



The fate of root canals obturated with Thermafil: 10-year data for patients treated in a master's program

Chiara Pirani¹ · Fausto Zamparini¹ · Ove A. Peters² · Francesco Iacono¹ · Maria Rosaria Gatto¹ · Luigi Generali³ · Maria Giovanna Gandolfi¹ · Carlo Prati¹

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Abstract

Objectives Retrospective description of the 10-year success rate of endodontic treatments with Thermafil (TF).

Materials and methods Patients treated by postgraduate students in an Endodontics Master's Program (2006–2008) were enrolled. All treated root canals were filled with TF and AH Plus. Teeth satisfying the inclusion criteria (206 teeth in 89 patients) were reexamined clinically and radiographically to estimate a 10-year survival and periapical health. Demographic and medical data were registered; collected information included pre-, intra-, and postoperative variables. Teeth were classified as “healthy” (PAI ≤ 2 in absence of signs/symptoms), “endodontically diseased” (presenting at least one of the following: PAI ≥ 3, signs/symptoms, retreated in the course of the follow-up, or extracted for endodontic reasons), or “non-endodontically diseased” (extracted for non-restorable fractures or periodontal disease). For teeth lost during the 10-year follow-up, details and reason of extraction were analyzed. Two PAI-calibrated examiners assessed outcomes blinded to preoperative status. Bivariate and multilevel analyses were performed (α level set at 0.05).

Results At 10 years, 179 (87%) teeth survived and 27 were extracted: 20 for non-endodontic reasons (excluded from success analysis) and 7 for endodontic reasons (considered “endodontically diseased”). Multilevel analysis revealed that the probability of extraction was increased by the presence of preoperative pain (odds ratio = 6.720; 95% confidence interval, 1.483–30.448) and by maxillary location (odds ratio = 2.950; 95% confidence interval, 1.043–8.347). Concerning periapical status, 159/186 teeth (85%) were assessed as “healthy.” Multilevel analysis confirmed that maxillary location (odds ratio = 3.908; 95% confidence interval, 1.370–11.146), presence of flare up (odds ratio = 9.914; 95% confidence interval, 2.388–41.163), and fracture occurrence (odds ratio = 35.412; 95% confidence interval, 3.366–372.555) decreased the odds of healing, respectively.

Conclusions After 10 years, teeth filled with Thermafil in a specialist master's program presented a survival and a periapical health comparable to cohorts where root canals were filled with other obturation techniques.

Clinical relevance Carrier-based techniques provide time savings for clinicians while satisfying clinical quality criteria for the root filling and consequently the clinical outcome.

Keywords Carrier-based system · Clinical outcome · Long term · Retrospective study · Survival

✉ Chiara Pirani
chiara.pirani4@unibo.it

¹ Endodontic Clinical Section, School of Dentistry, Department of Biomedical and Neuromotor Sciences (DIBINEM), Alma Mater Studiorum University of Bologna, Via San Vitale 59, 40125 Bologna, Italy

² Arthur A. Dugoni School of Dentistry, University of the Pacific, San Francisco, CA, USA

³ Department of Surgery, Medicine, Dentistry and Morphological Sciences with Transplant Surgery, Oncology and Regenerative Medicine Relevance, School of Dentistry, Endodontic Section, University of Modena and Reggio Emilia, Modena, Italy

Introduction

Filling the root canal system is a crucial step in a root canal treatment (RCT), aiming to prevent the passage of microorganisms and fluid along the root canal [1]. In 1978, Johnson devised a new method to thermo-plasticize gutta-percha and densely fill root canals [2]. Over time, a carrier-based obturation has become popular owing to the ease of use and the possibility to obtain consistently adequate technical results [3]. Even though more advanced versions of core carrier systems are present in the market, still, Thermafil (TF) remains as a very well-known and proven obturation technique [4–6]. Unfortunately, to date, available data on clinical outcomes of

teeth filled with the TF system stems from widely varying research designs [4–11]. Moreover, information is lacking comparing carrier-based systems to warm vertical compaction. Conversely, a number of clinical studies analyzing the outcomes of root canal treatments filled with carrier-based and lateral condensation have been published [4, 6–10].

Despite the fact that warm vertical condensation provides an excellent three-dimensional seal *in vitro* [12, 13], with an increased density of gutta-percha in the apical region [14, 15], there is no consensus in the literature concerning the superiority of warm techniques over cold lateral techniques regarding clinical outcomes.

Finally, while several clinical studies have evaluated RCT outcomes over short/medium observation times [5, 6, 10, 16–18], long-term assessments of teeth treated by specialists are rare.

Therefore, the primary aim of this 10-year retrospective study was to describe the survival and success of RCT when canals were obturated with TF; secondarily, factors influencing success and survival rate were identified.

Materials and methods

Sample size estimation

The sample size concerning the healing rate was based on results from a previous study [11]. Hypothesizing that teeth without periapical lesions healed 15% more than teeth with lesions, in the range between 90 and 75% of healing rate [19], with 80% power and 5% significance in a one-tailed test, a minimum of 77 teeth is needed in each of the two groups. Seventy-four teeth with periapical lesions were encountered in this retrospective study.

