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Capping carious exposures in adults: a randomized controlled trial investigating MTA vs. calcium hydroxide

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Abstract

Aim The aim of this multicentre, parallel-group randomized clinical trial was to compare the effectiveness of mineral trioxide aggregate (MTA) and a conventional calcium hydroxide liner (CH) as direct pulp capping materials in adult molars with carious pulpal exposure.

Methodology Seventy adults aged 18 to 55 years were randomly allocated to two parallel arms: MTA (White ProRoot, Dentsply, Tulsa Dental, Tulsa, OK, USA) (n=33) and CH (Dycal[®], Dentsply DeTrey GmbH, Konstanz, Germany) (n=37). The teeth were temporized for one week with glass ionomer (Fuji IX, GC Corp, Tokyo, Japan), and then permanently restored with a composite resin. The subjects were followed up after 1 week and at 6, 12, 24, and 36 months. The primary outcome was the survival of the capped pulps, and the secondary outcome was postoperative pain after 1 week. Survival was defined as a non-symptomatic tooth that responded to sensibility testing and did not exhibit periapical changes on radiograph. At each check-up, the pulp was tested for sensibility and a periapical radiograph was taken (excluding the radiographs taken at the 1-week follow up). Kaplan-Meier survival analysis and log-rank test was used to assess the significant difference in the survival curves between groups. Chi-square test was used to assess the association between the materials and preoperative and postoperative pain.

Results At 36 months, the Kaplan-Meier survival analysis showed a cumulative estimate rate of 85% for the MTA group and 52% for the CH group ($p=0.006$). There was no significant association between the capping material and postoperative pain.

Conclusions MTA performed more effectively than a conventional CH liner as a direct pulp capping material in molars with carious pulpal exposure in adult patients. This study has been registered at ClinicalTrials.gov, number NCT01224925.

Introduction

Direct exposure of the pulp to the oral environment involves the risk of destructive breakdown and, if not properly treated, will lead to apical periodontitis, eventual root canal treatment, or tooth extraction (Kakehashi *et al.* 1965). Direct pulp capping is a method designed to preserve pulp vitality through hard tissue repair of the open exposure (Hørsted-Bindslev & Bergenholtz 2010), and a recent cost-effectiveness analysis has shown it to be superior to root canal treatment in the long run, provided the patient is a young adult and there is no proximal exposure (Schwendicke & Stolpe 2014).

Calcium hydroxide (CH) was introduced almost 100 years ago as a pulp capping material, and the first scientific studies of CH showed superior healing compared to an inert material when tested for direct pulp capping (Hermann 1930, Nyborg 1955, Komabayashi & Zhu 2010). In retrospective studies, the 5-year success rate after direct pulp capping with CH in pulpal exposures ranged from 37% to 82% (Hørsted *et al.* 1985, Barthel *et al.* 2000, Mente *et al.* 2014). The age of the patient has shown a clear effect, with a higher success rate in younger subjects (Hørsted *et al.* 1985, Mente *et al.* 2014). Among strictly adult patients, direct pulp capping with CH yielded a rather low success rate (less than 35% after one year of follow-up) in a multicentre randomized clinical trial (RCT) (Bjørndal *et al.* 2010). Yet, direct pulp capping (with CH) is reported to be the most common method used to treat carious exposure in young adult patients (Oen *et al.* 2007, Stangvaltaite *et al.* 2013).

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Twenty years ago, mineral trioxide aggregate (MTA) was first tested as a pulp capping material, and histological studies have since shown that it produces better dentine bridge formation than does CH (Pitt Ford *et al.* 1996, Nair *et al.* 2008, Accorinte *et al.* 2009, Eskandarizadeh *et al.* 2011). In a case series study that included children and adults (age 7-45 years), Bogen *et al.* (2008) used MTA for direct pulp capping over carious exposures. The pulp survival rate was 95% for a group that was followed for at least 5 years, indicating a high success rate regardless of the patient's age. In a retrospective study, also composed of subjects from all age groups, direct pulp capping using MTA yielded a significantly higher survival rate (80%) than CH (60%) after a median follow-up time of 42 months (Mente *et al.* 2014). Another case series study, restricted to adults who were at least 18 years of age, demonstrated a comparatively low success rate (56%) for direct pulp capping using MTA after a 2-year follow-up (Miles *et al.* 2010).

