Odne™ Fill

Scientific Compendium

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1 Introduction

The main clinical requirements of a root canal sealer are tissue compatibility and the ability of the sealer to provide a long-lasting seal of the root canal against bacterial colonization. At the same time, the sealer needs to be easy to use to avoid complications during application. The tissue compatibility of the sealer depends on its material composition. The sealing ability depends on its flowability to allow it to fill all accessible areas of the root canal, its bacterial tightness, and its dimensional stability.

With Odne™Fill, Odne™ provides a new concept to obturate root canals. Maintaining the advantages of classical obturation systems based on gutta percha and a sealer, it additionally provides unprecedented flowability, sealing ability, and ease of use. Odne™Fill is a hydrophilic, radiopaque, light-curable endodontic obturation material. It consists of a liquid, highly flowable material that is applied into the prepared and cleaned root canal using a syringe and converted into a solid polymer by photocuring with Odne™Cure (the corresponding micro-laser curing light). Odne™Fill is an all-in-one-material obturation solution that does not require gutta-percha points.

Odne™Fill is based on a hydrogel, a class of biomaterials known for their excellent biocompatibility and tissue-like properties. Due to its high flowability, Odne™Fill easily flows into all accessible spaces within the root canal system that remain inaccessible for gutta percha or paste-like sealers; and this, without the need for tedious compaction techniques. It adapts to any root canal geometry, does not require a standard root canal shape, and thus, allows for minimal invasive shaping techniques. Its hydrophilicity ensures a tight seal to moist dentine, and since it is an all-in-one-material obturation solution, it minimizes the number of material interfaces within the root canal and, thus, the risk for interface leakage. Its photocuring ability provides instant, on-demand curing, lowering the risk of sealer leakage after the procedure. In its cured stage, Odne™Fill has comparable mechanical properties as natural pulp tissue, thus avoiding mechanical stress on the root dentine and allowing easy removal for re-treatments or post-placement.

2 Description of Odne™Fill

2.1 Composition of Odne™Fill

Odne™Fill consists of a water-based formulation that converts into a stable hydrogel upon photocuring. It contains a photocurable polyethylene glycol (PEG) derivative, radiopaque fillers, water, a photoinitiator, and stabilizers. The chemistry of the formulation has been optimized to provide radiopacity and long-term dimensional stability of the cured obturation material.

To ensure long-term stability of the cured hydrogel, the photocurable PEG derivative has been specifically developed for Odne™Fill. The radiopaque fillers in Odne™Fill are specifically chosen to provide high light penetration and photocuring depth as well as low viscosity and high flowability. The bespoke photoinitiator ensures rapid and reliable photocuring also in narrow or curved root canals.

The formulation and its components are protected by several patents.

2.2 Reactions in Odne™Fill

Odne™Fill is cured into its solid state by photopolymerization. The curing reaction is based on a radical-initiated polymerization, the same that has been used reliably in any photocured restorative composite or adhesive for the last decades. Radical-initiated polymerization ensures rapid, on-demand curing and a high degree of monomer conversion while being insensitive to environmental conditions such as temperature or moisture.

Odne™Fill's curing mechanism is substantially different from the polyaddition or step growth reactions applied in epoxy-amine resins (e.g., AH 26®, AH Plus®) or the hydraulic setting of MTA cements and bioceramics (e.g., BioRoot™ RCS, EndoSequence® BC Sealer). Step growth reactions suffer from slow reaction rates and sensitivity to the exact mixing ratio of its components. Slow curing reactions and an unprecise mixing ratio can lead to the leakage of uncured sealer components. Hydraulic setting requires the presence of sufficient amounts of water and can lead to incomplete curing in canals that are not sufficiently hydrated. The radical-initiated curing reaction of Odne™Fill provides a reliable, rapid, on-demand photocuring of the obturation material, thus mitigating risks of sealer leakage or incomplete setting.

The proprietary photoinitiator used in Odne™Fill is a highly active, water-compatible photoinitiator. It is the first photoinitiator used within dental materials that can photocure material up to a depth of cure of more than 40 mm.

Upon irradiation, the photoinitiator generates radicals that start the polymerization chain reaction. The radicals react with the polymerizable end groups of the PEG molecules and lead to polymerization and cross-linking. Thus, the liquid formulation is converted into a solid hydrogel within seconds.

The resulting hydrogel is a flexible, pulp tissue-like, water-containing polymer. Upon the absorption of moisture from the surrounding dentine, it can expand and thus create a tight seal within the root canal. Due to the softness of the material, the expansion cannot create forces sufficient to damage the root dentine.

2.3 Application and photocuring of Odne™Fill

Odne™Fill is provided in a single-use, disposable plastic syringe. It is applied through the Odne™Fill Tip, a 33G flexible cannula connected to the syringe via a luer lock. Using the tip positioned at the apex of the canal, the material is backfilled while slowly retrieving the tip. Due to its low viscosity and high hydrophilicity and flowability, Odne™Fill flows into any accessible space within the root canal, including hard-to-access areas such as isthmuses, fused, and C-shaped canals.

The photocuring is initiated using Odne™Cure, a high-precision laser curing light. The light is applied through thin, flexible Odne™Cure Tips that can be inserted into the canal and deliver the light reliably to the material.

3 Properties of Odne™Fill

The material properties of Odne™Fill have been characterized according to the ISO standard for "Root canal sealing materials" (ISO 6876:2012) by an accredited laboratory (NIOM, Nordic Institute of Dental Materials) on behalf of Odne. They have further been analyzed by an independent study conducted by Josette Camilleri, University of Birmingham.

3.1 Radiopacity

The radiopacity of a root canal sealing material is an important property that allows visualization of the root canal filling on X-rays to evaluate the quality of the filling and the treatment success. Odne™Fill has a radiopacity of 3.3 mmAl when measured according to the method published ISO13116:2014.[1] It fulfills the requirement of ISO 6876 (radiopacity > 3 mmAl) and lies between that of other root canal sealers (Table 1). It allows for visualization of the root canal filling in 2D intraoral X-rays and 3D CBCT images.

