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Direct pulp capping – a retrospective study

Proteções pulpares diretas – estudo retrospetivo

Sara Margarida Simões Malva

Orientador: Prof. Doutor João Carlos Ramos

Co-orientador: Dra. Alexandra Vinagre

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S. Malva, A. Vinagre, J. C. Ramos

Department of Dentistry, Faculty of Medicine, University of Coimbra

Av. Bissaya Barreto, Blocos de Celas
3000-075 Coimbra
Portugal

e-mail: sara_malva_1@hotmail.com

Abstract

Background: Preserving pulp vitality is one of the most important goals of modern conservative dentistry. Although materials and techniques are widely described in the literature, treating pulp exposures due to caries lesions, mechanical factors or trauma in a conservative and effective way still remains an important and unpredictable challenge.

Aim: The objective of this work was to make a retrospective clinical and radiological evaluation of the long-term success of pulp capping in permanent teeth.

Materials and methods: Thirty-seven pulp capped teeth were elected from a total of 104 cases according to determinate inclusion criteria such as asymptomatic teeth without signals of irreversible pulpitis, adequate bleeding control to perform capping and restorative procedures, pulp capping procedures done by two defined experienced operators, good oral and general health, minimum of 12 months of follow-up and well-documented technical data from the procedures. Patients provided written and informed consent to participate in the study. Clinical evaluation of pulp-capped teeth was performed based on World Dental Federation criteria and complemented with some additional specifications.

Results: The global survival rate of pulp capping was 94.4%, 88.2% and 70.2% determined for the 12^{th}, 60^{th} and 120^{th} month respectively. Unfavourable outcomes registered a mean survival time of 63.8±47.9 months. Significant differences were found for capping material, as

mineral trioxide aggregate showed a statistically significant better performance than adhesive systems (p= 0.011). Data regarding aetiology of the exposure, age of the patient, preoperative symptoms, use of rubber dam isolation, contamination, and pulpal bleeding were statistically analysed for failure and none seemed to influence the outcome of the treatment (p>0.05 for all features).

Conclusion: Within the limitations of interpretation of the results of this study due to the ratio between the number of cases observed and the number of variables recorded, direct pulp capping proved to be a successful long-term therapy. Mineral trioxide aggregate seems to have higher efficacy than adhesive systems as a pulp-capping material.

Key words: pulp capping, pulp exposure, adhesive systems, mineral trioxide aggregate, and retrospective study

Resumo

Introdução: A manutenção da vitalidade pulpar é um dos objetivos mais relevantes da dentisteria moderna e conservadora. Contudo, apesar de na literatura constar uma descrição ampla dos materiais e das técnicas, o tratamento de exposições pulpares devido a lesões de cárie, iatrogénicas ou traumatismos dentários, de um modo conservador e efetivo, permanece como um desafio imprevisível.

Objetivo: O objetivo deste trabalho é realizar um estudo retrospetivo para avaliar o sucesso a longo prazo das proteções pulpares diretas nos dentes permanentes.

Materiais e Métodos: Trinta e sete protecções pulpares diretas foram selecionadas e observadas neste estudo, de um total de 104 casos clínicos, de acordo com os seguintes critérios de inclusão: proteções pulpares diretas realizadas por dois operadores, com mínimo de 12 meses, em dentes que não apresentavam sinais ou sintomas de patologia pulpar irreversível e que obtiveram uma hemostase adequada para se proceder à colocação do material de proteção pulpar e restaurador, cujos pacientes apresentavam um bom estado de saúde oral e sistémica, assinaram o consentimento informado, e sobre os quais se encontrava disponível informação sobre o tratamento efetuado. Os critérios de avaliação clínica das proteções pulpares foram executados com base nos critérios de avaliação da *World Dental Federation*, tendo sido complementados com alguns parâmetros considerados importantes na avaliação deste tipo de tratamentos.

Resultados: A taxa de sobrevivência global foi de 94.4%, 88.2% e 70.2% aos 12 meses, 60 meses e 120 meses, respetivamente. Os casos de insucesso registaram um tempo médio de sobrevivência de 63.8±47.9 meses. Foram encontradas diferenças estatisticamente significativas respeitantes ao material, sendo que o cimento de agregado trióxido de minerais mostrou um melhor desempenho em relação aos adesivos (p= 0.011). Foram também analisados fatores relativos à etiologia da exposição, a idade do paciente, os sintomas pré-operatórios, contaminação durante o procedimento e a hemorragia pulpar. Nenhum destes fatores se mostrou determinante para o insucesso do tratamento (p> 0.05 para todos os fatores).

Conclusão: Apesar das limitações inerentes ao estudo devido ao número de casos observados e ao número de variáveis, as proteções pulpares demonstraram ser um tratamento com resultados favoráveis a longo prazo. Os cimentos de agregado de trióxido de minerais parecem ter uma melhor eficácia em relação aos sistemas adesivos como material de proteção pulpar direta.

Introduction

Dental pulp plays an important role in the enervation and defence of the tooth, as well as in the formation and nutrition of dentin. Pulp exposure is defined in the Medical Subject Headings [1] as “the result of pathological changes in the hard tissue of a tooth caused by carious lesions, mechanical factors, or trauma, which renders the pulp susceptible to bacterial invasion from the external environment”.

In normal conditions, when subjected to an injury, dental pulp has the ability to form a new dentin-like tissue as part of the healing and defence process [2, 3]. The conservative treatment options for pulp exposures can be classified as according the deep of the exposition and tissue preservation as “indirect” pulp capping direct conservative pulp capping or direct pulp capping with pulpotomy [4-6]. Indirect pulp capping is usually performed in deep dentin cavities treated with adhesive restorations, or, adhesive restorations over cavity bases [7-9]. Direct pulp capping consists on placement of biocompatible material in direct contact with the exposed pulp tissue, without any dentin interposition, in order to allow pulp healing while

maintaining its function and vitality [10]. Generally, conservative pulp capping should be considered whenever the tooth is asymptomatic, answers normally to sensitivity tests and has no radiographic or clinical evidence of apical pathogenesis [4, 6].

