RECENT ADVANCEMENTS OF ENDODONTIC SEALERS-A REVIEW
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Abstract
The main aim of this article is to review the literature on endodontic sealers and to analyse the recent advancements. The degree of endodontic success is directly proportional to a clinician’s knowledge of the root canal anatomy and the techniques selected while performing treatment. Properly performed endodontic therapy is the cornerstone of restorative and reconstructive dentistry.

Three-dimensional sealing of the root canal is one of the main goals of endodontic treatment to prevent the reinfection of the canal and for preserving the health of the periapical tissues, thereby ensuring the success of root canal treatment.

Thus, several types of endodontic sealers have been recommended to achieve this goal. It is important to note that not only the apical seal of the root canal but the coronal seal is of equal importance for the success of endodontic treatment.

Key Words: Calcium hydroxide, Root canal, Sealants, Zinc oxide eugenol.

Introduction:
The main aim of root canal therapy is the removal of microbial contaminants in conjunction with the total closure of the root canal system. Root canal sealers along with solid core materials play a major role in achieving the three dimensional sealing of the root canal system.

These sealers are binding agents which are used to adapt the rigid gutta percha to the canal walls and to fill up the voids, accessory canals and irregularities within the canal. Root canal sealers, although used only as adjunctive materials in the obturation of root canals, have been shown to influence the outcome of endodontic treatment. A perfect combination of sealing ability and biocompatibility is what an ideal root canal sealer should possess.
Sealers:
The sealers are responsible for the principal functions of the final root filling: sealing off of the root canal system, entombment of remaining bacteria and the filling of irregularities in the prepared canal. Several, quite different chemical formulations have served as bases for root canal sealers. (1)

Properties of an Ideal Root Canal Sealer:
According to Grossman (1982), the following requirements must be met by an ideal root canal sealing material (2):

1. It should be tacky when mixed to provide good adhesion between it and the canal wall when set.
2. It should make a hermetic seal.
3. It should be radiopaque so that it can be visualized on the radiograph.
4. The particles of powder should be very fine so that they can mix easily with liquid.
5. It should not shrink upon setting.
6. It should not discolor tooth structure.
7. It should be bacteriostatic or at least not encourage bacterial growth.
8. It should set slowly.
9. It should be insoluble in tissue fluids.
10. It should be well tolerated by the periapical tissue.
11. It should be soluble in common solvents if it is necessary to remove the root canal filling.

Criterion 10 may be expanded by stating that an ideal sealer should not provoke an immune response in periradicular tissue and it should be neither mutagenic nor carcinogenic.

While each property may be desirable in itself, it must be clear that technical and practical, and even some of the biologically desirable properties must be subordinate to the primary functions of the root filling: filling and sealing.

Sundqvist & Figdor (3) assigned three primary functions to the root filling:
- sealing against ingrowth of bacteria from the oral cavity
- entombment of remaining microorganisms
- Complete obturation at a microscopic level to prevent stagnant fluid from accumulating and serving as nutrients for bacteria from any source.

Classification of Endodontic Sealers:
A. Classified according to the chemical composition – Ingle (4)
Zinc oxide-eugenol based cements,
Calcium hydroxide containing cements.
Resin based cements.
Glass Ionomer based cements.
Experimental Sealers.

B. According to Clark:

- Absorbable.
- Non-absorbable.

FUNCTIONS OF ROOT CANAL SEALERS: (5)

- As Antimicrobial agent
- Helps in filling the discrepancies between the filling material and the dentin walls
- As a binding agent between the filling material and the dentin walls.
- As a lubricant and gives radiopacity.

Conventional Types of Endodontic Sealers

Solvent-based sealers:
The Johnston–Callahan technique (6) of conditioning the dentin surface and softening and churning the gutta-percha into the root canal has been applied in variations until today. Rosin-chloroform as a sealer/softener may be used, and ‘chloropercha,’ formulations with dissolved or milled gutta-percha in the chloroform have added body to the dentin-gutta percha interface. Zinc oxide may be added to the mix for even more substance and to reduce shrinkage. Leakage because of shrinkage remains a problem with these methods, however (7), and these materials are hardly taught at dental schools any more, and, apparently, not much used in practice.

