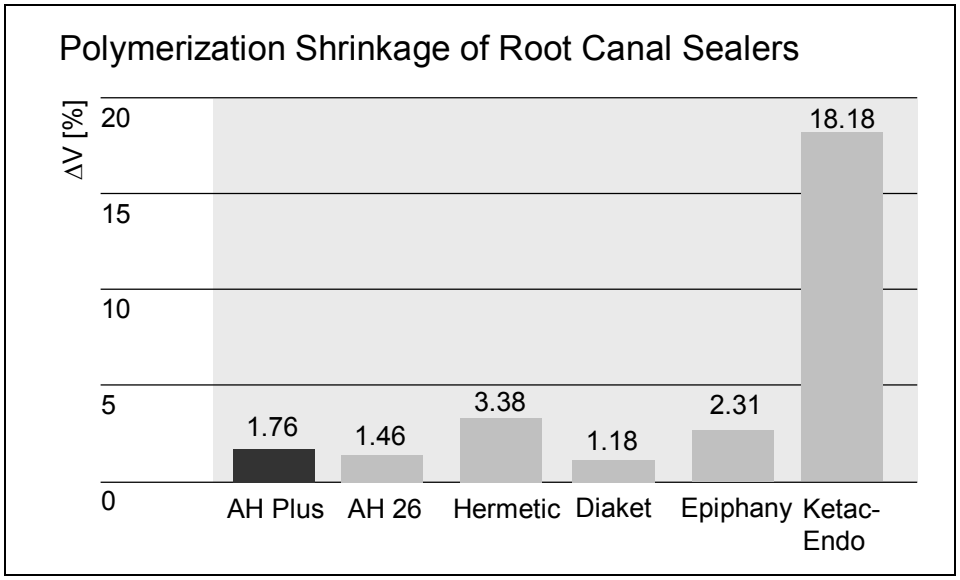

Figure 4 Shrinkage of AH Plus, AH 26, and other root canal filling materials

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).

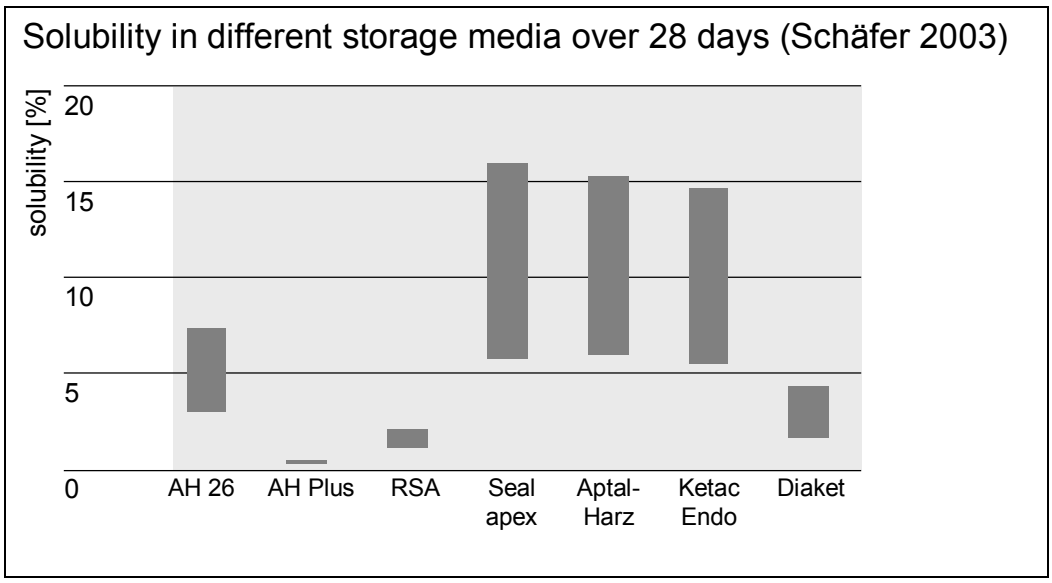

Figure 5 Minimal and maximal solubility in saliva pH 4.5, 5.7, 7, and water of different root canal filling materials

However, AH Plus showed significantly lower 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 (Figure 5) and did not comply with the maximum wight loss in water after 24 hours of 3% according to ISO 6876 (2001) [3)].

