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Comparison of occurrence and intensity of postoperative pain in endodontic treatment with BioRoot ™ RCS: a randomized clinical

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Comparison of Occurrence and Intensity of Postoperative Pain in Endodontic Treatment with BioRoot ™ RCS: A Randomized Clinical

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1. ABSTRACT

OBJECTIVE

The aim of this clinical trial was to assess the effect of resin-based (AH Plus) and bioceramic sealer (BioRoot ™ RCS) on the occurrence and intensity of postoperative after a single visit endodontic treatment.

MATERIALS AND METHODS

Single or biradicular teeth that needed endodontic treatment were randomly assigned one of two groups according to the obturation material: AH Plus (Dentsply-Maillefer) or BioRoot ™ RCS (Septodont). Treatments were performed in a single visit by the students of Master of Endodontics. Demographic and clinical details were noted by the operator and the patient was asked to rate the incidence and intensity of preoperative and postoperative pain on a questionnaire rating scale before anesthesia, immediately after completion of treatment, and at 8, 24, and 48 hours after the treatment. Mann-Whitney U tests were used to determine if there was a significant difference between the variables with a significance level of $P < 0.05$.

RESULTS

A total of 75 patients were treated. Thirty-four in AH Plus group and 41 in BioRoot ™ RCS group. The means and standard deviation of the prevalence of post-op pain were 1.27 ± 1.77 immediate postoperatively, 1.24 ± 1.92 at 8h, 0.60 ± 1.65 at 24h, 0.34 ± 1.34 at 48h intervals postoperatively. There was no statistically significant difference in postoperative pain regarding the sealer used ($P > .05$). Only the periapical diagnosis affected the postoperative pain immediately after completion of the treatment interval ($P < .05$). Patients with preoperative pain with the diagnosis of symptomatic apical periodontitis significantly had more incidence of postoperative pain immediately after the treatment. ($P > .05$)

CONCLUSION

Both sealers performed similarly with regard to the occurrence of postoperative pain and its intensity. Patients who had preoperative pain with the diagnosis of symptomatic apical periodontitis were associated with significantly higher incidence of postoperative pain.

2. INTRODUCTION

Throughout the history of endodontics, many techniques and root canal filling materials have been developed. Thermoplastic techniques have been proposed to obtain a more suitable apical seal (1).

The main objective of the root canal filling is the seal with the peri-radicular tissues thus, preventing any exchange or input/output of bacteria. It has been shown that the vast majority of endodontic failures are related to incomplete or inadequate sealing (2). In a radiographic study, Ingle et al. (3) found that 58% of endodontic failures were due to an incomplete seal.

Therefore, a three-dimensional filling of the pulp canal space should be attempted in which there are no empty spaces with materials that can ensure a long-standing and durable seal (4). Obturation is a reflection of the cleaning and shaping which is performed before. It is evaluated in terms of length, shape, density, and coronal seal. However, obtaining an impermeable seal may not be feasible because of the tubular porous dentine structure and the irregularities of the root canal system (5).

To date, the gutta-percha continues to be the dominant core material used in endodontics. The basic composition of the cones is 20% gutta-percha and up to 80% zinc oxide with smaller amounts of color additives (6). Core materials like gutta-percha do not produce a bond with the walls of the root canal. Therefore, sealants are required to compensate and seal the space between the wall of dentin and the shutter material. This interface is the weakest part of the obturation (7). To date, no sealant meets all criteria of an ideal sealer based on those proposed by Grossman (7).

Endodontic sealants or cements should be biocompatible and well tolerated by periradicular tissues (8). However, all sealants exhibit some degree of cytotoxicity when freshly mixed, although this is significantly reduced after setting (9). Therefore, cement with a shorter setting time would be more appropriate. Much of the sealants are resorbable when exposed to fluids and periradicular tissues (10). Healing and tissue repair, in general, do not appear to be affected by most sealers (11,12). However, the degradation products of sealers may have an adverse effect on the proliferative capacity of the cellular response (8), so it should not be extruded voluntarily towards the perirradicular tissues (9).

Resin sealers provide adequate adhesion and do not contain eugenol. One of the most widely used and successful sealers is the AH Plus sealer (Dentsply Maillefer, Tulsa, OK). It is a modification of the AH-26, which was a slow setting epoxy resin that released

formaldehyde during setting (13). Maintaining comparable sealing capabilities, the AH Plus is an epoxy phenol resin-based sealer that releases less formaldehyde (14) with a working time of about 4 hours and a setting time of about 8 hours.

A new category of root canal sealers based on bioceramics, also known as hydraulic cement, has recently gained popularity. These sealers are based on bioceramic materials like mineral trioxide aggregate (MTA) and Biodentine, which have been previously used for various vital pulp therapy treatments (15,16). These premixed bioceramic sealers have a faster setting time and smaller particle size, overcoming the limitation of the conventional bioceramic materials like MTA (7). Apart from having the properties of conventional bioceramic cement, these sealers, rather than shrinking, expand up to 0.2% in the root canal space creating and adding to the hermetic seal (17). They also possess high alkalinity, bond to the dentin, high flowability, and ability to set in moisture conditions (7). This type of cement also exhibits antimicrobial properties against Enterococcus faecalis, a known resistant bacteria to disinfection procedures (18).

BioRoot ™ RCS (Septodont, Saint Maur Des Fosses, Franc) is composed of zirconium oxide, calcium silicate, calcium phosphate monobasic, calcium hydroxide, and various fillers and thickeners. The material is available in powder and liquid form with a calibrated spoon. As a hydrophilic sealant, it uses the sealer moisture to complete the setting reaction and does not shrink in contact with the environment. It is biocompatible and has antimicrobial properties during the setting reaction. The manufacturer recommends to place the sealer in the coronal and middle thirds of the root canal and then introduce the gutta-percha master cone to obturate the canal.

Various experimental methods have been used to evaluate the microfiltration after root canal filling, including; radioisotopes (19), dyes (20), bacteria (21), protein (22), glucose (23), bubble or fluid filter (24). There have employed a variety of *in vitro* techniques and conditions, often producing contradictory results. All materials and techniques result in some degree of apical filtration (25). However, after endodontic treatment clinical success rates are high despite the various conditions, materials, and filling techniques (26,27).

By conventional radiographic techniques, it is not possible to assess the quality of the seal established during root canal sealing. Although inadequate sealing and filtration are correlated, the radiographic assessment of the obturation does not correlate well with filtration (28), i.e., adequate sealing observed radiographically, cannot be associated with an adequate seal (29).

Endodontic sealers placed in the root canals may also interact with the periodontal ligament through apical foramen, lateral canals and can affect the periodontal healing process.

The obturation process in the root canal treatment procedure may induce postoperative pain, which has previously been associated with different types of sealers (30,31). The intensity of this postoperative pain depends on different factors, including the composition of the sealer (32).