At the time the present study was launched, there were no RCTs comparing MTA and CH as direct pulp capping materials. Recently, however, Hilton *et al.* (2013) published a practice-based RCT that included patients from all age groups who had pulp exposures of both carious and non-carious origin. After 2 years of follow-up, the success rate was higher for MTA (80.3%) than for CH (68.5%).

A recent meta-analysis suggests that MTA performs better than CH for direct pulp capping (Li *et al.* 2015). Only one randomized prospective study was available, performed by Hilton *et al.* (2013), and the histological evaluations have primarily been based on healthy teeth, thus undermining the generalizability of the results to adult patients with carious exposures.

Therefore, the aim of this multicentre, parallel-group RCT was to compare the effectiveness of MTA and CH as a DPC material in adult molars with carious pulpal exposure.

Materials and Methods

Trial design, operators and subjects

This multicentre study was a randomized, controlled, parallel, patient-blinded, two-arm superiority trial with a 1:1 allocation ratio that followed the CONSORT guidelines (www.consort-statement.org). Subjects were recruited from three public clinics in northern Norway, including clinics in Sandnessjoen and Alta and the student clinic at UiT, The Arctic University of Norway, and one private clinic in Klaipeda, Lithuania. Six different dentists performed the treatments. Ethical approval (2010/2112-4) was obtained on September 14, 2010, from the Regional Committee for Medical and Health Research Ethics in Northern Norway. Participation in the study was voluntary, and written informed consent was obtained from all participants.

Inclusion criteria

Strict inclusion criteria were applied as follows: age 18 to 55 years; 1st or 2nd permanent molar with a proximal carious lesion (primary or secondary caries); no history of pain or the presence of pain indicating, at most, reversible pulpitis; positive response to a cold test or to electric pulp testing according to the routine choice of each clinic, bitewing radiograph showing a carious lesion in at least the inner 1/3 of the dentine; periapical radiograph showing closed apex and normal periapex (with no radiolucency or widening of the periodontal ligament space); attachment loss not exceeding 4 mm; non-contributory medical history (including pregnancy); and no use of medication (no antibiotics during the previous month). Only one pulp cap was to be included per subject. In cases where a subject had several eligible molars, the one with the deepest lesion was chosen.

Criteria for diagnosis and treatment

Written criteria for diagnosis and treatment were applied in all of the study clinics. The clinical procedure was designed to mimic the study by Bogen *et al.* (2008) as much as was possible in a multicentre study. Briefly, the tooth was anaesthetized and isolated with a rubber dam, and the caries was removed using a complete excavation strategy (Bjørndal *et al.* 2010). The cavity outline (Class II) was cut down to sound enamel using a high-speed bur and water-cooling. With a round bur at low speed, the carious dentine was then completely removed from the non-pulpal walls of the cavity until the dentine was found to be hard when checked with a sharp probe and all cavity margins were inside the sound tooth structure. To ensure good prerequisites for the sealability of the margins of the cavity, a caries detector dye (Kurary, Medical Inc., Tokyo, Japan) was applied. On the pulpal wall(s), only a hand excavator was used to remove the caries until no or little dye staining was present. In cases of pulpal exposure, the bleeding was controlled within 10 minutes using cotton pellets soaked in buffered 0.5% NaOCl.

Exclusion criteria

Exclusion criteria included a lack of pulpal exposure after complete removal of the caries and failure to control the bleeding in exposed pulp within 10 minutes.

Randomization

Randomization was implemented centrally at the UiT using the envelope method, with block sizes 4-6-4-6, with each study clinic acting as a separate allocation unit. Envelopes were sent to the study clinics in batches of 20. The envelope revealed the treatment group to which the subject was allocated and was opened only after bleeding of the pulp was successfully controlled. Patients were not informed of their allocation group.

