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ORIGINAL ARTICLE

Prognostic factors in direct pulp capping with mineral trioxide aggregate or calcium hydroxide: 2- to 6-year follow-up

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Abstract
Objectives The aim of this retrospective study was to evaluate the influence of various predictors on healing outcomes after direct pulp capping (DPC) using either mineral trioxide aggregate (MTA) or calcium hydroxide (CH) as a pulp-dressing agent.
Materials and methods The present study included 172 mature asymptomatic permanent teeth with carious-exposed pulp. The teeth were treated with DPC, using either MTA or CH, and the treatment outcome was evaluated clinically and radiographically. The effect of potential clinical variables on the treatment outcome of DPC was evaluated clinically and radiographically during a 24–72-month follow-up. In order to assess the cumulative successes of CH and MTA after DPC, Kaplan-Meier survival analysis and log-rank test was used. The subgroups were compared by means of the log-rank test. Also, univariate Cox regression analysis was used to determine hazard ratio of clinical variables.
Results One hundred and fifty-two teeth of 172 capped teeth were available for follow-up, with an overall recall rate of 87.6 % for MTA vs 89.3 % for CH. The mean period of follow-up was 37.3 (±17.2) months. Overall success rates of 85.9 and 77.6 % in the MTA and CH groups were observed, respectively. The cumulative success rate of both materials was not statistically different when analysed by the Cox proportional hazard regression analysis ($P = 0.282$). The Kaplan-Meier survival curves revealed that 2-year overall pulp survival was 91.4 %, while the 4- and 6-year survival rates were 84 and 65 %, respectively. None of the clinical variables had a considerable influence on the outcome of DPC ($p > 0.05$).
Conclusions MTA-capped teeth demonstrated a slightly higher success rate than CH, revealing that it can be recommended as a reliable direct pulp-capping material. None of the clinical variables investigated significantly affected posttreatment healing.
Clinical relevance DPC with MTA is a straightforward procedure with favourable outcome of 24- to 72-month follow-ups in vital mature asymptomatic permanent teeth with cariously exposed pulp, and it may be considered a realistic alternative therapy to RCT.

Keywords Calcium hydroxide · Direct pulp capping · Mineral trioxide aggregate

Introduction

Preserving pulp vitality should always be the primary aim of endodontic treatment. A prerequisite for any intervention to preserve vitality is the presence of either healthy pulp tissue or pulpal damage that can be reversed [1]. Vital pulp therapy (VPT), namely stepwise excavation, indirect or direct pulp capping (DPC) and partial/full pulpotomy, is a procedure in which cariously or traumatically exposed dental pulp is covered with a protective dressing or cement. The specific aim of VPT is to preserve and maintain complete/partial coronal/radicular pulp vitality and stimulate the formation of a tertiary dentinal bridge [2–6].

Historically, the use of DPC for mature permanent teeth with carious pulp exposure has been the source of extreme controversy in dentistry. Most authors have recommended a

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pulpectomy instead of DPC [7, 8]. Although a prospective study reported a high success rate (up to 91.5 %) after pulpectomies of vital teeth [9], two meta-analyses reported a lower success rate of approximately 82 % [10, 11]. The results of a recent systematic review showed that VPT using either mineral trioxide aggregate (MTA) or calcium hydroxide (CH) was a reasonable alternative treatment to pulpectomies in vital permanent teeth with cariously exposed pulps, with predictable results and an overall success rates ranging from 72.9 to 99.4 % [12]. This fact is also supported by more recent studies presenting favourable outcomes with MTA (89.1–95.5 %) by Song et al. [13] and Marques et al. [14].

Many pulp-capping materials are available for use with DPC, but CH has remained the dominant material for many years. Recently, MTA has been advocated as a superior material for pulpal therapy [13–15] because it is a biocompatible, non-mutagenic cement [16, 17], with a good sealing ability [18, 19]. Several human studies of uninflamed, traumatically exposed pulps have histologically shown that the dentine bridge formation obtained with MTA was of better quality than that obtained with CH [20, 21].

Clinical studies have evaluated both short- and long-term results of DPC using CH [6, 22–34]. Clinical studies of MTA pulp-capping treatment of cariously exposed permanent mature or immature teeth are limited [13, 14, 35–38]. Recently, some studies compared the influence of significant predictors on the clinical outcomes of DPC using CH and MTA [39–42]. However, the majority of DPC studies that used either CH or MTA were retrospective in nature, and they were performed by supervised undergraduate students or by dentists. In DPC studies with CH or MTA, the authors reported about 70–98 % favourable treatment outcome [12, 33]. Although some authors presented overall success rate of DPC with CH ranging between 59.3 and 61 % [30, 31], interestingly, only two studies with DPC using CH reported extremely low short-term (31.8 % after 1 year) [32] and long-term (37 % after 5 years and 13 % after 10 years) [29] success rates.