Bioceramic sealers are proposed to enhance the outcome of endodontic treatment. It has been suggested that they promote the differentiation of odontoblasts by releasing biologically active substances (33). Compared to the AH Plus sealer (Dentsply Maillefer, Ballaigues, Switzerland), calcium silicate hydraulic cements are demonstrated to be less cytotoxic to the periodontal tissues (34). Within the authors' limited knowledge, only one study published comparing the postoperative pain regarding bioceramic sealers and found no difference between AH Plus and Total Fill (FKG Dentaire SA, La Chaux-de-Fonds, Switzerland) (35). To date, no studies have compared the use of BioRoot ™ RCS bioceramic sealer on the occurrence and intensity of postoperative pain after endodontic treatment.

The Visual Analog Scale Rating is a simple way to measure the intensity of pain, be it preoperative or postoperative pain. Its simplicity, reliability, and validity, as well as its ratio scale properties, make the VAS the optimal tool for describing pain severity or intensity (36). The results are reproducible and change in the records reflects a real difference in the patient's opinion (37).

The results of the Toronto study (38) evaluating the 4 – 6 years success and failure rates of endodontic treatment reported success rates of 87% with a suitable radiographic length and 77% in cases of inadequate length. If it was performed using vertical compaction, a 90% success rate was reported, and 80% with lateral condensation. The success rate of a root canal treatment varies according to the study though results range between 80-100% (39).

In two recent systematic reviews, four variables that significantly affect the prognosis of endodontic treatment were established; the presence of preoperative PA, density, and apical extension of the sealing material and quality of the restoration (40,41). However, it seems that the previous periapical pathology is one of the determinants of the success of root canal treatment. Therefore, a proper seal appears to be mandatory. To date, endodontic sealers were only used to compensate for the lack of adhesion between the core material and the dentin wall in the root canals. Thus, a minimal amount of sealer is assumed to seal interface material - dentin wall. However, with these new materials, it seems to maintain a proper seal with larger thicknesses of the sealer compound and less technical and sensitive techniques such as a cold and single cone technique.

To date, there are no studies reporting results of prognosis in root canal treatments and retreatments filled with BioRoot ™ RCS. Therefore, we believe it is necessary to evaluate *in vivo* results in terms of prognosis and postoperative pain of these emerging materials, which have to report promising results *in vitro.*

3. OBJECTIVES

1. Evaluate postoperative pain occurrence in single visit endodontic treatment performed with a bioceramic sealer (BioRoot ™ RCS) compared to resin-based AH Plus sealer, immediately after the treatment, 8h, 24h, and 48h intervals postoperatively.
2. Evaluate the variables that can be related with the occurrence of postoperative pain.

4. WORK HYPOTHESIS

4.1 Null hypothesis (H_0)

1. There will be no statistically significant differences in occurrence of postoperative pain in root canals filled with BioRoot ™ RCS compared to gutta-percha and AH Plus sealer.
2. There will be no statistically significant differences in occurrence of postoperative pain in root canal treatment according to each of the variables evaluated.

4.2 Alternative hypothesis (H_1)

1. There will be statistically significant differences in occurrence of postoperative pain in root canals filled with BioRoot ™ RCS compared to gutta-percha and AH Plus sealer.
2. There will be statistically significant differences in occurrence of postoperative pain in root canal treatment according to each of the variables evaluated.

5. MATERIAL AND METHODS

This study was a randomized controlled trial of patients who consulted the University Dental Clinic at the *Universitat Internacional de Catalunya* attended by the Endodontic master's students. This study was presented and approved by the Ethics Committee of the *Universitat Internacional de Catalunya* (CEIC).

5.1 Sample selection

The necessary statistical sample size between the following variables is calculated: type of sealant material used (BioRoot ™ RCS, AH Plus) and qualitative values categorization systems PAI and CBCTPAI, establishing an increase in the scale and value of success/failure (≤ +1;> 1). Assuming an alpha risk of 0.05, a beta risk of 0.05 and a power of 95% sample, the required sample obtained by the group resulted in 42. Given an estimate upwards of 20% of drop-outs in recalls, and with a 10% added by the statistical group to reduce the possible potential loss due to inadequacy of certain radiographic images for analysis, the final sample size is 54.6 (55 cases per group).

5.2 Inclusion criteria

- Patients that demonstrate an understanding of the study and willingness to participate as evidenced by signing the voluntary informed consent and received a signed and dated copy of the informed consent form.
- Older than 18 years old.
- Understands and is willing to comply with all study procedures and restrictions.
- Not the presence of clinically significant and relevant abnormalities of clinical history or oral examination.
- Eligible for single-visit endodontic treatment

5.3 Exclusion criteria

- General: Patients with systemic diseases, diabetes, immunocompromised and pregnant women, or any clinically significant or relevant oral abnormalities.
- Specific: root resorption, root fractures, the impossibility of restoration, and retreatment cases are not the treatment of choice.

5.4 Procedure for the Root canal treatment

Treatments were performed following the protocol established by the Department of Restorative Dentistry and Endodontics at the University Dental Clinic of the University. Procedures performed were always under absolute isolation and instrumentation systems and different devices accepted by literature the Department of Restorative Endodontics.

Periapical radiographs were taken with a radiovisiograph (RVG) Kodak 6200 (Kodak, Carestream Health, Rochester, NY, USA) using a paralleling technique, using positioners of type XCP-DS sensor positioning system (Dentsply Rinn, Elgin, IL, USA) with an X-ray beam (Heliodent DS, Sirona Dental Systems, LLC, Charlotte, NC, USA) operating at 60 kV and 7 mA with an exposure time of 0.12 s. Two pictures, one orthoradial and other angulated were made.

The cases were divided into two groups randomly by using six-sided dice, three of which will have a number one (group 1) and three with a number two (Group 2).

- Group 1: sealing with BioRoot ™ RCS was performed.
- Group 2: sealing with AH Plus ™ was performed.

After obtaining the criteria for successful root canal preparation (34), the procedure of obturation was performed in the same visit. The root canal filling in Group 1 was performed with BioRoot ™ RCS (Septodont, Lancaster, USA) sealer with a single master cone technique (Septodont, Lancaster, USA). In Group 2 the root canal filling was performed with a thermoplastic technique of vertical condensation of warm gutta-percha with resin cement (AH-Plus, Dentsply Maillefer, Tulsa, USA) and gutta-percha alpha Taper (Autofit, Analitic, SybronEndo, Orange, CA). Subsequently removing the excess with an Endo Z (Dentsply Maillefer, Tulsa, USA) bur and a flowable composite was placed on the floor of the pulp chamber (Tetric, IvoclarVivadent AG, SchaanFurstentum, Liechtenstein). A final periapical radiograph with the above parameters for initial radiographs was performed.