Intervention

In the CH group, a thin layer of a commercial liner (Dycal[®], Dentsply DeTrey GmbH, Konstanz, Germany) was applied to the pulpal exposure and left to set. In the MTA group, white ProRoot[®] (WMTA) (Dentsply, Tulsa Dental, Tulsa, OK, USA) powder was mixed according to the manufacturer's instructions and a 2 mm-thick layer was placed directly over the pulpal exposure and the surrounding dentine, leaving at least 2 mm of dentine and enamel available circumferentially for the bonded composite restoration. After placement of the MTA, a flat, water-moistened cotton pellet was placed directly over the material. As the setting of the MTA needed to be checked after one week, the cavities in both groups then received a temporary filling (Fuji IX glass ionomer cement; GC Corp, Tokyo, Japan). After one week, the entire temporary filling was removed for patients in the MTA group, and the hardness of the MTA was verified with a dental probe. In the CH group, part of the temporary filling was left under the permanent filling. Any postoperative pain was recorded, pulpal status was checked applying a cold or electric pulp testing, and if there were no symptoms, the cavity was permanently restored with a composite resin material used at the study clinic.

Follow up and outcome measures

The primary outcome was the survival of capped pulps. Survival was defined as a non-symptomatic tooth that responded to sensibility testing and did not exhibit any periapical changes radiographically. Follow-up included pulpal testing and periapical radiograph at 6, 12, 24, and 36 months. One of the authors (E.K.), who was blinded to the material group assignments by masking the coronal part of the radiographs, assessed the final periapical radiographs.

The secondary outcome measure was postoperative pain 1 week after treatment. The patients were asked whether they had any pain or had experienced it during the first three days.

Power calculation

The power calculation was based on the intention to show a 30% difference in success rates. The following parameters were used (binomial scale): type I error: 5%; expected success rate in the CH group: 55% (based on Barthel *et al.* 2000); minimal difference between success rates not to be overlooked: 30%; type II error: 5%. The calculations revealed the need for 64 subjects in each group. After adding 20% for eventual drop-outs, 160 subjects were needed and planned to be recruited in one year.

Statistical methods

For the primary outcome, a Kaplan-Meier survival analysis was used to study the survival of the capped pulps. The log-rank test was used to assess the significant difference in the survival curves between groups. As the intention-to-treat (ITT) principle was applied, the analysis comprised all allocated cases. The effect size was calculated according to Parmar & Machin (1995). The number needed to treat (NNT) to save one pulp was calculated (Laupacis *et al.* 1988). A secondary Kaplan-Meier analysis was performed to study the influence of the preoperative lesion depth on survival. The cases were categorized into two groups defined by the depth of the lesion (into-the-pulp and not-into-the-pulp), and the MTA and CH groups were combined for this analysis.

For the secondary outcome, a Chi-square test was used to assess the association between the materials and preoperative and postoperative pain. Data were entered and analysed using the statistical program package IBM SPSS Statistics 21.0 (IBM, Somers, New York, NY, USA).

Results

Patient recruitment began in October 2010, but due to the strict inclusion criteria it progressed much slower than anticipated. To ensure that the study could be finalized in the time stipulated by the Ethics Committee, recruitment ended in January 2013, although only 80 patients had been recruited. Ten subjects were excluded due to a lack of pulpal exposure after the complete removal of caries. Consequently, 70 subjects were randomly allocated to either the CH group (n=37) or the MTA group (n=33) (Figure 1, Table 1). The study was closed when all patients had received at least 36 months of follow-up, had the capped pulp fail, or had been lost to follow-up.

The Kaplan-Meier survival analysis showed an 85% cumulative survival rate of pulps in the MTA group and 52% in the CH group. This difference was significant ($p=0.006$) according to the log-rank test (Figure 2). The effect size was 0.25, and the number needed to treat was three (NNT=3).

The sub-analyses showed no significant difference (Log Rank Chi square =0.323; $p=0.570$) in the cumulative survival rates between into-the-pulp and not-into-the pulp groups, 0.58 and 0.71, respectively.

Almost half of the subjects (34/70) had experienced preoperative pain at baseline that was not more severe than reversible pulpitis; these subjects were equally distributed between the two material groups (Table 1). Only 18 of the 70 subjects reported postoperative pain at 1 week (Table 2).

Regardless of the presence of preoperative pain, there were no significant associations between the material and postoperative pain, although postoperative pain was observed slightly more often (10/33) in the MTA group than in the CH group (8/37) (Table 2). No adverse effects were reported in either group.

Discussion

In this RCT on direct pulp capping that compared MTA and CH in adults, the estimated survival rate in the MTA group was 85% after 3 years of follow-up. The result is consistent with those of Hilton *et al.* (2013), who conducted the first large multicentre RCT, which revealed a more than 80% success rate after direct pulp capping with MTA. Although the median follow-up time for that study was less than two years, the success rate for MTA was slightly lower than that in the present study. Moreover, as the study also included non-carious exposures (13.7%) and patients younger than 18 years, its evidence is limited with respect to the choice of material over carious exposures in adult molars.

