Treatment Outcome of Mineral Trioxide Aggregate or Calcium Hydroxide Direct Pulp Capping: Long-term Results

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Abstract

Introduction: This controlled, historic cohort study project continues a previously reported trial aiming to assess treatment outcome of direct pulp capping with mineral trioxide aggregate (MTA) versus calcium hydroxide (CH). Potential prognostic factors were re-evaluated on the basis of a larger sample size and longer follow-up periods. **Methods:** Clinical and radiographic outcomes of 229 teeth treated with direct pulp capping between 2001 and 2011 were investigated 24 up to 123 months post-treatment (median = 42 months). Pre-, intra-, and postoperative information was evaluated and statistically analyzed using a logistic regression model as well as generalized estimating equation logit models. **Results:** Two hundred five patients (229 teeth) were available for follow-up (74% recall rate). The overall success rates were 80.5% (95% confidence interval [CI], 74.5–86.5) of teeth in the MTA group (137/170) and 59% (95% CI, 46.5–71.5) of teeth in the CH group (35/59). Multivariate analyses (generalized estimating equation logit model) indicated a significantly increased risk of failure for teeth that were directly pulp capped with CH compared with MTA (odds ratio = 2.67; 95% CI, 1.36–5.25; $P = .001$). Teeth that were permanently restored ≥2 days after direct pulp capping had a significantly worse prognosis irrespective of the pulp capping material chosen (odds ratio = 3.18; 95% CI, 1.61–6.3; $P = .004$). **Conclusions:** The results of this study indicate that MTA provides better long-term results after direct pulp capping compared with CH. Placing a permanent restoration immediately after direct pulp capping is recommended. *(J Endod 2014;40:1746–1751)*

Key Words

Calcium hydroxide, dental pulp capping, dental pulp exposure, human, mineral trioxide aggregate, treatment outcome

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Deep caries, dental trauma, and iatrogenic procedures can result in pulp exposure. Vital pulp therapy has become a fairly predictable alternative treatment to pulpectomy (1). Calcium hydroxide (CH) is widely accepted as the material of choice for direct pulp capping. However, clinical success rates vary considerably from 13% (2) up to 97.8% (3). Closer examination of clinical data on direct pulp capping with CH or its compounds reveals that success rates decrease as follow-up periods increase. Clinical trials report that 1–2 years after vital pulp therapy, success rates of more than 90% have been achieved (3–5). After 2–5 years, success rates drop from 81.8% to 37% (2, 6–9). Ten years after vital pulp therapy with a setting CH paste, treatment outcome is considered successful in only 13% of cases (2).

Mineral trioxide aggregate (MTA), a tricalcium silicate–based cement, has become more and more popular as an alternative material for vital pulp therapy. *In vitro* trials and histologic studies report favorable results regarding the chemical and physical properties, antibacterial activity, biocompatibility, and sealing properties of MTA (10–12). Clinical success rates are equally promising (1, 9, 13–18). Comparing treatment outcome of CH and MTA used for vital pulp therapy, it has been suggested that MTA might be the material of choice (1, 17, 18). The drawbacks of MTA are its high costs, long setting time, and potential for discoloration of the tooth (19). Regardless of the material used, the factors influencing treatment outcome of vital pulp therapy are still relatively unknown, and information is inconclusive (1).

Phase 1 of the present study evaluated treatment outcome of MTA versus CH in direct pulp capping. The study was conducted as a controlled, single-center, historic cohort study project (9). The results suggested that MTA was more reliable in maintaining pulp vitality after direct pulp capping. Because of a slightly too small sample size, differences in treatment outcome after direct pulp capping between MTA and CH were borderline significant (odds ratio [OR] = 0.43; 95% confidence interval [CI], 0.19–1.02; $P = .05$) (9).

The aims of phase 2 were 2-fold. The first was to confirm the superiority of MTA (ProRoot MTA; Dentsply Maillefer, Ballaigues, Switzerland) over CH (Hypocal SN; Merz Dental, Lütjenburg, Germany) for direct pulp capping with statistical significance. The second aim was to re-evaluate potential prognostic outcome factors on the basis of a larger sample size and longer follow-up periods than in phase 1.

Materials and Methods

The study protocol of this study was approved by the Ethics Committee of the University of Heidelberg, Heidelberg, Germany (Ref. 018/2011). The study population comprised patients seeking dental treatment at the Department of Conservative Dentistry, University Hospital of Heidelberg. Patients who had received direct pulp capping treatment between February 2001 and February 2011 were selected for potential inclusion. Inclusion and exclusion criteria were described in detail in the report about phase 1 of this project (9). In contrast to phase 1, the minimal follow-up period was considered to be 2 years. A tolerance of 14 days was accepted.

Recruitment of Patients

Potential participants were contacted and invited to attend follow-up examinations. Patients who were willing to attend were given detailed information about the

study before and on the day of the follow-up examination. Clinical examinations were only performed after written informed consent had been signed by patients and/or guardians.

Clinical and radiographic procedures, which were performed at follow-up examinations, were described extensively in the report about phase I of this project (9).

Pre- and Intraoperative Data

The acquisition of all pre- and intraoperative information from the patients' records as well as the entering of the data into a specifically designed database spreadsheet were described in detail in the previously published report of phase 1 (9). Teeth with incomplete pre- or intratreatment records were excluded from the study.