Zinc-oxide-eugenol-based sealers:
Zinc-oxide-eugenol materials have dominated the past 70 to 80 years. Prototypes are Rickert’s sealer, commercial in the form of Kerr Pulp Canal Sealer, and Grossman’s sealer, which has several commercial variants, among them Roth sealer and ProcoSol. Rickert added silver powder for X-ray contrast, whereas Grossman used bismuth and barium salts. On the European scene, paraformaldehyde was added for antibacterial activity, as in the controversial N2 paste and in Endome’thasone. Zinc-oxide-eugenol-based sealers have some antibacterial activity of their own, but will also exhibit some toxicity when placed directly on vital tissues.
Glass-ionomer-based sealers:
No longer marketed, these were considered to be biocompatible and to show some adhesion to dentin, both of which are seen as desirable properties in a root filling. Since their introduction some 20 years ago, they have been used widely despite laboratory findings of leakage and disintegration (8,9).

Resin-based sealers:
By far the most successful of the resin-based sealers has been the AH series. The prototype was developed more than 50 years ago by Andre Schroeder in Switzerland (10), and is a bis-phenol resin using methenamine for polymerization. As methenamine (also known as urotropin) gives off some formaldehyde during the setting reaction (11), substitutes were sought and found in a mixture of amines that could effect polymerization without the formation of formaldehyde. AH Plus is the result of this product development. Another resin formulation, until recently widely used in many parts of the world, is the resorcin formaldehyde type (12). A variant of the phenol–formaldehyde or Bakelite resin, this sealer is strongly antibacterial, but shrinks and leaves a reddish hue on the surrounding tooth structure (hence the nickname ‘Russian Red’). As it is advocated for use without the necessity for a guttapercha central cone, and as it sets to a very hard and insoluble mass, retreatment of root fillings with this material may become a very frustrating experience. Forfe’nan and Traitement SPAD are Western European examples. Simple methyl-methacrylate as a combined pulp fixative and root filling has also been reported, designed for young permanent molars with carious pulp exposure without total necrosis and infection. Shrinkage, poor biocompatibility during setting and water immiscibility are concerns with this type of material. A possible improvement was hoped for with the application of hydroxyethyl methacrylate (Hydron), but case reports, clinical experience and biocompatibility concerns (13) quickly dampened the enthusiasm for this material as a root filling material. Diaket (3M ESPE) is a sealer that sets by chelation, but it contains polyvinyl chloride in polymer form as a main ingredient. It has attracted modest attention in the literature, but appears to be performing well in in vitro tests, including biocompatibility (14). EndoREZt is based on urethane dimethacrylate (UDMA) (15). It has some hydrophilic properties assumed to improve performance even if moisture is present. Recently, EndoRez has been marketed in conjunction with resin-coated gutta-percha points (16), which through bonding to the sealer supposedly gives better adhesion and seal throughout the filling mass. This concept is taken to its full distance in the Epiphany/Resilon or RealSeal (Kerr) product (17). Here, a primer is applied to the dentin surface after a chelator has worked to remove the smear layer. Then a dual-curing sealer based on BisGMA,
UDMA and hydrophilic methacrylates with radio opaque fillers coats the primed dentin wall. Completion of the filling is by the insertion of cones or thermally plasticized pieces of Resilon core material. The sealer may bond effectively to dentin via the primer, and with the chemical integration of the sealer with the core, this has given rise to a concept of a homogeneous, ‘monoblock’ root filling with little or no voids. Tests in vitro and in vivo also show impressive performance by this material (18, 19).

Recent Advancements of Endodontic Sealers:

The Concept of Monoblock

The term monoblock literally means a single unit. Franklin R. Tay first described the concept of monoblock in endodontics (20).

Primary Monoblock

It has only one interface that extends circumferentially between the material and the root canal wall. A classic example of primary monoblock would be obturating the root canals with gutta percha, without using the sealer. Use of Hydron sealer alone is another example of this concept. The lack of sufficient strength and stiffness is the major drawback and this led to the development of Secondary monoblocks.

Secondary monoblock

Secondary monoblocks are the ones having two circumferential interfaces, such as one between the cement and dentin and the other between the cement and the core material. A classic example would be the use of sealer for obturation, wherein one interface is between Gutta Percha point and sealer and the the second one between the sealer and root canal wall. Interest in utilizing the monoblock concept for reinforcing the root canal space was got resurfaced in around 2004 with the advent of bondable root filling materials that were launched as alternatives to conventional gutta-percha as obturating materials.