5.5 Postoperative Pain Evaluation

To evaluate the incidence and severity of pain two questionnaires of data collection were developed.

1. The first was completed by the master student who performed the treatment and supervised by the teacher responsible for the Master of Endodontics. In

this questionnaire, detailed patients data including demographics, age, sex, and clinical data like tooth number, vitality, diagnosis, type of pain, probing depths, what type of sealer used, etc. were filled.

2. The second questionnaire was completed by the patient. This had the VAS scale, where the patient marked the intensity of pain he had just before anesthesia and the pain immediately after, at 8, 24, and 48 hours after completing the treatment. This VAS scale was made by the Visual Analog Scale Rating by Husskison which is a 100 mm straight line where one end represented zero pain and the other end maximum pain. The patient had to vertically mark corresponding to their perception of pain. Patients returned the completed questionnaire in the next visit where the reconstruction of the tooth was performed. To quantify the pain, the VAS scale was measured in millimeters until the mark made by the patient and it received a numerical rating between 0 to 10.

5.6 Statistic analysis

Statgraphics Centurion XV (StatPoint Technologies, Inc., Warrenton, VA, USA) for statistical analysis software will be used. The Kolmogorov-Smirnov test of normality was performed to check the normality of the sample. The majority of the samples were not normally distributed therefore the Mann-Whitney U tests were used to determine if there was a significant difference between variables with a significance level of $P < 0.05$.

6. RESULTS

A total of 75 patients participated in the study. Of the total included patients, 38 (50.66%) were men, and 37 (49.33%) were females. The most common age range was above 50 years with 37 patients (49.33%), followed by the age group of 31-50 years, where 31 (41.33%) patients were present. Maxillary arch had fifty treated teeth (66.66%), where the most common type was the maxillary anterior teeth (*n*=31, 41.33%) followed by maxillary biradicular teeth (*n*=19, 25.33%). An equal number of samples were present in teeth with symptomatic and asymptomatic apical periodontitis as their periapical diagnosis (*n*=28, 30.66%), while 28 teeth (37.33%) had normal apical tissues. Only one tooth (1.33%) was diagnosed as having a chronic apical abscess (Table 1).

Table 1
Frequency of Different Variables in Relation to Treatment Mode and their Distribution (P Value)

Variables		Total *n* = 75	AH Plus *n* = 34	BCS *n* = 41	P Value
Type Of Tooth	Maxillary Anteriors	31 (41.33%)	14 (41.17%)	17 (41.4%)	0.6332
	Maxillary Biradicular	19 (25.33%)	7 (20.5%)	12 (29.2%)	
	Mandibular Anteriors	11 (14.66%)	5 (14.7%)	6 (14.6%)	
	Mandibular Biradicular	14 (18.66%)	8 (23.5%)	6 (14.6%)	
Sex	Male	38 (50.66%)	15 (39.47%)	23 (60.52%)	0.3788
	Female	37 (49.33%)	19 (51.35%)	18 (48.64%)	
Arch	Maxillary	50 (66.66%)	21 (61.76%)	29 (70.73%)	0.528
	Mandibular	25 (33.33%)	13 (38.24%)	12 (29.26%)	
Age	18-30	7 (9.33%)	4 (11.76%)	3 (7.3%)	0.880
	31-50	31 (41.33%)	13 (38.24%)	18 (43.90%)	
	50	37 (49.33%)	17 (50%)	20 (48.70%)	
Pulp Diagnosis	Vital	30 (40%)	17 (56.66%)	13 (43.33%)	0.08
	Non-Vital	45 (60%)	17 (37.77%)	28 (62.22%)	
Periapical Diagnosis	Normal	28 (37.33%)	13 (46.42%)	15 (53.57%)	0.459
	Symptomatic	23 (30.66%)	7 (30.43%)	16 (69.56%)	
	Asymptomatic	23 (30.66%)	13 (56.52%)	10 (43.47%)	
	C. Abscess	1 (1.33%)	1 (100%)	0	

* Significant difference when $p<0.05$
BCS = Bioceramic Sealer

A total of 37 (49.33%) experiences postoperative pain of varying intensity. Only one patient reported severe pain postoperatively. There was no significant difference related to postoperative pain with any variable studied except with periapical diagnosis. Though it was only significant at immediate post-op, while it was not significant at 8, 24, or 48 hours postoperatively (Table 2).

Table 2
Median and Interquartile Range (IQR) Values of Pre and Postoperative Pain Acc. to Different Clinical Variables Studied

Median and IQR of Pain at different intervals	Sex		Tooth Type		Arch		Pulp Diagnosis		Periapical Diagnosis		Type of Sealer	
	Male n = 38	Female n = 37	Front n = 42	Bi-cuspids n = 33	Upper n = 50	Lower n = 25	Vital n = 30	Non-Vital n = 45	Sympt-omatic n = 23	Asymp-tomatic n = 23	AH Plus n = 34	BCS n = 41
Immediate Pre Op (Median ± IQR)	0 ± 2.7	1 ± 2.3	0 ± 2.87	1.2 ± 2.25	0 ± 2.9	2.1 ± 4	1.35 ± 2.97	0 ± 3.2	2 ± 4	0 ± 1.42	0 ± 1.95	1.5 ± 3.7
P Value (p < .05)	0.764		0.180		0.352		0.561		0.032*		0.375*	
Immediate Post Op (Median ± IQR)	0 ± 2.25	0 ± 2.4	0 ± 2.45	0 ± 2.45	0 ± 2.65	0 ± 1.55	0 ± 2.32	0 ± 2.5	2.3 ± 2.8	0 ± 0.35	0 ± 1.95	0 ± 2.65
P Value (p < .05)	0.928		0.818		1.835		0.936		0.028*		0.298	
After 8 Hrs (Median ± IQR)	0 ± 1.85	0 ± 2	0 ± 2	0 ± 2.1	0 ± 2.15	0 ± 1.7	0 ± 1.67	0 ± 2.2	2 ± 2.6	0 ± 1.55	0 ± 1.87	0 ± 2.45
P Value (p < .05)	0.711		0.711		0.575		0.435		0.076		0.200	
After 24 Hrs (Median ± IQR)	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 1.65	0 ± 0	0 ± 0	0 ± 0
P Value (p < .05)	0.872		0.696		0.896		0.568		0.368		0.936	
After 48 Hrs (Median ± IQR)	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0	0 ± 0
P Value (p < .05)	0.976		0.857		0.810		0.362		0.412		0.496	

