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Surface Adaptability of a Novel Root Canal Filling Material: A Micro-CT Ex Vivo Evaluation

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Abstract

Background/Objectives: This study evaluates the adaptation of a novel filling material (Odne®Fill, Switzerland) to the walls of the shaped root canal using micro-computed tomography. **Methods**: Fourteen extracted human molars (6 maxillary and 8 mandibular), comprising a total of 32 root canals, were included. After canal preparation, all canals were filled with Odne®Fill according to the manufacturer's instructions. Periapical radiographs and micro-computed tomography were used to assess the extent of canal wall coverage by the filling material. Surface coverage was quantified by image segmentation and statistically analyzed. **Results**: The percentage of canal wall coverage ranged from 93.31% to 99.98%. The mean coverage rate was 97.63% (SD 1.70%) and the median was 98.23%, indicating a high degree of adaptation of the filling material to the ex vivo prepared canal walls. **Conclusions**: Under the conditions of this ex vivo study Odne®Fill demonstrated high canal wall adaptation values. These findings should be interpreted with caution and further comparative and long-term studies are required before clinical relevance can be established.

Keywords: root canal treatment; root canal filling; filling material; adaptation

1. Introduction

Root canal obturation is performed after chemomechanical preparation and disinfection of the root canal system[1,2]. Its primary purpose is to fill the prepared canal space and thereby reduce the risk of reinfection. Over the years, a wide range of obturation materials and techniques have been introduced for this purpose[3,4]. Conventional root canal filling is still mainly based on gutta-percha used in combination with a sealer placed between the core material and the instrumented canal wall[5]. It is the most widely used core material due to its physical and chemical stability and its ability to be thermoplasticized[6]. The two most widely used techniques in clinical practice are cold lateral compaction and warm vertical compaction of gutta-percha [7,8].

Cold lateral compaction has long been one of the most commonly used obturation techniques and has frequently served as a reference method in endodontic research. However, this technique has several limitations, including incomplete adaptation of the filling material to the canal wall [9] and the potential generation of high compaction forces.

Warm vertical compaction has therefore been advocated as an alternative because thermoplasticized gutta-percha can adapt more closely to the prepared root canal system and may also fill anatomical irregularities more effectively[10]. Nevertheless, this technique is technique-sensitive and more time-consuming [11,12].

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Despite its longstanding clinical use, gutta-percha does not bond to dentine and does not adhere to the canal wall[13]. This limitation has stimulated the search for alternative obturation concepts and materials that may improve adaptation to the prepared root canal surface[14].

In this context, Odne®Fill (ODNE, Dübendorf, Switzerland), a low-viscosity light-curable hydrophilic gel, has recently been introduced as a novel root canal filling material[15]. According to the manufacturer and the cited background literature, the material is injectable and intended for use even in minimally prepared canals. Its delivery system, including a fine canula and a dedicated fiber-optic tip for intracanal light curing, is designed to facilitate placement throughout the root canal system, including anatomically complex areas.

As this material represents a fundamentally different obturation concept from conventional gutta-percha-based techniques, its adaptation to the prepared canal wall requires evaluation. Micro-computed tomography offers a non-destructive method for three-dimensional assessment of root canal fillings and can be used to quantify the extent of canal wall coverage by the filling material. Therefore, the aim of the present ex vivo study was to evaluate the adaptation of Odne®Fill to shaped root canal walls using micro-computed tomography.

The introduction should briefly place the study in a broad context and highlight why it is important. It should define the purpose of the work and its significance. The current state of the research field should be carefully reviewed and key publications cited. Please highlight controversial and diverging hypotheses when necessary. Finally, briefly mention the main aim of the work and highlight the principal conclusions. As far as possible, please keep the introduction comprehensible to scientists outside your particular field of research. References should be numbered in order of appearance and indicated by a numeral or numerals in square brackets—e.g., [1] or [2,3], or [4–6]. See the end of the document for further details on references.

2. Materials and Methods

Sample size calculation and statistical analysis

Sample size calculation was performed using G*Power 3.1 for macOS (Heinrich Heine University Düsseldorf, Düsseldorf, Germany) based on previous studies [16][17]. Assuming $\alpha = 0.05$ and a power of 95%, the minimum required sample size was 29 canals. In total, 32 root canals were included for this ex vivo study.

Surface coverage between the obturation material and the root canal wall was analyzed using a one-sample t-test in MATLAB (Statistics and Machine Learning Toolbox, MathWorks, Natick, MA, USA) to assess the surface coverage between the novel obturation material and the root canal wall.

To evaluate whether the mean coverage differed from predefined selected clinical reference benchmark values of 95% and 97% a one-sample t-test was performed. P-values, confidence intervals, and test statistics were recorded. This approach allowed quantitative validation of the obturation quality by determining whether the observed mean filling material—canal interface coverage statistically satisfied or exceeded clinically acceptable standards.