Resilon, a bondable root filling material which falls into this category, may be used for either lateral or warm vertical compaction techniques. As Resilon is applied using a methacrylate-based sealer to self-etching primer treated root dentin, it contains two interfaces, one between the sealer and primed dentin and the other between the sealer and Resilon, and hence may be classified as a type of secondary monoblock.

Tertiary monoblock

Tertiary monoblocks are the ones having an additional third circumferential interface between the bonding substrate and the abutment material. Fiber posts that contain either an external silicate coating or those that contain
unpolymerized resin composite for relining root canals that are too wide or not perfectly round for the fitting of conventional fiber posts may be considered as tertiary monoblocks.

Tenax Fibre post (Coltene) have a specific resin coating on its surface, which when cured with dual cure resin ParaCore (Coltene) forms a typical Tertiary monoblock: with one interface between the fibre post and the resin coating; the second one between the resin coating and the luting cement; and the third one between the luting cement and the root canal wall. Another product that falls into this category is the EndoRez system (Ultradent), in which the conventional gutta-percha cones are coated with a proprietary resin coating.

**Recent Endodontic Sealers**

**ProRoot Endo Sealer**

It is a calcium silicate-based root canal sealer that is designed to be used in conjunction with a root filling material in either the cold lateral, warm vertical or carrier-based filling techniques. The major components of the powder component are tricalcium silicate and dicalcium silicate, with the inclusion of calcium sulphate as a setting retardant, bismuth oxide as a radiopacifier and a small amount of tricalcium aluminate.

The liquid component consists of a viscous aqueous solution of a water soluble polymer. Similar to other tricalcium silicate and dicalcium silicate-containing biomaterials, the sealer produces calcium hydroxide on reaction with water (21).

**Herbal Sealer (Biosealer)**

It is a root canal sealer based on Copaifera multijuga oil-resin. Trees belonging to the genus Copaifera are distributed around northern South America, mainly in the Amazon Rainforest. It is one of the most popular and promising phytomedicines used in Brazil. The powder is composed of zinc oxide, calcium hydroxide, bismuth subcarbonate, natural resin (rosin) and borax, and the liquid is purified Copaifera multijuga oil-resin (22).

**Nanoseal plus root canal sealer**

A common cause of failure of root canal treatment is due to the inability to seal the accessory canal in most cases. One of the newest update in endodontics is the development of the first endodontic sealer based on nanotechnology which actively seals the tiny gaps thereby reducing the infection.

It is made up of calcium phosphate hydroxyapatite nanoparticles range from 40-60 nm. The rod shaped active nanoparticles can penetrate the dentinal tubules & enter accessory canals to ensure that all the spaces are effectively sealed (23).
Hybrid root seal

It is a commercially available fourth generation self-adhesive dual-cure sealer, available in the powder-liquid form. It is an insoluble, radiopaque material that can be used either with resilon or Gutta-percha. The liquid comprises of 4-META, monofunctional methacrylate monomers and photo-initiators, while the powder consists of a mixture of zirconia oxide filler, silicon dioxide filler and polymerization initiators. 4-META is able to promote monomer diffusion into the acid-conditioned and underlying intact dentin and produces functional hybridized dentin with polymerization (24, 25).

The formation of the hybrid dentin is the major mechanism of bonding and also the high quality hybridized dentin resists acidic challenges (26). However, polymerization shrinkage is inherent to methacrylate resin-based sealers that tend to produce debonding at the resin-dentin interface.

Gutta flow 2 sealer

This is a modification of the original Gutta flow sealer which was available in the cartridge form. The excellent flow of this material made it the sealer of choice. However, the larger armamentarium required was a drawback. Of late, Gutta Flow 2 has been introduced which is available in the syringe form and has an excellent property of slight expansion after mixing which helps in better sealing.

iRoot SP/EndoSequence BC sealer

The manufactures of these sealers claim the ability to form hydroxyappetite during the setting process and ultimately create a chemical bond between dentinal wall and the sealer (27,28). These are convenient, premixed, ready-to-use, injectable white cement paste developed for permanent root canal filling and sealing applications. These are insoluble, radio opaque and aluminium free material based on a calciumsilicate composition, which requires the presence of water to set and harden. Dentin is composed of approximately 20% (by volume) of water and “iRoot SP” uses this water to initiate and complete its setting reaction (29). It exhibits potent antimicrobial action, excellent bio-compatibility, and significant stimulation of periodontal regeneration and is osteoconductive. These sealers are also termed as Bioceramic sealers in general.