The aim of this retrospective study was to evaluate the influence of various predictors on 2–6-year outcomes of DPC using either MTA or CH to treat permanent mature teeth with cariously exposed pulp.

Materials and methods

Study population

Enrolled 169 patients with 175 teeth were referred to the first author (MKÇ) for diagnosis and treatment planning at the Department of Endodontics, School of Dentistry, Ege University, İzmir, Turkey, between January 2007 and December 2013. A detailed explanatory information sheet including the treatment (vital pulp therapy), postoperative care, possible complications and alternative treatment options (root canal treatment), follow-up examinations and the follow-up dates was given to the patients. In addition, at the Faculty of Dentistry at Ege University, all patients sign an informed consent prior to their clinical examination and treatment. In this procedure, the patients are informed and agree by their signature that their data can be used for educational and academic purposes. The Human Ethical Committee of Ege University reviewed the study protocol afterwards and ensured the compliance according to the Helsinki criteria and approved all procedures (B.30.2.EGE.0.20.05.00/OY/60, 13 January 2015).

A standard clinical examination was performed by a single operator (MKÇ) preoperatively to assess the patients' medical and general oral condition, sensitivity to percussion and palpation, mobility of the affected teeth, periodontal probing depth and sensitivity to electrical pulp testing of the involved tooth. Preoperative radiographs were taken with dental X-ray film (Ektaspeed Plus; Eastman Kodak, Rochester, NY, USA) and a paralleling device (XCP; Rinn Co, Elgin, IL, USA) under standard radiographic exposure conditions.

Inclusion and exclusion criteria

The patient selection and inclusion criteria for DPC were as follows: a non-contributory medical history, the teeth with no previous operative treatment and mature apices, a response within normal limits to an electric pulp test, no history of spontaneous pain, no tenderness to percussion or palpation, no mobility, periodontal probing within the normal range (attachment loss 3 mm) and radiographs showing a normal healthy appearance of periradicular tissues. The exclusion criteria were prolonged spontaneous pain, difficulty controlling pulpal bleeding from the exposure site, pulp exposure of both axial sites, a non-restorable tooth, coronal or root canal calcification in a periapical radiograph and lack of informed consent. Only one tooth was included at random for this study. All data were collected by a single operator (MÇK), who also performed the operations. The clinical and radiographic findings and results were recorded and stored manually in the patient sheets. In order to perform statistical analyses, the data were later transferred into Excel pages.

Treatment procedures

The teeth were anaesthetised with 2 % mepivacaine (Citanest; AstraZeneca, London, UK) without a vasoconstrictor, isolated with a rubber dam. The carious enamel lesions were removed using a high-speed handpiece with diamond burs. The carious dentine lesions were then completely eliminated using mechanical excavation with a low-speed round bur and a spoon excavator. This process was continued until reaching the hard dentine, even after the pulp was exposed. Bleeding of the pulp

stump was controlled with a sterile saline-soaked cotton pellet, which was applied with gentle pressure for 1–10 min. Teeth with bleeding from exposed pulp that persisted for longer than 10 min were excluded from the study and were subjected to a full pulpotomy. After homeostasis, CH mixed with distilled water (Merck, Darmstadt, Germany) or MTA (ProRoot MTA; Dentsply, Tulsa, OK, USA) was applied on the exposed pulp. A sterile wet cotton pellet was placed over the MTA. In both groups, the cavity was provisionally restored with zinc oxide-eugenol (ZOE) cement (Kemdent, Wiltshire, UK). After 2–7 days, the teeth were permanently restored with a thin protective layer of resin modified glass ionomer (Vitrobond; 3 M ESPE, St. Paul, MN, USA) and a bonded resin composite (Filtek Z250, 3 M ESPE, St. Paul MN, USA) or amalgam (Degussa, Frankfurt, Germany). The teeth were randomly assigned to either CH or MTA groups and received the allocated interventions.

Preoperative and intraoperative data

Preoperative data included gender and age of patients, and location and type of tooth. Intraoperative data included size/site (occlusal or cervical)/number of pulp exposure and type/class of permanent restoration, capping material and recall time and were recorded.

Clinical and radiographic assessment of outcome

DPC therapy was considered clinically and radiographically successful when the following criteria were fulfilled: absence of clinical symptoms, a positive response to cold or electrical pulp testing, radiographic absence of any intra-radicular pathology (internal resorption or calcification) and the maintenance of the preoperative healthy periapical tissue as radiographic sign.

