

ProRoot® Bio Sealer Fact File

Bioceramic sealers have emerged as a significant advancement in endodontics, offering good biocompatibility, sealing ability and bioactivity [1]. Among them, materials based on Mineral Trioxide aggregate (MTA) technology are particularly valued for their capacity in promoting hard tissue formation and high initial pH. This fact file focuses on the physico-chemical properties of the ProRoot® Bio Sealer, the biological responses and some clinical aspects, providing a comprehensive understanding of its potential in root canal treatment.

1 ProRoot® Bio Sealer – description

ProRoot® Bio Sealer is primarily based on Mineral Trioxide Aggregate (MTA) chemistry and contains calcium silicates and calcium aluminates, non-staining tantalite as a radiopacifier and other proprietary excipients to enhance handling and flow properties (see the table below showing the main components). MTA has been widely used in a variety of applications in endodontics as supported by a broad body of evidence. MTA has excellent physical and biological properties such as biocompatibility, bioactivity, and sealing ability [1-4]. This sealing capacity is largely attributed to MTA's bioactivity and ability to release calcium ions to promote the formation of a hydroxyapatite layer in the presence of phosphate-containing physiological fluids [1, 5-7].

Main Component	Role	wt%
Tantalite	Non-staining radiopacifier	< 50
Bioactive cement	Bioactive, responsible for setting, high pH and hydroxyapatite formation	< 67
Calcium silicates	Major bioactive component, responsible for setting, high pH and hydroxyapatite formation	< 35
Calcium aluminates	Bioactive component, contributes to faster setting, improves mechanical properties and elevates acid resistance	< 32

Table 1
Primary components of ProRoot® Bio Sealer. Bioactive cement refers to tricalcium silicate, dicalcium silicate, calcium aluminate, grossite and tricalcium aluminate.

ProRoot® Bio Sealer is a ready-to-use, pre-mixed and injectable resin-free material, that facilitates its direct application into the root canals. During injection, the organic liquid in ProRoot® Bio Sealer is displaced by water from surrounding tissues or dentin tubules, initiating a hydration reaction that leads to setting without the need of previous powder/liquid or base/catalyst mixing.



2 Bioactivity and Biocompatibility

When a bioceramic sealer, such as the ProRoot® Bio Sealer, comes into contact with tissue fluids in the root canal environment, it undergoes a hydration reaction. This chemical reaction leads to the setting of the sealer and to the release of calcium & hydroxide ions. The hydroxide ions contribute to a pH increase (alkaline environment) and the calcium ions react with phosphate ions from surrounding tissues to precipitate hydroxyapatite on the sealer surface. This bioactivity is expected to enhance the sealing ability by forming a bond between the dentin and sealer material and promotes periapical healing.