A large number of materials have been suggested for use in pulp capping. Summarily, the ideal material should be biocompatible, able to resist long-term bacterial leakage and, ideally, stimulate the remaining pulp tissue to promoting the formation of new dentin while guarantees an adequate surface sealing [4, 11]. An historical overview of such materials include zinc oxide eugenol, calcium hydroxide, glass ionomer cements, adhesive systems and mineral trioxide aggregate cements (MTA), among many other much less studied and reported [4, 11, 12]. For many years, the material of choice has been calcium hydroxide [11, 13, 14]. Most recently, MTA cements became a reference for use in vital pulp therapy [11, 15] with positive and relatively consistent results among the studies [4, 16].

There are several factors that may influence the likelihood of pulp capping success, including cause of pulp exposure, previous pulp health, bleeding and haemostasis, bacterial contamination, pulp-capping material, restoration quality, status of root maturation, patient age, health and oral hygiene [12, 16]. However, for many of these factors, there is little or no scientific evidence supporting its real effect on treatment prognosis. Direct pulp capping is more likely to success following mechanical exposures (traumatic or iatrogenic) rather than caries removal procedures [4, 17]. Caries penetration to deep dentin and into pulp tissue, will result in bacterial contamination, which leads to pulp inflammation and compromising dental pulp healing [4, 18]. Although that it has been clearly shown that root canal treatment on teeth with vital pulp gives a reliable prognosis [19], concerning survival rate associated to posterior treatment needs, the analyses is less favourable, especially in posterior teeth [16]. Some possible reasons for this could include the loss of some proprioceptive function, damping property, and tooth sensitivity, which are provided by vital pulp as a defence mechanism against harmful stimuli [16], which together with the structural loss increasing the probability of fracture [3, 20]. Following modern conservative dentistry concepts, whenever is it possible and indicated, vital pulp should always be preserved [16]. This approach is particularly important in immature permanent teeth, where the apexogenesis is the primary goal [11, 21-25].

The aim of this retrospective study was to evaluate the long-term success of direct capping treatments performed under clinical routine conditions.

Materials and methods

This retrospective study was conducted at Dentistry Department of Coimbra Medical School of Coimbra University and approved by the Coimbra Medical School Ethics Committee.

For this study, subjects were selected from a 104 patients data file with direct pulp capping made between March 1997 and November 2010. Only, direct pulp capping treatments that meet the following inclusion criteria were selected: teeth without symptoms and signals of irreversible pulp inflammation; bleeding control adequate to capping and restorative procedures; pulp capping performed only by two experienced operators; good oral and general health; 12 months of a minimal follow-up; patients provided written and informed consent to participate in the study; and, enough documented personal data from pulp capping procedures available.

Only fifty-four teeth, from fifty-three patients met those clinical inclusion criteria. From these, 17 were posteriorly excluded due to refuse to participate in the study (7) and impossibility of contact (10).

The indication for a pulp capping was given when a dental pulp was exposed on account of carious lesions, trauma or iatrogenically. Only teeth with clinically pulp health or signals of reversible pulp inflammation, without recognizable radiographic changes indicated pulp necrosis, and no persistent bleeding after exposure, were included in this study. The treatment was realized without oral contamination, and included the application of an adhesive system, mineral trioxide aggregate, Biodentine™, or calcium hydroxide, as direct pulp capping material, followed by composite or amalgam restoration.

The treatment outcome was considered clinically well succeed when the tooth remains in the mouth, without endodontic treatment, pulp stayed vital with normal response to thermal sensitivity tests (but non-exclusion criteria), without signs of pulp disease. The treatment was radiographically successful when examination shows no apical pathology, periodontal ligament space enlargement or internal or external root resorptions.

Clinical evaluation of the restorations of those pulp capped teeth was performed based on World Dental Federation criteria [26] and complemented with some additional specification (annex 1). These criteria related to patients´ symptoms (spontaneous pain or induced pain), biological aspects (tooth vitality, presence or absence of abscess, postoperative sensitivity, secondary caries, erosion, abfraction, and the periodontal condition), tooth properties (horizontal and vertical percussion pain, mobility, tooth discoloration and tooth integrity) as well as the restoration properties (fracture, retention,

marginal and surface staining, marginal adaptation and proximal contour and contact). For radiographic examination a retro-alveolar x-ray was taken to explore changes in pulp chamber, periodontal ligament, bone, particularly in the apical area and, restoration. The examiner was calibrated with the tool e-calib (electronic calibration), as recommended by World Dental Federation for training and calibrating these criteria evaluation. This calibration is on World Wide Web and can be accessed by www.e-calib.info (University of Munich).

Besides clinical evaluation, it was taken a digital macro-photography to document the restorations status.

Data was divided into categories (age, material, aetiology of exposure, previous symptomatology, haemorrhage, rubber dam isolation and contamination) and analysed for failure rate and mean survival time (time between pulp capping and control). Categorical data were introduced into contingency tables to determine independency of categories (Qui-square and Fisher's exact test). All categories were tested for normality and the difference between two population parameters was estimated either using methods based on the two-sample *t* test for the comparison of means or using non-parametric methods based on the Mann-Whitney test for the comparison of medians.

Kaplan-Meier estimates for survival probabilities over time were calculated for the material used for pulp capping.

Statistical analysis was performed using PAWS Statistics 18.0 (IBM).

Results

Of the 54 cases of pulp capping, 37 were able to come in for a control appointment, providing a recall rate of 68.5% with a mean follow-up period of 94 (±43) months.

The ratio of performed direct pulp capping procedures between operators was 2:1 (25:12) without statistically significant differences in the failure rates between them (p=1.0).

Frequency analysis revealed a balanced gender distribution, 59.5% accounting for female patients (n=22) and 40.5% for male patients (n= 15).

