



# Predicting the outcome of initial non-surgical endodontic procedures by periapical status and quality of root canal filling: a cohort study

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## Abstract

To assess the previous periapical status and the quality of root canal filling as predictors of the outcome in initial non-surgical endodontic procedures. A retrospective cohort study was designed in which the presence of a previous periapical lesion was determined radiographically. The quality of the root filling was evaluated in terms of homogeneity, taper, and apical extension. The response variable was dichotomized to success and failure. Bivariate analyzes and a mixed generalized linear model interpreted the association between the explanatory variables and the outcome of the initial non-surgical endodontic procedures. A total of 349 roots were evaluated, and a failure rate of 13.18% was established. Poor filling quality was determined in 8.3% of the roots. As a main result, the presence of a preoperative periapical lesion did not determine a significant risk to the failure of the initial treatment. Unlike, a poor quality of the obturation determined association with an unfavorable outcome like this: (1) homogeneity (OR 2.32;  $p=0.0181$ ); (2) taper (OR 5.8;  $p=0.0$ ); and, (3) extension (OR 3.41;  $p=0.0$ ). Therefore, a significant association between inadequate quality of the root filling and failure of the primary non-surgical endodontic procedures was found. Short length of filling was highly associated with failure. The presence of previous periapical lesion was not found to be a significant predictor for treatment outcomes.

**Keywords** Dental radiograph · Non-surgical endodontics · Periapical lesion · Prognosis · Root canal obturation

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## Introduction

In 2007, the American Dental Association (ADA) published the results of a survey regarding dental services rendered from 2005 to 2006. Such registry reported an average of 15 million non-surgical endodontic procedures were performed during that year [1]. In Colombia, South America the latest *Estudio Nacional de Salud Oral* (National Study on Oral Health) established a prevalence of cavitation caries with coronal destruction (ICDAS 4–6) of 65% [2], which in part explains why a full range of endodontic approaches are needed, especially when caries involves pulp tissue. This fact presents the initial non-surgical endodontic treatment, is an essential option for tooth retention.

By definition, an endodontic procedure prevents or restores the health of periapical tissues [3]. Clinical studies showed that an initial non-surgical endodontic procedures (EP), has mean success rates ranging of 73.5% to 92.3% [4–9], despite the above, rates of up to 38.4% of the persistence of periapical disease, are published [10–12]. A failures

of initial non-surgical EP will require a second intervention, therefore, this could cause accumulated potential damage to the root canal system [10].

In regard to, it is important to recognize and to monitor the clinical factors related to failure to obtain optimal and predictable results during the primary treatment [10]. In this way, Ricucci et al. concluded that the probability of success of the initial non-surgical EP decreases in about 9% when a preoperative periapical lesion is present [13]. Likewise, Tsesis et al. noted that a poor-quality root canal filling decreases positive outcomes in around 21% [14].

On the other hand, if the dynamic nature of periapical disease is taken into account [15], cross-sectional studies have not been able to identify a direct association between these factors [16]; therefore, a longitudinal evaluation could identify the predictors of common failure and examine the relationship between treatment failures with clinical factors, followed in time. According to the literature analyzed; previous periapical pathology and quality of the obturation, are the most common [17–19]. Within this context, the following null hypothesis was posed: There is no difference between the likeliness that the initial non-surgical initial non-surgical EP fails in the presence or absence of previous periapical lesion and/or poor-quality initial non-surgical EP. Thus,  $H_0: P_1 = P_2$ . Consequently, to develop such theoretical statement, the present investigation aimed at determining, through a cohort study, the association between a preoperative periapical lesion (periapical status), quality of the filling, and the outcomes of initial non-surgical EP.

## Material and methods

### Type of study

An observational, analytical, non-concurrent cohort study was designed and implemented. The unit of study was “Root”. The cohort included all subjects treated at *Universidad Nacional de Colombia, Facultad de Odontología (FOUN)*, Postgraduate Program in Endodontics in Bogotá, Colombia. The protocol was approved by our Institutional Review Board/Ethics Committee (Code # CIE-096-16) according to the Declaration of Helsinki on medical protocol and ethics. Subjects were identified with a number to guarantee privacy and confidentiality throughout the study subsequent to their signing the informed consent.