To ensure Odne™Fill's low viscosity and high flowability, the radiopaque filler content was kept minimal. Therefore, Odne™Fill is less radiopaque than epoxy-amine sealers such as AH Plus®. However, it can be visualized successfully using state-of-the-art X-ray imaging techniques with appropriate exposure settings.

Table 1. Radiopacity of different root canal sealing materials.

Material	Radiopacity (mmAl)
BioRoot™ RCS	3.0 ± 0.2
Odne™Fill	3.3 ± 0.3
AH Plus®	10.6 ± 0.4

3.2 Flow & film thickness

Viscosity and flowability are important properties of a root canal sealing material since they influence the ability of the material to flow into all areas of the root canal system to be filled and, thus the completeness and tightness of the root canal filling. ISO 6876 suggests measuring "flow" and "film thickness" to characterize these properties.

When measured according to the ISO method, the flow of Odne™Fill is "out of range" of the method, i.e., the material flows wider than the measuring plates, indicating its unprecedented flowability. It thus meets the ISO requirement of ≥ 17 mm. Odne™Fill shows a film thickness of ≅ 3 µm, which is an unprecedentedly low value and meets the requirement of the standard (≤ 50 µm) (Table 2).

Table 2. Flow and Film Thickness of different root canal sealing materials.

Material	Flow (mm)	Film Thickness (µm)
Odne™Fill	Out of Range	3.0 ± 0.0
BioRoot™ RCS	21.1 ± 5.3	51.3 ± 6.6
AH Plus®	21.7 ± 2.0	10.6 ± 0.4

3.3 Hydrophilicity

Hydrophilicity is an important property that influences the physical bonding of the sealer to the dentinal surfaces and, thus, its sealing ability. The higher the hydrophilicity of the sealer, the better it flows within the root canal and the better it bonds to the moist dentine. Classical obturation systems based on gutta percha and sealer face the challenge that the sealer needs to bond both: to the moist, hydrophilic dentine and to the dry, hydrophobic gutta percha. Debonding of the sealer from either the dentine or the gutta percha has therefore been observed.[2]

The hydrophilicity of Odne™Fill was investigated through contact angle measurements at the University of Birmingham. The contact angle is inversely proportional to the hydrophilicity, meaning the lower the contact angle, the higher the hydrophilicity. A 5 µl water droplet was dispensed onto the surfaces of different sealers (including Odne™Fill, AH Plus®, and BioRoot™ RCS). Odne™Fill demonstrated significant hydrophilicity, with a contact angle of 41.5° ± 2.7 (Table 3). Among the three sample surfaces, AH Plus® exhibited the lowest wetting behavior, while BioRoot™ RCS displayed the highest wettability.

Table 3. Contact Angle of Odne™Fill, BioRoot™ RCS, and AH Plus®.

Material	Contact Angle (°)
Odne™Fill	41.5 ± 2.7
BioRoot™ RCS	21.1 ± 2.7
AH Plus®	71.2 ± 3.5

An additional contact angle measurement was conducted at the University of Zürich to compare the wettability of Odne™Fill with AH Plus® and EndoSequence® BC Sealer when in contact with dentinal surfaces. In this study, a droplet of each material was placed on polished occlusal dentine surfaces of human molar teeth, and the resulting contact angles were measured (Figure 1). Among the three materials, Odne™Fill exhibited the highest hydrophilicity, with a contact angle of 41.10° ± 5.80. In contrast, AH Plus® showed a contact angle of 83.24° ± 9.22, and EndoSequence® BC Sealer had a contact angle of 92.84° ± 8.46.

Figure 1: Wettability comparison between AH Plus®, Odne™Fill and BC Sealer.

3.4 Shrinkage, Solubility and Expansion

To achieve a high degree of sealing, root canal sealers must not shrink or degrade, depolymerize, or solubilize. Furthermore, expansion of the sealer must not create mechanical stress that can lead to root fractures.

Being a water-based hydrogel, Odne™Fill swells upon absorbing moisture from the surrounding dentine. This compensates for any polymerization shrinkage that is inherent to all in-situ polymerized dental resins. However, since the hydrogel remains in a soft, pulp-like texture in its cured state, it cannot exert mechanical stress damaging root dentine. Therefore, Odne™Fill is self-compacting and adapts to any root canal geometry. The moderate swelling ensures a bacteria-tight seal.

The solubility of BioRoot™ RCS, Odne™Fill, and AH Plus® was measured according to ISO 6876:2012. While the solubility of Odne™Fill was higher than that of AH Plus®, Odne™Fill is by far not as soluble as BioRoot™ RCS sealer. Furthermore, upon repeating the solubility experiment with the same material specimen, the solubility of the material decreases to < 0.3% during the second cycle. It is, therefore, evident that the initially high solubility is not caused by material degradation but by an initial washout of a minimal amount of the non-toxic radiopaque filler.

Table 4. Solubility of Different Root Canal Sealing Materials.

Material	Solubility (%)
BioRoot™ RCS	15.9 ± 0.9
Odne™Fill	5.5 ± 0.1
AH Plus®	0.1 ± 0.07

4 Preclinical Studies

4.1 Biocompatibility

Biocompatibility ensures that a medical device or biomaterial is compatible with a biological system. A biocompatible material should generate an appropriate host response and prevent excessive and persistent inflammation, tissue destruction, or rejection by the host. Odne™Fill is classified as an implant device in permanent contact with the pulpodentinal system of the tooth (ISO7405:2018) or as an external communicating device in long-term contact with dentine (ISO10993-1:2018). The Odne™Fill syringe in which the Odne™Fill material is provided is an indirectly contacting component of the device and is evaluated through the evaluation of the final finished (packaged) Odne™Fill material. The biocompatibility of Odne™Fill has been evaluated according to ISO7405:2018, ISO10993-1:2018, and the 2020 FDA Biocompatibility guidance within a risk management process according to ISO 14971:2019. Assessment and testing where required, were conducted by NAMSA (France and Germany) and WuXi AppTec (USA). Additional studies assessing the neurotoxicity and the periapical tissue response after root canal obturation were also carried out at Harvard University and Tohoku University.