Ages ranged from 8 to 68 years, with a mean age of 26 years. Patients were grouped into age cohorts for further analysis considering material distribution, failure rates and survival periods.

Anterior teeth accounted for 51.4% of the direct pulp capping (n=19) while the remaining 48.6% were carried out in posterior teeth (n=18) (Table I).

Table I. Distribution of the treated teeth with regard to the arches.

Teeth	Maxilla		Mandible	
	Number	Percent	Number	Percent
Incisor	16	43.3%	0	0
Canine	3	8.1%	0	0
Premolar	7	18.9%	1	2.7%
Molar	5	13.5%	5	13.5%

All capped teeth were permanent, 33 of which were mature teeth with a closed apex and 4 were immature teeth, presenting incomplete apexogenesis. Up to date, all immature teeth, treated with MTA, have completed root formation and remain vital.

Eight of 37 direct pulp capped teeth showed unfavourable outcome such as irreversible pulp inflammation or necrosis, leading to root canal treatment. This corresponds to a simple failure rate of 21.6%. Nevertheless, two of the cases considered non-successful had received endodontic treatment previously to the control appointment in private dental offices without a clarified reason.

Pulp capping was performed with four different materials and techniques. In 21 cases (56.7%) adhesive system was applied directly over the exposure. Fourteen cases (37.8%) received MTA (ProRoot® MTA, Maillefer, Dentsply), 1 Biodentine™ (2,7%) and 1 calcium hydroxide (2.7%). All teeth were then restored with composite, with exception for one amalgam restoration in a posterior tooth.

Taking into consideration the failure rate of the different materials, adhesive system was the worst performing pulp-capping agent, as all unfavourable outcomes were associated with its use. Thus, adhesive system associated pulp-capped teeth had a simple failure rate of 38.1%, corresponding to 8 of 21 teeth, while MTA, Biodentine™ and calcium hydroxide had no unsuccessful outcomes. MTA showed a statistically significant better performance than adhesive systems ($p= 0.011$). The samples treated with the other capping agents were not enough to be considered representative and therefore were not considered for statistical analysis.

Data regarding technical and clinical issues potentially related to the outcome of the treatment was also collected from the records of the patients. The use of rubber dam isolation and the presence or absence of salivary or gingival exudates' contamination were the technical issues considered. The clinical features assessed were age, preoperative symptomatic complains, aetiology of the exposure and pulpal bleeding. These records were

statistically analysed for failure and none seemed to influence the outcome of the treatment ($p>0.05$ for all features). The results are summarized in the contingency Table II.

Table II. Influence of the technical and clinical issues in the treatment outcome.

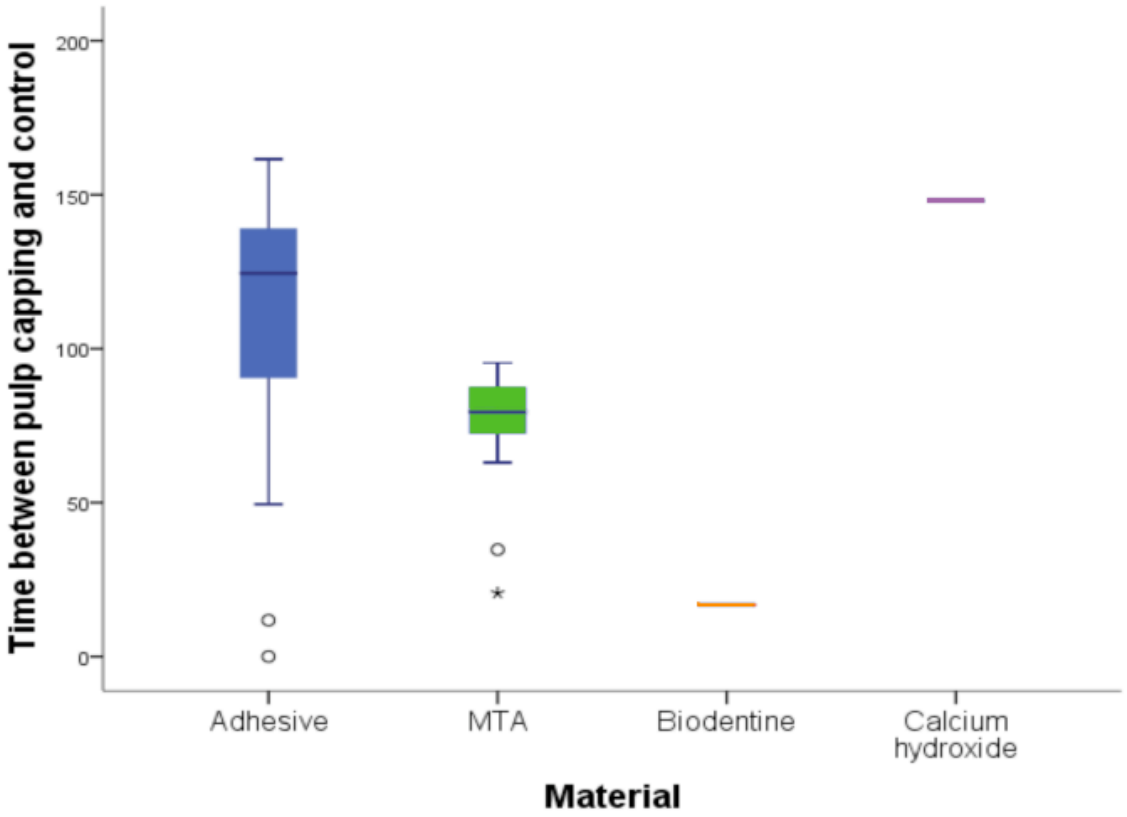
		Failure			
		No	Yes	Total	p
Time between pulp capping and control (months)		29 Time: 101.8± 39.4	8 Time: 63.8± 47.9	37	0.035
Material	Adhesive system	13	8	21	0.013
	MTA	14	0	14	
	Calcium Hydroxide	1	0	1	
	Biodentine	1	0	1	
Aetiology	Iatrogenic	5	1	6	0.23
	Caries	19	7	26	
	Trauma	5	0	5	
Age	0-9	4	0	4	0.091
	10-19	6	4	10	
	20-29	12	2	14	
	30-39	1	1	2	
	40-49	3	0	3	
	50-59	3	0	3	
	≥ 60	0	1	1	
Rubber dam	Yes	27	8	35	1
	No	2	0	2	
Contamination	Yes	2	1	3	0.53
	No	27	7	34	
Preoperative Symptoms	Yes	8	2	10	1
	No	21	6	27	
Bleeding	Yes	15	3	18	0.692
	No	14	5	19	