### Eligibility criteria

Inclusion criteria:

- Participants, classified under the criteria ASA I and ASA II, who provided permanent teeth with initial Non-surgi-

cal endodontic procedures, performed under the clinical protocols established in the endodontics program clinics of the Universidad Nacional of Colombia, which at the time of post-treatment control they will have a definitive, stable and functional permanent restoration, that appeared intact radiographically and clinically [20]. A radiographic image and the previous diagnosis recorded in the clinical history confirmed the presence or absence of periapical pathology that determines the exposure factor for the analyzed cohort. A postoperative clinical and radiographic data that allowed measurement of the variables under study and the final outcomes in terms of success or failure during follow-up periods greater than one year.

Exclusion criteria:

- Participants at the follow-up appointment were pregnant or in orthodontic treatment.
- Root-treated teeth with obvious ledges, perforations, fractured instruments, or any other type of intraoperative errors identified in the apical third of the root [21].

### Sample size

The exposure factor “Poor-Quality Root Canal Filing” was included to calculate the sample size. This established a 0.5 proportion for failed roots having “Poor-Quality Root Canal Filing” [20]. Likewise, it was established that the proportion of failed roots without the exposure factor was 0.24 [20]. To include the largest number of subjects, according to the calculation of the sample size, a non-probabilistic consecutive selection of subjects who met the eligibility criteria was established.

### Variables

The analyzed explanatory variables included; demographics, age, gender, and dental features, such as tooth type and location. Periapical status prior to initial was also identified and included [22]. Quality of the root canal filling was studied in terms of adequate endodontic filling: homogeneity, no voids present [16]; taper as continuous narrowing [16]; and the apical limit of the filling as determined by the distance between the final extent of the filling material and the radiographic apex, Flush fill: 0–2 mm. The Inadequate endodontic filling includes: root fillings end more than > 2 mm as a short fill; and the Overfill: < 0 mm [23], inadequate density, unfilled canals, and/or poor condensation [20].

The dependent variable, which was analyzed clinically [24] and radiographically [25], was divided by two researchers (CD and CG) into success or failure. “Success” was defined as an absence of symptomatology

[24] and radiographic evidence of the restitution of the space of the periodontal ligament at the apical third. An increase of such space without exceeding twice its width was deemed acceptable [25]. The presence of symptomatology and/or evidence of apical radiolucency was considered a "Failure" [24, 25]. The reading of the radiographic images was supported by a previous concordance-consistency study, where the highest degree of the agreement established a Kappa value of 0.80 (inter observer) and 1 (intra observer). The aforementioned values settled a "good" concordance and an "almost perfect" consistency [26].

The radiographic images at the follow-up appointment were taken using a SIRONA equipment Heliodent 580921003350 Series 50602 (Dentsply Sirona, Salzburg, Austria) operated at 60-63Kv, 8 mA, and 0.25–0.32 s of exposure, for a radiation dose of 0.033 mSv, according to the type and location of the tooth. A paralleling technique was implemented using the XCP ring (Dentsply Rinn, Elgin, IL). All radiographic observations were performed by two researchers (CD and CG) using the digital equipment Radio Visio Graphy® 5100® (RVG) (Carestream Health Inc., Rochester, NY) and the Dental Imaging Carestream software (Carestream Health Inc., Rochester, NY). Observations were recorded in tables and stored in digital files using Microsoft Excel 2007/12.0 software (Microsoft Corporation, Redmond, WA).

### Statistical analysis

For continuous variables, a univariate analysis determined ranges, percentiles, averages, and standard deviation. For discrete variables, a count established the proportion and the percentage frequency (*n*). To verify if there were significant differences between the distribution of factors and "success" or "failure", a Kruskal–Wallis analysis was set at 95% confidence level. A bivariate analysis, with the chi-square independence test, estimated the possibility of association between each factor and the treatment outcome at 95%.

Given the fact that regularly a patient contributes with more than one root, a generalized linear mixed model was designed [27, 28]. This model established the correlation between roots or teeth of the same individual in addition to the randomized effect in each patient, thus estimating more complex associations between outcomes of interest (success or failure) and explanatory variables as a whole. A cluster analysis (Multivariate Analysis) classified the quality of the root canal filling in five groups, according to homogeneity, taper, and apical limit of the filling (Fig. 1).