4.1.1 Biocompatibility studies of Odne™Fill according to ISO 10993

Being a medical device in long-term (> 30 days) contact with dentine, Odne™Fill is subject to a thorough biological evaluation according to ISO7405:2018 and ISO10993-1:2018. All endpoints for biological evaluation recommended by the standards were addressed by performing biological testing, literature searches, safety database searches, and risk assessment.

With due consideration to all data gathered, Odne™Fill is concluded to be biocompatible and safe when used as intended for the obturation of root canals.

4.1.2 Neurotoxicity studies of Odne™Fill

Assessing the neurotoxicity of endodontic sealers is important as sealers can inadvertently flow beyond the root canal system and come into contact with periapical tissues, including nerve endings. Such contact may lead to nerve injury, resulting in post-operative pain for patients, including mild discomfort, soreness, throbbing aches, severe pain, and swelling.[3] Understanding the toxicological effects of sealers may help prevent treatment failures and ensure favorable endodontic clinical outcomes.

In a study carried out by Prof. Jennifer L. Gibbs at Harvard University, the neurotoxic effects and changes in expression of neurotoxicity markers were assessed using a resin-based sealer (AH Plus®), calcium silicate-based sealer (Endosequence® BC Sealer) and a hydrogel-based root canal filling material (Odne™Fill in both liquid form, representing worst-case apical extrusion before curing, and solid form, for assessment of neurotoxicity of the filling material after curing). The investigation was conducted using in vitro models of human and mouse sensory neurons. Cell viability was determined using a live/dead cell assay and an MTT assay. Neurotoxicity markers expression was measured by qPCR.

In mouse sensory neurons, it was observed that AH Plus® induced a dose-dependent reduction in neuron viability at concentrations exceeding 0.027 g/ml. In contrast, BC Sealer and liquid Odne™Fill exhibited decreased neuron viability only at higher concentrations (above 0.084 g/ml), indicating lower neurotoxicity compared to AH Plus®. Solid Odne™Fill had no significant effect on neuron viability (Figure 2A). Overall, AH Plus® was identified as the most toxic material, while solid Odne™Fill was the least toxic. BC Sealer and liquid Odne™Fill fell in between with an intermediate neurotoxicity profile (Figure 2B). When assessing the toxicity of these endodontic materials on human neuron-like cells, similar trends were observed: AH Plus® remained the most toxic, BC Sealer and Solid Odne™Fill were the least toxic, and Liquid Odne™Fill showed intermediate toxicity. While nerve endings may come into contact with liquid Odne™Fill if extruded beyond the apical foramen, its flowability and water-solubility enable rapid dissipation. The long-term interaction with nerves primarily involves the leachables from the solid material, and the measured neurotoxicity for solid Odne™Fill is, therefore, more representative of *in vivo* use. Nevertheless, even in the worst-case scenario with liquid Odne™Fill, the measured neurotoxicity remains lower than that of AH Plus®.

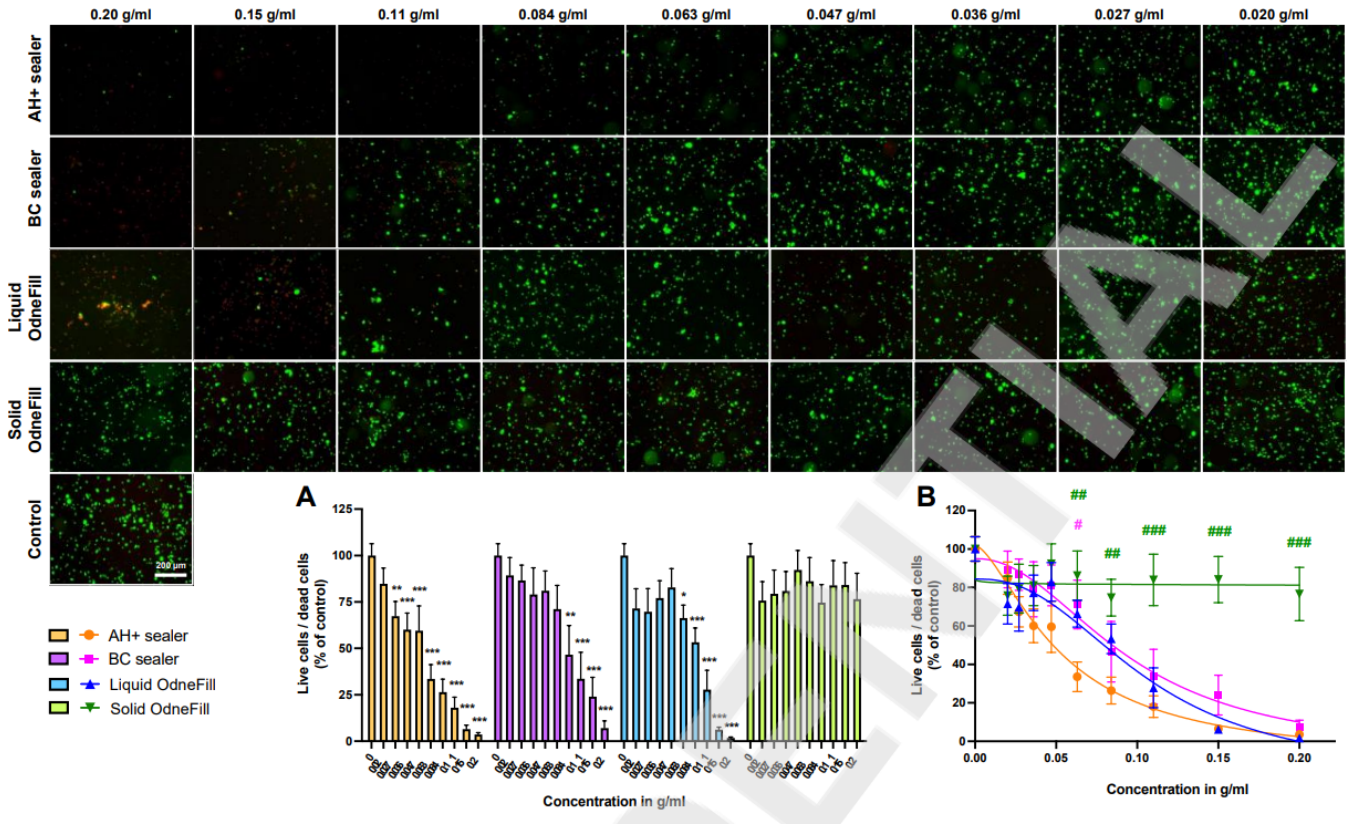

Figure 2. Dose-dependent effects of endodontic sealers on mouse sensory neuron viability. AH Plus® induced a dose-dependent reduction in neuron viability at concentrations exceeding 0.027 g/ml, while BC and Liquid Odne™Fill exhibited decreased neuron viability only at 0.084 g/ml. Solid Odne™Fill had no significant effect on neuron viability. * p< 0.05, **p<0.01, ***p<0.001 compared to control, Dunnett's test. (B) # p< 0.05, ## p<0.01, ## p<0.001 compared to AH+ sealer, Tukey's test.