* Significant difference when $p<0.05$
BCS = Bioceramic Sealer

Table 3 shows the frequency and percentage of pre and postoperative pain values according to the different groups. Preoperative pain was present in 46% (35/75) of the patients, and 44% (33/75) and 42% (32/75) remained symptomatic for the next 8 and 24 hours, respectively (Table 4). Also, a higher intensity of preoperative pain was associated with a higher incidence of postoperative pain (P < .05). While there was a significant difference between the preoperative pain and the type of sealer used, there was no significant difference at any time point interval in the postoperative pain (Table 2). The significant difference in preoperative pain was probably due to the number of symptomatic patients in the Bioceramic group (n = 16) compared to AH Plus group (n = 7). Also, there was no significant difference in the postoperative pain according to the type of sealer compared with symptomatic or asymptomatic periapical diagnosis (Table 5)

Table 3
Frequency and Percentage of pre- and Postoperative pain according to the different treatment groups

Level of preoperative Pain n (%)		Level of Postoperative pain n (%)		At Immediate Post Op	At 8 hrs	At 24 Hrs	At 48 Hrs
No Pain 38 (50.6%)	AH Plus 21 (61.76%)	No Pain	AH Plus	16 (76.19%)	18 (85.71%)	19 (90.47%)	20 (95.23%)
			BCS	15 (88.23%)	13 (76.47%)	15 (88.23%)	15 (88.23)
		Slight Pain	AH Plus	5 (23.80%)	3 (14.28%)	1 (4.76%)	1 (4.76%)
			BCS	1 (5.88%)	2 (11.76%)	1 (5.88%)	1 (5.88%)
		Moderate Pain	AH Plus	1 (4.76%)	1 (4.76%)	1 (4.76%)	0
			BCS	0	1 (5.88%)	0	0
		Severe Pain	AH Plus	0	0	0	0
			BCS	0	1 (5.88%)	1 (5.88%)	1 (5.88%)
	BCS 17 (41.46%)						
Slight Pain 26 (34.66%)	AH Plus 11 (32.35%)	No Pain	AH Plus	3 (27.27%)	2 (18.18%)	7 (63.63%)	10 (90.90%)
			BCS	5 (33.33%)	6 (40%)	14 (93.33%)	15 (100%)
		Slight Pain	AH Plus	7 (63.63%)	8 (81.81%)	3 (27.27%)	1 (9%)
			BCS	9 (60%)	8 (53.33%)	1 (6.66%)	0
		Moderate Pain	AH Plus	1 (9%)	1 (9%)	1 (9%)	0
			BCS	1 (6.66%)	1 (6.66%)	0	0
	BCS 15 (36.58%)						
Moderate Pain 10 (13.33%)	AH Plus 2 (5.88%)	No Pain	AH Plus	1 (50%)	2 (100%)	2 (100%)	2 (100%)
			BCS	2 (25%)	2 (25%)	5 (62.5%)	5 (62.5%)
		Slight Pain	AH Plus	1 (50%)	0	0	0
			BCS	3 (37.5%)	3 (37.5%)	1 (12.5%)	2 (25%)
		Moderate Pain	AH Plus	0	0	0	0
			BCS	3 (37.5%)	3 (37.5%)	2 (25%)	1 (12.5%)
	BCS 8 (19.51%)						
Severe Pain 1 (1.33%)	AH Plus 0	Slight Pain	AH Plus	0	0	0	0
			BCS	0	0	0	1 (100%)
		Moderate Pain	AH Plus	0	0	0	0
			BCS	0	0	1 (100%)	0
		Severe Pain	AH Plus	0	0	0	0
	BCS 1 (2.43%)		BCS	1 (100%)	1 (100%)	0	0

* Significant difference when $p<0.05$
BCS = Bioceramic Sealer

Table 4
The Distribution of Patients with Respect to the Pain Scores and Tested Materials at 4 Time Points (Immediate Post Op, after 8 Hours, 24 Hours and 48 Hours)

Post Op Pain AH Plus (*n*=34) BCS (*n*=41)	**No Pain**	**Slight Pain**	**Moderate Pain**	**Severe Pain**
Pre Op *n* (%)	AH Plus = 23 (67.64%) BCS = 17 (41.46%)	AH Plus = 7 (20.5%) BCS = 9 (21.95%)	AH Plus = 4 (11.76%) BCS = 13 (31.7%)	AH Plus = 0 BCS = 2 (4.87%)
Immediate Post Op *n* (%)	AH Plus = 20 (58.82%) BCS = 22 (52.65%)	AH Plus = 13 (38.23%) BCS = 13 (31.70%)	AH Plus = 1 (2.94%) BCS = 5 (12.19%)	AH Plus = 0 BCS = 1 (2.43%)
Post Op 8 Hrs *n* (%)	AH Plus = 22 (64.70%) BCS = 21 (51.21%)	AH Plus = 11 (32.35%) BCS = 13 (31.70%)	AH Plus = 1 (2.94%) BCS = 5 (12.19%)	AH Plus = 0 BCS = 2 (4.87%)
Post Op 24 Hrs *n* (%)	AH Plus = 28 (82.35%) BCS = 34 (82.92%)	AH Plus = 4 (11.76%) BCS = 3 (7.31%)	AH Plus = 2 (5.88%) BCS = 3 (7.31%)	AH Plus = 0 BCS = 1 (2.43%)
Post Op 48 Hrs *n* (%)	AH Plus = 32 (94.11%) BCS = 35 (85.11%)	AH Plus = 2 (5.88%) BCS = 4 (9.75%)	AH Plus = 0 BCS = 1 (2.43%)	AH Plus = 0 BCS = 1 (2.43%)

BCS = Bioceramic Sealer

Table 5
Median and Interquartile Range (IQR) Values of Pre and Postoperative Pain Acc. To Periapical diagnosis in each group

Median and IQR of Pain at different intervals (Median ± IQR)	Symptomatic Apical Periodontitis		Asymptomatic Apical Periodontitis	
	AH Plus *n* = 7	BCS *n* = 16	AH Plus *n* = 13	BCS *n* = 10
Immediate Pre-Op	0 ± 3.55	2.25 ± 4.3	0 ± 1.8	0 ± 0.97
P Value (p < .05)	0.271		0.667	
Immediate Post-Op	0.75 ± 2.25	2.5 ± 3	0 ± 1.4	0 ± 0
P Value (p < .05)	0.342		0.7278	
After 8 Hrs	0 ± 2.2	2 ± 2.5	0 ± 2	0 ± 1.37
P Value (p < .05)	0.258		0.872	
After 24 Hrs	0 ± 0.37	0 ± 1.85	0 ± 0	0 ± 0.97
P Value (p < .05)	0.689		0.638	
After 48 Hrs	0 ± 0	0 ± 0.35	0 ± 0	0 ± 0
P Value (p < .05)	0.645		0.928	

* Significant difference when $p<0.05$
BCS = Bioceramic Sealer

7. DISCUSSION

The study aimed to assess the effects of resin-based (AH Plus) and Bioceramic sealer (BioRoot ™ RCS) on the occurrence and intensity of postoperative pain after a single visit endodontic treatment. As per the results, there was no statistically significant difference found in the existence or intensity of postoperative pain in the teeth obturated using two different sealers tested (P<.05), the null hypothesis *(H_0)* was therefore accepted.