Treatment Intervention

Treatment providers were either dentists or undergraduate students. The departmental operative protocol for the endodontic management of exposed pulps and the general indications for direct pulp capping were followed by all clinicians in the department, including undergraduate students. The guidelines, which apply in the department, were described in detail in the previous report of phase 1 (9) and were applied unchanged for phase 2 of the study project.

Observer Calibration

Clinical Calibration. In phase 1, observers were calibrated by an independent clinical examination of 24 patients on the same day (9). Given the very high interexaminer reliability in phase 1, the clinical calibration process was simplified for phase 2. The considerably greater number of patients in phase 2 meant that 4 examiners would have been required to perform the clinical follow-up examinations. Submitting the clinical calibration patients to 4 examinations in 1 day would not have been reasonable.

In phase 2, the 4 designated examiners (S.H., M.L., D.P., and A.M.) performed a calibration regarding probing depth measurements and the assessment of furcation involvement on study models. The step-by-step procedure of this clinical calibration using study models has been described in detail elsewhere (20). A tolerance range of 1 mm for probing depth measurements and 1 grade regarding furcation involvement were accepted in this study. None of the observers were the treatment providers.

Radiographic Calibration. Before the radiographic assessment, 1 observer (T.P.) had been trained using the periapical index (PAI) according to Ørstavik et al (21). Calibration was conducted by using a calibration kit of 100 radiographic images, which was kindly provided by the developers of this index (21).

Outcome Assessment

Outcome was assessed on the basis of clinical and radiographic findings as previously described in the phase 1 report (9). In addition to the radiographic assessment of the periapical tissue based on the PAI, the periapical radiographs were assessed by 2 examiners (J.M. and T.P.) to evaluate any pathologic changes associated with the pulp capped teeth. If there was any disagreement between the 2 examiners, they discussed the radiographic findings to come to a consensus. The absence of any radiographic and clinical symptoms was considered a "success."

Outcome failure was indicated by the presence of clinical signs or symptoms, PAI $\geq$2, condensing apical periodontitis, internal root resorption, longitudinal root fracture, root canal treatment subsequent to direct pulp capping, loss of function, or extraction of the previously pulp capped tooth.

Statistical Analysis

The sample size was calculated on the basis of phase 1 (9). Power calculation indicated that 208 teeth (MTA: 156, CH: 52) were required for phase 2 if the follow-up periods were $\geq$2 years. Expecting that the number of direct pulp capping treatments with CH would continuously decrease compared with the number of MTA pulp capping treatments, a ratio of 75% MTA treatments to 25% CH-treated teeth was assumed. The calculated sample size was selected to display an OR of 0.365 at a significance level of 5%. The statistical power was set at 80%.

The median, first and third quartiles, minima and maxima, and relative and absolute frequencies were calculated for descriptive analyses. The 95% CIs for the success rates of the CH and MTA groups were calculated. A Kaplan-Meier survival curve was used to investigate differences in the success rates. Survival times (point at which the status "success" was determined) were calculated from the date of treatment to the date of last contact or to the date of "failure."

In the MTA group, more than 1 tooth per subject was occasionally included in the study. That fact was taken into account by applying a generalized estimating equation (GEE) logit model to assess possible associations between potential prognostic factors and success rates. In the CH group, only 2 teeth belonged to the same subject. Therefore, possible associations between potential prognostic factors and success rates were assessed using a logistic regression model, which required that 1 tooth had to be chosen randomly for statistical analyses and the other was excluded. Selection bias was avoided by performing sensitivity analysis (ie, replacing the randomly included tooth with the excluded tooth). Potential prognostic factors that proved to have a statistically significant influence on treatment outcome as result of univariate analyses were included in a multivariate GEE logit model. Because of the explorative study design, all P values have to be interpreted as descriptive values. No correcting for multiple testing was performed. P values $<.05$ were considered statistically significant.

Following the recommendations of Ørstavik et al (21), the Cohen kappa test was used for PAI calibration. Intraexaminer reliability and interexaminer agreement regarding the clinical calibration using study models were calculated as a percentage.

The data were statistically analyzed using SAS 9.3 software (SAS Institute Inc, Cary, NC) and SPSS 21.0 (SPSS Inc, Chicago, IL).

Results

Calibration Process

The clinical calibration involved 1008 probing depth measurements and 144 assessments of furcation involvement (20). Measurements were performed by each observer and checked statistically in respect to concordance with "authorized measurements." Interexaminer agreement ranged from 95%–96% for probing depth (95% for examiner #4 and 96% for examiners #1, 2, and 3) and from 92%–94% for furcation involvement (92% for examiner #4, 93% for examiner #2, and 94% for examiners #1 and 3). Intraexaminer reliability ranged from 97%–98% for probing depth (97% for examiner #3 and 98% for examiners #1, 2, and 4), and there was 100% intraexaminer reliability for furcation involvement for all examiners. A high level of consensus was achieved regarding probing depth measurements and the assessment of furcation involvement.

Interexaminer agreement concerning PAI calibration was $\kappa = 0.89$. Intraexaminer reliability was $\kappa = 0.92$. Both of these kappa values indicate "almost perfect agreement" (22).