Follow-up examination

The patients were followed up periodically to assess the clinical and radiographic signs of healing. The minimum follow-up period was 2 years. Previously informed patients were contacted by telephone for their follow-up every 3 months for up to 1 year and then at 6-month intervals for 2 years and thereafter at 10- or 12-month intervals until the end of the study. On every follow-up visit, the clinical and radiographic evaluations were performed according to the abovementioned criteria by two examiners (one endodontist and one oral radiologist) who had at least 10–26 years of clinical experience and were not involved in the clinical procedure**.** The outcome of radiographic success was defined by using a modification of Strindberg criteria [43]. Radiographically, teeth with normal contour with width of periodontal ligament and lamina dura and additionally the absence of any radiographic pathology (e.g. internal resorption or calcification of coronal/root canal systems) were considered as healed. Teeth with widening of the periodontal ligament or periapical radiolucency were judged as failed. Two independent experienced observers were calibrated prior to their assessment through individual evaluation of 25 radiographs independent from this study. After the completion of the calibration sessions, preoperative, posttreatment and follow-up radiographs from this study were evaluated by the same examiners in a darkened room by using an illuminated viewer box with ×2 magnification one at a time in a random order and in a blinded manner, and this was repeated on a separate occasion 2 weeks later. When there was disagreement, the two observers discussed the case in an effort to come to a consensus. Inter- and intraexaminer agreement scores were calculated by using Cohen kappa statistic.

Statistical analysis

The dependent variable in all the analyses was specified as ‘success at last follow-up’. The Kaplan-Meier analyses and log-rank test were used to calculate the cumulative success proportion and mean time. Prognostic clinical variables were also identified with Univariate Cox proportional hazard regression analysis. Post hoc analyses were performed according to the survival of the teeth in both groups using NCSS Trial and PASS 2000 programmes (http://www.ncss.com/download/pass/free-trial). All hypothesis tests were two-tailed and performed at a significant level of 0.05. The analyses were done using SPSS software version 20.0 (IBM SPSS Inc., Chicago, IL, USA).

Results

One hundred and seventy-five teeth were initially included in the study; however, 20 of them were not available for recall and were considered drop out due to the following reasons: 13 patients could not be contacted in spite of repeated mailing and phone calls, and the remaining 7 patients refused to participate into the recall examination (an overall recall rate of 87.6 % for MTA vs 89.3 % for CH) (Fig. 1). Additionally, three teeth with excessive uncontrolled bleeding (longer than 10 min) were excluded from the study. These teeth were treated with a full pulpotomy and received successful outcomes. The follow-up period was 24–72 months after DPC with a mean period of 37.3 (±17.21) months. The age of the patients at the time of DPC was between 14 and 55 years with a mean of 29.7 (± 10.59) years. The examiners disagreed only on two cases which required subsequent joint evaluation to reach consensus. The Cohen’s kappa value ranged from 0.890 to 1.0, revealing very good intra- and interexaminer reliability in the evaluation of the pre- and postoperative radiographs. Also, none of the teeth presented internal resorption or calcification

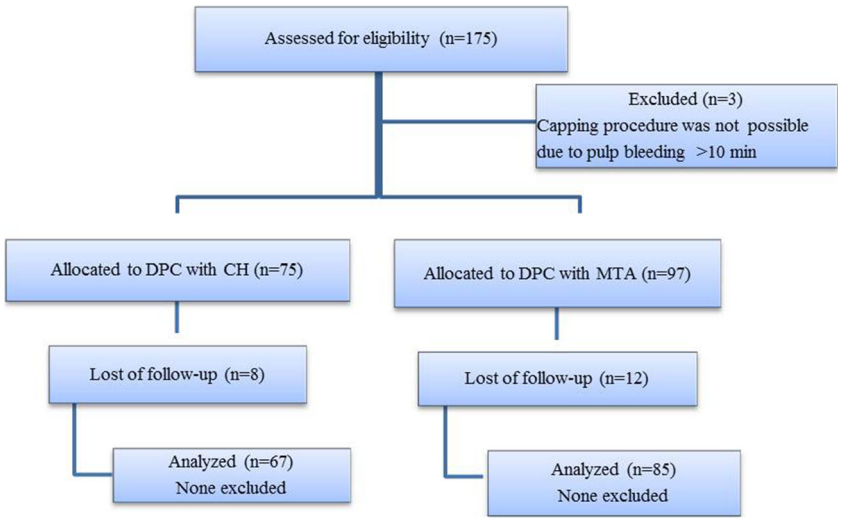

Fig. 1 Patient flow chart of capped teeth with calcium hydroxide or MTA

of coronal/root canal systems postoperatively. Ultimately, a total of 152 teeth were included in the analysis (recall rate = 86.8 %). Of the 152 teeth, 27 teeth (18.3) failed and 125 censored (81.7 %). The success rate in the MTA and CH group was 85.9 % (73/85 teeth) and 77.6 % (52/67 teeth), respectively. The follow-up periods were recorded as within 2 years for 68/152 teeth, 25 to 48 months for 47/152 teeth and 49 to 72 months for 37/152 teeth, respectively.