Finally, the adjustment of the model assumed a binomial distribution according to the response variable, which is summarized as follows: Endodontic Treatment Outcome = Gender + Age + Cluster + Patient Random Effect + Error. Statistical analyses were performed using the statistical software R version 3.3.3 (GNOME Foundation TM, Orinda, CA). Multivariate General Linear Models (MLGM) were adjusted using the lme4 package (R Core Team, Vienna, Austria) [28, 29].

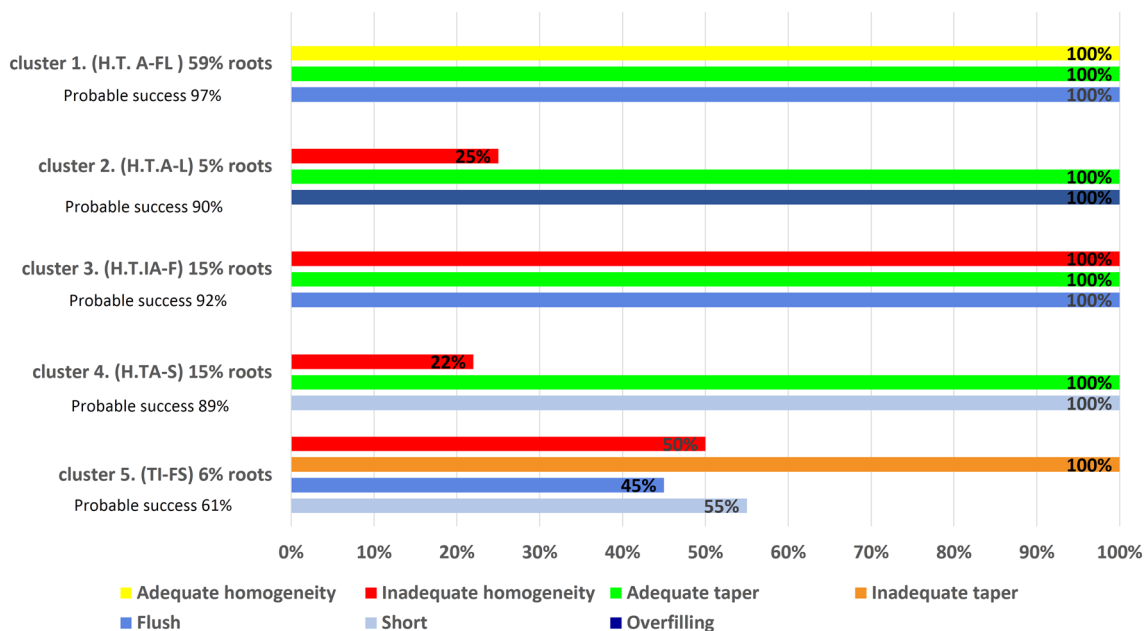


Fig. 1 Cluster analysis

**Table 1** Number of teeth per subject

Number of teeth per subject	Número of subject (%)	Total number of teeth contributed
1	106 (69.2)	106
2	23 (15.0)	46
3	14 (9.1)	42
4	6 (3.9)	24
6	2 (1.3)	12
7	2 (1.3)	14
Total	153	244

## Results

For the exposure factor, the calculation of the sample size with a confidence level of 95% and a power of 90% established 164 teeth with correction of continuity and a 1:1 distribution and 82 units of study for each group of exposure [30]. The study population consisted of 228 patients ( $56.26 \pm 12.27$  years; 61.31% were women and 38.68% were men), from which a total of 153 individuals who met the eligibility criteria were obtained. Such subjects provided 244 teeth for a total of 349 roots with initial non-surgical EP. Some patients contributed with more than one tooth (Table 1) and a 13.18% failure rate was determined. Regarding the follow-up period for the included teeth, the univariate analysis established an average of  $5.3 \pm 4.29$  years, also determined that most of the roots did not show apical lesion and adequate quality of root canal filling (Table 2).