Specimens and canal preparation

Human molars were extracted for reasons unrelated to this study. Maxillary (n = 6) and mandibular molars (n = 8) without signs of alteration or root resorption were stored in a moist environment at body temperature until use. After sectioning at the cement-enamel junction and removal of the crowns, 32 root canals were prepared, cleaned, and dried according to the manufacturer’s instructions.

Shaping and filling procedures

A manual K-file with a tip diameter of 0.08 mm was inserted into each root canal until its tip became visible at the apical foramen. The working length was established at 1.0 mm short of this length and was monitored during canal preparation using the integrated apex locator of the endodontic motor (X-Smart Pro Plus, Dentsply Sirona, Bensheim, Germany). The recorded working length was subsequently confirmed by a digital periapical radiograph. All root canals exhibited moderate curvatures ranging from 10° to 30°.

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Root canal preparation was performed with Reciproc Blue instruments (VDW, Munich, Germany) using an endodontic motor (X-Smart Pro Plus, Dentsply Sirona, Bensheim, Germany) at the settings recommended by the manufacturer. Each instrument was advanced apically in 3-mm increments until the predetermined working length was reached. When the Reciproc Blue R25 instrument did not readily progress to the full working length, an R-Pilot file (VDW, Munich, Germany) was used to establish glide path and patency.

After three apically directed pecking motions, the instrument was removed and cleaned of debris in a sponge soaked with 5.25% sodium hypochlorite on an Interim Stand (VDW, Munich, Germany). The final apical preparation size was 0.25 mm. During canal preparation, irrigation was performed alternately with 5.25% sodium hypochlorite and 17% EDTA. Final irrigation was carried out using the OdneClean hydrodynamic cavitation-based irrigation system with single-use OdneClean tips (ODNE AG, Dübendorf, Switzerland). Owing to their diameter of 190 µm, the OdneClean tips could be inserted easily into the prepared canals. Distilled water was used as the irrigant according to the manufacturer’s instructions. The insertion depth and intracanal position of the irrigation tip were controlled using the supplied silicone stop (Endostop).

Root canal filling was performed with Odne®Fill, material (Lot 1352ED). The position of the flexible conical 33G plastic canula of the Odne®Fill, , device was adjusted by positioning the Endostop rubber stop at 1.0 mm short of the previously determined working length. After use in one canal, the tips were discarded in accordance with the manufacturer’s instructions.

All filled root canals were subsequently examined by periapical radiography and micro-CT to assess the extent of canal wall coverage by the filling material (Figure 1).

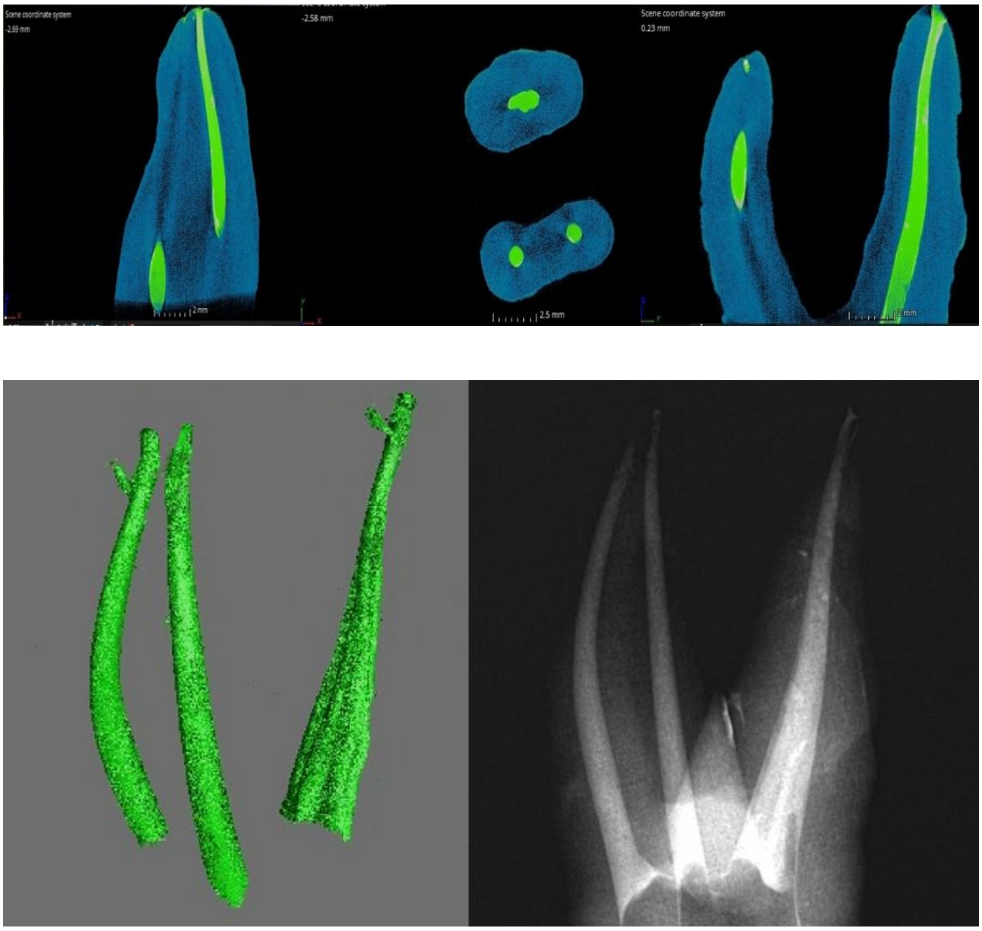

Figure 1. CT and radiographic image of the root canal filling.