The Kaplan-Meier analyses revealed that the cumulative survival rate after DPC with MTA was 93 % at the 24th month, 89 % at the 48th month and 71 % at the 72nd month, while CH yielded 90, 78 and 59 % survival rates at the 24th, 48th, and 72nd month, respectively (Fig 2a, Table 1). Overall, 2-year pulp survival was 91.4 %, while the 4- and 6-year survival rates were 84 and 65 %, respectively (Fig 2b, Table 2). The cumulative success rates of both materials was not statistically different when analysed by the Cox proportional hazard regression analysis ($P = 0.282$, Table 2). None of the clinical variables were significantly effective on the outcome of DPC when all data were combined ($P > 0.05$, Table 2). Also, none of the evaluated clinical variables had a statistically significant influence on the outcome of DPC with two materials (CH and MTA) separately ($P > 0.05$, Tables 3 and 4). Therefore, a further multivariate Cox proportional hazard regression analysis was not performed to determine the decisive factor for the survival rate. Fifteen cases in the CH group and 12 cases in the MTA group were classified as failures. The clinical and radiographic findings of these patients are shown in Table 5. The failed cases were subjected to root canal treatment. One tooth with a vertical root fracture was extracted.

Discussion

There are limited published data comparing the effectiveness of CH and MTA in clinical situations involving carious pulp exposure [39–42]. Therefore, this study both compared the effects

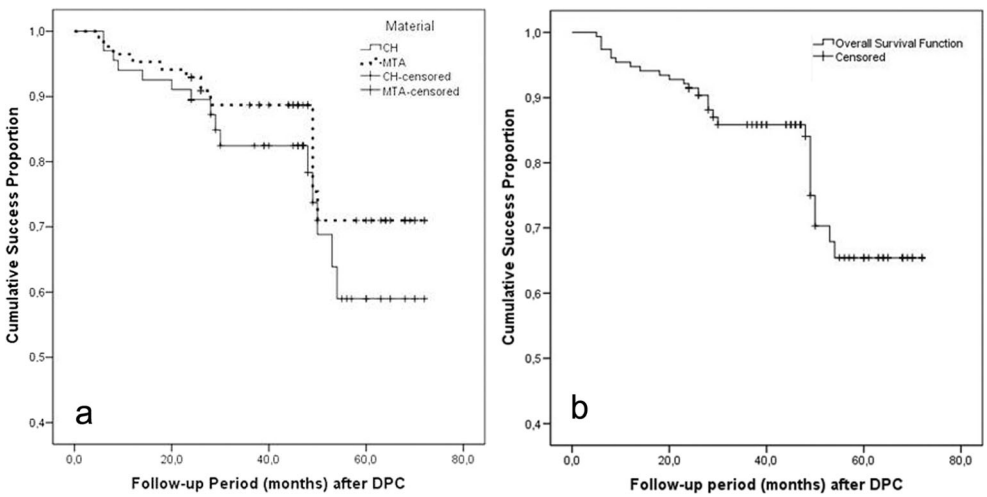

Fig. 2 **a** The Kaplan-Meier survival curves in relation to selected capping materials. **b** Survival curve of the overall outcome

Table 1 Cumulative success proportion and std. error associated with follow-up period

Period (months)	CH	MTA	Overall
24	0.90 ± 0.037	0.93 ± 0.028	0.91 ± 0.023
48	0.78 ± 0.064	0.89 ± 0.039	0.84 ± 0.036
72	0.59 ± 0.097	0.71 ± 0.085	0.65 ± 0.065

of various predictors on the treatment outcome of DPC, and presented the results of previous short-term or long-term follow-up studies that used CH and MTA as dressing material.

In this study, neither the patient's age nor gender affected the outcomes of DPC. This finding is in accordance with those reported in previous studies [6, 24, 28, 29, 31, 36, 38–40]. In contrast, some authors stated significantly greater number of unfavourable treatment outcomes after DPC with increasing age [14, 25, 27, 30, 33, 42].