The Kruskal–Wallis test determined with a 95% confidence that there was sufficient statistical evidence ( $p = 0.913$  and  $p = 0.596$ ) to state that the distribution of the “follow-up” and “age” continuous variables was equitable between “success” and “failure” and it would not generate statistical differences regarding treatment outcomes for a later adjustment of the model. The bivariate analysis, Chi square estimated the possible significant association through the odds ratio (OR) value between the variables and failure of the initial non-surgical EP. In general, for the “Type of Tooth” variable, premolars were associated to failure (OR 2.17,  $p = 0.01523$ ). “Inadequate-Quality Root Canal Filling” and anterior teeth or molars were highly associated with failure (OR 6.5,  $p = 0$ ). According to the conditions that determined the quality of the initial non-surgical EP, short fillings were more related to failure (OR 3.41;  $p = 0.0$ ) when compared to flush or overfillings. Similarly, inadequate taper homogeneity posed a significant risk for failure (OR 2.32;  $p = 0.0181$  and OR 5.8;  $p = 0.0$ , respectively) (Fig. 2). The presence of a preoperative periapical lesion was not associated with the initial non-surgical EP failure (OR 1.02;  $p = 1.0$ ).

**Table 2** Univariate analysis

	Success <i>n</i> (%)	Failure <i>n</i> (%)	Total <i>n</i> (%)
Total	303 (86.8)	46 (13.2)	349 (100)
Time (continuous data)			$5.3 \pm 4.29$
<i>Sex</i>			
Male	110 (81.5)	25 (18.5)	135 (38.7)
Female	192 (89.7)	22 (10.3)	214 (61.3)
<i>Location of the tooth</i>			
Mandibular	111 (85.4)	19 (14.6)	130 (37.2)
Maxillary	191 (87.2)	28 (12.8)	219 (62.8)
<i>Tooth type</i>			
Incisor	70 (88.6)	9 (11.4)	79 (22.6)
Premolar	86 (94.5)	5 (5.5)	91 (26.1)
Molar	146 (81.6)	33 (18.4)	179 (51.3)
<i>Root type</i>			
Only	123 (91.1)	12 (8.9)	135 (38.7)
Buccal	22 (88.0)	3 (12.0)	25 (7.2)
Distal	69 (82.1)	15 (17.9)	84 (24.1)
Palatine	53 (84.1)	10 (15.9)	63 (18.0)
Mesial	35 (83.3)	7 (16.7)	42 (12.0)
<i>Periapical status</i>			
Lesion	78 (86.7)	12 (13.3)	90 (25.8)
No lesion	224 (86.5)	35 (13.5)	259 (74.2)
<i>Quality of root canal filling</i>			
Adequate	286 (89.4)	34 (10.6)	320 (91.7)
Inadequate	16 (55.2)	13 (44.8)	29 (8.3)
<i>Homogeneity</i>			
Adequate	242 (89.3)	29 (10.7)	271 (77.7)
Inadequate	60 (76.9)	18 (23.1)	78 (22.3)
<i>Taper</i>			
Adequate	291 (88.4)	38 (11.6)	329 (94.3)
Inadequate	11 (55.0)	9 (45.0)	20 (5.7)
<i>Apical limit of the filling</i>			
Short	42 (64.6)	23 (35.4)	65 (18.6)
Flush	247 (92.2)	21 (7.8)	268 (76.8)
Overfilling	13 (81.2)	3 (18.8)	16 (4.6)

### Data distribution

Regarding the variable “Quality of the Root Canal Filling”, the MLGM adjusted to age and sex and the proposed categories for the cluster analysis were grouped as follows:

- Cluster 1 (H-TA-FLF) or reference category: Adequate homogeneity and taper with a flush filling in 100% of the cases, which established a probable success rate of 97%.
- Cluster 2 (H-TA-OVF): adequate homogeneity in 75% of cases, adequate taper, and overfilling in 100% of cases. This category was not associated with failure (OR 0.22; IC 95% 0.01–4.69;  $p = 0.33$ ) and determined a probable success rate of 90%.