Study design

A total of 420 patients attended the Endodontic Clinical Section, Dental Clinical School of DIBINEM—University of Bologna from January 2006 to January 2008, for evaluation and treatment of endodontic pathosis. Of these, 230 subjects received RCT and were enrolled in full compliance with the Declaration of Helsinki [20]. Every subject signed an informed consent form accepting the treatment plan, to cover costs of treatment and maintenance, including participation in the follow-up program and inclusion in an eventual study. Records of treated patients were accessed from April 2016 to January 2018, and only subjects fulfilling all inclusion criteria were enrolled: local residents; age range between 18 and 70 at the time of treatment; ASA I and II; adequate oral hygiene, with Plaque Index of $\leq 20\%$ [21]; and preoperative probing depth of ≤ 5 mm. From these, only subjects that had a definitive restoration placed within 2 weeks after a root canal treatment and presented with full clinical and radiographic

data [11] with a minimum of 10-year follow-up were included in the present study.

Clinical protocol

The initial study protocol was approved by the University of Bologna, Department of Oral Sciences ethical committee. All treatments were performed by postgraduate students attending a Master's Program in Endodontics, supervised by trained tutors.

A standardized protocol was followed, involving anesthesia with mepivacaine (Carboplyina, Molteni, Scandicci, Italy) and rubber dam isolation (Hygienic Dental Dam, Coltène Whaledent, Cuyahoga Falls, USA) before creating a straight-line access. Inadequate coronal restorations and decay were removed before instrumenting root canals. Primary treatment was performed in the following manner: a step-down procedure with Gates-Glidden burs #2-3-4 (Dentsply Maillefer, Ballaigues, Switzerland) was followed by subsequent use of manual K-files (Dentsply Maillefer) or nickel-titanium instruments (ProTaper Universal, Dentsply Maillefer) following the manufacturer's instructions. Canals were irrigated by alternating 5% NaOCl (Nicolor, Ogna, Muggiò, Italy) and 10% EDTA (Tubuliclean, Ogna) solutions throughout instrumentation. Final irrigation was performed with 3 min NaOCl, 3 min EDTA, and 3 min NaOCl.

In the case of endodontic retreatment, ultrasonic tips (StartX, Dentsply Maillefer) were used to remove any existing metal and fiber posts under magnification. Pre-existing root filling material was removed with K-files and Gates-Glidden aided by solvents (Endosolv E or Endosolv R, Septodont, Saint-Maur-des-Fossés, France). If it was not possible to reach the entire working length (WL), files were used to the point of the canal that hand files had penetrated to. Working length was in all cases established with the aid of an electronic apex locator (Root ZX, Morita, Tokyo, Japan) and radiographically confirmed. TF Size verifiers were used to select TF obturators that fitted passively at WL. Obturators were disinfected in a 5% NaOCl solution for 1 min. Canal walls were then coated with a thin layer of AH Plus sealer (Dentsply-DeTrey, Konstanz, Germany) using a K-file. The selected obturator was heated in the Thermaprep Plus oven (Dentsply Maillefer) and slowly introduced into the canal until its final position. After 8–10 s, the obturator was sectioned with a Thermancut bur, keeping it in position with light pressure. A radiograph was then taken to reveal the quality of the filling. Between appointments, access cavities were temporized with Coltosol (Coltène Whaledent, Altstätten, Switzerland).

Teeth were definitively restored under rubber dam isolation within 2 weeks after root filling. After applying a self-etching dentin-bonding agent (Clearfil SE BOND, Kuraray, Osaka, Japan), flowable (Gradia Flow, GC Corporation, Tokyo, Japan) and high-filled composite resins (Gradia, GC Corporation) were applied incrementally in 1.5 mm layers

and light-cured (Elipar 3 M ESPE, St. Paul, USA). Cavities that encompassed more than one marginal ridge (both ridges, one ridge, and one or more cusps) were restored using fiber posts. Post space was prepared with #4-3-2 Gates-Glidden drills; dentin was etched with 35% phosphoric acid for 15 s, rinsed with water for 10 s, and dried with paper points. Carbon posts (Tech 2000 XOP, Isasan, Rovello Porro, Italy) were luted with Scotchbond 1/RelyX Arch (3 M ESPE). Severely compromised teeth with more than one missing marginal ridge and one or more missing cusps were restored with provisional resin crowns cemented with Temp Bond (Kerr Dental, Scafati, Italy) temporary cement. In these cases, porcelain fused to metal crowns were placed 3 to 6 months after endodontic treatment and cemented with a polycarboxylate cement (Heraeus Kulzer, Hanau, Germany).

Outcome evaluation

Data were collected from both clinical assessment and radiographic evaluation. The final outcome evaluation was performed by two previously calibrated examiners, with equivalent experience who were blinded to both preoperative data and patients’ names. Another examiner was consulted in case of disagreement. A Periapical Index (PAI) [22] score was determined for each root in the study. Multi-rooted teeth were assigned a PAI score based on the root with the highest score.

Twenty-eight variables were considered in the initial univariate model, out of which five were demographic/medical conditions (Table 1) and 23 were pre-, intra-, and postoperative factors (see Tables 2, 3 and 4). Root filling quality was assessed in terms of length as follows: adequate, short fill (>

2 mm from the radiographic apex), overfilling (sealer/gutta-percha extruded from the radiographic apex), and in terms of density of the filling material (radiographic absence/presence of voids). Post-endodontic coronal restorations were described as having crown coverage or composite restoration and post placement.