The type and location of tooth have also been reported to affect the treatment outcomes after DPC. In contrast to Auschill et al. [30], some authors reported higher rates of unfavourable treatment outcomes with anterior teeth than with posterior teeth [25, 28]. On the other hand, other authors reported that the type of tooth (anterior vs. posterior or mandible versus maxillary) had no significant influence on the treatment outcome [6, 24, 29, 31, 33, 38–42], which is in accordance with the results of the present study.

Erroneously, clinicians probably assume that larger pulp exposures have a poorer prognosis, and they may include pulpal exposure size in their decision-making criterion [45]. Several authors suggested that DPC should be attempted only when the exposure is small (<1 mm^2 or 1 mm in diameter) [24, 25, 30, 31, 34]. However, some researchers reported treatment success following capping of large exposures with a diameter of >1 mm [6, 27, 36, 37]. In this study, there was no significant difference in the treatment success of teeth with pulpal exposure of up to 1 mm when compared to teeth with pulpal exposure of >1 mm, which is in agreement with previous studies [6, 27, 36, 37]. Additionally, some investigators reported successful treatment outcomes in teeth with multiple pulpal exposure following DPC with CH or MTA [27, 37], as was the case in the present study.

In some studies, the type of pulp exposure (carious vs. mechanical) had no significant effect on the outcome of DPC [25, 39, 40], whereas others found a reduced clinical success rate in carious exposures compared with mechanical exposures [31, 44]. Similarly, in a recent clinical trial, pulp capping of deep caries-exposed permanent teeth with MTA reported a lower success rate of 56.2 % after 2 years [36]. The success of DPC may depend on the complete removal of all disintegrated tissue [46]. The favourable results of the present study support this idea.

In a series of animal studies, the authors reported that the dentine bridge that formed in response to cervical pulp exposure cut off the blood supply to the coronal pulp, leading to pulpal necrosis [47, 48]. By obliterating the canal entrance, pulp capping the cervical pulpal exposure could complicate subsequent root canal treatment [49]. Some clinical studies reported that the survival rate of teeth with pulp exposed on the occlusal site was better than on teeth with pulp exposed on the axial site [27, 42]. On the contrary, the site of exposure (occlusal vs. axial) did not influence the treatment outcome in this study. This finding is in agreement with previous human clinical studies [14, 29, 39, 40]. It may also confirm the opinion of Pereira and Stanley [50] who observed in an animal study that the site of pulpal exposure has no effect on the pulp's healing ability.

Recent studies described the use of an adhesive direct-placement composite restoration or a full-coverage crown as the final restoration following DPC [14, 35, 37–40, 42]. However, amalgam restorations were reported to be superior to composite and glass ionomer cement as a permanent filling material in restorations, especially in deep and pulpally exposed cavities [34, 51]. Nevertheless, it has been shown that amalgam or composite restorations did not show any significant differences in teeth with 'clinically healthy' pulps after DPC [29, 33, 36]. Our results were in accordance with the findings of these studies.

Several studies reported that the survival rates of teeth with class I restorations were significantly better than teeth with other classes of restoration [31, 34]. The results of previous studies correlate with the findings of the present study. However, studies by Mente et al. [39, 40] revealed that the size of the coronal restoration (i.e. small or large) and the quality of the restoration at follow-up did not significantly influence the outcome of DPC.

Recently, some authors suggested that the success of DPC in the hands of skilled dentists is not superior to undergraduate students [34, 39, 40]. However, in some retrospective clinical studies, DPC with CH or MTA had lower success rate when performed by inexperienced practitioners [29, 31, 36]. Moreover, Baume and Holz [44] mentioned that the operator's skill seemed to influence the outcome of DPC. The findings of some studies have provided support for this idea, with higher success rates of 92 and 98 % [35, 37]. In the present study, one operator performed the DPC treatment in order to eliminate the adverse impact of using multiple operators on the treatment outcome and to provide more reliable results.

Various judgement criteria for success have been used in the assessment of the outcome of DPC in the literature, some of which are controversial. Armstrong and Hoffman [22] used a lack of clinical symptomology and the radiographic presence of secondary dentin as criteria for success. Al-Hiyasat et al. [31] used 3-year postoperative radiography results as the criteria for success, whereas Dammaschke et al. [33] did not include any radiographic assessment. In other studies, capped teeth were classified at clinical follow-up into 'uncertain or questionable' categories if the

Table 2 Univariate Cox regression analysis (success and failure frequencies, *P* value, Hazard ratio statistics) for both treatment groups (CH and MTA) according to the potential clinical variables