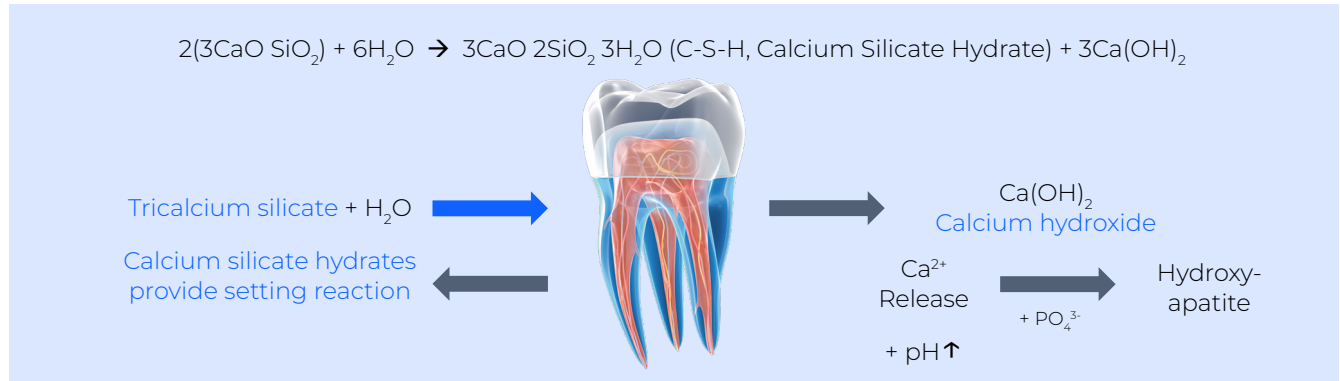


Figure 1

Representation of reaction of ProRoot® Bio Sealer with its environment, exemplified with tricalcium silicate.

According to the reaction shown above, ProRoot® Bio Sealer is able to induce a high pH value of up to 11 [14]. The formation of hydroxyapatite induced by ProRoot® Bio Sealer can be proven by X-ray diffraction (XRD) and visualized via scanning electron microscopy (SEM) (Figure 2) [8]. Sealer samples were immersed in a phosphate-buffered saline (PBS) solution for both experiments for 28 days. Compared to benchmark epoxy based resins such as AH Plus®, bioceramic sealers such as ProRoot® Bio Sealer have bioactive properties, thanks to their ability to induce hydroxyapatite formation and a prolonged alkaline pH. XRD analysis has shown that ProRoot® Bio Sealer contains higher bioactive cement content compared to other bioceramic sealers available on the market (Figure 3).

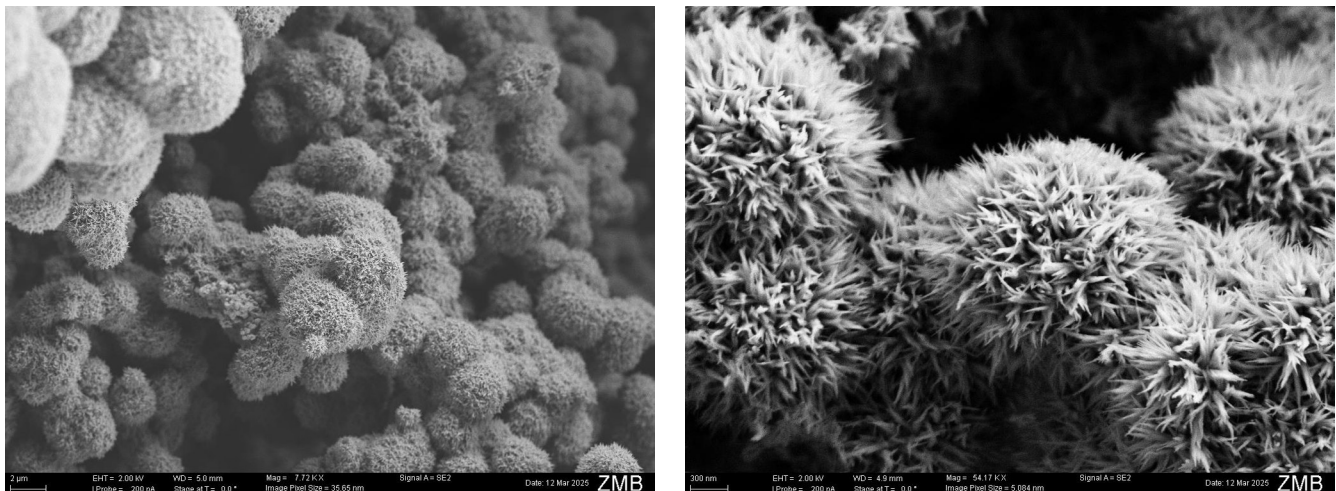


Figure 2

SEM images of hydroxyapatite crystals on samples of ProRoot® Bio Sealer, University of Zurich [8]. (on the left : ~x7'000 magnification, on the right : ~x54'000 magnification)