Calcium Hydroxide Based Sealers:

The first clinical use of calcium hydroxide as a root canal–filling material was probably by Rhoner in 1940 (30). It took another 20 years for calcium hydroxide to become popular for apexification, the sealing of perforations, and management of resorption (31). A “miracle’ material” Biocalex (Laboratoire SPAD, Dijon, France), developed by
French researchers, was believed to make radical changes to endodontic instrumentation methods (32). The calcium hydroxide containing a pulp-capping agent, Dycal (Dentsply-Caulk, Milford, DE), also became popular as a sealer among some clinicians in late 1970s (33). Shortly afterward, root canal sealers based on calcium hydroxide became available. Because calcium hydroxide–containing sealers have been in use over a quarter of a century and remain popular, a literature review on these materials focusing on their physical and biological properties is timely. The two most important reasons for using calcium hydroxide as a root-filling material are stimulation of the periapical tissues in order to maintain health or promote healing and secondly for its antimicrobial effects. The exact mechanisms are unknown, but the following mechanisms of actions have been proposed:

- Calcium hydroxide is antibacterial depending on the availability of free hydroxyl ions (34, 35). It has a very high pH (hydroxyl group) that encourages repair and active calcification. There is an initial degenerative response in the immediate vicinity followed rapidly by a mineralization and ossification response (36).
- The alkaline pH of calcium hydroxide neutralizes lactic acid from osteoclasts and prevents dissolution of mineralized components of teeth. This pH also activates alkaline phosphatase that plays an important role in hard tissue formation (37)
- Calcium hydroxide denatures proteins found in the root canal and makes them less toxic.
- Calcium hydroxide activates the calcium-dependent adenosine triphosphatase reaction associated with hard tissue formation (38, 39)
- Calcium hydroxide diffuses through dentinal tubules and may communicate with the periodontal ligament space to arrest external root resorption and accelerate healing (36, 39).

Review of calcium hydroxide–based root canal sealers shows that these materials do not fulfil all the criteria described by Grossman (40). Most studies are laboratory based or in animal models, which may differ from the clinical situation. The antibacterial effects of calcium hydroxide in sealers are variable. Cytotoxicity appears to be milder than for other groups of sealers. Solubility is a concern, but leakage cannot be linked directly to solubility, with studies reporting the potential for the formation of calcific repair tissues in the vicinity of the materials (2)

‘Endodontic grafting’ (41)

Filling of the root canal apical third must be looked upon separately from the filling of the rest of the canal having under consideration the active and constant metabolic processes occurring in the periapical area. Special attention must
be paid to the interface formed between dentinal root canal walls, gutta-percha and sealer on one side and periodontium and body fluids on the other side. Long-term hermetic sealing of apical third achieved in constantly wet environment is an obligatory condition to ensure lack of microbial growth. Another extremely important factor promoting hard tissue closure of the canal is presence of osseoconductivity as sealer’s feature. Perfect and lasting in wet environment hermetic seal of apical third combined with osseoconductivity of endodontic sealer ensure conditions for hard tissue closure of root canal apical orifice in time. Filling of the root canal with ceramic sealer, which due to its osseoconductivity action promotes the physiological closure of the canal by cementoid hard tissue, can be called “endodontic grafting.” Such endodontic grafting can ensure the lasting root’s health while it constantly remains in contact with body fluids. The use of bioceramic-based sealers with their features

- osseoconductivity,
- hydrophylity,
- adhesiveness and
- Chemical bonding to root canal dentinal walls appears to be an effective approach to eliminate on long term, the microspace, otherwise remaining between the root canal walls and the materials filling the root canal. Such microspace is a potential place for possible microbial growth, because of microleakage observed with other kind of sealers.