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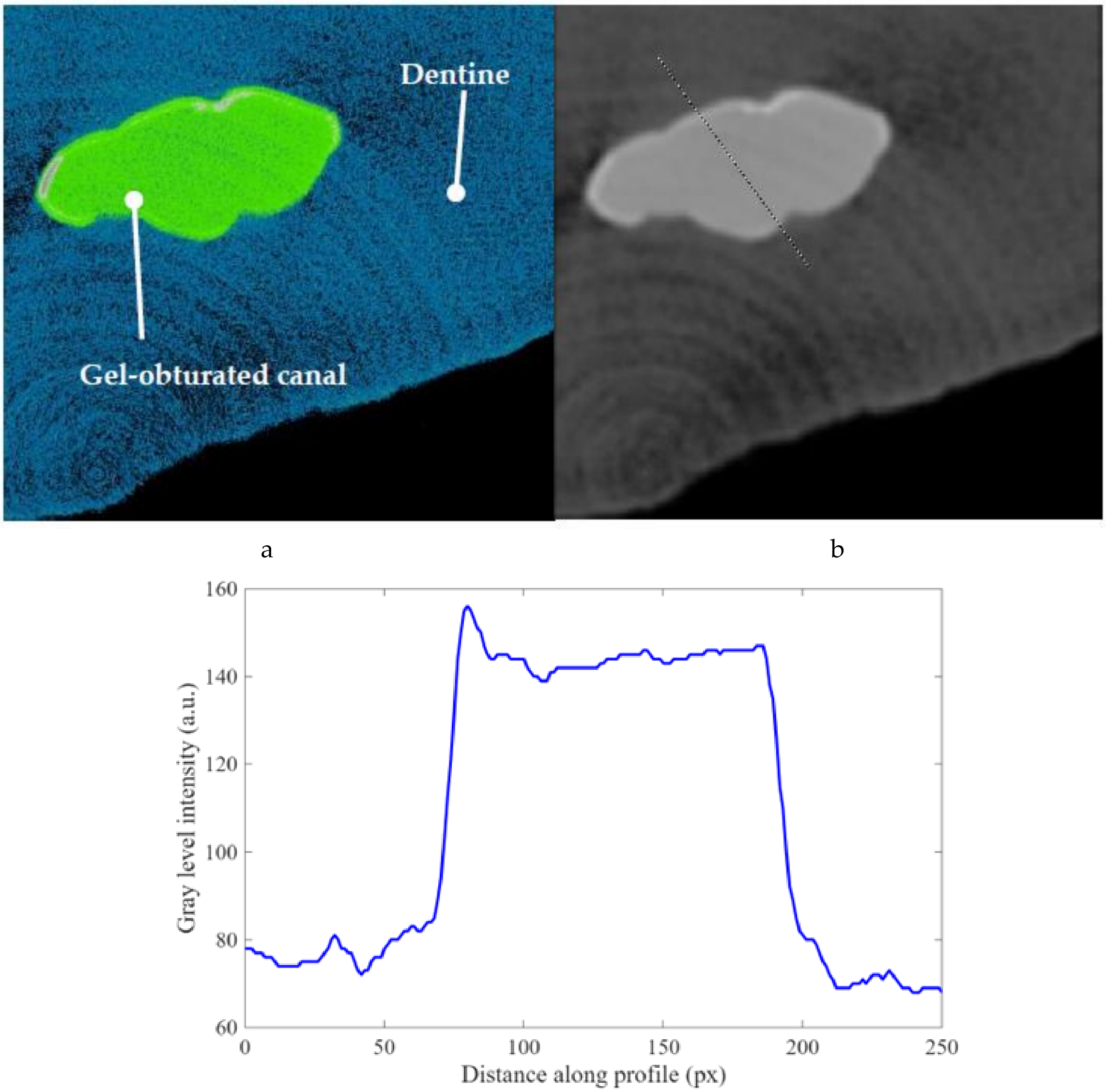
CT imaging and image construction

Micro-CT imaging was performed using a ProCon X-Ray Alpha device (ProCon X-Ray, Sarstedt, Germany) equipped with an XWT-225-TCNG X-ray tube (X-Ray WorX, Garbsen, Germany) and a Shad-o-Box 6K HS CMOS detector with a resolution of 49.5 µm (Teledyne DALSA, Ontario, Canada). Samples were scanned at 80 kV and 120 µA (9.6 W). For each scan, 1,440 projection images were acquired over 360° with a rotation step of 0.25° and an exposure time of 1.2 s per projection. Images were acquired without filters at a geometric magnification of 6.96- to 9.157-fold, resulting in a voxel size ranging from 4.978 to 7.122 µm, depending on tooth size. The average scan time was approximately 45 min. Image reconstruction was performed using VGStudio MAX 2025.2 software (Volume Graphics, Heidelberg, Germany).