Pulp exposure occurred due to caries in 26 cases, due to trauma in 5 cases and the remaining 6 due to iatrogenic interventions during tooth treatment. Three of the 5 cases associated with dental trauma were subjected to pulpotomies instead of conservative direct pulping procedures and up to date remains vital (Table II).

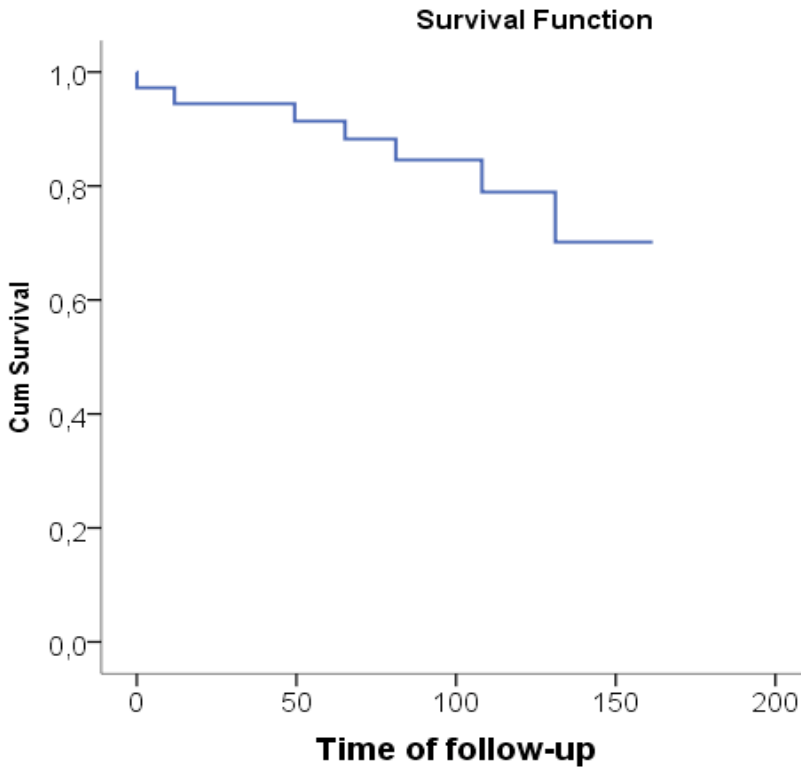
Regarding the survival time, patients with unfavourable outcome had a mean time of follow-up (period between the pulp capping appointment and failure) of 63.8±47.9 months, ranging from one day to a maximum of 131 months, while successful cases had a mean follow-up period of 101.8±39.4 months. This difference was found to be statistically significant ($p=0.035$).

When considering both materials and survival time, adhesive presented a mean follow-up period of 109±45.8 months and MTA a mean follow-up period of 74±22.6 months. The distribution of the values is represented in graphic 1. Despite the better success rate of

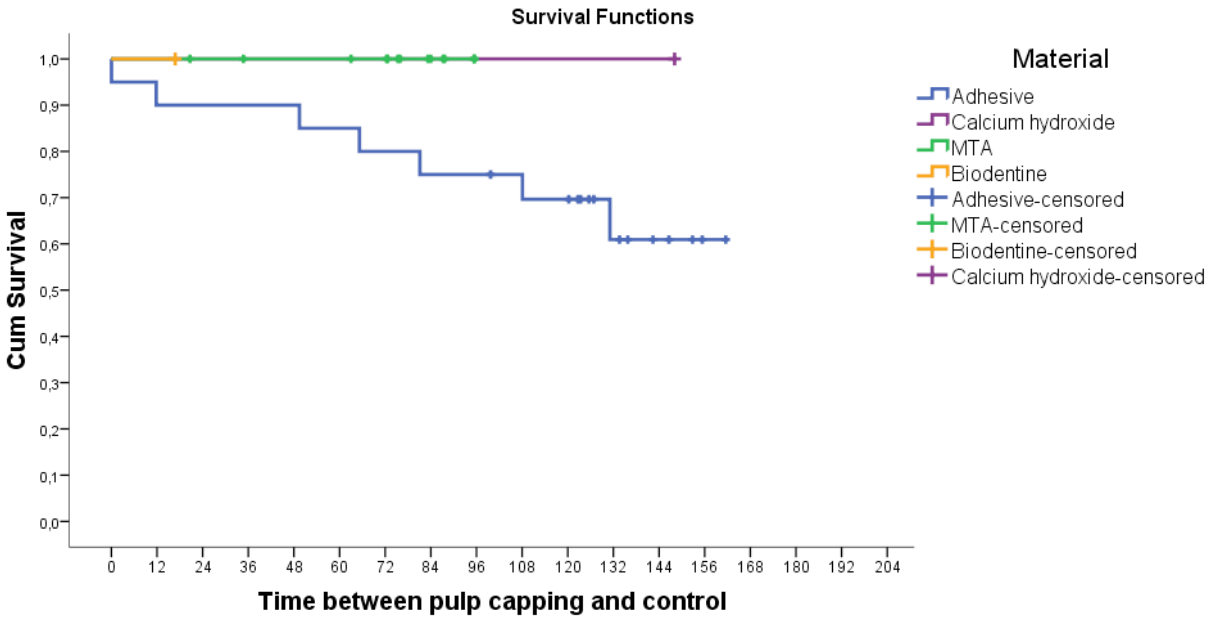
the MTA, adhesive showed a superior mean follow-up time (P=0.004). The Kaplan Meier function was used to determine the time survival rate of all cases and to establish associations between the capping material and the failure rate over the time. The results are represented in the graphics 2 and 3. The censored cases, represented by the crosses over the graphic lines, indicate the latest control for each successful case. From the Kaplan Meier function, a global survival rate of 94.4%, 88.2% and 70.2% was determined for the 12th, 60th and 120th month, respectively. Considering the factor material, a 100% survival is expected for MTA while only 90% is expected for adhesive at the 1st year. At the 5th and 10th year of follow-up the cumulative survival function of the adhesive decreases to 80% and 60%, respectively.