At the end-point evaluation, teeth presenting a PAI score of ≤ 2 in addition to no symptoms and no clinical signs of apical periodontitis represented the healthy group [22, 23] and were accounted as a success. The remaining teeth were split into two groups: non-endodontic disease and endodontic disease. The former group was composed of teeth extracted for non-endodontic reasons (root fractures or periodontal disease), the latter group presented either a PAI score of ≥ 3 , symptoms, clinical signs of disease or undergone further treatment before the end-point (orthograde or surgical s, hemisection, or extraction due to endodontic pathosis) (Fig. 1). The reasons for extraction were derived from the treatment records and the most recent radiograph was used to extract information concerning the treatment data.

Statistical analysis

Univariate and bivariate distributions were used, aiming to retrospectively describe survival and periapical health and their association with clinical parameters (pre-, intra-, and postoperative variables). Multilevel analysis (mixed effects model) was performed at the patient and tooth level aiming to identify clinical parameters significantly affecting survival and periapical health. Kaplan-Meier (KM) survival analysis described the cumulative survival of the teeth examined and analyzed the influence of the causes of extraction. The significance level was a priori set at $\alpha = 0.05$.

Results

A total of 206 teeth in 89 patients fulfilled all the inclusion criteria and were available for review after 10 years (Table 1). No significant effect on survival was observed in grouping teeth according to demographic, behavioral, and medical parameters of patients. Teeth of female patients presented a significantly higher healing rate than males (93 vs 79%, $p = 0.006$).

Descriptive analysis of pre-, intra-, and postoperative parameters of the study cohort and bivariate results for both survival and periapical health are reported in Tables 2, 3 and 4.

The average survival time was 8.5 ± 3.2 years (for teeth that were extracted, follow-up ended on the extraction date). The average extraction time was 5.4 ± 3.2 years after treatment. In total, 27 teeth were lost during the 10-year follow-up period: 20 for non-endodontic reasons (excluded from the analysis of periapical health) of which 15 for crown/root fracture and five

Table 1 Descriptive analysis of demographic, behavioral, and medical parameters of patients included in the study cohort

| Variables | Patients treated (N) |
|--------------------------|----------------------|
| Gender | |
| Female | 49 |
| Male | 40 |
| Age group | |
| < 30 | 7 |
| 30–50 | 27 |
| > 50 | 55 |
| Smoke | |
| Yes | 14 |
| No | 75 |
| Bisphosphonate treatment | |
| Yes | 10 |
| No | 79 |
| ASA | |
| 1 | 50 |
| ≥ 2 | 39 |
| Total | 89 |

Table 2 Descriptive analysis of preoperative parameters of the study cohort. Significant associations are set in *italics*

| Variables | Teeth treated (<i>N</i>) | <i>N</i> | Survive % <i>N</i> | <i>P</i> value | Teeth assessed (<i>Na</i>)* | <i>N</i> | Healthy % <i>Na</i> | <i>P</i> value |
|------------------------------------|----------------------------|----------|--------------------|----------------|-------------------------------|----------|---------------------|----------------|
| Preoperative parameters | | | | | | | | |
| Group of teeth | | | | 0.352 | | | | 0.108 |
| Anterior | 41 | 38 | 93% | | 39 | 32 | 82% | |
| Premolar | 59 | 52 | 88% | | 52 | 49 | 94% | |
| Molar | 106 | 89 | 84% | | 95 | 78 | 82% | |
| Number of canals | | | | 0.199 | | | | 0.181 |
| ≤ 2 | 100 | 90 | 90% | | 91 | 81 | 89% | |
| > 2 | 106 | 89 | 84% | | 95 | 78 | 82% | |
| Tooth location | | | | 0.467 | | | | 0.013 |
| Maxilla | 101 | 86 | 85% | | 90 | 71 | 79% | |
| Mandible | 105 | 93 | 89% | | 96 | 88 | 92% | |
| Previous restoration | | | | 0.333 | | | | 0.148 |
| None | 59 | 55 | 93% | | 55 | 51 | 93% | |
| Amalgam | 43 | 37 | 86% | | 39 | 31 | 80% | |
| Composite | 55 | 45 | 82% | | 48 | 38 | 79% | |
| Crown | 49 | 42 | 86% | | 44 | 39 | 89% | |
| Previous pain | | | | 0.038 | | | | 0.847 |
| Present | 131 | 109 | 83% | | 114 | 97 | 85% | |
| Absent | 75 | 70 | 93% | | 72 | 62 | 86% | |
| Initial diagnosis | | | | 0.703 | | | | 0.086 |
| Pulpitis (reversible/irreversible) | 85 | 72 | 85% | | 75 | 64 | 85% | |
| Periapical lesion | 42 | 38 | 90% | | 38 | 33 | 87% | |
| Previously treated without lesion | 21 | 19 | 90% | | 19 | 19 | 100% | |
| Previously treated with lesion | 39 | 32 | 82% | | 36 | 26 | 72% | |
| Endo-perio | 3 | 3 | 100% | | 3 | 3 | 100% | |
| Prosthetic reason (Vital) | 16 | 15 | 94% | | 15 | 14 | 93% | |
| Percussion test | | | | 0.432 | | | | 0.385 |
| Negative | 131 | 112 | 85% | | 117 | 98 | 84% | |
| Positive | 75 | 67 | 89% | | 69 | 61 | 88% | |
| Pulp vitality | | | | 0.393 | | | | 0.887 |
| Yes | 92 | 82 | 89% | | 85 | 73 | 86% | |
| No | 114 | 97 | 85% | | 101 | 86 | 85% | |
| Type of treatment | | | | 0.606 | | | | 0.846 |
| First treatment | 146 | 128 | 88% | | 131 | 114 | 87% | |
| Retreatment | 60 | 51 | 85% | | 55 | 45 | 82% | |
| PAI initial | | | | 0.764 | | | | 0.186 |
| PAI ≤ 2 | 132 | 114 | 86% | | 118 | 104 | 88% | |
| PAI ≥ 3 | 74 | 65 | 88% | | 68 | 55 | 81% | |
| Occlusal contact | | | | 0.120 | | | | 0.152 |
| Yes | 204 | 178 | 87% | | 184 | 158 | 86% | |
| No | 2 | 1 | 50% | | 2 | 1 | 50% | |
| Total | 206 | 179 | 87% | | 186 | 159 | 85% | |