When cells were treated with AH Plus®, a high number of genes (48 out of 84) showed increased activity (more than a two-fold increase). The upregulated genes initiate pathways that promote programmed cell death (apoptosis) and influence processes such as cell growth and repair, immune responses, and hormone actions. These processes are upregulated as part of the cell`s survival strategy, which occurs when cells are damaged, stressed, or infected. EndoSequence® BC Sealer and solid Odne™Fill exhibit minimal gene upregulation (only 3 genes for both materials). These findings are illustrated in Figure 3A-H.

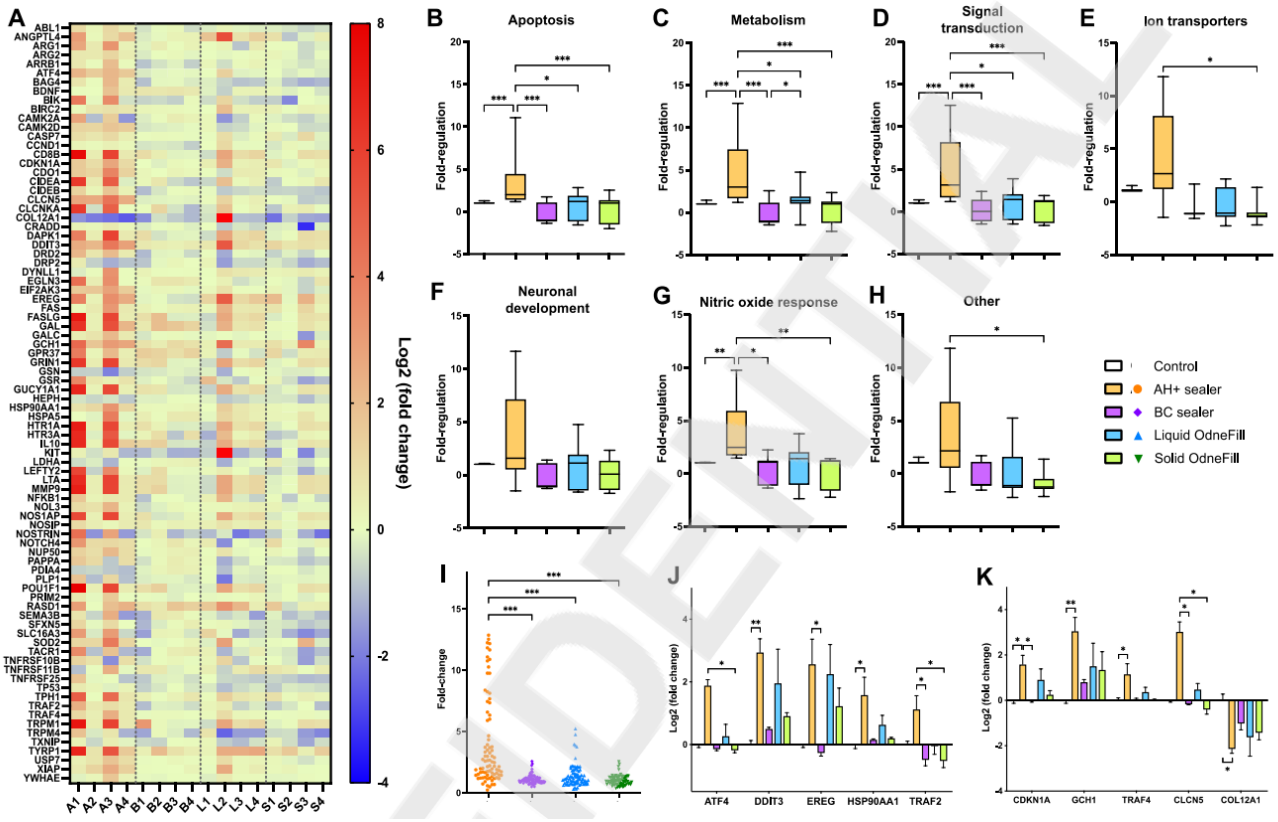

Figure 3: Effects of endodontic material on neurotoxicity marker expression. AH Plus® induced substantial up-regulation in 48 out of 84 tested genes. Both EndoSequence® BC Sealer and Solid Odne™Fill exhibit minimal gene upregulation in only 3 genes.

4.1.3 Tissue response upon extrusion of Odne™Fill

The periapical tissue response to different endodontic sealers is currently being studied by Dr. Yoshio Yahata at Tohoku University in an in-vivo rat root canal model. The study compares the periapical tissue response after intentional apical extrusion of uncured, liquid Odne™Fill to the extrusion of AH Plus®. The evaluation involves histopathological examination and immunohistochemistry at three different time points: 3 days (acute phase), 28 days (chronic phase), and 90 days (prolonged phase).

Preliminary results indicate that at 3 days, there were no significant differences between Odne™Fill and AH Plus®; most samples exhibited mild inflammation in both groups. However, by 28 days, the Odne™Fill group showed a clear trend of improvement in inflammation, while many samples in the AH Plus® group still displayed severe inflammation. This suggests that Odne™Fill may perform better in terms of periapical tissue response than AH Plus®. The study is still ongoing, and final results are pending. However, it already indicates that the tissue response to extruded, uncured Odne™Fill is favorable.

4.1.4 Summary

Odne™Fill concluded to be biocompatible and safe when used as intended for the obturation of root canals.