Higher Bioactive Cement Content

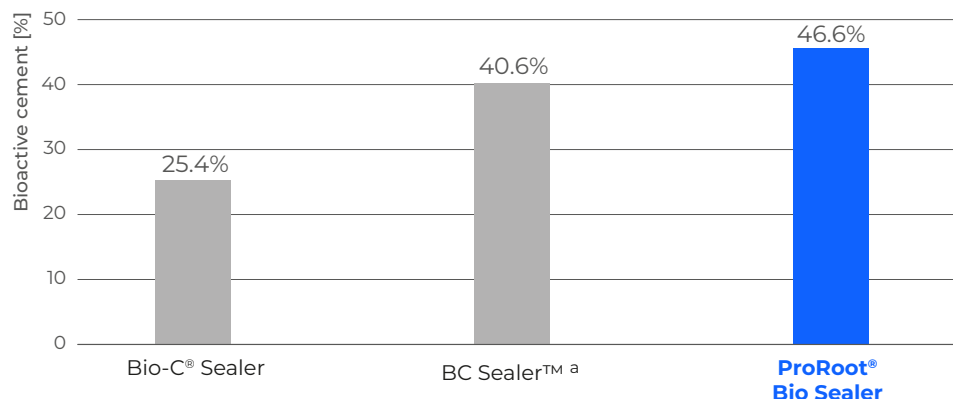


Figure 3

Bioactive cement content of ProRoot® Bio Sealer compared to other bioceramic sealers [15].

^a BC Sealer™ stands for the three equivalent sealers EndoSequence® BC Sealer™ (Brasseler) / TotalFill® BC Sealer™ (FKG) / EdgeBioCeramic™ Sealer (EdgeEndo).

3 Basic material properties – ISO standard testing

The clinical performance of a root canal sealer is a function of its physico-chemical properties, including radiopacity, flow, setting time and film thickness. Each property contributes to the sealer's ability to seal the root canal and promote long-term treatment success. The requirements and test methods for sealers are specified in the ISO standard 6786:2012 "Dentistry – Root canal sealing materials", and are shown in the table below, for the ProRoot® Bio Sealer.

Tests	ISO 6786 requirements	Clinical relevance	ProRoot® Bio Sealer
Radiopacity (mmAl)	≥ 3 mmAl/mm	Enables clear visualization on Xrays and CBCT to assess the quality of the root canal fill.	6 mmAl/mm ^a
Flow (mm)	≥ 17 mm	Allows the sealer to penetrate irregularities, improving sealing ability. E.g. high flow promotes penetration in canal and dentinal tubules, low flow reduces the risk of extrusion.	25.33 mm [10]
Set Time (hours)	As stated in IFU (within 10%)	Ensures the materials set reliably.	2 h 41 min [16]
Film thickness (µm)	≤ 50 µm	A low film thickness facilitates placement of gutta-percha at correct working length, enhancing the seal.	14.66 µm [10]

Table 2

Material properties according to ISO 6786 of ProRoot® Bio Sealer.

^a Data from the IFU.

ProRoot® Bio Sealer provides an adequate radiopacity, well above the 3 mm Al equivalent limit defined in ISO 6786, allowing the clinician to clearly distinguish the sealer from surrounding anatomical structures on 2D and 3D X-rays. It shows a favorable flow, promoting its ability to fill the space in the canal, while minimizing the risk of extrusion into periapical tissues. Its setting time is comparable to other sealers in the market, providing enough time for the clinician to work without premature hardening. The film thickness of the ProRoot® Bio Sealer is low, allowing for a precise placement of root canal obturation and penetration into the lateral canals. All together, these physico-chemical properties enhance confidence in the procedure by promoting the seal integrity.

4 Clinical aspects

Cold and warm obturation compatibility. ProRoot® Bio Sealer demonstrates compatibility with both cold and warm obturation techniques, including carrier-based. Its physical and chemical properties remain stable under the thermal conditions associated with warm vertical compaction, still providing adequate flow during single cone obturation [9].