In the CH group, the estimated survival rate of the pulps was 52%. This finding is in contrast with another multicentre RCT (Bjørndal *et al.* 2010), in which the success rate for DPC using CH dropped to 32% after 1 year, although both studies were limited to adults and used Dycal as the DPC material. The present result is consistent with those of Hilton *et al.* (2013), who reported a success rate of 68.5% after a median 1.2 years of follow-up. The slightly higher success rate in the latter study can be explained by the shorter follow-up time and by the inclusion of children and adolescents.

When the baseline data revealed an uneven distribution of the lesion depth among the study groups (Table 1), Kaplan-Meier sub-analysis was performed. The preoperatively assessed depth of the lesions did not have a significant effect on healing, reflecting the fair comparison between the arms, although the inflammatory status of the pulp could not be controlled fully.

The secondary outcome measure was postoperative pain after one week. Pain was observed slightly more often in the MTA group than in the CH group but was not significantly different between materials (Table 2). This finding is consistent with the study by Iwamoto *et al.* (2006), in which capping healthy pulps with WMTA and CH (Dycal) yielded no difference in postoperative

pain, although a histological study showed less inflammation in human teeth capped with MTA in comparison to CH (Aeinehchi *et al.* 2003). However, as the power calculation was not performed separately for the secondary outcome that analysis was underpowered and it may hide the existing differences in the occurrence of pain.

The strengths of this RCT are as follows: i) study inclusion restricted to adult patients and carious exposed molars only, ii) follow-up time (full three years), and iii) low drop-out rate, as only five patients were lost during the follow-up period (Figure 1). It was appropriate to restrict the study to adult patients only because previous RCTs on partial pulpotomy among children and adolescents have shown equally good success with MTA and CH, irrespective of whether Dycal or an originally introduced slurry was used in the CH arm (Qudeimat *et al.* 2007, Chailertvanitkul *et al.* 2014). The origin of the exposure was limited because exposed pulps with carious lesions are considered to have lower success rates after direct pulp capping compared to exposures of traumatic origin, and thus a pulpectomy is recommended instead of direct pulp capping in mature teeth with carious exposure (European Society of Endodontology 2006, American Association of Endodontists 2013).

Only half the number of subjects originally sought for study inclusion could be recruited. However, this potential shortcoming did not lead to type II error because the results revealed a significant difference between the material groups, rendering the number of subjects inconsequential.

Despite the written, uniform treatment criteria, deviation from the study protocol occurred in certain instances. Instead of proximal cavities, four occlusal cavities were also included. As these teeth were equally distributed between the groups, this had no bearing on the comparison of the materials. The use of a rubber dam was not consistent. This inconsistency may not have influenced the results: according to the recent RCT by Hilton *et al.* (2013), good direct pulp capping results were obtained even though a rubber dam was used only in 19% of that study's cases.

In eleven cases, periapical radiographs were missing at baseline. Among these 11 cases, nine teeth exhibited a sound periapex at six months, and the remaining teeth, one in each group, failed at 6 months due to a diagnosed apical periodontitis. Thus, the lack of a periapical radiograph at baseline

may have negatively affected the overall success in both groups but did not affect the comparison of the groups.

As the two materials tested need different types of applications, it was not possible to blind the operators. Thus, the chair-side assessment of the final radiographs could also not be secret. However, prior to the final statistical analyses, all radiographs were assessed for periapical changes in a separate, blinded setting. The randomization process did not consider the depth of the carious lesion, as preoperative radiographs were primarily taken to verify the eligibility of the patient, i.e. that the lesion had reached at least the deepest third of the dentine. The subjects with missing bitewing radiographs (n=39) were equally distributed between the MTA (n=21) and CH (n=18) groups. According to the intention-to-treat principle, all patients, irrespective of protocol deviations, were included in the final data analysis.