Postoperative pain of slight or mild intensity is common and justifiable, even after an acceptable standard of treatment performed (42). Activation of local inflammatory responses in the periapical tissues is likely the reason for postoperative pain and has been associated with the release of inflammatory mediators (43). These mediators, such as reactive oxygen species (ROS), are released when a foreign body or cytotoxic substances, such as endodontic sealers, may come in contact with the periapical tissues (44). In vitro studies have shown that even the gold standard, AH Plus endodontic sealer, appears to be slightly toxic to the periapical tissues. While its slight extrusion didn't affect the treatment outcome, but its bulk extrusion has been associated with clinical symptoms and delayed periapical healing (34,45,46). Recent calcium silicate-based sealers have demonstrated to be less cytotoxic and genotoxic than regular endodontic sealers and rather have been associated with bioactivity (47–49). The bioceramic sealer, BioRoot ™ RCS have shown not to affect the DNA double-strand derived from the periodontal ligament cells, while other sealers were found even to break it (49). However, these novel bioceramic silicate cements have limited data concerning their efficacy, especially in their potency to produce postoperative endodontic pain.

Different scales and methods have been used to assess postoperative pain. The Visual Analog Scale by Huskinsson (50) has been used in this study as it is fairly simple to use and understand for both the operator and the patient. It is represented by a straight line of 5, 10, or 20 cm long, where one end represents no pain while the other end represents maximum pain. Its reproducibility and ease of use have been successfully demonstrated in many other studies (51–53). A more mobile-technology based eVAS scale, available on the Interactive Clinics app (Bit Genoma Digital Solutions SL), has demonstrated to be highly reliable and consistent with the paper version of VAS (54). As the students of the Master of Endodontics also perform the restoration of the teeth at the university, the patients are bound to return and therefore a physical form was preferred while designing the study. Also, the availability of such apps was unknown to the authors at the time.

Performing a single-visit root canal treatment or completing the treatment in multiple visits has been a debate for a long time in the field of endodontics. Several studies have been published concluding that root canal treatment performed in a single visit has been associated with better patient cooperation, less chair time, better management of schedule, cost-effective, and most importantly, there was no difference in the outcome of the treatment (55–57). Some studies found fewer flare-ups, although not significant, in single visit root canal treatment (56,58). A higher incidence of postoperative pain was also found when the treatment was performed by graduate students (59). Therefore, all the treatments carried out in our study were performed in a single visit by the students of Master of Endodontics at the Universitat Internacional de Catalunya. This contributed to fewer confounding factors in the current study and a more reliable data and result outcome. Pain after endodontic treatment has also been associated more with molars than with premolars or anterior teeth (51). Therefore, only premolars and front teeth were included. This was also done to facilitate time, obturation, and reduce errors such as over instrumentation (60).

A significant difference was found in our study in the occurrence of postoperative pain regarding periapical diagnosis ($P < .05$). This was because, in our study, patients with symptomatic apical periodontitis experienced more pre- and postoperative pain than patients with asymptomatic apical periodontitis. Though both symptomatic and asymptomatic apical periodontitis cases had the same sample size (n=23), there were more symptomatic cases in the bioceramic sealer group, which might have affected the results. The results were in accordance with Segura-Egea et al. (61), where they concluded that symptomatic patients had more pain, although they did not consider preoperative pain as a variable. Many studies like Ali et al. (51), Garcia et al. (53), and Sadaf et al. (62) also concluded that patients with preoperative pain, are more likely to experience postoperative pain and therefore are also in accordance with the current study.

Pulpal status (Vital/nonvital) had no statistically significant difference in the current study. This is in agreement with other similar studies (63,64) but not with the study performed by Azim et al. (65) where they found non-vital pulpal status to be statistically associated with more flare-ups. In the current study one tooth (1.3%) diagnosed with necrotic pulp had severe pain at all the postoperative intervals which was eventually diagnosed as a flare-up. However, the incidence of flareups for non-vital pulpal status in the study of Azim et al. (65) was just 1.8% when only vital and non-vital samples were calculated (15 flare-ups out of 791 samples). The probable reason for the dissimilarity in the results could be the retrospective nature of their study and also the presence of retreatment group in their statistical analysis.

The different types of sealers did not significantly affect the postoperative pain outcome, which is in accordance with Graunaite et al. (35), where they perform a similar study. Sadaf et al. (62) also found that postoperative pain was not significantly affected by sealers even if extruded into the periapical tissues. All the obturations performed in the bioceramic group were by a single master cone, cold condensation technique and that of the AH Plus group were by warm vertical condensation technique, therefore it can also be concluded that the obturation technique did not influence the postoperative pain. This is in accordance with a meta-analysis performed by Li Peng et al. in 2007 (66), although a recent systematic review by Nagendrababu et al. in 2016 (67) showed that postoperative pain was associated with extrusion of material, probably due to warm vertical condensation technique, and therefore they suggested the use of cold lateral condensation for less postoperative pain.

Though 59% of women and 50% of men experienced some kind of postoperative pain, however, the present study found no statistically significant differences between sex. This is not in agreement with the results of Ali et al. (51) or Segura-Egea et al. (61), as they found women to have significantly more pain than in men. The differences may be due to the smaller sample size of this study and the fact that the intensity of pain is subjective. The threshold of each person cannot be evaluated, and therefore, it is difficult to evaluate why there wasn't a significant difference between males and females.

There were no significant differences found between the type of tooth or arch regarding the postoperative pain in this study. The results are not in agreement with Graunaite et al. (35), where they found a significantly higher likelihood of pain occurring in the lower premolars. This might be due to the smaller sample size of mandibular premolars (n=14*)* in comparison to the maxillary anterior teeth (n=31*)* in this study.

Parirokh et al. (68) showed bupivacaine, a long-acting anesthetic agent, to reduce the incidence of postoperative pain after a single-visit root canal treatment in cases of acute irreversible pulpitis. In this study, no regulations regarding the anesthesia administered to the patients were determined, nor was the data was recorded. The operators were given the free will to administer anesthesia according to their needs. Though regularly only 4% articaine with 1:100,000 or 1:200,000 are readily available at the university clinics, this might have influenced the results, and therefore is a limitation of this study. A significant difference between symptomatic and asymptomatic apical periodontitis was only found to be immediate postoperatively and not at later intervals of 8h, 24h, and 48h, which could be reasoned to the short-acting anesthetic agent, articaine, than a long-acting one like bupivacaine (69).