Furthermore, AH Plus showed the greatest stability in solution and Tubli-Seal EWT(R) performed well, but Endion had higher solubility values [2)].

The linear expansion of AH Plus is very low (0.129 ± 0.08) whereas a newer root sealing material Epiphany exhibits a 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 root-canal sealers (Grossman's sealer (GS), 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 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].

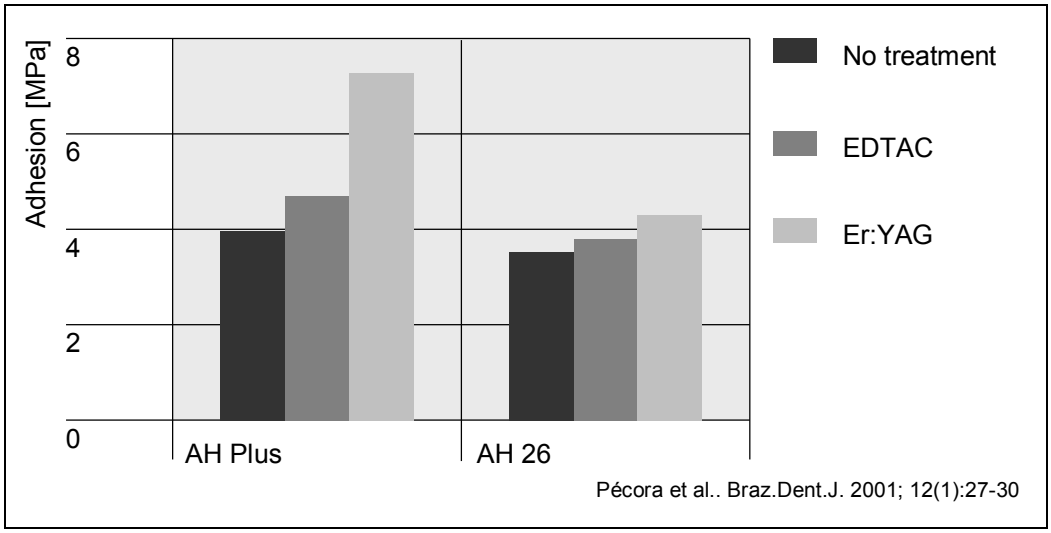

Figure 6 Adhesion to root canal dentine after various pre-treatment

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.