Significant associations are highlighted with Bold typeface

Na* Total of 186 teeth include seven teeth extracted for endodontic reasons, assessed as ‘endodontically diseased’

for periodontal disease. Seven teeth were extracted for endodontic reasons (considered “endodontically diseased”).

Figure 2 shows a Kaplan-Meier survival distribution for the examined teeth; two peak times of extraction were observed:

Table 3 Descriptive analysis of intra-operative parameters of the study cohort. Significant associations are set in italics

| Variables | Teeth treated (N) | N | Survived % N | P value | Teeth assessed (Na)* | N | Healthy % Na | P value |
|----------------------------|-------------------|-----|--------------|--------------|----------------------|-----|--------------|--------------|
| Intra-operative parameters | | | | | | | | |
| N of appointments | | | | 0.070 | | | | 0.904 |
| Single | 52 | 49 | 94% | | 50 | 43 | 86% | |
| Multiple | 154 | 130 | 84% | | 136 | 116 | 85% | |
| Instrument type | | | | 0.108 | | | | 0.845 |
| Hand files | 168 | 149 | 89% | | 154 | 132 | 86% | |
| Ni-Ti | 38 | 30 | 79% | | 32 | 27 | 84% | |
| Curvature radius | | | | 0.228 | | | | 0.611 |
| Straight | 98 | 89 | 91% | | 90 | 79 | 88% | |
| Moderate | 98 | 81 | 83% | | 87 | 73 | 84% | |
| Severe | 10 | 9 | 90% | | 9 | 7 | 78% | |
| Root filling quality | | | | 0.450 | | | | 0.202 |
| Underfilled | 50 | 43 | 86% | | 44 | 34 | 77% | |
| Adequate | 105 | 94 | 90% | | 96 | 85 | 89% | |
| Overfilled | 51 | 42 | 82% | | 46 | 40 | 87% | |
| Voids | | | | 0.019 | | | | 0.012 |
| Yes | 31 | 31 | 100% | | 31 | 22 | 71% | |
| No | 175 | 148 | 85% | | 155 | 137 | 88% | |
| Localization voids | | | | / | | | | 0.408 |
| Coronal | 6 | 6 | 100% | | 6 | 5 | 83% | |
| Middle third | 19 | 19 | 100% | | 19 | 14 | 74% | |
| Apical | 6 | 6 | 100% | | 6 | 3 | 50% | |
| Apical diameter | | | | 0.194 | | | | 0.055 |
| < 35 | 130 | 116 | 89% | | 120 | 107 | 89% | |
| 35 | 76 | 63 | 83% | | 66 | 52 | 79% | |
| Instrument separation | | | | 0.581 | | | | 0.558 |
| Yes | 2 | 2 | 100% | | 2 | 2 | 100% | |
| No | 204 | 177 | 87% | | 184 | 157 | 85% | |
| Flare-up | | | | 0.411 | | | | 0.011 |
| Yes | 15 | 12 | 80% | | 13 | 8 | 62% | |
| No | 191 | 167 | 87% | | 173 | 151 | 87% | |
| Total | 206 | 179 | 87% | | 186 | 159 | 85% | |

Significant associations are highlighted with Bold typeface

Na* Total of 186 teeth include seven teeth extracted for endodontic reasons, assessed as ‘endodontically diseased’

within 46 months (early extractions) and over 120 months (delayed extractions). Out of the seven extracted teeth for endodontic disease, four were lost within the early peak-time period (early extractions). Concerning the extraction cause, a chi-square analysis did not identify significant differences ($p = 0.657$) between early and delayed extractions. The estimated mean survival time was shorter for extractions due to endodontic disease (45 months mean life, 95% CI 11–80 months) in comparison with fracture (74 months mean life, 95% CI 57–92 months) and periodontal disease (63 months, 95% CI 36–91 months) (Fig. 3). The lower boundary of the 95% confidence interval was 11 months for a diagnosis of endodontic pathosis, 57 for fracture, and 36 for periodontal disease.

The presence of preoperative pain, the presence of voids in the root filling material, and the occurrence of intra/postoperative complications had a significant effect on survival in a bivariate analysis (Tables. 2, 3 and 4).