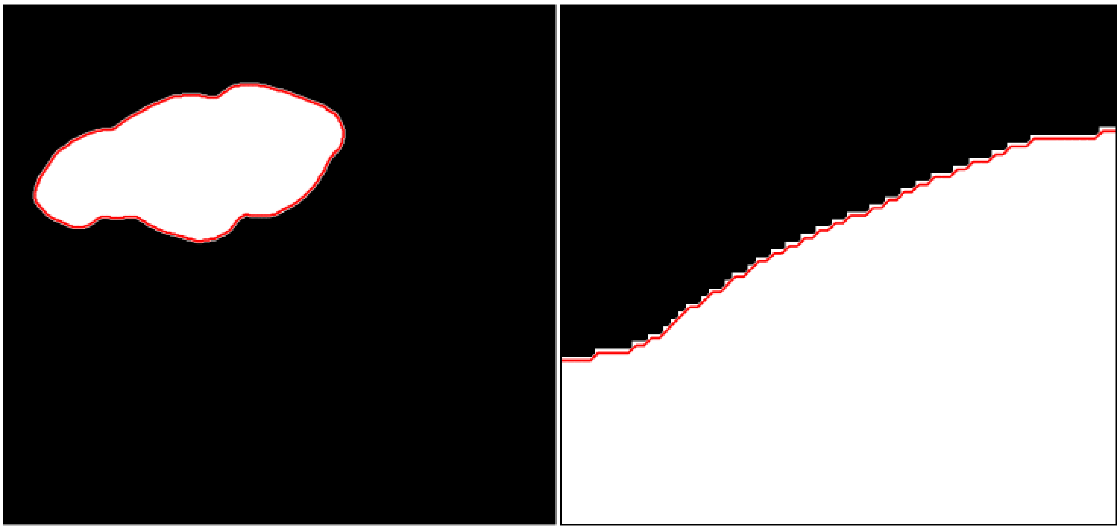
Determination of the surface ratio in obturated root canals using image segmentation

Each coloured image of a micro-CT slice (Figure 2a) has been segmented primarily on the basis of grayscale intensity (Figure 2b).



a b

c



d e

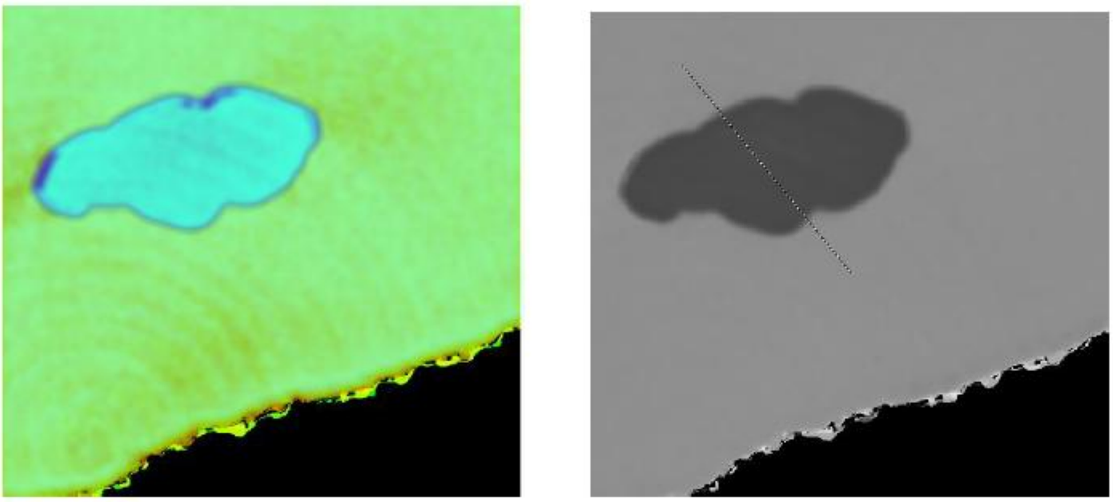
Figure 2. a. RGB image, b. Filtered grayscale image. c. Plot of the pixel values along the line segment of grayscale image. d. Red gel contoure. Gel contour limit.

The improfile function was used to extract intensity profiles along representative lines crossing the interface between the filling material and the canal wall in order to define fixed threshold values. A global intensity threshold was then applied to the filtered grayscale image to isolate pixels corresponding to the filling material (Figure 2c).