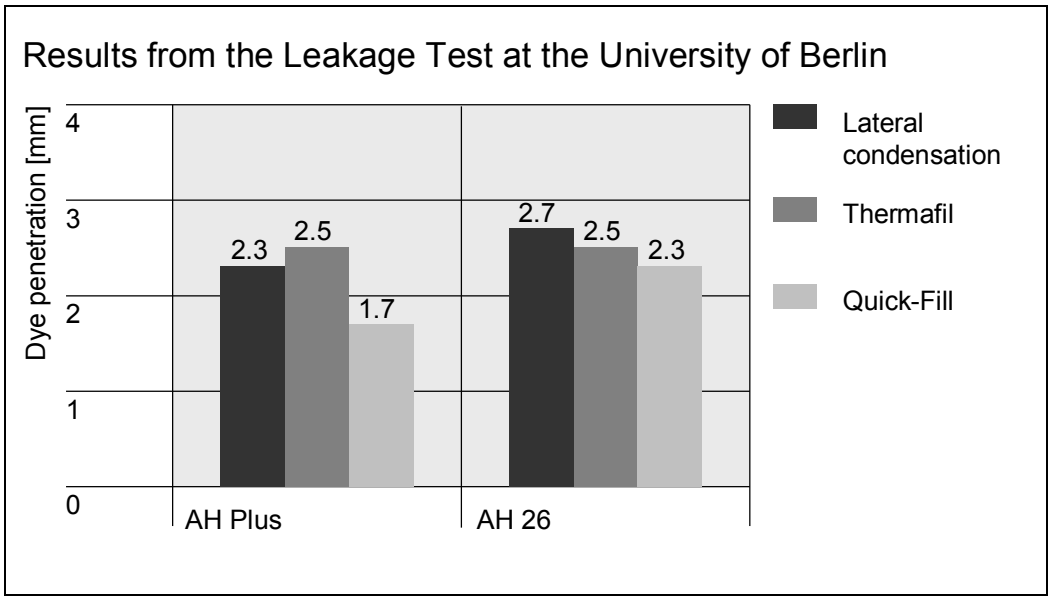

Figure 7 Penetration depths of AH Plus and of reference material as a function of the filling technique employed.

4.2 Study II

In a further study the sealing ability of AH Plus and reference materials (AH 26, Diaket) 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

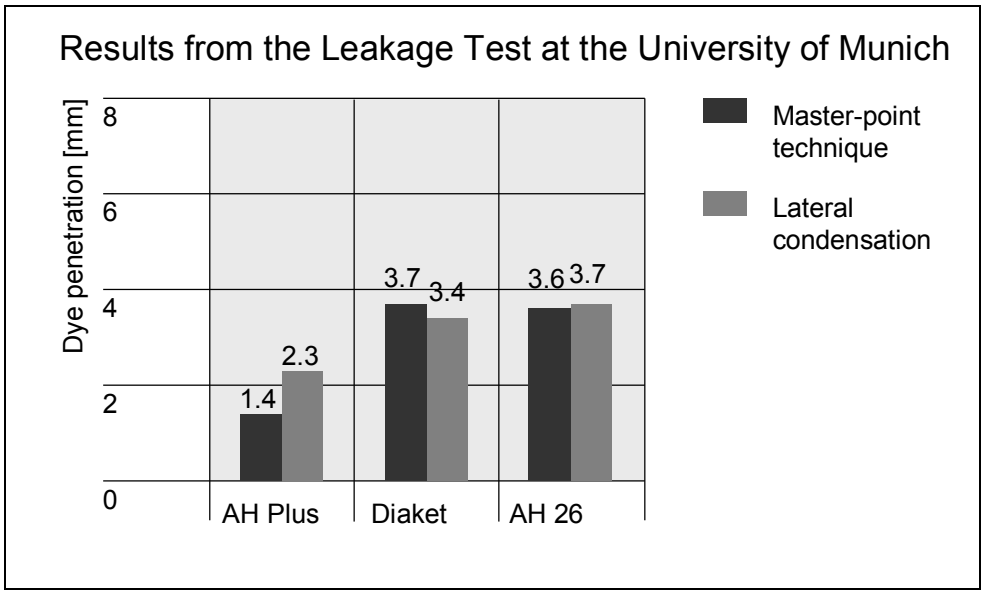

Figure 8 Penetration depth of AH Plus™ and reference materials as a function of the filling technique employed.

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), AH26 (0.319 ± 0.075 µL), AH Plus (0.330 ± 0.085 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 ($p > 0.06$) at 30 days. 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 AH26 and AH Plus allowed leakage of bacteria and fungi. Samples with AH26, 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)].

AH26 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, 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.