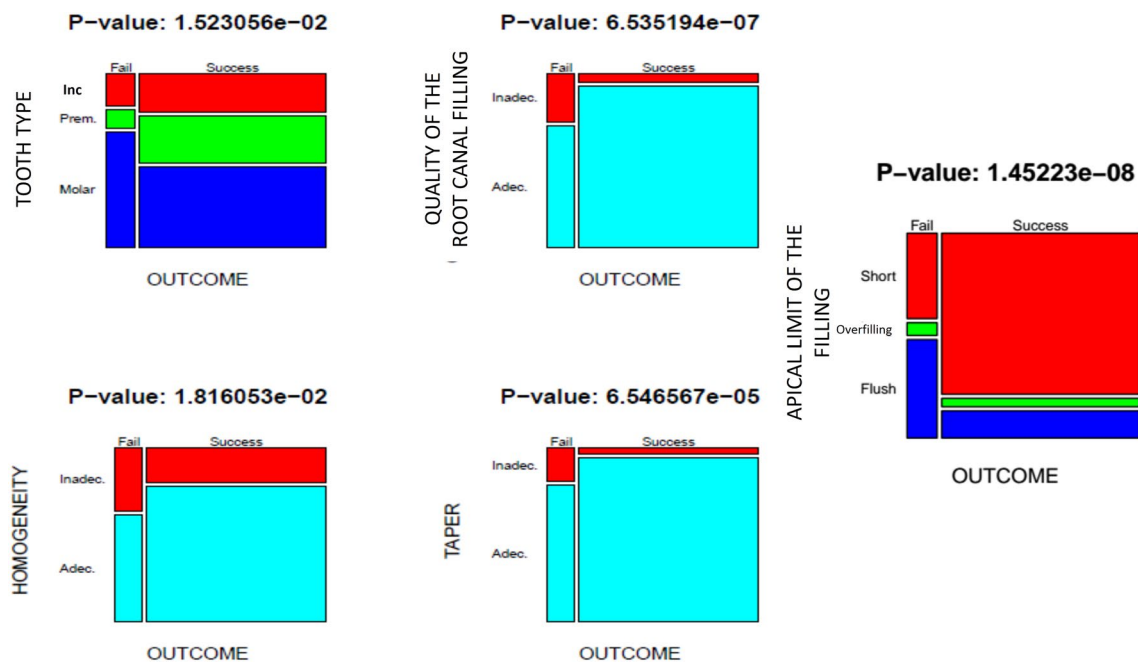


Fig. 2 Bivariate analysis. Association between variables and outcomes

- Cluster 3 (HI-TA-FLF): inadequate homogeneity, adequate taper, and flush filling in 100% of cases. This category was not related to failure (OR 0.28; IC 95% 0.05–1.60;  $p=0.15$ ) and determined a probable success rate of 92%.
- Cluster 4 (H-TA-SF): adequate homogeneity in 88% of cases, adequate taper, and short filling in all included cases. This category was highly related to failure (OR 5; IC 95% 0.05–0.86;  $p=0.031$ ) and determined a probable success rate of 89%.
- Cluster 5 (HI-TI-SF): inadequate homogeneity in 50% of cases, inadequate taper in all cases, and a short filling in 55% of cases. This category was highly related to failure (OR 25; IC 95% 0.002–0.583;  $p=0.018$ ) and a probable success rate of 61%. (Fig. 1).

The statistical significance in regards to the incidence of the "Quality of the Root Canal Filling" factor over the outcome of the initial non-surgical EP allowed the rejection of the null hypothesis (Table 3).

### Discussion

The objective of the present research was to determine the association between the quality of root canal filling and preoperative periapical lesion (periapical status), and the outcomes of the initial non-surgical EP. To accomplish this purpose, a retrospective cohort study was designed. This cohort included 153 patients who contributed to 349 dental

Table 3 MLGM: quality of endodontic filling and its effect on the outcomes

	OR	95% CI	p value
Cluster 1 (H.T.A-FL)	–	Reference	–
Cluster 2 (H.T.A-L)	0.22	0.01–4.69	0.33
Cluster 3 (H.T.IA-F)	0.28	0.05–1.60	0.15
Cluster 4 (H.TA-S)	5	0.05–0.86	0.031*
Cluster 5 (TI-FS)	25	0.002–0.583	0.018*

\* $p \leq 0.05$

roots. In general, we found that inadequate-quality root canal fillings represented a risk factor for the initial non-surgical EP failure. The mean follow-up period was 5.3 years, with a failure rate of 13.18%, which is in agreement with other cohort studies that report failure rates ranging from 7.7 to 11% [5, 6, 11]. Of note, certain reports, which have estimated the prevalence of post-treatment periapical disease between 40 and 49%, may arise as confounders for cross-sectional studies [12, 20].