Just before the launch of the present study, Bogen *et al.* (2008) reported excellent results for direct pulp capping using MTA. Hence, the MTA-arm in this study was designed to follow their method, but the caries removal differed drastically. Bogen *et al.* used high/low speed burs to remove the remaining caries, which inevitable led to pulpal exposure, whereas this study intended to save those pulps that still may have been protected by a layer of sound dentine. By using hand excavation only, which is at least partly self-limiting process, i.e. in principle an excavator does not cut sound dentine, ten pulps were saved in the group where the radiological assessment did not show that lesion was already penetrated into the pulp. The use of dye may have further increased the risk for exposure as the non-infected dentine may have been stained as well (Kidd *et al.* 1993), but on the pulpal walls, minor staining was allowed to remain to avoid exposure. Among the dentists in northern Norway, who were chosen to implement the study, total excavation was still the method of choice for treating deep carious lesions (Stangvaltaite *et al.* 2013); this still seems to be so in the US and parts of Europe (Oen *et al.* 2007, Schwendicke *et al.* 2016a). Thus, there were no ethical concerns when choosing total excavation for this study, although a recent consensus statement does not recommend this approach (Schwendicke *et al.*, 2016b).

The fact that this study was implemented as a routine treatment in a normal, everyday practice (public as well as private clinics) indicates the high external validity of the results and renders the results applicable to all adult patients with carious exposures.

CH still is the gold standard for vital pulp therapy in trauma cases and in carious exposures in adolescents (Cvek 1978, Mejare & Cvek 1993, Qudeimat *et al.* 2007, Bakland & Andreasen 2012). However, the present study does not support the use of CH as a dressing material for carious exposures among adults: based on the low NNT value (=3), one root canal treatment can be avoided for every three direct pulp cappings when MTA is chosen instead of CH.

Under favourable conditions, the success rate for single-visit pulpectomy in premolars and molars has been shown to be 93% after three years (Gesi *et al.* 2006), but the overall outcome of root canal treatment is lower among general practitioners than among specialists (Ng *et al.* 2007). Consequently, the relatively high 3-year success rate found for direct pulp capping using MTA in the present study (85%) may also challenge the treatment-of-choice guidelines for carious exposures in adult molars, particularly if high-quality endodontics are not available. It needs to be determined whether this promising result can be applied to other MTA or calcium silicate products.

Conclusion

MTA was more effective than conventional CH dressing as a direct pulp capping material in molars with carious pulpal exposure in adult patients, although the baseline inflammatory status of the capped pulps could not be fully controlled in this study.

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Conflict of Interest statement

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

References

Accorinte ML, Loguercio AD, Reis A *et al.* (2009) Evaluation of two mineral trioxide aggregate compounds as pulp-capping agents in human teeth. *International Endodontic Journal*, **42**, 122-8.

Aeinehchi M, Eslami B, Ghanbariha M, Saffar AS (2003) Mineral trioxide aggregate (MTA) and calcium hydroxide as pulp-capping agents in human teeth: a preliminary report. *International Endodontic Journal*, **36**, 225-31.

American Association of Endodontists (2013) *Guide to Clinical Endodontics*, 6th Edition. Chicago, IL: American Association of Endodontists. [WWW document].URL <http://www.aae.org/clinical-resources/aae-guide-to-clinical-endodontics.aspx>

Bakland LK, Andreasen JO (2012) Will mineral trioxide aggregate replace calcium hydroxide in treating pulpal and periodontal healing complications subsequent to dental trauma? A review. *Dental Traumatology*, **28**, 25-32.

Barthel CR, Rosenkranz B, Leuenberg A, Roulet JF (2000) Pulp capping of carious exposures: treatment outcome after 5 and 10 years: a retrospective study. *Journal of Endodontics*, **26**, 525-8.

Bjørndal L, Reit C, Bruun G *et al.* (2010) Treatment of deep caries lesions in adults: randomized clinical trials comparing stepwise vs. direct complete excavation, and direct pulp capping vs. partial pulpotomy. *European Journal of Oral Sciences*, **118**, 290-7.

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Bogen G, Kim JS, Bakland LK (2008) Direct pulp capping with mineral trioxide aggregate: an observational study. *Journal of the American Dental Association*, **139**, 305-15.

Chailertvanitkul P, Paphangkorakit J, Sooksantisakoonchai N *et al.* (2014) Randomized control trial comparing calcium hydroxide and mineral trioxide aggregate for partial pulpotomies in cariously exposed pulps of permanent molars. *International Endodontic Journal*, **47**, 835-42.

Cvek M (1978) A clinical report on partial pulpotomy and capping with calcium hydroxide in permanent incisors with complicated crown fracture. *Journal of Endodontics*, **4**:232-7.