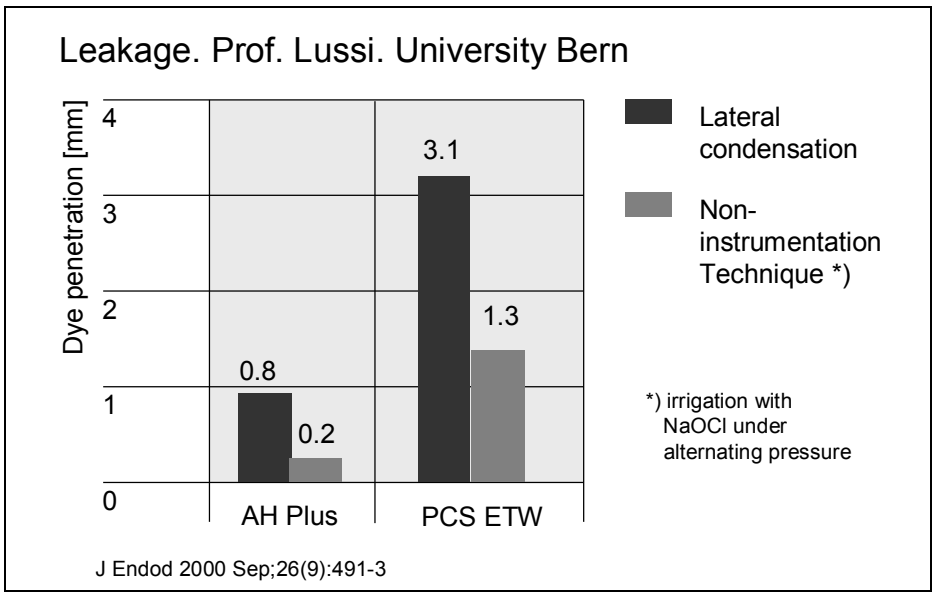

Figure 9 Comparison of Leakage of AH Plus and PCS ETW using lateral condensation and non-instrumentation technology

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 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 endodontic sealers (Endion, AH26, AH-Plus, Procosol and Ketac Endo) were investigated [22] after 2, 20 and 40 days. It was found that 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 (AH26 and AH-Plus) was evaluated in vitro [28]. The experiments included two cell lines, L929 mouse skin fibroblasts and RPC-C2A rat pulp cells. AH26 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 2mm 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 [32)], 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	6months	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 Directions for Use

AH Plus is a two-component paste/ paste root canal sealer based on epoxy-amine resin, offering the following features:

- Long term sealing properties
- Outstanding dimensional stability
- Self-adhesive properties
- Very high radioopacity
- Excellent scientific documentation in many clinical and in-vitro studies
- Use as reference and standard in many investigations
- Extensive market history
- Complies with the requirements of ISO 6876:2001 (E) for dental root canal filling materials.

AH Plus comes in the following deliveries:

- as AH Plus in tubes for manual mixing of pastes A and B
- as AH Plus Jet™ Mixing Syringe for direct intra-oral application, offering a more precise, convenient and faster procedure.

COMPOSITION

AH Plus Paste A	**AH Plus Paste B**
Bisphenol-A epoxy resin	Dibenzyldiamine
Bisphenol-F epoxy resin	Aminoadamantane
Calcium tungstate	Tricyclodecane-diamine
Zirconium oxide	Calcium tungstate
Silica	Zirconium oxide
Iron oxide pigments	Silica
	Silicone oil

INDICATION
Permanent obturation of root canals of teeth of the secondary dentition in combination with root canal points.

CONTRAINDICATION
Hypersensitivity against epoxy resins, amines, or other components of the root canal filling material.

WARNINGS
AH Plus contains epoxy resins (paste A) and amines (paste B) which may cause sensitisation in susceptible persons.
When overfilling occurs, the material is normally tolerated very well by the surrounding tissue. In cases where larger amounts of material are pressed into the canalis mandibularis, immediate surgical removal of the material has to be considered, as with all root canal materials according to state-of-the-art policy.

PRECAUTIONS
Do not use AH Plus in persons allergic to epoxy resins or amines or any other components of the products.
Avoid contact of single pastes or unset mixed paste with skin or oral mucosa. After incidental contact, wash and rinse with plenty of water. Wear suitable gloves and protective glasses.

Under certain storage conditions, AH Plus Paste B may slightly separate. It has been shown that this process does not negatively affect the performance of the mixed product.