In different in-vitro studies, resin-based sealers like AH Plus and Bioceramic sealers like Total Fill or BioRoot ™ RCS have been studied for their toxicity and biocompatibility (34,48,49). They demonstrate bioceramic sealers to be less cytotoxic and more biocompatible with the periodontal ligament cells (48,49). Though these differences did not seem to affect clinically, long term prognostic studies are still needed.

8. CONCLUSIONS

Within the limitation of the study:

8.1 There is no correlation of postoperative pain occurrence in single visit endodontic treatment performed with a bioceramic sealer (BioRoot ™ RCS) compared to resin-based (AH Plus) sealer, immediately after the treatment, 8h, 24h or 48h intervals postoperatively.

8.2 The presence of preoperative pain with the diagnosis of symptomatic apical periodontitis was the only variable significantly associated with higher incidence of postoperative pain at, immediately after the treatment interval, following a single visit endodontic treatment.

9. FUTURE EXPECTATIONS

The study will continue until the sample size is acquired and we aspire to evaluate the success rate of the groups being tested at 1, 2, 4 and 6 years after treatment out of which we already have a control of 21 patients.

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Annex I: TFM Approval Letter

FACULTAD DE ODONTOLOGÍA
Comisión Científica – TFM

Proyecto de Trabajo Fin de Máster: END-ECL-2017-03

4 de junio de 2020

Dr. Juan Gonzalo Olivieri
Investigador Principal
Área de Endodoncia
Facultad de Odontología
Universitat Internacional de Catalunya

Estimado Dr. Juan Gonzalo Olivieri,

La Comisión de Trabajos Final de Máster de la Facultad de Odontología de la Universitat Internacional de Catalunya, en su sesión del día 12 de enero de 2018 revisó y aprobó el proyecto de investigación:

Título:	outcome of endodontic treatment and retreatment with bioroot ™ rcs: a prospective randomized clinical study
Investigador Principal:	Dr. Juan Gonzalo Olivieri
Tutor:	Dr. Fernando Durán-Sindreu
Alumno:	Tousif Iqbal Nathani (European Master's Degree in Endodontics)
Duración:	3 años

El número de identificación del proyecto TFM es: END-ECL-2017-03

Antes de comenzar su trabajo experimental, deberá asegurarse de que cuenta con la aprobación ética del Comité Ético de Investigación correspondiente.

Atentamente

Dra. Marta Satorres Nieto
Vicedecana de Investigación

Annex II: CEIM approval letter

CEIC Comitè Ètic d'Investigació Clínica

CUO Clínica Universitària d'Odontologia | Universitat Internacional de Catalunya

APROVACIÓ ESTUDI PEL CEIC / APROBACIÓN ESTUDIO POR EL CEIC / RESEARCH ETHICAL COMMITTEE APPROVAL STUDY

Codi de l'estudi / Código del estudio / Study Code: END-ECL-2017-03
Versió del protocol/ Versión del protocolo / Study version: 1.1
Data de la versió/ Fecha de la versión/ Version date: 04/10/2017
Títol/ Título / Title: Pronóstico del tratamiento y retratamiento de conductos obturados con un cemento biocerámico: un estudio clínico aleatorizado controlado
Investigador Principal / Main researcher: Dr. Juan Gonzalo Olivieri
Investigador Secundari / Second researcher: Fernando Durán-Sindreu

Sant Cugat del Vallès, 12 de desembre de 2017

Benvolgut Doctor,

Els membres del CEIC de la Clínica Universitària d'Odontologia, els hi agraeixen l'aportació científica en el camp de la investigació i la presentació del Protocol en aquest Comitè per a la seva avaluació.

Valorades les noves aportacions realitzades a l'estudi, sol·licitades pel nostre CEIC, el passat dia 8 de novembre de 2017, li comuniquem que el dictamen final ha sigut FAVORABLE.

Li informem que s'haurà de presentar al Comitè d'Ètica d'investigacions clíniques de la CUO, i a través de la Comissió Científica, un informe preliminar mensual del seguiment de l'estudi i un informe final un cop finalitzat aquest.

El Comitè, tant en la seva composició, com en els PNT, compleix amb les normes de BPC (CPMP/ICH/135/95) i amb el Real Decreto 1090/2015, i la seva composició actual és la següent:

- Dr. Magí Brufau de Barberà (Presidente, Medico-estomatólogo)
- Dr. Pau Ferrer Salvans (Vicepresidente, Farmacólogo clínico)
- Dra. Deborah Violant Holz (Secretaria, Odontóloga)
- Sra. Elisenda Harder (Miembro, Persona ajena a la profesión sanitaria)
- Sra. Patricia Dominguez Tordera (Miembro, Farmacéutica Hospitalaria)
- Dr. Joan Janáriz Roldán (Miembro, Médico especialista en medicina interna i oncología)
- Sra. Isabel López García (Miembro, Enfermera)
- Sra. Olga Díaz Fernández (Miembro, Unidad de atención al usuario)
- Dr. Andreu Hernando Chaure (Miembro, Jurista)
- Sr. Antonio Domingo Cerezo (Miembro, Persona ajena a la profesión sanitaria)
- Sra. Núria Farré Pagès (Miembro, Odontóloga)

Que en aquesta reunió del Comitè Ètic d'Investigació Clínica es va cumplir amb el quorum preceptiu legalment.

Atentament,

Apreciados Doctores,

Los miembros del CEIC de la Clínica Universitària d'Odontologia, les agradecen su aportación científica en el campo de la investigación y la presentación del Protocolo a este Comité para su evaluación.

Valoradas las nuevas aportaciones realizadas al estudio, solicitadas por nuestro CEIC, el pasado 8 de novembre de 2017, le comunicamos que el dictamen final ha sido FAVORABLE.

Le recordamos que deberá presentar al Comitè d'Ètica d'Investigacions Clíniques de la CUO, y a través de la Comisión Científica, un informe preliminar mensual del seguimiento del estudio y un informe final una vez finalizado el mismo.

Atentamente,

CEIC Comitè Ètic d'Investigació Clínica

CUO Clínica Universitària d'Odontologia | Universitat Internacional de Catalunya

Dear Doctors,

The members of the CEIC of the Clínica Universitària d'Odontologia, appreciate your contribution in the field of research and the presentation to this Committee of the referred study for its evaluation.

After having rated the new contributions to the study, requested by our Ethic Committee, on the 8th November 2017, the decision was to APPROVE it.

We remind, that you should present a monthly preliminary report during the study and a final report when the study finishes, through the Academic Commission, to the Clinical Research Ethics Committee of the CUO.