Retreatment easiness. The ex vivo study by Carrillo et al. [11] investigated the retreatability of three calcium silicate based sealers: EdgeBioCeramic™ Sealer (EdgeEndo, USA), EndoSequence® BC Sealer™ (Brasseler, USA) and ProRoot® Bio Sealer* during non-surgical retreatment procedures. The goal was to assess how easily these sealers could be removed from root canals, focusing on the time required for retreatment. Straight root canals were obturated using a single gutta-percha cone technique with each of the three sealers. Retreatments were performed after 21 days (teeth stored at 37°C, 100% humidity) using rotary NiTi instruments without the use of solvents, measuring the success rate of regaining apical patency and recording the time to complete the retreatment. The key findings are the following:

- **Apical Patency:** ProRoot® Bio Sealer* achieved 100% success rate in regaining apical patency, outperforming EndoSequence® BC Sealer™ (63.64%) and EdgeBioCeramic™ Sealer (69.77%).
- **Retreatment time:** The time required to complete retreatment was significantly shorter for ProRoot® Bio Sealer* (mean 169 s) compared to the two other sealers (288 s with EndoSequence® BC Sealer™ and 230 s with EdgeBioCeramic™ Sealer).

ProRoot® Bio Sealer* demonstrated superior performance in term of retreatability making it a good choice for successful and time efficient retreatment procedures.

Clinical success rate. In an on-going randomized controlled clinical trial, the performance of the ProRoot® Bio Sealer, EndoSequence® BC Sealer™ and AH Plus® was compared regarding the healing rate, radiographic behavior, and post-operative pain [12]. Thus far, 217 patients have been treated with the ProRoot® Bio Sealer. The first outcomes show a very high short term healing rate at 6 and 12 months, more stable radiographic visibility over time compared to leading bioceramic sealers, and a post-operative sensitivity similar to AH Plus® and EndoSequence® BC Sealer™.

In another retrospective clinical study by Lepure et al. [13], the success rate of treatments performed on 687 teeth, with either ProRoot® Bio Sealer* or EndoSequence® BC Sealer™, was compared over a minimum of one year follow-up period. The success rate was defined as teeth healed or in the process of healing (i.e. reduced size of the radiographic periradicular lesion). ProRoot® Bio Sealer showed a slightly higher success rate, 96.5 % vs. 94.9% with EndoSequence® BC Sealer™.

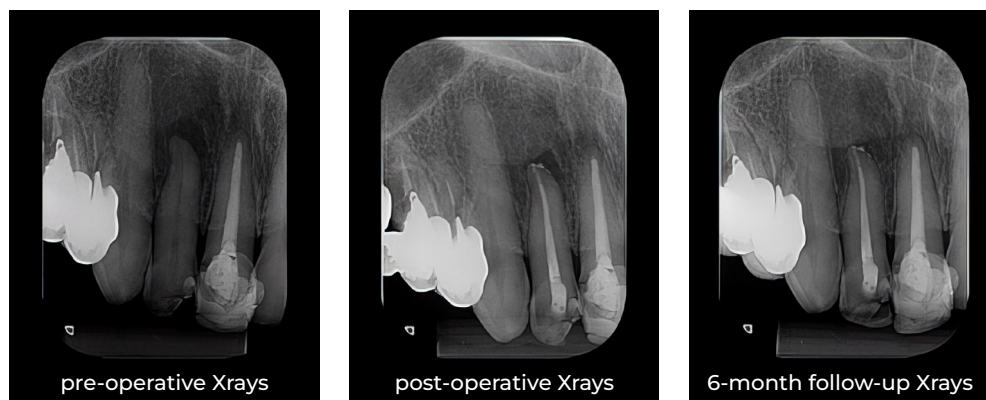


Figure 4
Representative post-operative peri-apical X-rays after obturation with ProRoot® Bio Sealer, with a 6-month follow-up [12].
Note the healing of the periapical pathology and the radiographic sealer stability.