In terms of neurotoxicity, it was observed that solid Odne™Fill exhibited the least toxicity when compared to AH Plus® and EndoSequence® BC Sealer. Liquid Odne™Fill showed intermediate toxicity, similar to the response induced by EndoSequence® BC Sealer. Among the four materials studied, AH Plus® was found to be the most toxic. An *in vivo* study using a rat model also revealed that after 28 days, Odne™Fill-treated groups exhibited clear improvement in inflammation compared to Day 3, while AH Plus®-treated groups still displayed severe inflammation. In summary, Odne™Fill is considered biocompatible and safe for human usage when used as intended for root canal obturation.

4.2 Apical extrusion

Apical extrusion during root canal treatment refers to the unintended displacement of filling substances beyond the apical foramen. Prof. Gustavo De-Deus at Fluminense Federal University, Rio de Janeiro, Brazil, assessed the extent of extrusion of Odne™Fill. They used a cadaver model with teeth inside bone blocks to evaluate sealer extrusion under close-to-mouth experimental conditions.

The study compared Odne™Fill to the gold-standard resin-based sealer AH Plus® applied with gutta percha in warm vertical compaction. The extrusion was categorized by radiographical assessment of the presence of filling material in the periapex into 4 groups: 0 = Root canals without over-extruded filling, 1 = Routinely normal extrusion, 2 = Significant but acceptable over-extrusion, 3 = Unacceptable over-extrusion.

Out of 26 teeth, 9 (34.6%) had extruded root canal filling. Among 13 teeth filled using the vertical compaction technique, 8 (61.5%) demonstrated extrusion. For 13 teeth filled with Odne™Fill, only one tooth (7.9%) showed extrusion (Figure 4). There is a statistically significant difference in the rate of extruded root canal filling between the two tested groups ($p>0.05$, Fisher test). This shows that the high flowability of Odne™Fill does not lead to excessive material extrusion during root canal treatment.

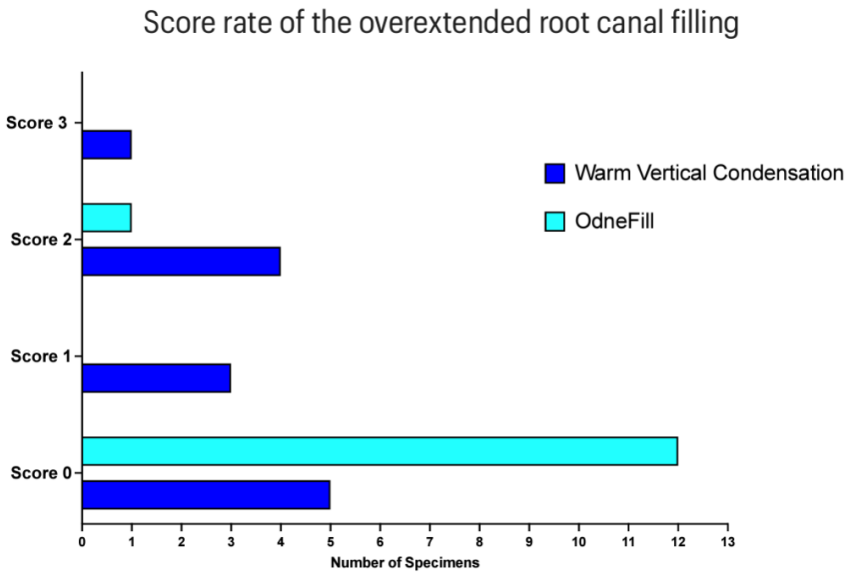

Figure 4. Extrusion score rate of root canal filling materials. Within the vertical compaction technique group, 8 teeth (61.5%) demonstrated extrusion. Within the Odne™Fill group, only one tooth (7.9%) showed extrusion.

4.3 Sealing ability

The success rate of root canal treatment depends strongly on the sealing ability of root canal sealers. In assessing sealing ability, various methods are employed, including dye penetration, fluid transport models, electrical conductivity, and bacterial leakage. In contrast to conventional endodontic sealers, the novel hydrogel-based material Odne™Fill provides water absorption as an inherent property, ensuring a tight seal within root canals. Since dye molecules used in various leakage tests are smaller than the hydrogel's pores, instant dye absorption occurs. The material can, therefore, not be studied using standard dye leakage tests.

Instead, a study carried out by Odne AG in collaboration with the University of Zurich evaluated the time to bacterial penetration of teeth obturated with Odne™Fill to that of teeth obturated by Gutta Percha + AH Plus® in lateral condensation using *E. faecalis*, a common endodontic pathogen. [4] Leakage of 50% of samples occurred after 40 and 190 days for AH Plus®/ gutta percha and Odne™Fill, respectively (Figure 5), thus showing a four times higher sealing ability of Odne™Fill compared with AH Plus®/ gutta percha.