Graphic 1 – Box plots chart for materials according the distribution of cases by follow-up time in months.



Graphic 2 – Kaplan Meier global survival function.



Graphic 3 – Kaplan Meier survival function for capping agent.

The follow-up appointment comprised a biological, clinical and radiological evaluation of the teeth submited to pulp capping (annex 1). The results are summarized in the Table III.

Twenty-nine teeth were considered vital.

Patients reported that none of the teeth had spontaneous or functional induced pain. However, 6 teeth were more sensitive to cold stimulus.

Thermal sensitivity test (TST) revealed 26 teeth with normal responses. Two teeth had extended reaction but reversible after the removal of the cold stimulus and one had no response, despite being considered successful.

Concerning the actual presence of pathology, 22 teeth had no primary or secondary signs of tooth decay. Seven teeth were diagnosed with lesions or suspicious lesions of undermining caries and 1 tooth had a small and localized demineralisation.

The periodontal evaluation of the treated tooth disclosed no cases of severe or acute gingivitis or periodontitis. Eight teeth revealed perfect hygiene, 16 teeth had minor plaque accumulation and 5 had bleeding on probing which increased the papilla bleeding index (PBI) in one grade when compared with a control tooth.

No abscesses or fistulas were diagnosed and all teeth had physiological mobility.

Two teeth showed pain on horizontal percussion and one tooth had pain on both horizontal and vertical percussion.

Tooth discoloration was detected in 6 teeth, 2 of which were capped with adhesive system and 4 of which were capped with MTA. Three of the discoloration cases had intensive haemorrhage during pulp capping procedures referred on the restoration appointment.

Some kind of fracture of the teeth was found in 11 cases. Small marginal fractures or hairline cracks were the most frequent and recorded for 10 teeth. Only one case showed enamel chipping.

The evaluation of the restorations found that a large number had complete integrity or signs of small hairline cracks. Still, 5 restorations had indication to be repaired or substituted as a consequence of chip fractures with damage of the margin or of the proximal contact, partial loss of material or multiple fractures. Pronounced or unacceptable staining of the margins or surface of the restorations was recorded for 5 cases. Considerable gaps, irregularities or ditching of the margins of the restoration were spotted in 12 cases.

Regardless the poor quality of the radiographs, the x-ray examination revealed no cases of apical pathology or interrupted *lamina dura*. Three cases were suggestive of pulp calcifications. Formation of new dentinal hard tissue was most marked in 24% of the cases and all immature pulp-capped teeth showed complete apexogenesis.

Table III. Clinical evaluation of pulp capping teeth.

			n	%
SYMPTOMS	**Spontaneous pain**	No	29	100,0
	Cold or heat induced pain	Yes	6	20,6
		No	23	79,4
	Functional pain	No	29	100,0
BIOLOGIC ASPECTS	**TST**	No hypersensitivity. Normal response.	26	89,7
		Minor hypersensitivity for a limited period of time.	2	6,9
		Intense hypersensitivity and delayed minor symptoms.	0	0
		No clinical detectable sensitivity.	1	3,4
	Presence of swelling	No	29	100
	Presence of fistula	No	29	100
	Actual pathology of caries, erosion, abfraction	No secondary or primary caries.	21	72,4
		Small and localized demineralisation, erosion or abfraction.	1	3,4
		Larger areas of demineralisation, erosion or abfraction. Dentine not exposed. Caries with cavitation and suspected undermining caries, erosion in dentine or abfraction in dentine.	7	24,1
		Deep caries or exposed dentine that is not accessible. Replacement necessary.		
	Periodontal condition	No plaque, no inflammation, no pocket.	8	27,6
		Little plaque, no inflammation, no pocket.	16	55,2
		Difference up one grade in severity of PBI compared to baseline and to a control tooth.	5	17,2
		Difference of more than one grade of PBI in comparison to a control tooth or increase in pocket depth >1mm requiring intervention.	0	0,0
		Several acute gingivitis or periodontitis.	0	0,0
TOOTH PROPERTIES	**Horizontal percussion pain**	Yes	3	10,3
		No	26	89,7
	Vertical percussion pain	Yes	1	3,4
		No	28	96,6
	Mobility	Physiological mobility.	29	100
	Tooth fracture	Complete integrity.	18	62,1
		Small marginal enamel fracture. Hairline crack in enamel.	10	34,5
		Marginal enamel defect. Enamel chipping. Multiple fractures.	1	3,4
		Major marginal enamel defects, dentine or base exposed. Large chipping enamel or wall fracture.	0	0,0
		Cusp or tooth fracture.	0	0,0
	Discoloration	Yes	6	20,7
		No	23	79,3

Table III. Clinical evaluation of pulp capping teeth (cont.)