Multilevel analysis revealed that the presence of preoperative pain increases the probability of extraction by more than six times in comparison with asymptomatic cases (odds ratio = 6.720; 95% confidence interval, 1.483–30.448); similarly, a maxillary location increases the probability of extraction by three times compared to a mandibular location (odds ratio = 2.950; 95% confidence interval, 1.043–8.347) (Table 5). The risk ratio was equal to 95% for maxilla/mandible and 89% for previous pain (presence/absence) denoting how survival was 5% less in the maxilla

Table 4 Descriptive analysis of postoperative parameters of the study cohort. Significant associations are set in italics

| Variables | Teeth treated (<i>N</i>) | <i>N</i> | Survived % <i>N</i> | <i>P</i> value | Teeth assessed (Na)* | <i>N</i> | Healthy % Na | <i>P</i> value |
|--------------------------|----------------------------|----------|---------------------|----------------|----------------------|----------|--------------|----------------|
| Postoperative parameters | | | | | | | | |
| Final restoration | | | | 0.220 | | | | 0.949 |
| Direct | 67 | 61 | 91% | | 63 | 54 | 86% | |
| Crown | 139 | 118 | 85% | | 123 | 105 | 85% | |
| Post placement | | | | 0.903 | | | | 0.749 |
| Yes | 59 | 51 | 86% | | 53 | 46 | 87% | |
| No | 147 | 128 | 87% | | 133 | 113 | 85% | |
| Complication | | | | 0.0001 | | | | 0.0001 |
| Perforation | 6 | 6 | 100% | | 6 | 6 | 100% | |
| Root fracture | 14 | 2 | 14% | | 5 | 1 | 20% | |
| Absent | 186 | 171 | 92% | | 175 | 152 | 87% | |
| Total | 206 | 179 | 87% | | 186 | 159 | 85% | |

Significant associations are highlighted with Bold typeface

Na* Total of 186 teeth include seven teeth extracted for endodontic reasons, assessed as ‘endodontically diseased’

and 11% less in the presence of previous pain. Deeping the type of pain, stratified analysis according to the type of pain (pulpal/periapical origin), demonstrated no significant association neither with survival ($p = 0.386$) nor with healing ($p = 0.071$ for PAI fin and $p = 0.189$ for PAI fin without extractions).

Out of the 186 surviving teeth, 159 (85%) were classified as healthy (endodontic success) at the 10-year follow-up. Tooth location, the presence of voids in the filling material, the occurrence of flare-up, and non-restorable fractures were significantly associated with a reduced success rate in the bivariate analysis (Tables. 2, 3 and 4). A multilevel analysis confirmed the following clinical variables that increase the odds of developing endodontic disease: maxillary location (odds ratio = 3.908; 95% confidence interval: 1.370–11.146), a flare-up presence (odds ratio = 9.914; 95% confidence interval, 2.388–41.163) and fracture occurrence (odds ratio = 35.412; 95% confidence interval, 3.366–372.555). Clinical relevance of tooth location, specifically, a maxillary location, reduces the healing of 14% respect mandible location (risk ratio = 0.86) as the presence of flare-up (risk ratio = 0.71) reduces the healing of 29% in comparison with its absence and fracture occurrence (risk ratio = 0.23) reduces the healing of 73% in comparison with the absence of such complications (Table 6).

Nonsignificant value using Hosmer-Lemeshow Goodness of fit test were obtained both for survival ($p = 0.674$) and healing ($p = 0.731$) indicating that the models predict the true estimate of the population.

Discussion

This cohort study described 10-year clinical outcomes of teeth after root canal treatment filled with Thermafil and evaluated,

by means of retrospective analysis, whether the success rate was comparable with the currently considered gold-standard technique in the literature. Retrospective investigations have been frequently used as the basis for further prospective and cohort studies since they allow the evaluation of a large number of variables that can affect the RCT outcome [24].