Root was used as a unit of measure, although this practice has been considered inappropriate and has a tendency to over-estimate success rates [31]. Ng et al. [4], did not support this contention. The authors included 50% of molar teeth and the proportions of successful treatments based on the tooth (77%) or root (81%) as a unit of the measure were also similar [4]. It was, therefore, decided to use root as a unit of measure. An additional justification was that some of the root-level independent variables such as the presence

of the periapical lesion, and quality of root canal filling, become better evaluated on the observation unit, "root".

A root filling is not a single event since it involves inherent characteristics such as homogeneity, taper, and apical extension of the filling material [6, 16,]. In this regard, Zhong et al., Santos et al., Song et al. have confirmed an association between the quality of the filling and the outcomes of initial non-surgical EP [5, 6, 20]. In the present investigation, the construction of clusters allowed to simulate the result of the treatment in the presence or absence of the different aspects of the root filling.

Thus, a short root filling played an important role in the failure of initial non-surgical EP in 11% of the cases, even when adequate homogeneity and taper were present. In addition, if homogeneity and taper are not adequate and a percentage of the population presented short fillings, the probability of failure increases up to 39%.

The abovementioned results are in agreement with those of Ricucci et al., who reported up to 66.7% of failure when short root fillings were present (OR 0.75; 95% CI 0.66–0.86,  $p=0.001$ ) [13]. Santos et al. determined that the presence of previous periapical lesion, as a risk factor for initial non-surgical EP failure, is significant only when an alteration of the taper is documented [6]. Therefore, the length of the filling, taper, and homogeneity should not be overlooked. Zhong et al. identified potential interactions between the homogeneity of the filling and the presence of previous periapical pathologies (OR 33.2; 95% CI 12.0–92.0,  $p=0.0001$ ) [5]. The authors performed the analysis starting from 35.5% of fillings with adequate quality, a percentage that could be considered low, albeit it is in agreement with available data [20].

Since the aim of the present research was to observe the outcomes of initial non-surgical EP without any confounding factors, roots with intraoperative accidents were excluded. Thus, 59% of the roots had a "perfect" filling in terms of homogeneity, taper, and apical limit of the filling [6] and a satisfactory root filling (2 out of 3 categories) in 91.69% of studied roots. Therefore, we did not find a significant association between the presence of previous periapical lesion and initial non-surgical EP failure, which might suggest how adequate preparation and filling technique are able to control the bacterial factor.

This latter idea reinforces the recommendation that better working conditions promote successful procedures and that the presence of preoperative infection is considered a potential cause of failure. With controlled root canal procedures, failure due to infection may be less likely to occur. Statements like "eradicating bacteria into the root canal is more difficult than preventing invasion to the apical third", can be counteracted by similar results [5].

Authors such as Fernández et al. [11] (OR 9.09 IC 95% 3.25–25.44,  $p=0.000$ ), Moreno et al. [12] (OR 1.43 IC

95% 1.01–2.04,  $p=0.05$ ), and Song et al. [21] (OR 2.13; IC 95% 1.621–2.815,  $p=0.001$ ) associated the quality of the restoration (a postoperative factor) with the success of the initial non-surgical EP. On the other hand, Craveiro et al. and Costa et al. determined that the quality of the root filling has a greater influence on the outcomes when compared to the quality of the restoration [32, 33]. Controlling the confounding factors, the present investigation included teeth with definitive restoration, an additional reason to associate treatment failure with the quality of root filling. Similarly, adequate operative procedures control periapical disease, thus surgical intervention, which in turn may alter the treated root dentin in a greater proportion [34].

## Conclusions

Within the limitations of the present investigation and due to the retrospective nature of the sample, a significant association between inadequate quality of the root filling and failure of initial non-surgical EP was found. Inadequate homogeneity and taper decrease the probability of success, however, it is the short length of the filling ( $>2$  mm) being the factor that showed the greatest association with failure. The presence of a previous periapical lesion did not show a significant prediction for treatment outcome.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee (Universidad Nacional de Colombia Code # CIE-096-16) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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