The resulting binary mask was subjected to morphological hole filling to eliminate internal voids caused by local intensity variations or partial-volume effects. This step ensured a continuous and physically plausible representation of the filling material within each slice (Figure 2d, e).

These slice-wise binary masks were used further for the volumetric reconstruction of the filling material throughout the shaped and filled root canal.

Hue saturation values (HSV) and hue images were created (Figure 3a and Figure 3b) allowing to plot the pixel values along a representative line segment in the hue image (Figure 3c).



a b

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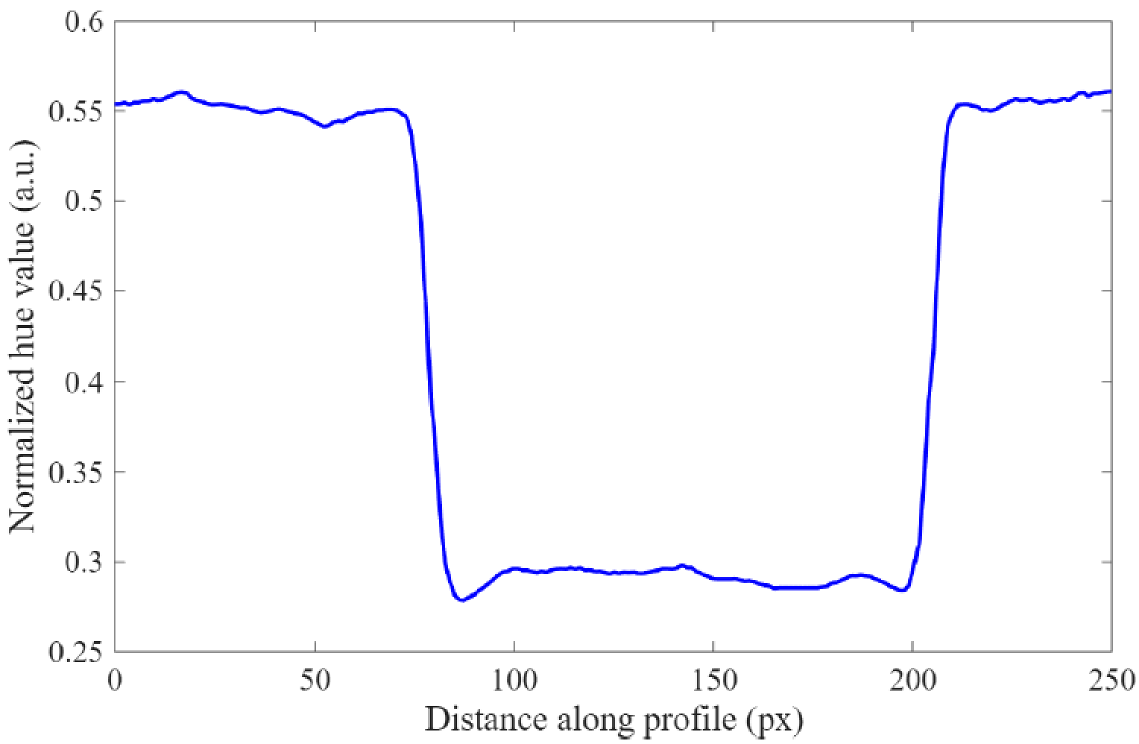

c

Figure 3. a. HSV image. b. Hue image. c. Plot of pixel values along the line segment of a hue image.

The initial region of interest comprised the entire canal cross-section including both filled and unfilled areas. To distinguish the filling material from voids within the canal, a second, more restrictive hue threshold was applied. This allowed identification of the uniform blue reference region corresponding to the intact canal background. By subtracting this strict blue mask from the broader canal region of interest (ROI), pixels representing color variations associated with the filling material or material interfaces were isolated. This differential segmentation strategy enabled reliable identification of the interface between the filling material and the root canal wall (Figure 4).

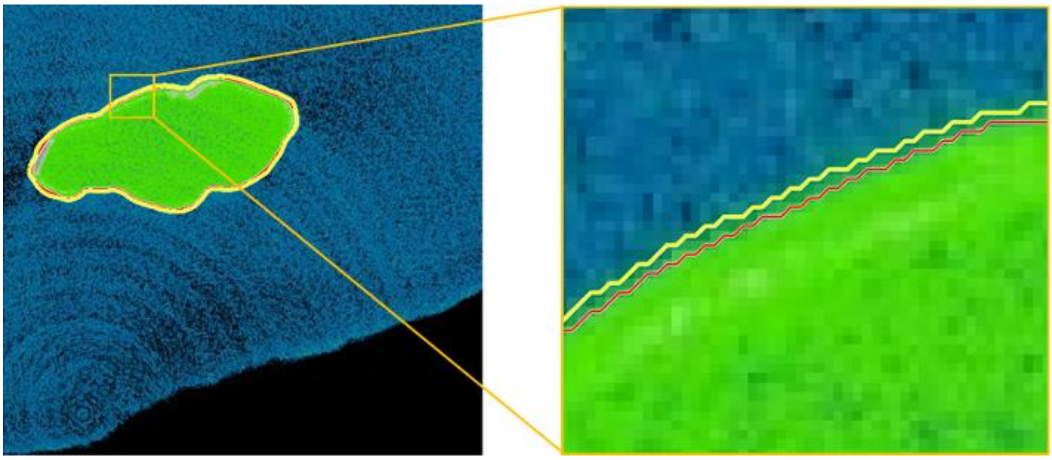

Figure 4. Interface between filling material and root canal wall.