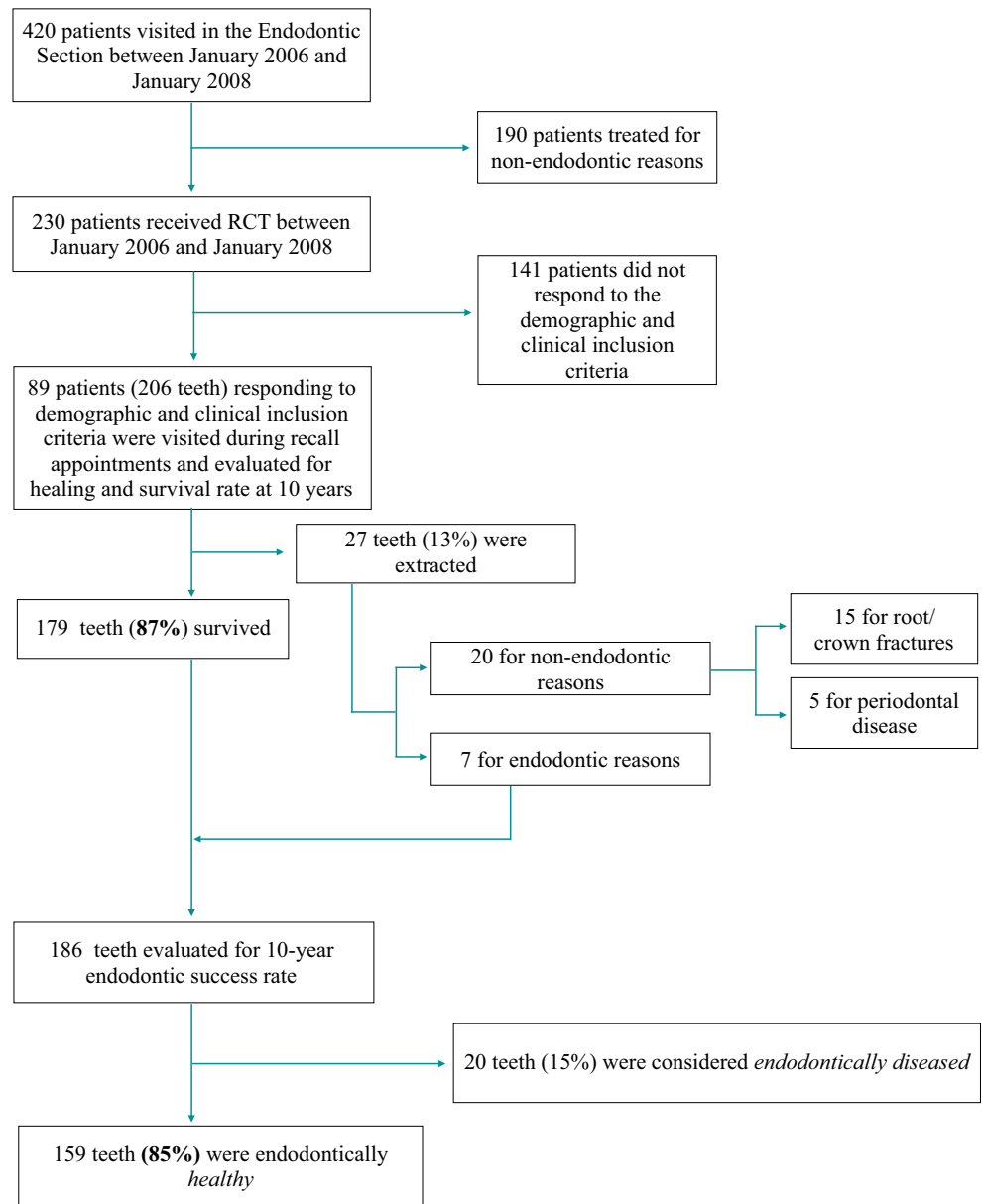
The major advantage of this kind of study is related to the availability of data, resulting in an easier and faster collection of information. Pre-, intra-, and postoperative conditions can be easily analyzed to explain the distribution of the disease during an extended observation time.

A strength of this observational investigation is the high degree of standardization of the clinical protocol of RCT and conservative restorations, performed during a postgraduate training course by operators with likely similar skills and degrees of experience. Different from most clinical studies, in order to statistically analyze the present data, a multilevel model was used to assume teeth as correlated within patients, and not as an independent entity [25, 26].

Clinical long-term follow-up studies on RCT performed with modern endodontic techniques are rare and often have an observation time of 1 or 2 years [27] while, to the best of our knowledge, this is the first clinical study aiming to evaluate the outcome of TF at 10 years. Only limited in vivo studies [4–6, 8, 10, 11] are available concerning the clinical use of TF. Moreover, the majority of these clinical studies evaluated a short/medium observation time [6–10].

In one phase of the Toronto Study project [16], the obturation technique emerged as a significant factor affecting the outcome, with a higher success rate for vertical compaction compared to lateral compaction. Another clinical study [28] suggested a significantly higher success rate for vertical compaction when compared to lateral condensation.