Eskandarizadeh A, Shahpasandzadeh MH, Shahpasandzadeh M, Torabi M, Parirokh M (2011) A comparative study on dental pulp response to calcium hydroxide, white and grey mineral trioxide aggregate as pulp capping agents. *Journal of Conservative Dentistry*, **14**, 351-5.

European Society of Endodontology (2006) Quality guidelines for endodontic treatment: consensus report of the European Society of Endodontology. *International Endodontic Journal*, **39**, 921-30.

Gesi A, Hakeberg M, Warfvinge J, Bergenholtz G (2006) Incidence of periapical lesions and clinical symptoms after pulpectomy-a clinical and radiographic evaluation of 1- versus 2-session treatment. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod*, **101**, 379-88.

Hilton TJ, Ferracane JL, Mancl L, NWP (2013) Comparison of CaOH with MTA for direct pulp capping: a PBRN randomized clinical trial. *Journal of Dental Research*, **92** (Suppl. 7), S16-S22.

Hørsted P, Sandergaard B, Thylstrup A, El Attar K, Fejerskov O (1985) A retrospective study of direct pulp capping with calcium hydroxide compounds. *Endodontics and Dental Traumatology*, **1**, 29-34.

Hørsted-Bindslev P, Bergenholtz G (2010) Treatment of vital pulp conditions. In: Bergenholtz G, Hørsted-Bindslev P, Reit C, ed. *Textbook of Endodontology*, 2nd edn.; pp. 47-72. Chichester, UK: Wiley-Blackwell.

Iwamoto CE, Adachi E, Pameijer CH, Barnes D, Romberg EE, Jefferies S (2006) Clinical and histological evaluation of white ProRoot MTA in direct pulp capping. *American Journal of Dentistry*, **19**, 85-90.

Kakehashi S, Stanley HR, Fitzgerald RJ (1965) The effects of surgical exposures of dental pulps in germfree and conventional laboratory rats. *Oral Surgery, Oral Medicine, and Oral Pathology*, **20**, 340-9.

Kidd EA, Joyston-Bechal S, Beighton D (1993) The use of a caries detector dye during cavity preparation: a microbiological assessment. *British Dental Journal*, **174**, 245-8.

Komabayashi T, Zhu Q (2010) Innovative endodontic therapy for anti-inflammatory direct pulp capping of permanent teeth with a mature apex. *Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology, and Endodontics*, **109**, e75-e81.

Laupacis A, Sackett DL, Roberts RS (1988) An assessment of clinically useful measures of the consequences of treatment. *New England Journal of Medicine*, **318**, 1728–33.

Li Z, Cao L, Fan M, Xu Q (2015) Direct pulp capping with calcium hydroxide or mineral trioxide aggregate: a meta-analysis. *Journal of Endodontics*, **41**, 1412-7.

Mejäre I, Cvek M (1993) Partial pulpotomy in young permanent teeth with deep carious lesions. *Endodontic & Dental Traumatology*, **9**, 238-42.

Mente J, Hufnagel S, Leo M *et al.* (2014) Treatment outcome of mineral trioxide aggregate or calcium hydroxide direct pulp capping: long-term results. *Journal of Endodontics*, **40**, 1746-51.

Miles JP, Gluskin AH, Chambers D, Peters OA (2010) Pulp capping with mineral trioxide aggregate (MTA): a retrospective analysis of carious pulp exposures treated by undergraduate dental students. *Operative Dentistry*, **35**, 20-8.

Nair PN, Duncan HF, Pitt Ford TR, Luder HU (2008) Histological, ultrastructural and quantitative investigations on the response of healthy human pulps to experimental capping with mineral trioxide aggregate: a randomized controlled trial. *International Endodontic Journal*, **41**, 128-50.

Ng YL, Mann V, Rahbaran S, Lewsey J, Gulabivala K (2007) Outcome of primary root canal treatment: systematic review of the literature – Part 1. Effects of study characteristics on probability of success. *International Endodontic Journal*, **40**, 921-39.

Nyborg H (1955) Healing processes in the pulp on capping; a morphologic study; experiments on surgical lesions of the pulp in dog and man. *Acta Odontologica Scandinavica*, **13** (Suppl. 16), 1-130.