Best regards,

Dr.Magí Brufau
President CEIC

Annex III: CEIM approval letter of secondary researcher inclusion

CEIC Comitè Ètic d'Investigació Clínica

CUO Clínica Universitària d'Odontologia | Universitat Internacional de Catalunya

APROVACIÓ ESMENA PEL CEIC / APROBACIÓN ENMIENDA POR EL CEIC

Esmena nº / Enmienda nº: 1
Data esmena / Fecha enmienda: 14/12/2017
Codi de l'estudi / Código del estudio / Study Code: END-ECL-2017-03
Versió del protocol/ Versión del protocolo / Study version: 1.2
Data de la versió/ Fecha de la versión/ Version date: 18/10/2017
Títol/ Título / Title: Pronóstico del tratamiento y retratamiento de conductos obturados con un cemento biocerámico: un estudio clínico aleatorizado controlado
Investigador Principal / Main researcher: Dr. Gonzalo Olivieri
Investigador Secundari / Second researcher: Tousif Nathani

Sant Cugat del Vallès, 15 de febrer de 2018

Benvolgut Doctor,

Els membres del CEIC de la Clínica Universitària d'Odontologia, li hi agraeixen l'aportació científica en el camp de la investigació i la presentació de l'esmena en aquest Comitè per a la seva avaluació.

Valorades les noves aportacions realitzades a l'esmena nº 1, sol·licitades pel nostre CEIC, el passat dia 1 de febrer de 2018, li comuniquem que el dictamen final ha sigut FAVORABLE.

Li informem que s'haurà de presentar al Comitè d'Ètica d'investigacions clíniques de la CUO, i a través de la Comissió Científica, un informe preliminar mensual del seguiment de l'estudi i un informe final un cop finalitzat aquest.

Atentament,

Apreciado Doctor,

Los miembros del CEIC de la Clínica Universitària d'Odontologia, le agradecen su aportación científica en el campo de la investigación y la presentación del Protocolo a este Comité para su evaluación.

Valoradas las nuevas aportaciones realizadas en la enmienda nº 1, solicitadas por nuestro CEIC, el pasado 1 de febrero de 2018, le comunicamos que el dictamen final ha sido FAVORABLE.

Le recordamos que deberá presentar al Comitè d'Ètica d'Investigacions Clíniques de la CUO, y a través de la Comisión Científica, un informe preliminar mensual del seguimiento del estudio y un informe final una vez finalizado el mismo.

Atentamente,

Dr. J.Manuel Ribera
President CEIC

Annex III: Document of information for patient participating in the study

Comitè Ètic d'Investigació Clínica

6. DOCUMENTO DE INFORMACIÓN AL PACIENTE PARTICIPANTE EN EL ESTUDIO DE INVESTIGACIÓN

Número del estudio: END-ECL-2017-03
Versión del protocolo: 1.2
Fecha de la versión: 08 Noviembre de 2017.
Fecha de presentación: 04 Octubre de 2017.
Título: Pronóstico del tratamiento y retratamiento de conductos obturados con un cemento biocerámico: un estudio clínico aleatorizado controlado.

Investigador/a Principal: Juan Gonzalo Olivieri
Investigador/a Secundario/Tutor: Fernando Durán-Sindreu
Departamento: Endodoncia
Línea de investigación: Investigación básica y aplicada en odontología
Título de la investigación: Pronóstico del tratamiento y retratamiento de conductos obturados con un cemento biocerámico: un estudio clínico aleatorizado controlado.

Hemos solicitado su participación en un estudio de investigación. Antes de decidir si acepta participar, es importante que comprenda los motivos por los que se lleva a cabo la investigación, cómo se va a utilizar su información, en qué consistirá el estudio y los posibles beneficios, riesgos y molestias que le pueda conllevar.

En el caso de participar en algún otro estudio, debe comunicarlo al responsable para valorar si puede participar en éste. Un paciente sólo puede participar en un estudio clínico.

Se trata de un estudio que intenta evaluar la evolución del dolor inicial tras el tratamiento de conductos. Se evalúan distintos cementos para la realización del tratamiento que se le ha de realizar. Usted podrá recibir un tratamiento u otro que será designado de manera aleatoria previamente. Todos ellos están aprobados y avalados por la literatura especializada. Le pedimos que consienta que para incluirle en el estudio y además que sus radiografías realizadas durante, después del tratamiento y en los controles clínicos habituales del mismo puedan ser utilizadas para el estudio.

Además, consiento que se realice una tomografía computerizada de haz cónico de control a los 6 años. Además en el caso que se requiera necesario, que consiente que se le realice una tomografía computerizada de haz cónico si se sospecha de alguna patología que no pueda identificarse mediante el control radiográfico convencional.

En caso de que el resultado del tratamiento resulte en fracaso del mismo, se procederá como en cualquier tratamiento hasta un año desde su realización, el importe del tratamiento será descontado del tratamiento a realizar en cada caso concreto.

PARTICIPACIÓN VOLUNTARIA

La participación en un ensayo es una decisión voluntaria y personal. En el caso de no querer participar o bien de querer abandonar el estudio, la calidad de la asistencia que recibirá no se verá afectada y se seguirán los protocolos habituales. Si decide participar, se le entregará la Hoja de información al paciente y el Consentimiento informado para que firme todas las hojas de ambos documentos.

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Si el Investigador Principal considera que el estudio puede perjudicar a su salud, le invitará a abandonarlo, y le dará las explicaciones pertinentes. Finalmente, una vez haya concluido su participación, deberá seguir los procedimientos indicados por el/la doctor/a para garantizar su seguridad.

El beneficio inmediato de participar en el estudio, es su contribución al conocimiento y desarrollo científico, además de una reducción en el tiempo del tratamiento y coste del mismo.

¿CÓMO SE VAN A UTILIZAR MIS DATOS DEL ESTUDIO?

Según el artículo 3.1.d del RD 1090/2015, de 4 de diciembre por el que se regulan los ensayos clínicos con medicamentos, los Comités de Ética de la investigación con medicamentos y el registro español de estudios clínicos, y el artículo 5 de la Ley 14/2007, de 3 de julio, de investigación biomédica y tratamiento de las muestras biológicas, el tratamiento, la comunicación y la cesión de los datos de carácter personal de los sujetos participantes en el ensayo, se ajustaran a lo dispuesto en la Ley Orgánica 15/1999, de 13 de diciembre, de protección de datos de carácter personal.

A su vez el equipo investigador seguirá los principios éticos en investigación médica en seres humanos establecidos en la Declaración de Helsinki (actualizada en octubre 2013).

El/la doctor/a del estudio podrá utilizar sus datos personales para la difusión de resultados dentro de la comunidad científica y garantizará la protección de estos datos a fin de no desvelar su identidad. Únicamente el/la doctor/a del estudio y su equipo investigador, tendrán acceso a la clave del código que permite asociar los datos del estudio con su identidad.

Cualquier uso continuado de los datos del estudio por parte del/de la doctor/a del tendrá los fines que se describen en este formulario. Si retira el consentimiento de utilizar sus datos del estudio, no podrá seguir participando en la investigación. Debe tener en cuenta que los resultados del estudio podrán aparecer publicados en la bibliografía médica, si bien su identidad no será revelada. En caso de que deban tomarse fotografías de la cara y/o cuerpo completo, se garantizará la protección de su identidad.