**Sealers for ‘endodontic grafting’**

Endodontic sealers that set hard and are stable in constantly wet environment are:


b. MTA-based products — “MTA — Angelus” (ANGELUS, Brazil), ProRoot (Dentsply, USA), Aureoseal (OGNA, Italy). The common feature of all these products is that when used to fill the apical third of the root canal, they guarantee adhesive hermetic seal (42). They do not get destroyed during their hardening and afterward while being constantly in contact with the wet periapical environment. They are very stable in time. Ceramic based sealers ensure much better apical seal than IRM, amalgam or Super EBA materials, and this excellent seal is combined with excellent biocompatibility and significant stimulation of periodontal regeneration (43, 44). Until recently the application of all these materials, except for iRoot SP and iRoot BP, required significant widening of the root canal apical third — up to #60–70 — and use of specially developed instruments to carry the materials to apical third of the canal. These purely
technological limitations were reducing ceramic based materials use as regular antegrade root canal filling materials.

The first author has developed an innovative method for filling of apical third of the root canal with MTA- and bioceramic-based sealers he has called the “capillary condensation” technique. This new technique does not require enlargement of the canal’s apical third more than # 35-40 / 04. Apical third of canal space is widened based on its original size and shape only.

**Method for ‘capillary condensation’ of ceramics-based endodontic sealers to fill the root canal**

Method comprises of several stages:

**Stage I:** Preparation of “coronal reservoir” from which ceramic sealer to be condensed aside to canal walls and toward and into canal’s apical third so that to seal the canal’s apical orifice.

Using Roane Gatez Gliden or Gatez Gliden drills, the coronal third of the root canal is conically widened to form a “coronal reservoir,” which is subsequently to be filled with MTA, BioAggregate, iRoot SP or iRoot BP material. From this point on, there are two different approaches:

A. “Coronal reservoir” is filled directly with ready to use material packed into syringes (iRoot SP or iRoot BP). Mini applicators included in the package are used for direct filling of reservoir with factory premixed material.

B. Powder-like ceramic material (MTA or bioceramic- based BioAggregate) is mixed with distilled water to form a paste with suitable viscosity to allow carrying it into the “reservoir” by plastic carrier designed by the author. Micro applicator handle, with “fluffy” head cut, may be used instead, too. The dentist can fold the plastic carrier as needed to make it suitable to easily get inside the “coronal reservoir.” Small portions of “ex tempore” mixed sealer are carried into the “reservoir” until it gets full. It is important to work in constantly slightly wet root canal. Before putting next small portion of MTA or BioAggregate sealer into reservoir, the dentist visually controls the moisture of the sealer mass. If necessary the tip of the plastic carrier is wetted with distilled water and put inside the reservoir to increase the humidity of the sealer mass inside. Thus the risk of drying of material at the bottom of the reservoir is avoided and ceramic sealer is prepared for condensation further inside the root canal.

**Stage II:** “Capillary condensation” of the sealer to fill the root canal

This stage is valid for both (A and B) types of ceramic sealers. Condensation of the sealer is made with “condensor” — an instrument designed by the authors. The basic rule is correctly chosen instrument to get freely inside into root canal within 1 mm less than canal’s measured working length (WL). In case of straight canals the number (#) of the instrument must be one number (#) less than MAF. In slightly or severely curved canals the number (#) of the used
The instrument must be two to three numbers (#) less than MAF. It is preferable to use NiTi made instruments, especially in curved canals. By pushing the condensor slowly in and then getting it out, without taking it totally out of “coronal reservoir,” the sealer is condensed inside the canal, aside to canal’s walls and at the same time toward its apical orifice, down to previously defined depth of 1 mm less than WL. Condensation must be done slowly and with maximum possible amplitude of the “push in and “take-out” movements. When condensing the powder-like ceramic sealers (MTA-based or BioAggregate) that are mixed “extempore” before use, there should not be a tactile feeling of “tightening” of the instrument inside the canal during condensation. If such a feeling appears, the dentist must take the condensor totally out of the canal and must wet the tip of the instrument with water before inserting it inside the canal again. The total time for the sealer’s condensation is approximately 10–15 seconds. Between 12 and 15 “push-in/take out” movements are needed to achieve a good feeling of the canal’s apical third and to ensure good adhesion of the sealer to canal’s walls, too. Ten seconds after the start of condensation (approximately 10 “push-in” movements) the dentist must take the instrument out of canal. There should not be hardened aggregates on the instrument’s surface, but only liquid white solution. Then one must look at the bottom of the “coronal reservoir.” If there is a “black hole,” this means more water must be added to the sealer inside the reservoir. The tip of plastic carrier is wetted with water and is put inside the reservoir. This is to be immediately followed by adding one more small portion of the mixed sealer into the reservoir. Water should not be added when using bioceramic-based iRoot SP and iRoot BP sealers. Only the additional portion of sealer must be added when using iRoot SP or iRoot BP! These two sealers are supplied premixed and “ready to use” and do not need additional water, they have already been factory mixed to optimal viscosity to fill the canal properly.