Fig. 1 Flowchart of the study

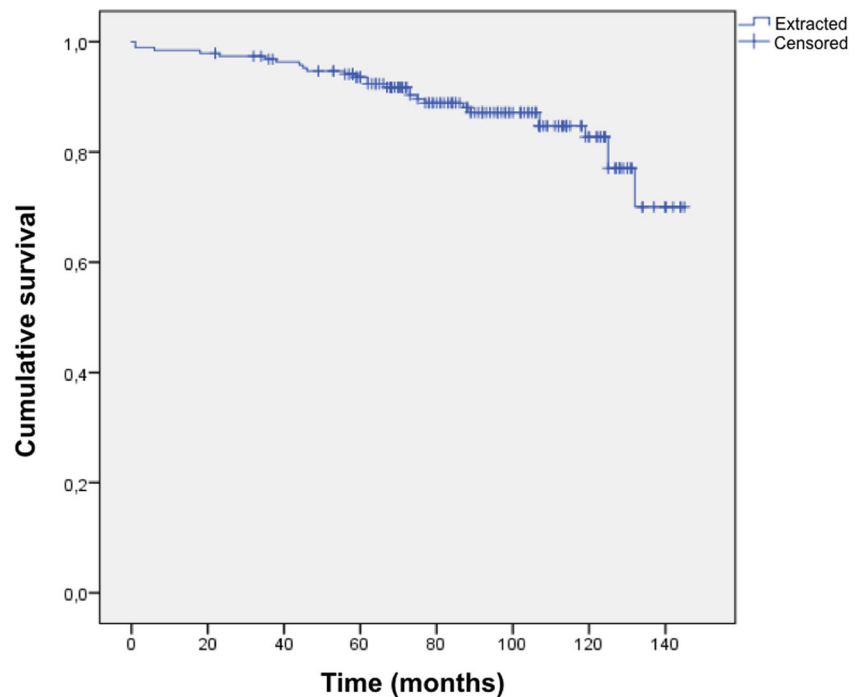


Survival

The current view in endodontic literature is to include tooth survival as an outcome descriptor. The high survival rate reported in the present dataset can be explained considering that carrier-based systems do not require load forces due to compaction of the gutta-percha and for this reason, there are no wedging effects [29]. In the present clinical study, the reported 87% long-term survival rate for teeth treated by postgraduate students is well within in the range reported by other studies with a similar follow-up period. The reported proportion surviving 10 years following treatment ranged from 75 [30] to 89% [31], with an estimated pooled proportion based on a meta-analysis of 86.7% [32].

Dammaschke et al. [33] showed that RCT conducted by students had a survival rate of 85.1% after 10 years. Mindiola et al. [34], in a retrospective epidemiological study at 10 years, reported a survival rate greater than 95%. Lumley et al. [19], in an observation time of up to 10 years, estimated a survival rate of 74% with no re-intervention. Fonzar et al. [35] reported that 93% of the root canal treated teeth survived 10-years. Burry et al. [36], in a retrospective study performed on patients with dental insurance, reported a survival rate for molars at the 10-year interval of 86%, with a significant relationship between providers and tooth type. Landys Borén [37], in a clinical study, reported that 81.5% of the teeth treated in a specialist clinic in endodontics survived at least 10 years. Moreover, they also found that only 7% of extracted teeth were related to endodontic pathosis.

Fig. 2 Kaplan-Meier survival function curve of 206 teeth treated with TF root fillings. A total of 27 teeth (13%) were extracted during the study period



Consistent with these results, we found that tooth loss is most frequently due to non-endodontic reasons, for reasons such as non-restorable fractures [30, 38]. In fact, 55% of extracted teeth (15/27) were lost for fractures, similarly to data reported previously [37, 39]. Most of the extracted teeth were lost either within 4 years after completion of root canal

treatment or over the 10-year period of the present study, highlighting the existence of two critical periods: early and delayed tooth loss. Moreover, from a Kaplan-Meier survival analysis, it emerged that more than half of extractions for the endodontic disease were performed within 46 months after the root canal treatment. This demonstrated a non-homogeneous

Fig. 3 Kaplan-Meier survival function curve of 27 teeth extracted during the study period, according to the cause loss: endodontic disease (seven teeth), non-restorable fracture (15 teeth), and periodontal disease five teeth

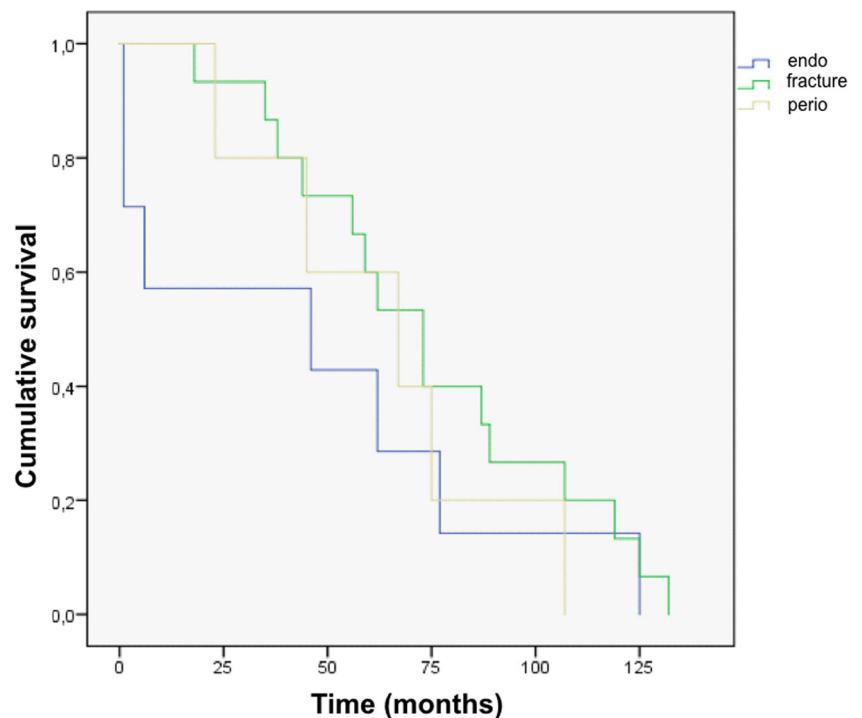


Table 5 Multilevel analysis exploring factors related to outcome “survival”

| Parameter | Odds ratio | <i>P</i> | 95% CI |
|-------------------------------|------------|----------|--------------|
| Intercept | 0.177 | 0.536 | 0.001–43.962 |
| Maxilla (reference: mandible) | 2.950 | 0.042 | 1.043–8.347 |
| Previous pain (reference: no) | 6.720 | 0.014 | 1.483–30.448 |

distribution of tooth loss for endodontic reasons and confirmed that extractions due to endodontic disease occur early [40, 41] even if their frequency is lower compared to other causes.