			n	%
RESTORATION PROPERTIES	**Fracture and retention**	No fractures/ cracks.	17	58,6
		Small hairline crack.	3	10,3
		Two or more hairline crack and/or material chip fracture not affecting the marginal integrity or proximal contact.	4	13,8
		Material chip fractures which damage marginal quality or proximal contacts. Bulk fractures with partial loss.	3	10,3
		Partial or complete loss of restoration or multiple fractures.	2	6,9
	Marginal and surface staining	No marginal or surface staining.	12	41,4
		Minor marginal and/or surface staining, easily removable by polishing.	5	17,2
		Moderate marginal and/or surface staining, not aesthetically unacceptable.	11	37,9
		Pronounced marginal staining, major intervention necessary for improvement. Unacceptable surface staining on the restoration, major intervention necessary for improvement.	1	3,4
		Deep margin staining not accessible for intervention. Severe surface staining generalized or localized, not accessible for intervention.	0	0
	Marginal adaptation	Harmonious outline, no gaps, no white or discoloured lines.	6	20,7
		Marginal gap, white line. Small marginal fracture easily removable by polishing. Slight, ditching or minor irregularities.	13	44,8
		Gap not removable. Several small marginal fractures. Major irregularities or ditching.	8	27,6
		Gap that exposed dentine/ base. Several ditching or marginal fractures. Larger irregularities or steps. Necessary repair.	2	6,9
		Partial or complete restoration is loose but in situ. Generalized major gaps and irregularities.	0	0,0
	Proximal contour and contact	Normal contact point. Normal contour.	15	51,7
		Contact point slightly too strong but no clinical drawback. Slightly deficient contour.	2	6,9
		Weak contact no indication of damage to tooth, gengiva or periodontal structures. Visible deficient contour.	3	10,3
		Too weak contact and possible damage due to food impactation. Inadequate contour. Repair possible.	1	3,4
		Too weak and clear damage due to food impactation and/or pain/gingivitis. Insufficient contour requires replacement.	1	3,4
		No applicable.	7	24,1

Discussion

The recruitment of patients and adherence to long follow-up periods are the main constrains associated to clinical trials. These are probably the reasons why there are only few long-term studies on pulp capping procedures with follow-up periods superior to 5 years [14, 20, 27, 28] and were also one limitation verified in the present study.

The progressive reduction of the recall rate over time decreases the power of the statistical analysis and might have an impact on the results. Nevertheless, the recall rate of this study (68.5%) was superior to other retrospective studies [5, 14, 17, 20], and, also, the cases lost to follow-up extension were homogeneously distributed by material.

Comparison of the results with those reported in the literature might not be possible, not only because of inherent differences in the protocol design, materials and techniques employed, but also due to the fact most of clinical studies are recent with short-term follow-up periods [5, 13, 17, 18, 27, 29-33]. In spite of that, it was possible to address some conclusions from this retrospective study as it presents a long period of follow-up and an important registration data available. The monitoring of the patients over 94±43 months allowed the determination of long-term survival rates, as well as the performance of pulp capping materials over time.

The 1st, 5th and 10th year cumulative survival rates determined to this study are in line with the other studies on pulp capping. For instance, Dammaschke et al. [20] reports a survival rate of 76.3% after 13 years, and 58.7% for the 9-year study of Willershausen et al. [14], which are similar to the 70.2% presented here for the 10th year. The last authors also present a 5 year (68%) and 1 year (80.1%) survival rate, inferior to our findings (88.2% and 94.9% respectively). These results are partially in accordance to the recent systematic review of Aguilar et al., which reports a success range of 72.9% to 99.4% on pulp capping treatments and suggests that the most important factors conditioning the outcome are the material, the existence or absence of preoperative symptoms, the extent of pulp damage (pulpotomy versus conservative direct pulp capping) and the maturation state of the tooth (open versus closed apex) [16].

Even though calcium hydroxide was the first well-described material for pulp capping procedures, this goal can be achieved with other materials, namely adhesive systems and inorganic cements, with highlight for mineral trioxide aggregate cements, that claim for better performance. In spite of the fact that the literature is sparse, in what concerns to clinical studies with large samples and long-term follow-up, some

particular publications describes very good performance for specific materials. Bogen et al. [27] published a prospective study on 49 MTA capped teeth with 98% survival rate after 9 years of follow-up. Concerning Biodentine™, a more recently introduced inorganic cement, for which the manufacturer claims the same indications, but with new advantages over conventional MTA cements, no peer reviewed important clinical trials have been published. The current study reveals a 100% cumulative survival for MTA at 96 months, whereas Biodentine™, regardless of the same success rate, only presents one case with 17 months of follow-up. While the literature tends to support the use of MTA cements for pulp capping treatments, yet more studies with longer periods of follow-up are needed to confirm Biodentine™ as a good and recommended material. Calcium hydroxide has been successfully used for decades [4]. Although the 100% success rate registered in this study, only presents one case with 151 months of follow-up. Despite this relative good result, long-term studies with high number of cases tend to the increase of the failure rates as the follow-up evaluation periods extend. This might be on the account of the tunnel defects generated during the dentin bridge formation and on the progressive degradation of the material [10, 14, 16, 20, 34]. Although the drawbacks, calcium hydroxide still remains the gold standard material to pulp capping for some authors [4, 25, 35].

A vast number of studies on the use of adhesive systems as direct pulp capping material have not presented consensual results regarding the clinical and histopathological findings. In what concerns pulp inflammation, some studies reported the presence of moderate to severe inflammation after pulp capping with adhesive [10, 34, 36-42], whereas others managed to prove few inflammatory cells on pulp tissue [43, 44]. Some authors claim that it is the presence of unpolymerized monomers at pulp-adhesive interface that initiates the inflammatory response [41], which could be the reason for the premature failing that occurred in our study. Notwithstanding this, various studies were consistent to reveal that reduced hard tissue or no dentin bridge at all was formed on the long run after pulp capping with adhesive, implicating them as a poor barrier material against late bacterial infection [10, 36-44]. The lack of hard tissue barrier facilitates bacterial pulpal leakage when the adhesion starts to fail, which could explain the high number of failures that occurred in adhesive group after the 48th month (62.5% of all failures) and its decrease on cumulative survival rate found in the present study (85% and 60.9% at the 4th and the 11th year, respectively).