**Stage III: Insertion of gutta-percha cones**

At the moment of choosing the correct size condensor, the dentist must also choose the same size gutta-percha master cone. Inserting of the gutta-percha cone inside the canal will serve three functions simultaneously.

A. It will finish the condensation of the sealer inside the root canal and will make sealer layer along the canal’s length even. It will eliminate any air still entrapped inside the canal, too.

B. It will create a pliable space inside the canal with which to accommodate the stress created by expansion of the ceramic sealers during their hardening. Bioceramic-based sealers BioAggregate, iRoot SP and iRoot BP have significant expansion of 0.20 percent.
C. By inserting the gutta-percha cones the possibility for re-entering the canal is maintained, and easier preparation of calibrated “bed,” for cementing a fiberglass post inside, is ensured.

The master gutta-percha cone is inserted slowly with “push-in” and “take-out” motions down to 1 mm less than WL. Additional smaller diameter gutta-percha cones may be added, if necessary. The ends of gutta-percha cones extending out of the root canal are cut and cones are condensed with round head metal instrument. During gutta-percha condensation excessive water and excessive sealer remnants are also pushed outside and are wiped out with small cotton pellet. A temporary filling is placed in the tooth cavity. After the ceramic sealer is hardened, preferably 24 hours after canals are filled, the final restoration is made.

**Features of ceramic-based endodontic sealers**

1. Ceramic-based sealers are highly hydrophilic and have low contact angle. These features allow them to spread easily over the dentin walls of the root canal and to get inside and fill the lateral micro canals, too. Thus necessity to instrument the canals with 06 or higher taper becomes no longer needed. Tooth tissues are preserved, and risk of root fractures is reduced. Very well-filled lateral micro canals can be seen on experimental samples. Filling is done with iRoot SP.

2. During setting hard ceramic-based sealers expand. Expansion of BioAggregate and iRoot SP and iRoot BP is significant — 0.20 percent. These new bioceramic sealers also form chemical bond with the canal’s dentin walls. That is why no space is left between the sealer and dentin walls. This is well demonstrated by light polymerization microscopy and much better demonstrated by large magnification scanning electron microscopy.

3. Bioceramic-based sealers are capable of achieving fast alleviation of the pain syndrome in cases of acute periapical inflammation. After appropriate instrumentation and cleaning of the root canal, followed by immediate filling with iRoot SP, pain rapidly diminishes and most often is totally gone within a period of 50 minutes to few hours.

4. In cases of MTA-based materials extrusion outside the root canal is associated with severe pain felt by the patient. When bioceramic-based sealers BioAggregate or iRoot SP are extruded, the pain is relatively small or totally absent. Such lack of pain may be explained with the characteristics of these new materials. During hardening they “produce” hydroxylapatite and after the end of hardening process they exhibit the same features as non-resorbable hydroxylapatite-based bioceramics used for bone replacement in oral surgery. Due to the hydroxylapatite formed, they are also osseoconductive.
5. MTA-based materials and BioAggregate have quite poor radiopacity, different from bioceramic based iRoot SP and iRoot BP sealers.

Based on the above findings, it is preferable that bioceramic-based iRoot SP sealer be used for “endodontic grafting” (i.e., filling of root canals) because of its excellent radio opacity. It is not possible to verify the quality of root canal filling achieved with MTA-based materials or BioAggregate using radiographies only, due to poor radio opacity of these materials.

**Conclusion:**

The qualities of different sealers should be considered before obturating the root canal. The efficiency of the sealer and the anatomy of the root canal influence the success and survival rates of the treatment. Traditional, zinc-oxide eugenol and epoxy resin sealers have stood the test of time and perform well clinically and in laboratory tests. It is exciting to see new formulas and concepts for root filling emerge with an obvious potential for improvement. It must be remembered that clinical studies have a high degree of variability because of the multitude of factors affecting outcome. Therefore, it may be difficult to document improved treatment results that are statistically significant in comparison with conventional materials of reference.

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