STORAGE
To be stored at temperatures between 10°C and 24°C.

Keep resin tubes or the double barrel syringe tightly closed.
Inadequate storage conditions will shorten the shelf life and may lead to a malfunction of the product

INTERACTIONS WITH OTHER DENTAL MATERIALS
None known.

ADVERSE REACTIONS
With sealers containing epoxy resins, the following adverse reactions were reported:
Reversible acute inflammation of the oral mucosa after contact with the unset paste.
In individual cases, local and systemic allergic reactions have been reported.

STEP BY STEP INSTRUCTIONS

Preparation of the Root Canal
Prior to application of AH Plus, prepare, clean, and dry the root canals to be filled using state-of-the-art endodontic techniques.

Dosage and Mixing
Using AH Plus in tubes: Mix equal volume units (1:1) of Paste A and Paste B on a glass slab or a mixing pad using a metal spatula[1]. Mix to a homogeneous consistency.
Caution**:** do not exchange caps of tubes. The coloured cap belongs to the coloured tube; the white cap belongs to the white tube.

Using AH Plus Jet Mixing Syringe
Remove the cap by turning it 90° counter-clockwise and pulling it.

Note: for AH Plus Jet Mixing Syringe, the syringe filling volumes of pastes A and B vary slightly. In order to ensure an appropriate mixing ratio, minor surplus of paste needs to be removed from the syringe prior to the first clinical application of AH Plus Jet Mixing Syringe. In this case, apply a small amount of AH Plus onto a mixing pad until both components paste A and paste B are equally extruded.

Attach the mixing tip to the syringe, aligning the notch, then turn the tip 90° clockwise. Ensure secure fit of the mixing tip. AH Plus Jet™ Mixing Syringe allows direct application of the sealer into the root canal orifices and into the coronal parts of the canals. The intra-oral tip can be rotated and adjusted in angle in order to meet individual anatomic conditions and treatment requirements. For infection control on intra-oral use, it is recommended to mantle AH Plus Jet Mixing Syringe with the Disposa-Shield® sleeve (ReOrder No.: A880065). Discard Disposa-Shield sleeve after use. For application of the sealer, carefully apply steady pressure onto the plunger. The two pastes are automatically mixed in equal volume units.

Having finished the sealer application, the mixing tip must be discarded. Remove the mixing tip by turning it 90° counter-clockwise and pulling it. Replace the cap on the syringe head, aligning the notch, then turn it 90° clockwise.

Application
As a standard technique, AH Plus is used in combination with gutta-percha, silver or titanium root canal points.

For filling techniques where most of the canal is obturated by endodontic point material, apply only a light coating of AH Plus to the canal walls. For the Master-Point-Technique, select a gutta-percha point (or alternatively a paper point or a reamer) in the size of the last instrument used during apical preparation. Wet the canal walls with AH Plus through a pumping or simultaneously rotating movement in a counter clockwise direction of the point/ reamer.

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

Alternatively, apply AH Plus onto the tip of a Lentulo spiral. 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. Withdraw Lentulo very slowly still running at low speed. Dip disinfected and dry point/s into AH Plus and insert them into the canal with a slow pumping motion.

Removal of Root Canal Filling
If AH Plus is used in combination with gutta-percha points, the root canal fillings can be removed using conventional techniques for the removal of gutta-percha.

Working Time
The working time is at minimum 4 hours at 23 °C[2].

Setting Time
The setting time is at minimum 8 hours at 37 °C[2].

CLEANING OF INSTRUMENTS
Spatulas, mixing slabs and instruments should be cleaned immediately after use with alcohol or acetone.

BATCH NUMBER(LOT) AND EXPIRY DATE ()
The batch number should be quoted in all correspondence which requires identification of the product.
Do not use after expiry date.

Patent No.: US 217998; EP 0673637

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. [33]

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. [34]

[2] measured according to ISO 6876:2001 (E).

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