The datasets obtained from slice-by-slice segmentation of both the filling material and the root canal area were subsequently used to calculate the surface coverage ratio for each obturated root canal.

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3. Results

The image segmentation procedure applied to the 32 filled root canals enabled quantitative assessment of surface coverage, defined as the adaptation of the filling material to the root canal wall. Overall, consistently high surface coverage values were observed across the investigated samples.

Surface coverage values ranged from 93.31% to 99.98%. The mean surface coverage was 97.63% (SD 1.70%), and the median was 98.23%, indicating overall high adaptation of the filling material to the canal wall with low variability among samples.

Results of the one-sample t-test

Two reference values, 95% and 97%, were used for statistical evaluation. Most measurements were clustered above 97%, whereas only a small number of values fell below this threshold. The median was above 97%, and the interquartile range was narrow, indicating a low dispersion of the data. In contrast, the 95% reference value was located near the lower end of the distribution (Figure 5).

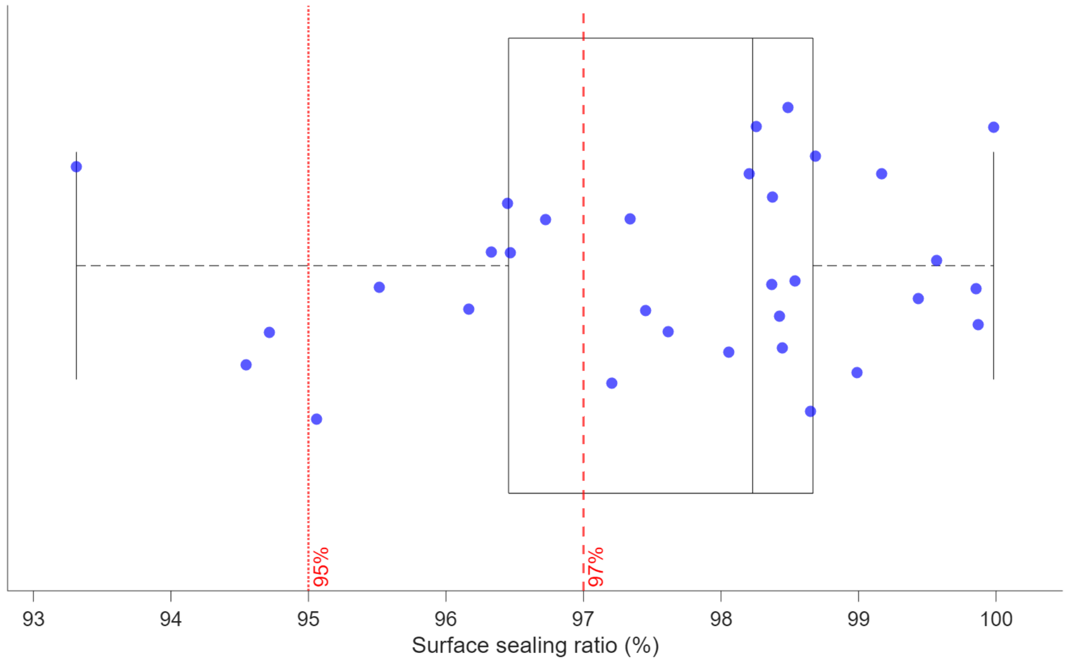

Figure 5. Horizontal box-and-scatter plot of distribution of the surface sealing ratio.

The box-and-scatter plot demonstrated a compact distribution of values without marked outliers, consistent with the low standard deviation. Overall, the data were more closely distributed around the 97% reference value than around 95%.

A quantile-quantile (Q-Q) plot was used to assess whether the measured surface coverage values approximated a normal distribution (Figure 6).