Variable	Censored (*n*, %)	Failure (*n*, %)	Total	*P* value	Hazard ratio (95 % CI)
Gender				0.578	
Male	69 (81.2)	16 (18.8)	85		1
Female	56 (83.6)	11 (16.4)	67		1.2 (0.5–2.6)
Age				0.552	
14–35 years	75 (81.5)	17 (18.5)	92		1
36–55 years	50 (83.3)	10 (16.7)	60		0.78 (0.3–1.7)
Tooth location				0.478	
Maxilla	50 (79.4)	13 (20.6)	63		1
Mandible	75 (84.3)	14 (15.7)	89		1.3 (0.6–2.8)
Tooth type				0.616	
Anterior	21 (84)	4 (16)	25		1
Posterior	104 (81.9)	23 (18.1)	127		0.7 (0.2–2)
Site of exposure				0.123	
Occlusal	78 (86.7)	12 (13.3)	90		1
Axial	47 (75.8)	15 (24.2)	62		
Size of exposure				0.441	
Up to 1 mm	90 (84.1)	17 (15.9)	107		1
1 ≥ mm	35 (77.8)	10 (22.2)	45		1.3 (0.6–2.9)
Number of exposure[a]				0.580	
One	104 (83.9)	20 (16.1)	124		1
Two	18 (78.3)	5 (21.7)	23	0.521	1.4 (0.5–3.6)
Three	3 (60)	2 (40)	5	0.366	2.0 (0.4–8.4)
Type of restoration				*0.387*	
Amalgam	54 (85.7)	9 (14.3)	63		1
Composite	71 (79.8)	18 (20.2)	89		0.7 (0.3–1.5)
Class of restoration[b]				0.594	
Class I	49 (89.1)	6 (10.9)	55		1
Class II	45 (78.9)	12 (21.1)	57		1.9 (0.7–5.1)
MOD	7 (63.6)	4 (36.4)	11		2.8 (0.8–10.1)
Class III	15 (83.3)	3 (16.7)	18		1.2 (0.3–4.8)
Class IV	5 (71.4)	2 (28.6)	7		2.6 (0.5–13.3)
Class V	4 (100)	(0)	4		0
Capping material				0.282	
CH	52 (77.6)	15 (22.4)	67		1
MTA	73 (85.9)	12 (14.1)	85		1.5 (0.7–3.2)

CI confidence interval, *CH* calcium hydroxide, *MTA* mineral trioxide aggregate

[a] The Hazard ratios were calculated between the variable one exposure and the variables two or three exposures respective

[b] The Hazard ratios were calculated between class 1 and one of the other three categories

sensitivity testing response of teeth lacking periapical radiolucency to was classed as questionable [23, 29]. Long-term clinical and radiographic evaluations are the most accurate predictors for measuring the pulpal survival rates following VPT [45]. Nevertheless, several authors classified the treatment success as an absence of clinical symptoms, a positive response to cold or electrical pulp testing, non-existence of any intra-radicular pathology (internal resorption or calcification) and apical periodontitis radiographically [2, 4, 6, 22, 37], in addition to the clinical or radiographic presence of dentine bridge formation [2, 22, 37]. However, in the present study, dentine bridge formation was not detected clearly on the radiographs, probably due to the low degree of dentine bridge mineralisation and the inability to direct the radiographic beam perfectly perpendicular to the axis of the tooth and the exposure site at the same time, as reported by others [6, 35].

Many investigators simply reported the success or failure rates of DPC treatment at specific follow-up times [12, 33]. According to Cvek [52] and Matsuo et al. [6], a follow-up time of

Table 3 Teeth and outcome across the various clinical predictors and estimated relative rates of success following direct pulp capping with calcium hydroxide. None of the clinical variables had significant impact on the outcome

Variable	Censored (*n*, %)	Failure (*n*, %)	Total	*P* value	Hazard ratio (95 % CI)
Gender				0.674	
Male	30 (79)	8 (21)	38		1
Female	22 (76)	7 (24)	29		1.2 (0.4–3.4)
Age				0.849	
14–35 years	31 (79)	8 (21)	39		1
36–55 years	21 (75)	7 (25)	28		1.1 (0.4–3.0)
Tooth location				0.482	
Maxilla	20 (74)	7 (26)	27		1
Mandible	32 (80)	8 (20)	40		0.7 (0.2–2.0)
Tooth type				0.975	
Anterior	9 (82)	2 (18)	11		1
Posterior	43 (77)	13 (23)	56		1.0 (0.2–4.5)
Site of exposure				0.729	
Occlusal	32 (82)	7 (18)	39		1
Axial	20 (71)	8 (29)	28		1.2 (0.4–3.4)
Size of exposure				0.421	
Up to 1 mm	37 (78)	9 (22)	46		1
1 ≥ mm	15 (75)	6 (25)	21		1.5 (0.5–4.3)
Number of exposure[a]				0.791	
One	42 (78)	12 (22)	54		1
Two	8 (80)	2 (20)	10		0.9 (0.2–4.1)
Three	2 (67)	1 (33)	3		2.0 (0.2–16.2)
Type of restoration				0.506	
Amalgam	22 (79)	6 (21)	28		1
Composite	30 (77)	9 (23)	39		1.4 (0.5–4.2)
Class of restoration[b]				0.960	
Class I	21 (84)	4 (16)	25		1
Class II	17 (74)	6 (26)	23		1.5 (0.4–5.3)
MOD	4 (67)	2 (33)	6		1.5 (0.2–8.1)
Class III	6 (75)	2 (25)	8		0.9 (0.1–7.8)
Class IV	2 (67)	1 (33)	3		2.4 (0.3–22.1)
Class V	2 (100)	0	2		0