Some studies have shown that etching and rinsing with 37% phosphoric acid induces pulp bleeding after conditioning [40, 44]. Likewise, the primer components of the adhesive can induce vasodilatation and increase the risk of uncontrolled haemorrhage,

which could be a source of contamination, adhesion impairment [4] and the main reason for the failure after pulp capping with etch and rinse adhesive systems. Concerning adhesive type, no scientific evidences establish the superiority of self-etching over etch and rinse adhesives, regarding haemorrhage prevention, cytotoxicity and dentin bridge formation [37]. All these factors work together to the maintenance of a chronic inflammatory response, which impairs complete pulp healing [40, 41]. On account of the stated reasons, adhesive systems tend to be increasingly disregarded as a direct pulp capping material.

Evidence points to MTA as the best material choice for pulp capping as it performs better than any other, including calcium hydroxide, at least at biological point of view. MTA is a biocompatible material with bactericidal properties and high sealing capacity that leads the pulp to an effective reparative healing process [29]. All the histological findings reveal that MTA leads to fewer inflammatory cells and greater formation of dentin bridges than calcium hydroxide [45-47]. Moreover, dentin bridge formation after pulp capping with MTA is consistently found in several studies addressing MTA alone [48-52].

Clinically, the results of MTA are promising as most studies present survival rates ranging from 89.6 to 97.96% [13, 27, 29-31, 33], when performed by experienced operators, which is in accordance to the present study. However, these rates drop when the procedures are made by a novice or in non-ideal clinical situations, which discloses the sensitivity of the technique [5, 17]. The present study confirms MTA as an effective pulp capping procedure, revealing sound clinical and radiographic vitality signs in the long-term.

The potential healing of the pulp depends on the cause of exposure and on its condition at the time of treatment however the literature is not consensual when referring to pulp capping survival. In fact, there are multiple causes for pulp exposure such as caries, mechanical/iatrogenic excavation or trauma that have been associated to different success rates of the treatment. The literature refers many studies that expose intentionally healthy pulps of third molars or premolars programmed to extraction with good results. Although interesting for the possibility of making histopathological analysis, this kind of researches do not reproduce the routine clinical procedures, therefore produce results than cannot be translated directly to daily practice. Clinically, the most frequent cause of exposure is caries. When pulp exposure occurs during caries removal, it is difficult to assess the inflammatory condition of the pulp, which is a very important constrain in the success of vital pulp therapy [16, 18]. The introduction of infected dentin chips into the pulp is one of the possible reasons for

treatment failure [18]. Regardless of this, the success rate for pulp capping of carious exposures ranges from 72.9% to 99.4% [16], which emphasizes the evidence that vital permanent teeth, even with carious exposed pulp might be managed successfully by vital pulp therapy [16]. Nonetheless, some authors refer that the prognosis of teeth capped after trauma appears to be more favourable than the prognosis of capped teeth due to deep carious lesions [17], with survival rates ranging from 75.8% to 98% [17, 28, 53]. Recommendations refer that the important steps after a traumatism are the minimization of the bacterial invasion of the pulp [28, 53, 54] and the achievement of pulp capping in the shortest time possible. Concerning traumatic exposures, yet, the age of the patients, the elapsed time between injury and treatment, and mobility of the teeth were not related to failure outcome [35]. Additionally, Hencova et al. [28] state that conservative pulp capping in trauma injured pulps results in higher rates of necrosis than partial pulpotomy. In the present study, 3 of the 5 cases that had traumatic pulp exposures, received pulpotomies. The remaining two teeth were treated with conservative direct pulp capping. So far, the 5 cases have succeeded without symptoms or signals of pulp pathology. On the other hand, exposure due to caries occurred in 26 cases and 7 failed (26.9% failure rate).

According some recent literature age seems to be a factor influencing treatment outcome [16, 18]. A systematic review by Aguilar et al [16] collected evidence on the outcome of teeth with open apex versus teeth with closed apex and found statistically significant differences for the direct capping of immature teeth. Despite that, the difference was not found for partial and full pulpotomies. However, other studies argue that the changes that occur in the physiology and cell supply of the pulp and after completed root formation do not affect its ability to tolerate capping [5, 17, 20]. Unfortunately, no conclusions can be withdrawn from this study, as there were no statistically differences between age groups regarding failure. Curiously, our data tend to a higher failure in younger patients but do not turn down the idea that pulp capping is a reasonable alternative to root canal therapy in both mature and immature teeth.

Some important considerations are due to the preoperative symptoms mentioned by the patient, as they can be a signal of pulp disease and salivary or gingival exudate contamination during the treatment. Pulp capping should be avoided in patients with preoperative symptoms as spontaneous pain and prolonged thermal sensitivity tests, and signals of irreversible pulpitis. More, it is not indicated in cases with presence of necrotic pulp tissue, lack of haemostasis and cases with radiographic findings of apical pathology and the increased of tooth mobility [4, 6, 34]. No associations were established between preoperative symptomatic complains and failure rate in our

study. These results are related to the initial patient selection, as patients with signs of irreversible pulpitis or necrosis were not eligible for pulp capping. In regard to contamination, no associations were found between the use of rubber dam and failure rate. Again, this result is probably misleading as only 2 cases were performed without rubber dam isolation and only 3 reported contamination during the procedures.

Bleeding has been reported as an important factor influencing pulp capping outcome [4, 16]. It is of most importance to evaluate both the presence or absence of haemorrhage and the achievement of haemostasis. Clinically, extended bleeding could be a signal of pulp inflammation, disclosing lower healing ability of pulp tissues. Moreover, the clot might be a stimulus to the migration of inflammatory cells, which might undermine the prognosis. The present study found no influence of the presence of haemorrhage during the procedures and the survival of the tooth. When performed with adhesive systems, incomplete monomer polymerization on the account of bleeding and vessels injury impairs effective pulp capping. To answer the problem of pulp haemorrhage, some solutions, including saline solution, sodium hypochlorite solution, clorohexidine and hydrogen peroxide, have been described to be used as irrigating agents or pressing with cotton pellets [16, 34]. A profuse bleeding that is difficult to stop indicates severe pulpal inflammation. In these cases, treatment procedure must be modified and should involve either the removal of a portion of the inflamed pulp tissue (partial pulpotomy) or the removal of all coronal vital pulp (full pulpotomy) [33].