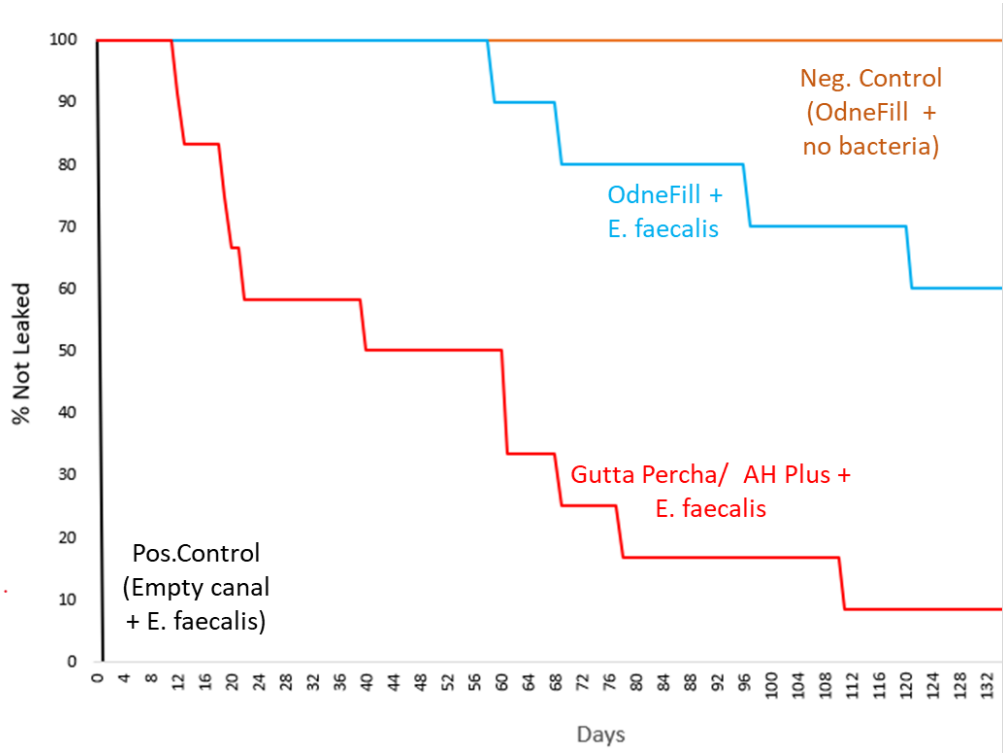

Figure 5. Survival curve of OdneFill, AH Plus®/ gutta percha, and positive and negative control after 136 days. Leakage of 50% of samples occurred after 40 and 190 days for AH Plus®/ gutta percha and Odne™Fill, respectively.

4.4 Stability

Since root canal sealing materials intend to seal the root canal from bacteria colonization for decades, it is of utmost importance that the material is stable against any degradation or loss of structural integrity that could impede its bacterial sealing ability. Under clinical use conditions, root canal sealing materials can degrade by hydrolysis (reaction with water) or under the influence of biological effects from enzymes or bacteria present within the root canal.

The Resilon/ Epiphany system was a root canal obturation system that had dramatic problems with long-term stability. The Resilon points contain polycaprolactone, a synthetic, biodegradable polyester.[5,6] Polyesters are susceptible to degradation by hydrolysis of the ester bonds, which link the monomer units of the polymer. The degradation can be catalyzed (accelerated) by the presence of acids, bases, or certain enzymes (esterases). It is also accelerated by an increase in temperature. Since ester hydrolysis produces acids, the degradation is self-accelerating. Therefore, polyesters, and especially polycaprolactone are commonly applied in medical applications where degradation is intended to occur within days or weeks (e.g., wound suture materials). It is, therefore, not suitable for long-term obturation of root canals.

Odne™Fill is based on a polyethylene glycol (PEG) hydrogel. PEG is a polyether, a class of polymers that is stable against hydrolytic degradation. Unlike polyesters, which were used in other sealing materials previously, such as Resilon, polyethers cannot be hydrolyzed under physiological conditions. Odne™Fill is photocured by radical polymerization of polymerizable endgroups on the PEG chains. These endgroups have been customized to provide very high stability against hydrolytic degradation.

4.4.1 Stability against hydrolytic degradation

Odne™Fill's stability and degradation pattern were studied in accelerated aging studies. Such studies are commonly applied in material science to simulate the stability of materials over prolonged periods. They are based on a common estimate that an increase in storage temperature by 10°C doubles the degradation speed. Accordingly, storage at 60°C for x months corresponds to storage at 37°C body temperature for 4.9x months. Material samples were incubated in distilled water and exposed to different temperatures. At different time points, samples were retrieved, dried to weight constancy, and the dry content was compared to that of fresh samples.

As shown in Figure 6, no change in dry content is observed after storage for 12 months at 60°C, which corresponds to 55 months at body temperature; the variance of the data points results from the precision of the method. Since no degradation trend can be seen over the period, extrapolation of the data ensures hydrolytic stability of the material for more than 20 years.

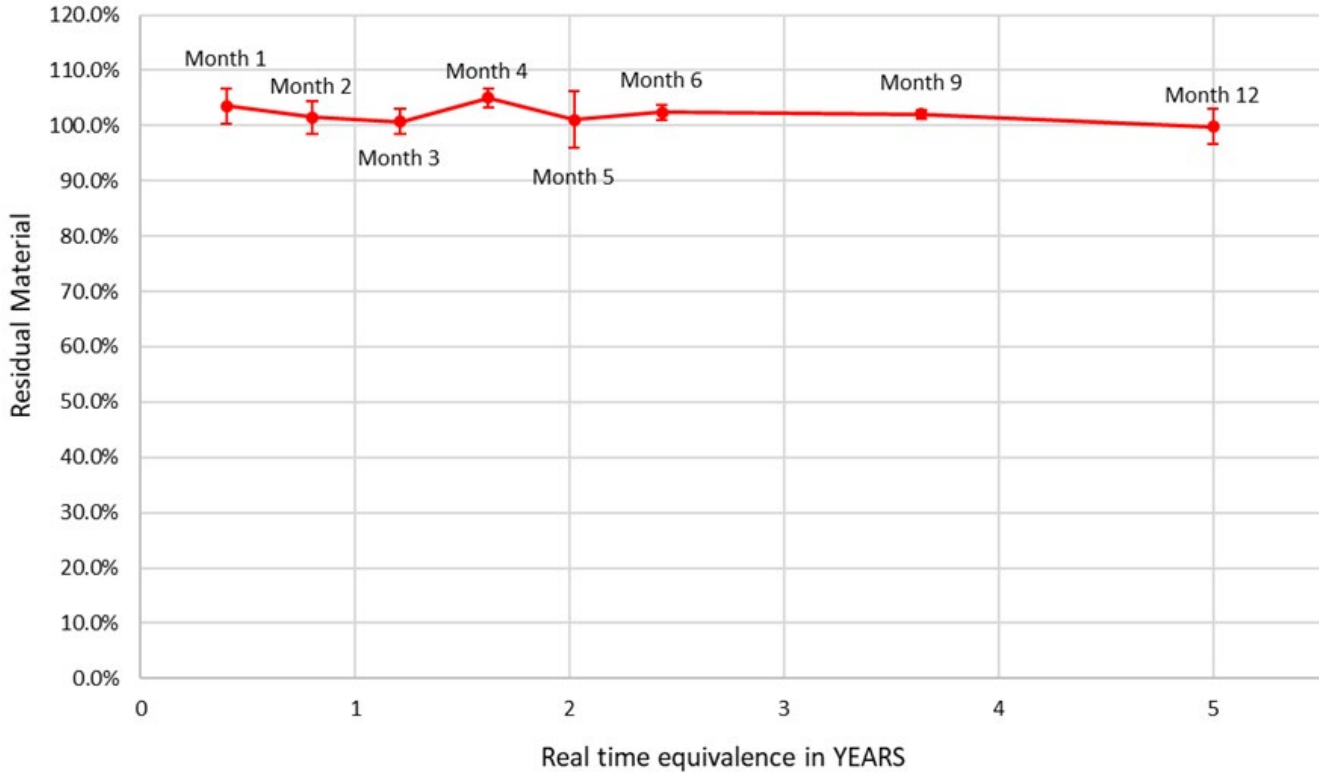

Figure 6. Dry content of cured Odne™Fill after storing for 12 months at 60 °C and corresponding equivalence at 37 °C.