In particular, we can speculate that in order to increase the survival rate, the endodontic time margin is before 46 months. This time frame is the higher limit of the interval of the accidental events responsible for the extractions. A similar number of extractions were noticed after 120 months, the 10-year period of the present study. However, this phenomenon can be related to the physiologic aging of the tooth structure, inducing changes in tooth microstructure and chemical composition [42].

The presence of preoperative pain was found to be related to a reduction of tooth survival at 10 years; this may be explained considering that patients who have experienced preoperative pain are more inclined towards tooth extraction when symptoms reappear. This observation is consistent with a previous report [43] stating that teeth with preoperative symptomatology have a higher chance of being extracted after treatment. However, no differences were noticed concerning the cause of pain: pulpal or periapical.

Among examined preoperative conditions, pulp vitality was found to have a crucial impact on tooth survival. Teeth with preoperative non-vital pulp were associated with a lower survival chance at 10 years, probably due to a greater tooth destruction and consequently presenting larger restorations and structural weakness. Similar conclusions have been reported by Stoll et al. [31].

In contrast to other studies, present findings suggested a lower survival rate for maxillary teeth when compared to mandibular. In particular, upper premolars were found to have a reduced survival.

Table 6 Multilevel analysis exploring factors related to outcome “periapical health”

| Parameter | Odds ratio | <i>P</i> | 95% CI |
|------------------------------------|------------|----------|---------------|
| Intercept | 0.055 | 0.001 | 0.022–0.141 |
| Maxilla (reference: mandible) | 3.908 | 0.011 | 1.370–11.146 |
| Flare-up (reference: no) | 9.914 | 0.002 | 2.388–41.163 |
| Perforation | 0.232 | 0.524 | 0.003–21.191 |
| Root fracture (reference: absence) | 35.412 | 0.003 | 3.366–372.555 |

It was interesting to note that the variable “instrument type” (manual instrumentation versus different nickel-titanium rotary instruments) did not produce a statistically significant difference on neither success nor survival [44]. Similarly, the final restoration type (presence/absence of crown placement) and post placement did not have a significant effect on either outcome descriptor.

Success

Overall, apical health at the end of the observation period was high, with 85%. However, root canal treatments were provided in a University dental school setting and for this reason, present findings should be generalized with caution. Root canal-treated patients at dental schools may have higher success rates and better quality of root fillings [36].

A recent clinical retrospective study [45] described a similar cohort and reported a corresponding long-term survival rate but differed in the success rate (79% compared to 85% obtained with TF in the present study). However, the clinical protocols in these two studies varied concerning providers (trained specialists vs postgraduates students).

Reportedly, the Therafil method simplifies the skill of gutta-percha insertion/compaction [3] providing a long-term sealing ability when used in association with AH Plus cement [46], enabling operators with a different level of experience to produce consistently adequate results. This significant difference between two obturation methods could suggest that less-experienced operators can provide effective long-term endodontic outcomes when a carrier-based obturation technique is used.

Reference to root filling voids was not substantial in our evaluation because of the high number of false positives reported by Liang et al. [47] when a two-dimensional radiographic model was used to assess the density of root fillings.

In this study, the success rate was negatively influenced by three factors, one of which was the occurrence of inter-appointment flare-ups that occurred in 15 of the analyzed cases. This finding is consistent with Ng et al. [43] who, at 2–4 years in 750 teeth treated by endodontic postgraduate students, reported a success rate of 80%, with a less favorable prognosis in the presence of a flare-up. A possible explanation is that flare-ups may be caused by extrusion of contaminated material during canal preparation, which could stimulate a foreign body reaction, an extra-radicular infection, or can express an incomplete chemo-mechanical debridement, leading to treatment failure [43], thus resulting in a higher probability of tooth extraction.

In the present retrospective study, several prognostic factors were associated with a reduced periapical healing, such as the occurrence of complications. Complications were divided between perforations and non-restorable fractures: however, the low number of teeth with complications (20 teeth) needs to be very careful in the interpretation of the results. Perforations

were found not to significantly affect the long-term success whereas non-restorable crown/root fractures were found to have an important negative effect on the healing rate. It should be emphasized that fracture occurrence, even in the long-term analysis, is confirmed as the most important factor-inducing treatment failure [39, 48]. Our results suggested a lower success rate for maxillary teeth than for mandibular, and this could be explained by the complex anatomy of the upper teeth [49].

Conclusions

The significant clinical impact of this paper lies in the high success rate (85%) of RCT obturated with TF/AH Plus when assessed in the long term. The use of carrier-based techniques entails timesaving for clinicians while satisfying the quality of the root filling and consequently the clinical outcome as demonstrated in this study, intended as periapical healing and survival.

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Compliance with ethical standards

Conflict of interest Chiara Pirani declares that she has no conflict of interest. Fausto Zamparini declares that he has no conflict of interest. Ove Peters serves as a consultant to Dentsply Sirona. Francesco Iacono declares that he has no conflict of interest. Maria Rosaria Gatto declares that she has no conflict of interest. Luigi Generali declares that he has no conflict of interest. Maria Giovanna Gandolfi declares that she has no conflict of interest. Carlo Prati declares that he has no conflict of interest.

Ethical approval All procedures performed in the present study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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