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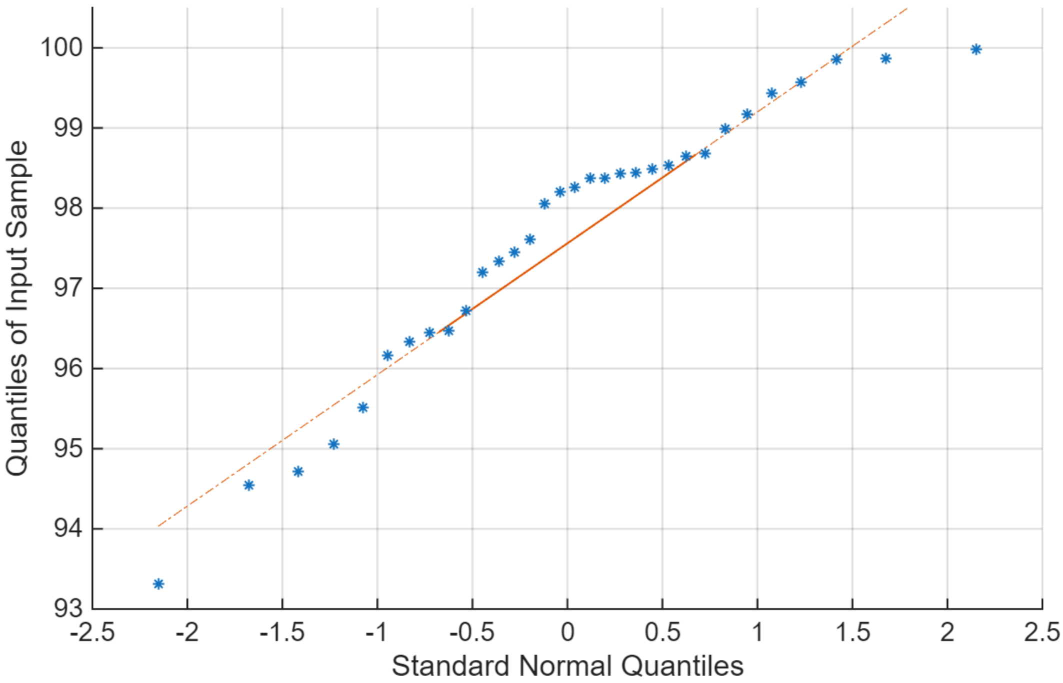

Figure 6. Q-Q plot of distribution of the surface sealing ratio.

Most data points were closely aligned with the reference line, particularly in the central part of the distribution, indicating that the assumption of approximate normality was acceptable. Minor deviations were observed at the lower and upper tails, which may be explained by the lower boundary of the minimum observed value and the upper limit of percentage data close to 100%. Overall, the Q-Q plot supported the use of a parametric test such as the one-sample t-test.

Statistical results of the one-sample t-test in relation to the a priori power analysis

Based on pre-study assumptions the expected difference of approximately 4% and a standard deviation of 5.71% resulted in an estimated effect size of d = 0.7 for 29 root canals. For the final study design, a reference effect size of d = 0.66 was assumed for 32 canals with $\alpha = 0.05$ and a power of 95%.

For the 95% reference value the observed effect size (d = 1.55) was larger than anticipated, indicating that the difference between the measured mean surface coverage and the 95% benchmark was greater than expected. For the 97% reference value, the observed effect size (d = 0.37) was smaller than the assumed a priori effect size, which is consistent with the smaller difference between the measured mean and this stricter reference value.

Overall, the findings were consistent with the a priori power analysis. The sample size of 32 canals was sufficient to detect medium to large effects with high statistical power, whereas smaller differences, such as those observed relative to the 97% reference value, should be interpreted more cautiously.

Within the limitations of this analysis, the material exceeded the 95% reference value and showed mean surface coverage close to 97%.

4. Discussion

Within the limitations of this ex vivo study the results indicate a high degree of adaptation of the novel filling material, ODNE®Fill to the root canal wall. The mean surface coverage was 97.63%, with a relatively small standard deviation, suggesting low variability among the samples. This finding indicates that high surface coverage was achieved consistently under the experimental conditions of this study.

The surface coverage values were clustered within a narrow range with most measurements close to or above 97%. Limited areas of incomplete wall contact may be explained by anatomical

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complexity, local canal irregularities or methodological factors related to the image acquisition and segmentation process.

The findings of this study should be interpreted as reflecting the performance of the material under controlled laboratory conditions rather than as a direct evidence of clinical sealing ability. The novel filling material controlled in the present study is an injectable light-curing hydrophilic material with water-like consistency before curing. It can be used in most of the canal anatomies regardless the used mechanical preparation method[15].

Minimal invasive mechanical instrumentation and even a non-instrumentation technique have already been described [18,19] but the filling of such geometries remains clinically a very challenging procedure.

For statistical interpretation the measured values were compared with predefined reference values of 95% and 97%. Relative to the 95% reference value, the observed mean surface coverage was clearly higher. The confidence interval is entirely above this threshold supporting the conclusion that the mean surface coverage exceeded 95%. In contrast, the comparison with the 97% reference value showed that the observed mean was close to this threshold, with only a small difference between the sample mean and the reference value.

These findings suggest that the material achieved a high surface coverage and performed well relative to both predefined reference values. However, this should not be interpreted as a proof of superior sealing ability or clinical effectiveness. Surface adaptation assessed by micro-CT represents only one aspect of the obturation quality. Other relevant properties, such as void distribution, dimensional stability, retreatability, resistance to leakage, and long-term behavior were not assessed in the present study and should be addressed by further studies.