¿CÓMO PUEDO ESTABLECER CONTACTO SI NECESITO OBTENER MÁS INFORMACIÓN O AYUDA?

Mediante la firma de este formulario, usted asiente que ha estado informado de las características del estudio, ha entendido la información y el/la doctor/a ha clarificado todas sus dudas. En caso de sufrir un daño relacionado con el estudio o para obtener respuesta a cualquier pregunta que pueda surgir durante la investigación, póngase en contacto con:

Nombre del IP Juan Gonzalo Olivieri
Nombre del IS Fernando Durán-Sindreu
Clínica Universitaria de Odontología. Universitat Internacional de Catalunya
Dirección: C/ Josep Trueta, s/n-08195, Sant Cugat del Vallés
Num. de teléfono: 93 504 20 30
Mail: jgolivieri@uic.es

Annex IV: Informed Consent

CEIC Comitè Ètic d'Investigació Clínica

7a. CONSENTIMIENTO INFORMADO

Número del estudio: END-ECL-2017-03
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Yo, Sr./Sra.: ……..

- He recibido información verbal acerca del estudio y he leído la información escrita que se adjunta, de la que he recibido una copia.
- He comprendido lo que se me ha explicado.
- He podido comentar el estudio y realizar preguntas al profesional responsable.
- Doy mi consentimiento para tomar parte en el estudio y asumo que mi participación es totalmente voluntaria.
- Entiendo que podré retirarme en cualquier momento sin que ello afecte a mi futura asistencia médica.

Mediante la firma de este formulario de consentimiento informado, doy mi consentimiento para que mis datos personales se puedan utilizar como se ha descrito en este formulario de consentimiento, que se ajusta a lo dispuesto en la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal.

Entiendo que recibiré una copia de este formulario de consentimiento informado.

Firma del paciente o la paciente
N.º de DNI

Fecha de la firma

DECLARACIÓN DEL INVESTIGADOR O LA INVESTIGADORA

El paciente o la paciente que firma esta hoja de consentimiento ha recibo, por parte del profesional, información detallada de forma oral y escrita del proceso y naturaleza de este estudio de investigación, y ha tenido la oportunidad de preguntar cualquier duda en cuanto a la naturaleza, los riesgos y las ventajas de su participación en este estudio.

20/10/17

Firma del investigador o investigadora
Nombre:

Fecha de la firma

Annex V: Information form about the treatment performed

NHC:	Date:
Student/Teacher:	Department:

Age	
Gender	
Tooth	

1. Presumption diagnosis

Normal pulp	
Reversible pulpits	
Irreversible pulpitis	
Necrosis	

2. Spontaneous pain

Yes	
No	

3. Continuous pain

Yes	
No	

4. Biting pain

Yes	
No	

5. Biting discomfort

Yes	
No	

6. Vertical percussion

Pain	
Discomfort	
No	

7. Lateral percussion

Pain	
Discomfort	
No	

8. Analgesics

Yes	
No	

9. Antibiotics

Yes	
No	

10. Periodontal Probing 1

Buccal	Mesial	
	Medial	
	Distal	
Palatal/Lingual	Mesial	
	Medial	
	Distal	

11. Periodontal Probing 2

Deep and narrow probing	Yes
	No

Location	B
	L/P

12. Abscess

Yes	
No	

13. Fistula

Yes	
No	

14. Location B / P

Marginal gingiva	
Attached gingiva	

15. Occlusal splint 1

Yes	
No	

16. PBL

1	
2	

3	
4	

17. Toxic habits

Tobacco	
Alcohol	
None	

Tobacco	< 10/day
Tobacco	≥ 10/day

Alcohol	< 10g/day
Alcohol	≥ 10g/day

*18. Radiographic features

Normal	
Periapical radiolucency	
Widening of the PL	

14. Periapical diagnosis

Normal	
Symptomatic Apical Periodontitis	
Asymptomatic Apical Periodontitis	

19. Occlusion

Right		Left	
Molar	Class I	Molar	Class I
	Class II		Class II
	Class III		Class III
Canine	Class I	Canine	Class I
	Class II		Class II
	Class III		Class III

22. Cavity

No restoration	
Crown	
Amalgam	Occlusal
	Mesial-occlusal
	Distal-occlusal
	MOD
	Cervical
Composite	Occlusal
	Mesial-occlusal
	Distal-occlusal
	MOD
	Cervical
	Occlusal
Incrustation	Overlay
	Inlay
	Onlay
Endocrown	

23. Procedure

No restoration	
Crown	
Amalgam	Occlusal
	Mesial-occlusal
	Distal-occlusal
	MOD
	Cervical
Composite	Occlusal
	Mesial-occlusal
	Distal-occlusal
	MOD
	Cervical
	Occlusal
Incrustation	Overlay
	Inlay
	Onlay
Implant	
No antagonist	

20. Restoration of the treated tooth

Caries	Occlusal
	Mesial-occlusal
	Mesial-occlusal
	Distal-occlusal
	MOD

21. Antagonist tooth

TopSeal	
BioRoot	

24. Restoration

Compo	
Inlay	
Overlay	

25. Crown

Yes	
No	

Annex VI: Form with the visual analog scale of the patient to record pre- and postoperative pain

CUO Clínica Universitària d'Odontologia | Universitat Internacional de Catalunya

Operador:		**CP:**	
Edad:		**Sexo:**	
Fecha:		**Profesor:**	

Señale sobre la línea, con una raya vertical , para señalar la intensidad del dolor que siente, teniendo en cuenta que el extremo izquierdo representa el "no dolor" y el extremo derecho representa el "máximo dolor" que pueda imaginar. **Si no hay dolor por favor marque sobre el No dolor y no sobre la línea.**

Si considera que necesita algún analgésico , tome aquél que se le ha indicado y haga constar la hora de la primera toma a continuación: _____

Ejemplo rellenar con el alumno

No dolor ——— *Máximo dolor*

Ultimas 24 horas

No dolor ——— Máximo dolor

Antes de anestesiar

No dolor ——— Máximo dolor

Al finalizar el tratamiento

No dolor ——— Máximo dolor

A las 8 horas

No dolor ——— Máximo dolor

A las 24 horas (al día siguiente)

No dolor ——— Máximo dolor

A las 48 horas (a los dos días)

No dolor ——— Máximo dolor

La información que se aporte al estudio será totalmente anónima y confidencial y se ajusta a lo dispuesto en la Ley Orgánica 15/1999, de 13 de diciembre, de Protección de Datos de Carácter Personal. Los documentos utilizados, serán guardados en un espacio seguro, al que solo el investigador principal tenga acceso.

Gracias por su colaboración