CI confidence interval, *CH* calcium hydroxide

[a] The Hazard ratios were calculated between the variable one exposure and the variables two or three exposures respective

[b] The Hazard ratios were calculated between class 1 and one of the other three categories

approximately 2 years is reasonable to reach a conclusion concerning the treatment outcome of DPC using CH. In the current study, the likelihood of tooth failure after DPC with CH or MTA was slightly higher in the first 2 years after the treatment, with the failure rate declining after more than 2 years.

Clinical studies reported success rates ranging between 80 and 100 % 1–2 years after DPC using CH [6, 22]. These results differ from those reported by Bjørndal et al. [32] who found an extremely low overall pulp survival rate (31.8 %) of deep carious-exposed adult teeth after DPC with CH in a 1-year follow-up study. Bjørndal et al. [32] presented the pre-treatment status of the pulp in cases of severe caries and/or pulpal inflammation and pre-treatment pain as the contributors of the treatment failure. Chailertvanitkul et al. [53] proposed that the small sample size of the capped teeth (22 capped teeth versus 292 teeth treated with stepwise and direct excavation) which were not definitively restored until 1 month after the pulp treatment and belonged to the adult patients aged >18 years, and improper use of a rubber dam may explain the low success rate in Bjørndal's et al. study [32].

Long-term (5-year) follow-up studies of DPC using CH reported success rates ranging from 37 to 81.8 % [24, 25, 29, 30, 34]. Studies with follow-up periods exceeding 5 years found various success rates: Attin et al. [28] 4–6 years 69.3 %,

Table 4 Teeth and outcome across various clinical predictors and estimated relative rates of success following direct pulp capping with MTA. None of the clinical variables had significant impact on the outcome

Variable	Censored (*n*, %)	Failure (*n*, %)	Total	*P* value	Hazard ratio (95 % CI)
Gender				0.266	
Male	39 (83)	8 (17)	47		1
Female	34 (89)	4 (11)	38		0.5 (0.1–1.7)
Age				0.249	
14–35 years	44 (83)	9 (17)	53		1
36–55 years	29 (91)	3 (9)	32		0.4 (0.1–1.7)
Tooth location				0.682	
Maxilla	30 (83)	6 (17)	36		1
Mandible	43 (88)	6 (12)	49		0.8 (0.2–2.4)
Tooth type				0.590	
Anterior	12 (86)	2 (14)	14		1
Posterior	61 (86)	10 (14)	71		1.5 (0.3–7.1)
Site of exposure				0.099	
Occlusal	45 (90)	5 (10)	50		1
Axial	28 (80)	7 (20)	35		2.6 (0.8–8.4)
Size of exposure				0.826	
Up to 1 mm	53 (87)	8 (13)	61		1
1 ≥ mm	20 (83)	4 (17)	24		1.1 (0.3–3.8)
Number of exposure[a]				0.548	
One	62 (89)	8 (11)	70		1
Two	10 (77)	3 (23)	13		2.0 (0.5–7.5)
Three	1 (50)	1 (50)	2		1.8 (0.2–14.7)
Type of restoration				0.431	
Amalgam	32 (91)	3 (9)	35		1
Composite	41 (82)	9 (18)	50		1.6 (0.4–6.3)
Class of restoration[b]				0.428	
Class I	28 (93)	2 (7)	30		1
Class II	29 (85)	5 (15)	34		3.2 (0.6–16.3)
MOD	3 (60)	2 (40)	5		6.5 (0.9–46.6)
Class III	8 (80)	2 (20)	10		0.9 (0.08–10.6)
Class IV	3 (75)	1 (25)	4		3.7 (0.3–41.0)
Class V	2 (100)	0	2		0

CI confidence interval, *MTA* mineral trioxide aggregate

[a] The Hazard ratios were calculated between the variable one exposure and the variables two or three exposures respective