The results should also be interpreted in the light of the study design. This was a single-arm laboratory investigation without a comparator group. Therefore, no conclusions can be drawn regarding superiority or equivalence in comparison with established obturation techniques. In addition, the use of extracted teeth and a manufacturer-specific preparation and irrigation protocol may limit transferability to routine clinical conditions.

Another point that merits consideration is the statistical approach. The predefined reference values of 95% and 97% were used as analytical thresholds in the present study; however, their clinical meaning should be interpreted with caution unless clearly supported by previous evidence. Moreover, failure to detect a significant difference from the 97% reference value should not be interpreted as statistical equivalence, but rather as indicating that the observed mean was close to this threshold.

The relatively small standard deviation confirms that the segmentation outcomes are not dominated by a few extreme values but rather reflect a stable and reproducible filling behavior.

A 97% benchmark was selected for assessing the performance under a more conservative and clinically ambitious criterion, beyond the traditionally accepted 95% threshold. The segmentation analysis provided a strong quantitative evidence that the gel achieves a high and uniform degree of surface coverage, forming a robust basis for subsequent statistical hypothesis testing against predefined performance benchmarks.

Table 1 presents the statistical results obtained for both benchmark comparisons using the two-tailed one-sample t-test.

Table 1. Statistical results of one-sample t-test for surface sealing ratio benchmarks.

Parameter	Benchmark 95%	Benchmark 97%
Sample size (n)	32	32
Significance level (α)	0.05	0.03
Decision (h)	1	0
p-value	6.51×10^{-10}	0.043
Mean surface ratio (%)	97.63	97.63
Standard deviation (%)	1.70	1.70
Degrees of freedom (df)	31	31

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t-statistic	8.78	2.11
Confidence interval of mean (%)	[97.02; 98.24]	[96.95; 98.31]
Cohen's d (effect size)	1.55	0.37

In case of 95% benchmark, the statistical test yielded h = 1, indicating the rejection of the null hypothesis at the selected significance level ($\alpha = 0.05$). The associated p-value was extremely small ($p = 6.51 \times 10^{-10}$), providing overwhelming evidence that the mean surface coverage is significantly different from and specifically higher than the 95% benchmark. The 95% confidence interval for the mean [97.02%; 98.24%] lies entirely above the benchmark value, reinforcing this conclusion. The statistic test ($t(31) = 8.78$) indicates a very strong deviation from the null hypothesis, which is consistent with the large standardized effect size obtained. The calculated Cohen's d = 1.55 corresponds to a large effect, far exceeding the commonly accepted threshold for strong practical relevance. According to the adopted reference scale for Cohen's d, this magnitude reflects a clear and obvious improvement beyond the benchmark, easily detectable even with moderate sample sizes. These results demonstrate that the new material obturation technique not only meets but substantially exceeds the 95% surface coverage criterion. The combination of a very low p-value, a narrow confidence interval well above the benchmark and a large effect size indicates a robust and reliable sealing performance under the investigated conditions.

In case of second two-tailed one-sample t-test with 97% benchmark, the test result was h = 0, meaning that the null hypothesis could not be rejected at the specified significance level. The obtained p-value ($p = 0.043$) lies above the stricter α threshold, indicating that the observed mean surface coverage is statistically indistinguishable from the 97% benchmark at this confidence level. The 97% confidence interval [96.95%; 98.31%] straddles the benchmark value, further supporting the interpretation that the true mean may be slightly below or above 97%. The corresponding statistic test ($t\ (31) = 2.11$) reflects a moderate deviation from the null hypothesis, markedly lower than that observed for the 95% benchmark. The calculated effect size (Cohen's d = 0.37) falls within the small-to-moderate range. According to the adopted effect size interpretation framework, this corresponds to a subtle but detectable difference with limited practical impact. This result should not be interpreted as a failure of the obturation technique. Instead, it indicates that the gel achieves a mean surface coverage that is statistically consistent with a very demanding 97% benchmark.

The comparison of the results for these selected two benchmarks is revealing a clear distinction in interpretation. Against the 95% benchmark the filling material demonstrates a statistically significant and practically large improvement, supported by a very large effect size. Setting a 97% benchmark the results are indicating statistical equivalence rather than superiority, with a small-to-moderate effect size and a confidence interval encompassing the benchmark value. This comparison highlights that the filling material reliably exceeds conventional performance expectations while approaching the upper limits of surface coverage realistically achievable in complex root canal geometries. The difference between the two benchmarks thus reflects not a contradiction but a gradation of performance evaluation, moving from confirmation of adequacy (95%) to verification of near-optimal behavior (97%).

5. Conclusions

Overall, the present findings show that the investigated material achieved high canal wall adaptation in this ex vivo model. These results support further investigation of the material, ideally in comparative studies including established obturation techniques and additional outcome measures that are more directly related to clinical performance. Further investigations are also suggested to compare this filling technique with the classical procedures and to control the long-time stability of the novel filling material.

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Conflicts of Interest: The authors declare no conflicts of interest.

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