Concerning the clinical evaluation of restored teeth, the results of the present study are in accordance with the relevant literature about longitudinal studies, which stated the marginal adaptation with slight gaps or irregularities and the moderate surface and marginal staining as the more prevalent clinical founds in medium and long-term follow-up evaluations of composite resin restorations [55-58].

Conclusions

Within limitations of the present retrospective study it is possible to conclude that:

- Direct pulp capping is an effective long-term therapy, with a global survival rate of 88.2% for a 5 year-period and should be considered as an option in cases of asymptomatic pulp exposures with controlled haemorrhage.

- MTA presents a 100% cumulative survival rate for a mean period of 74±22.6 months and appears to be the material of choice for pulp capping of permanent teeth.

- It is advisable that the minimum evaluation period of clinical studies on direct pulp capping procedures be extended beyond 48 months.

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Annex 1. Clinical criteria to evaluate pulp capping teeth.

Symptoms	
Spontaneous pain	1.Yes 2.No
Cold or heat induced pain	1.Yes 2.No
Function induced pain	1.Yes 2.No

Biological Aspects	
Presence of abscess	1.Yes 2.No
Presence of *fistula*	1.Yes 2.No
Thermal sensitivity test (TST)	1. No hypersensitivity. Normal response. 2. Minor hypersensitivity for a limited period of time. 3. Intense hypersensitivity and delayed minor symptoms. 4. No clinical detectable sensitivity.
Actual pathology of caries, erosion, abfraction	1. No secondary or primary caries. 2. Small and localized demineralisation, erosion or abfraction. 3. Larger areas of demineralisation, erosion or abfraction. Dentine not exposed. 4. Caries with cavitation and suspected undermining caries, erosion in dentine or abfraction in dentine. 5. Deep caries or exposed dentine that is not accessible. Replacement necessary.
Periodontal condition	1. No plaque, no inflammation, no pocket. 2. Little plaque. No inflammation, no pocket. 3. Difference up one grade in severity of PBI compared to baseline and to a control tooth. 4. Difference of more than one grade of PBI in comparison to a control tooth or increase in pocket depth > 1mm requiring intervention. 5. Several acute gingivitis or periodontitis.

Annex 1. Clinical criteria to evaluate pulp capping teeth (cont.)

Dental Properties	
Horizontal percussion pain	1. Yes 2. No
Vertical percussion pain	1. Yes 2. No
Mobility	1. Physiological mobility 2. Horizontal mobility ≤ 1mm 3. Horizontal mobility > 1mm 4. Horizontal or/ and vertical mobility
Tooth discoloration	1. Yes 2. No
Tooth integrity **(enamel cracks, tooth fracture)**	1. Complete integrity 2. Small marginal enamel fracture. Hairline crack in enamel. 3. Marginal enamel defect. Enamel chipping. Multiple fractures. 4. Major marginal enamel defects, dentine or base exposed. Large chipping enamel or wall fracture. 5. Cusp or tooth fracture.

Annex 1. Clinical criteria to evaluate pulp capping teeth (cont.)

Restoration Properties	
Fracture and retention	1. No fractures/ cracks 2. Small hairline crack. 3. Two or more hairline crack and/or material chip fracture not affecting the marginal integrity or proximal contact. 4. Material chip fractures which damage marginal quality or proximal contacts. Bulk fractures with partial loss. 5. Partial or complete loss of restoration or multiple fractures.
Marginal and surface staining	1. No marginal or surface staining. 2. Minor marginal and/or surface staining, easily removable by polishing. 3. Moderate marginal and/or surface staining, not aesthetically unacceptable. 4. Pronounced marginal staining, major intervention necessary for improvement. Unacceptable surface staining on the restoration, major intervention necessary for improvement. 5. Deep margin staining not accessible for intervention. Severe surface staining. Generalized or localized, not accessible for intervention.
Marginal adaptation	1. Harmonious outline, no gaps, no white or discoloured lines. 2. Marginal gap, white line. Small marginal fracture easily removable by polishing. Slight, ditching or minor irregularities. 3. Gap not removable. Several small marginal fractures. Major irregularities or ditching. 4. Gap that exposed dentine/ base. Several ditching or marginal fractures. Larger irregularities or steps. Necessary repair. 5. Partial or complete restoration is loose but in situ. Generalized major gaps and irregularities.
Proximal contour and contact	1. Normal contact point. Normal contour. 2. Contact point slightly too strong but no clinical drawback. Slightly deficient contour. 3. Weak contact, no indication of damage to tooth, gingival or periodontal structures. Visible deficient contour. 4. Too weak contact and possible damage due to food impactation. Inadequate contour. Repair possible. 5. Too weak and clear damage due to food impactation and/or pain/gingivitis. Insufficient contour requires replacement. 6. No applicable.

Annex 1. Clinical criteria to evaluate pulp capping teeth (cont.)

Radiographic examination	
Restoration	1. No pathology. Harmonious transition between restoration and tooth. 2. Acceptable material excess (positive or negative step). 3. Marginal gap (visible positive or negative step). Poor radiopacity of filling material. 4. Secondary caries, large gaps. Fracture/loss of restoration or tooth.
Apical pathology	1. Yes 2. No
Thickening periodontal ligament	1. Yes 2. No
***Lamina dura* interruption**	1. Yes 2. No
Internal resorption	1. Yes 2. No
External resorption	1. Yes 2. No
Distrofic pulp calcification	1. Yes 2. No
Pulp stone	1. Yes 2. No
Anquilosis	1. Yes 2. No
Hard tissue formation	1. Yes 2. No
Apexogenesis	1. Yes 2. No
Root canal treatment	1. Yes 2. No