[b] The Hazard ratios were calculated between class 1 and one of the other three categories

Ahrens and Reuver [23] up to 8 years 68 %, Willershausen et al. [34] up to 9 years 58.7 %, Hørsted et al. [25] >10 years 72.7 % and Reuver [27] 4–24 years 66 %. Dammaschke et al. [33] revealed an overall survival rate of 76.3 % after 13.3 years and reported that the failure of DPC was most likely to occur within the first 5 years. In our study, the clinical and

Table 5 Failures by combined clinical and radiologic criteria

Failures	CH group		MTA group	
	n = 15	%	*n* = 12	%
Irreversible pulpitis (symptomatic, thermal test+)	4	26.5	3	25
Evidence of pulp necrosis without pain and apical periodontitis	6	40	5	42
Pulp necrosis with acute apical periodontitis	4	26.5	3	25
Vertical root fracture	1	7	1	8

radiographic success rates after DPC with CH were similar in the 24- and 25–72-month follow-ups, concurring with the findings of other researchers [24, 28, 33]. In contrast, in a retrospective study, Barthel et al. [29] found an extremely low level of surviving pulp (13 %) after 10 years following DPC. This low rate of success was attributed to an inability to control 69.3 % of the patients in recalls, a lack of a standardised clinical treatment protocol (the use of zinc phosphate cement and glass ionomer cement as temporary restorative materials), variations between the periods of permanent restoration placements, a lack of control over the variables, the inexperience of the supervised undergraduate students who were the treatment providers [29] and a small number of patients aged 10–20 years [53].

Three recent retrospective clinical studies directly compared the effect of CH and MTA on the treatment success rate of teeth with cariously exposed pulp following DPC [39, 41, 42]. They recorded successful treatment outcomes of 67.4, 78 and 80.3 % in the MTA group and 52.5, 60 and 68.5 % in the CH group in 1–3-year follow-ups [39, 41, 42]. Although these studies reported that MTA was more effective than CH as a direct pulp-capping material [39–42], some comparisons of long- and short-term survival rates following DPC with MTA found that the long-term survival decreased over time [36, 42]. Miles et al. [36] reported a decrease in survival rates from 67.7 % after 1 year to 56.2 % after 2 years, and Cho et al. [42] 2013 reported a decrease from 89.9 % after 1 year to 67.4 % after 3 years. On the other hand, Bogen et al. [37] and Mente et al. [39] found no time-dependent decline in the success rate after DPC. However, in the second phase of their study, Mente et al. [40] reported that follow-up time may be considered as a prognostic factor for MTA, but not for CH. In the present study, the success rate in the MTA and CH group was 85.9 and 77.6 %, respectively. The cumulative success rate of both materials was not statistically different when analysed by the Cox proportional hazard regression analysis ($P = 0.282$). The Kaplan-Meier survival curves revealed that overall 2-year pulp survival was 91.4 %, while the 4- and 6-year survival rates were 84 and 65 %, respectively. Additionally, none of the evaluated clinical variables had a statistically significant influence on the outcome of DPC with two materials (CH and MTA) separately.

The presence of a single operator during the patient evaluation, treatment and data collection procedure is an important feature of the study that eliminated the operator bias. Additionally, postoperative clinical and radiographic evaluation of the patients by two independent experienced examiners who were not involved in the clinical procedure may be stated as another strength of this retrospective study. On the other hand, unequal distribution of the patients between the test groups and different follow-up periods may be considered as the methodologic limitations in this study. The small size of the study sample is also another limitation of the present study, and this was the result of having only one operator to perform the treatments. A post hoc power analysis revealed that in order to achieve a 0.05 significance level and 80 % power for a two-tailed test, an overall sample size of 398 teeth (of which 175 are in group CH and 223 are in group MTA) is required. Therefore, the present study project will continue to include new patients prospectively and will enrol more than one specialist to perform DPC in order to achieve higher number of sample size to provide a sound conclusion.

Conclusion

Within the limitations of this long-term retrospective clinical study comparing the 2–6-year outcome of DPC by using two different capping materials, the following conclusions can be drawn: even though statistically differences were not significant, MTA-capped teeth demonstrated a slightly higher success rate than CH. None of the clinical variables investigated significantly affected posttreatment healing.

Compliance with ethical standards

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

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Ethical approval The Human Ethical Committee of Ege University reviewed the study protocol afterwards and ensured the compliance according to the Helsinki criteria and approved all procedures (B.30.2.EGE.0.20.05.00/OY/60, 13 January 2015).

Informed consent For this type of study, formal consent is not required.

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