4.4.2 Stability against biodegradation

Odne™Fill's stability against enzymatic biodegradation via ester bond cleavage was studied internally by Odne using the same methods that Tay *et al.* had used for studying Resilon.[7–9] Material samples were incubated in an *E. faecalis* suspension, in human saliva and cholesterol esterase for up to 28 days and analyzed gravimetrically and by SEM. PBS and an alkaline solution of pH 12 served as negative and positive controls.

Throughout the study, no material disintegration was observed. No loss of material dry content occurred under any of the conditions. SEM images show that the surface structure remains unchanged in any of the test conditions, only in case of the positive control a slight change in polymer network structure is noted (Figure 7). It is, therefore, evident that human saliva, common endodontic bacteria, and oral enzymes do not induce enzymatic biodegradation of Odne™Fill.

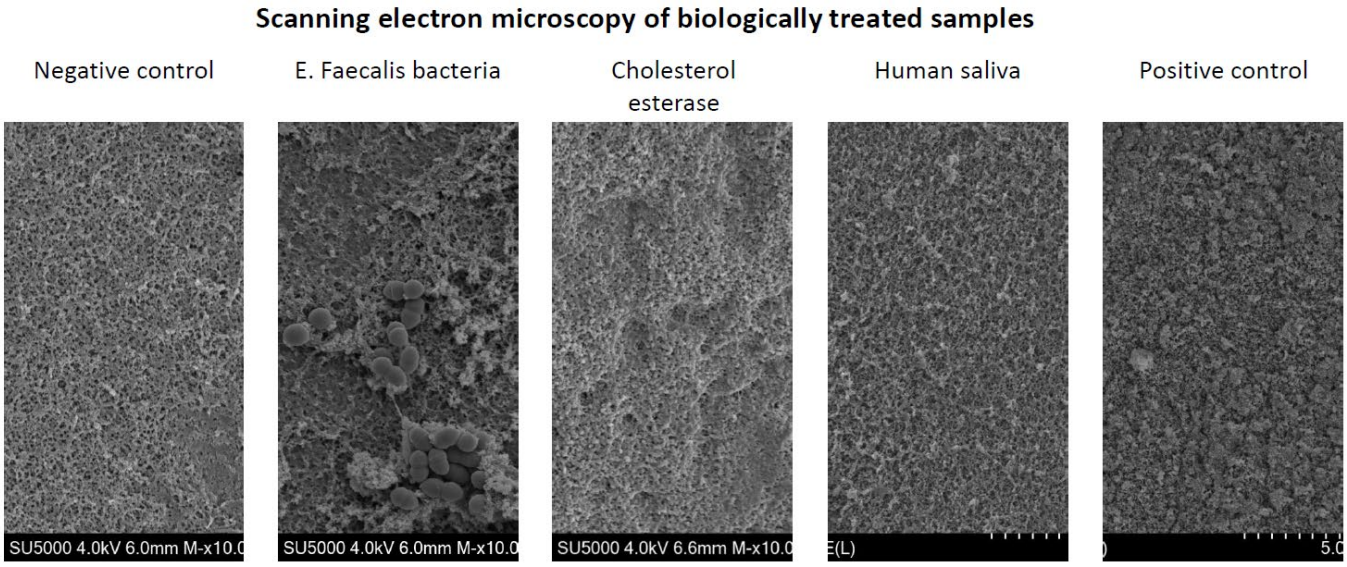

Figure 7. SEM images of Odne™Fill incubated in different storage solutions.

A similar study was conducted by Professor Josette Camilleri from the University of Birmingham, a renowned expert in dental material testing.[1] Odne™Fill samples were incubated with 0.15 wt/v% lipase and cholesterol esterase, studying potential weight loss and topographical changes by SEM. AH Plus® and BioRoot™ RCS were used as controls. Throughout the study, Odne™Fill did not show any weight loss or microstructural changes, unlike the control: AH Plus® showed weight loss upon contact with enzyme solution, and BioRoot™ RCS showed weight loss and surface changes (Figure 8, Figure 9). Thus, it is shown that Odne™Fill is more resistant to enzymatic degradation than established root canal sealers.