Oen KT, Thompson VP, Vena D *et al.* (2007) Attitudes and expectations of treating deep caries: a PEARL Network survey. *General Dentistry*, **55**, 197-203.

Parmar MKB, Machin D (1995) *Survival Analysis – Practical Approach*; p. 243. Chichester, UK: John Wiley & Sons.

Pitt Ford TR, Torabinejad M, Abedi HR, Bakland LK, Kariyawasam SP (1996) Using mineral trioxide aggregate as a pulp-capping material. *The Journal of the American Dental Association*. **127**(10):1491-4.

Qudeimat MA, Barrieshi-Nusair KM, Owais AI (2007) Calcium hydroxide vs mineral trioxide aggregates for partial pulpotomy of permanent molars with deep caries. *European Archives of Pediatric Dentistry*, **8**, 99-104.

Schwendicke F, Stolpe M (2014) Direct pulp capping after a carious exposure versus root canal treatment: a cost-effectiveness analysis. *Journal of Endodontics*, **40**, 1764-70

Schwendicke F, Stangvaltaite L, Holmgren C *et al.* (2016a) Dentists' attitudes and behaviour regarding deep carious lesion management: a multi-national survey. *Clinical Oral Investigations*, Mar 12. [Epub ahead of print].

Schwendicke F, Frencken JE, Bjørndal L et al. (2016b) Managing Carious Lesions: Consensus Recommendations on Carious Tissue Removal. *Advanced Dental Research*, **28**, 58-67.

Stangvaltaite L, Kundzina R, Eriksen HM, Kerosuo E (2013) Treatment preferences of deep carious lesions in mature teeth: questionnaire study among dentists in Northern Norway. *Acta Odontologica Scandinavica*, **71**, 1532-7.

Figure legends

Figure 1 CONSORT flow chart of the 80 eligible subjects up to the 36-month follow up.

ITT, intention-to-treat.

Figure 2 Kaplan-Meier analysis of pulp survival. The estimated cumulative proportion surviving was 0.515 for CH (N=37) and 0.846 for MTA (N=33).

Table 1 Baseline characteristics of participants.

Characteristic	MTA group n=33 (100%)	CH group n=37 (100%)	Lack of carious exposure n=10 (100%)
<i>Age (years)</i>			
Mean	30.2	30.9	
SD	9.7	9.9	
Range	18-52	18-55	
<i>Tooth number</i>			
Upper first molar	13 (39.4%)	10 (27%)	3 (30%)
Upper second molar	7 (21.2%)	7 (19%)	4 (40%)
Lower first molar	5 (15.2%)	14 (38%)	2 (20%)
Lower second molar	8 (24.2%)	6 (16%)	1 (10%)
<i>Cavity type</i>			
Occlusal	2 (6.1%)	2 (3%)	-

Mesial-occlusal	13 (39.4%)	16 (20%)	4 (40%)
Distal-occlusal	11 (33.3%)	11 (14%)	6 (60%)
Mesial-occlusal-distal	7 (21.2%)	8 (10%)	-
<i>Preoperative pain</i>			
Yes	16 (48%)	18 (49%)	4 (40%)
No	17 (52%)	19 (51%)	6 (60%)
<i>Caries depth*</i>			
2/3 into the dentine	6 (18.2%)	5 (13%)	4 (40%)
>2/3 into the dentine	15 (45.4%)	8 (22%)	6 (60%)
Into the pulp	12 (36.4%)	24 (65%)	-

*Assessed from the preoperative periapical or BW radiograph

Table 2. The frequency of postoperative pain in relation to preoperative pain and the capping material used. N=70.

Capping material		Pre-operative pain ^b		Postoperative pain ^a			Total
				No	Mild,	Mild,	
					first	occasionally,	any point
					3 days only	entire week	
CH	Yes	15	4	0	0	19	
	No	14	3	0	1	18	
Subtotal			29	7	0	1	37
MTA	Yes	15	1	1	0	17	
	No	8	4	2	2	16	
Subtotal			23	5	3	2	33
Grand total			52	12	3	3	70

^aPain at any point during the first week.

^bPain at any point during one month prior to the procedure

Statistical analysis with Chi-square test:

Capping material vs. Preoperative pain; $p > 0.05$

Group with preoperative pain: capping material vs. postoperative pain; $p > 0.05$

Group without preoperative pain: capping material vs. postoperative pain; $p > 0.05$