5 Conclusion

ProRoot® Bio Sealer represents a reliable solution in modern endodontics, combining favorable physical properties with good biocompatibility, clinical outcomes and easy retreatability. Continued research will further clarify its role in contemporary root canal treatment and contribution for long-term endodontic success.

6 References

1. Camilleri, J., et al., Present status and future directions: Hydraulic materials for endodontic use. *International Endodontic Journal*, 2022. 55: p. 710-777.
 2. Prati, C. and M.G. Gandolfi, Calcium silicate bioactive cements: Biological perspectives and clinical applications. *Dent Mater*, 2015. 31(4): p. 351-70.
 3. Torabinejad, M. and M. Parirokh, Mineral trioxide aggregate: a comprehensive literature review--part II: leakage and biocompatibility investigations. *J Endod*, 2010. 36(2): p. 190-202.
 4. Parirokh, M. and M. Torabinejad, Mineral trioxide aggregate: a comprehensive literature review--Part III: Clinical applications, drawbacks, and mechanism of action. *J Endod*, 2010. 36(3): p. 400-13.
 5. Han, L., S. Kodama, and T. Okiji, Evaluation of calcium-releasing and apatite-forming abilities of fast-setting calcium silicate-based endodontic materials. *Int Endod J*, 2015. 48(2): p. 124-30.
 6. Reyes-Carmona, J.F., M.S. Felipe, and W.T. Felipe, Biomineralization ability and interaction of mineral trioxide aggregate and white portland cement with dentin in a phosphate-containing fluid. *J Endod*, 2009. 35(5): p. 731-6.
 7. Tay, F.R., et al., Calcium phosphate phase transformation produced by the interaction of the portland cement component of white mineral trioxide aggregate with a phosphate-containing fluid. *J Endod*, 2007. 33(11): p. 1347-51.
 8. SEM analysis 2025, DS funded, University of Zurich, external data on file. For more information, contact Consumables-Data-Requests@dentsplysirona.com.
 9. In vivo case study comparing handling of bioceramic sealers using warm obturation technique. External data on file. For more information, contact Consumables-Data-Requests@dentsplysirona.com.
 10. Tekir, B., et al., Physicochemical Properties of Hydraulic Calcium Silicate Sealers in Comparison with Resin and Calcium Hydroxide-Based Sealers: An In Vitro Study. *Turkiye Klinikleri J Dental Sci*. 2024;30(1):83-91
 11. Carrillo, C.A., et al., Retrieval of Calcium Silicate-based Root Canal Sealers During Retreatment: An Ex Vivo Study. *J Endod*, 2022. 48(6): p. 781-786.
 12. Randomized controlled ongoing clinical trial (>450 follow-up cases) comparing bioceramic sealers with AH Plus® resin-based sealer. Gustavo De-Deus. University of Rio de Janeiro. External data on file. For more information, contact Consumables-Data-Requests@dentsplysirona.com.
 13. Lepure, C., et al., Clinical outcomes of nonsurgical root canal treatment using NeoSEALER® Flo and EndoSequence® BC Sealer™: A retrospective analysis with short-term follow-up. *Clin Oral Invest*, 2024. 28(11): p. 598.
 14. In vitro pH study, demonstrated pH level of up to 11. Internal data on file. For more information, contact Consumables-Data-Requests@dentsplysirona.com.
 15. Based on crystalline portion evaluated by XRD analysis comparing different bioceramic sealers. Internal data on file. For more information, contact Consumables-Data-Requests@dentsplysirona.com.
 16. Pradelli, J.A., et al., Physicochemical and antibiofilm properties of new ready-to-use and powder/gel bioceramic endodontic sealers. *Braz Oral Res*, 2025. 39: p. e076.
- * ProRoot® Bio Sealer is an equivalent sealer to NeoSEALER® Flo (NuSmile, Ltd, USA).



Manufactured by
NuSmile, Ltd
3315 West 12th St
Houston, TX 77008
USA

www.dentsplysirona.com