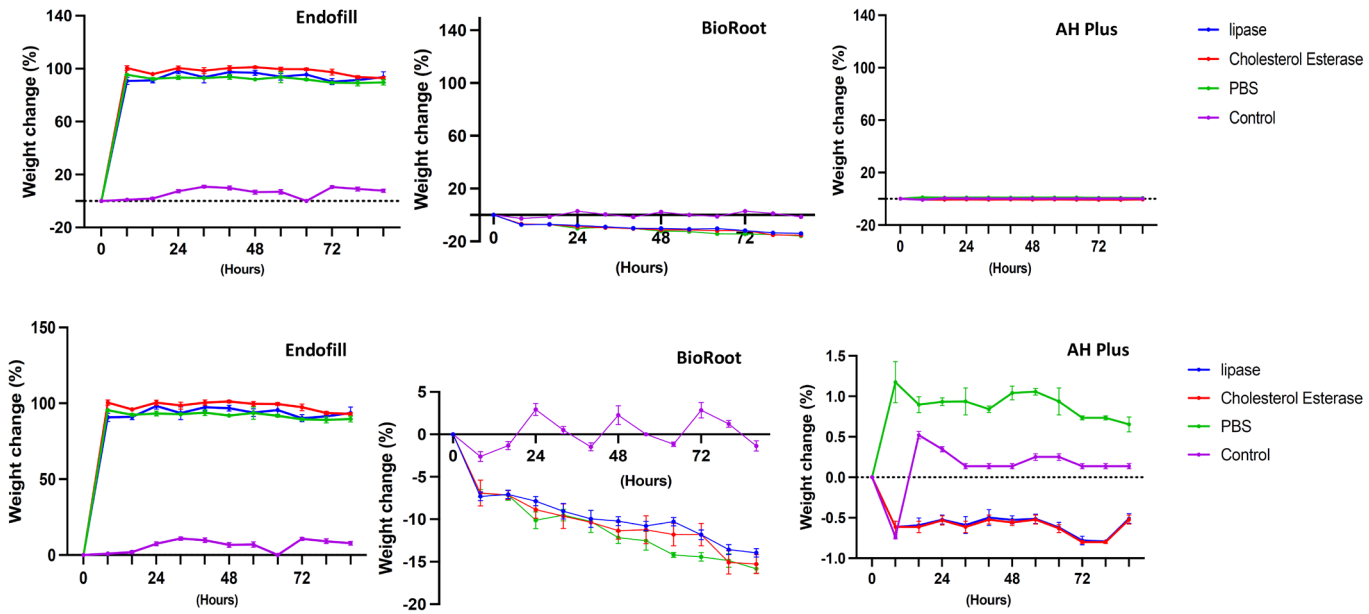

Figure 8. % weight change analysis post enzymatic degradation of Odne™Fill (termed Endofill in here), BioRoot™ RCS, and AH Plus® after treatment with lipase enzyme, cholesterol esterase enzyme, PBS and the control without any treatment incubated at 37˚C for 3 days, changing the solution every 4 hours. The positive y-axis shows a weight gain, while the negative y-axis shows a weight loss ($p<0.001$). The first panel shows a similar y-axis, and the second panel shows the details of the changes reported.

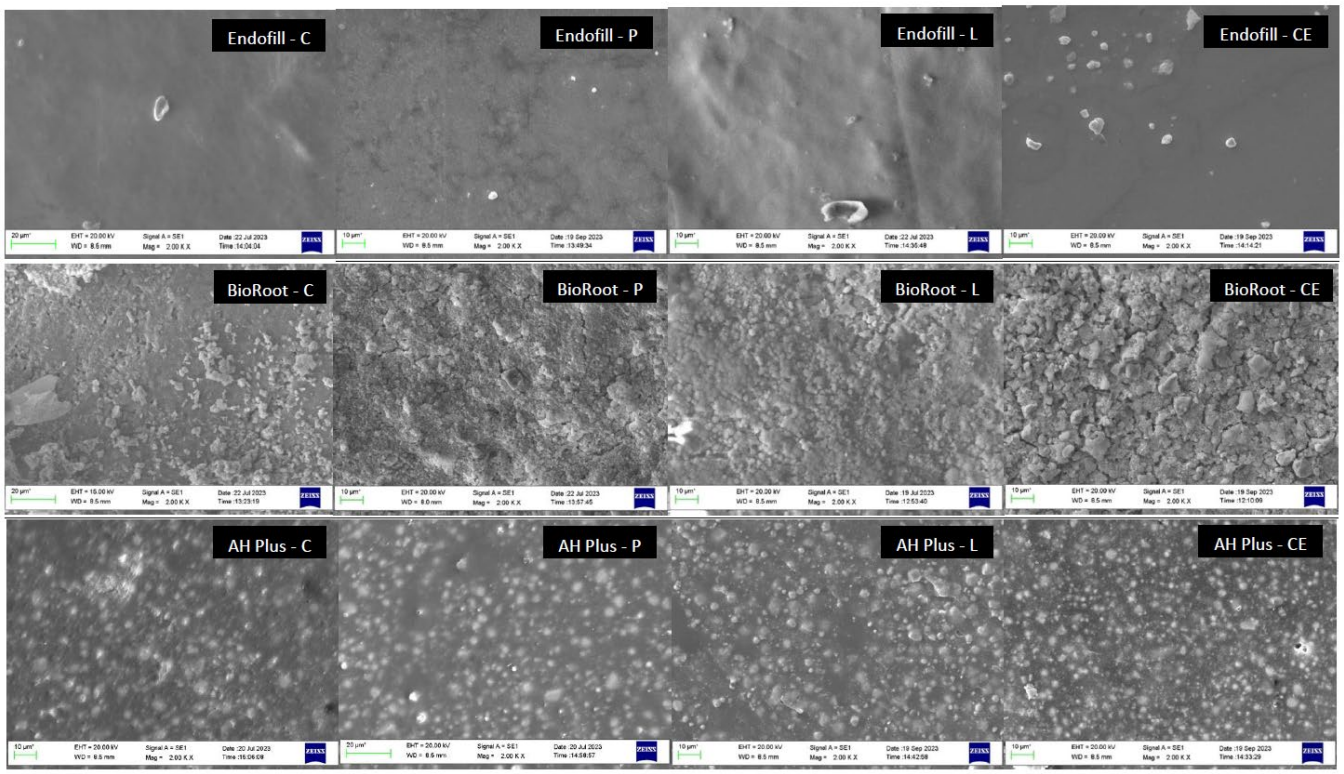

Figure 9. SEM images at 2k magnification of Odne™Fill (termed Endofill in here), BioRoot™ RCS, and AH Plus® treated for 72 hours with lipase (L), cholesterol esterase (CE), PBS (P) and the control untreated materials (C).

4.4.3 Summary

Odne™Fill has been tested for its stability against hydrolytic degradation (chapter 4.4.1) and showed no loss of material dry content or surface integrity even when treated under accelerated conditions (60 °C for 12 months). Odne™Fill has been tested for its stability against biodegradation by bacteria or enzymes (chapter 4.4.2) and showed no weight loss or surface changes.

It is thus confirmed that Odne™Fill is stable for use as a root canal filling material, and no degradation or loss of structural integrity is expected throughout the lifetime of a root canal filling of 10 – 20 years.

5 References

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