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Selective versus stepwise removal of deep carious lesions in permanent teeth: a randomised controlled trial from Egypt—an interim analysis

Mohamed E Labib,[1] Olfat E Hassanein,[2] Makeen Moussa,[1] Asmaa Yassen,[2,3] Falk Schwendicke[4]

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[1]Operative Dentistry, Misr International University (MIU), Cairo, Egypt
[2]Conservative Dentistry, Cairo University, Giza, Egypt
[3]Restorative Dentistry, British University in Egypt, Cairo, Egypt
[4]Operative and Preventive Dentistry, Charite Universitatsmedizin Berlin Campus Benjamin Franklin, Berlin, Germany

Correspondence to
Dr Falk Schwendicke;
falk.schwendicke@charite.de

ABSTRACT

Objectives To compare the success, survival and costs of selective versus stepwise carious tissue removal (SE/SW) in permanent teeth with deep (>2/3 dentine depth) carious lesions.

Design Randomised controlled, unicentre, clustered two-arm superiority trial.

Setting Outpatient clinic of a private university in Cairo, Egypt.

Participants One hundred and fifteen participants (n=132 teeth), aged 18–47 years, from Cairo, Egypt, were enrolled. Premolars/molars with occlusal/occlusal-proximal deep lesions (radiographically >2/3 dentine), sensible pulps, without spontaneous pain, were included.

Interventions Peripheral carious tissue removal to hard dentine was performed. Pulpo-proximally, soft dentine was left. A glass ionomer (GI) restoration was placed. After 3–4 months, teeth were randomly allocated to SE (n=66), with reduction of the GI into a base and no further tissue removal, followed by a composite resin restoration, or SW (n=66), with full removal of the GI, additional excavation until firm dentine pulpo-proximally, followed by a GI-based composite restoration. Mean follow-up was 1 year.

Primary and secondary outcome measures Primary outcome was success (absence of endodontic/restorative complications). Secondary outcomes were tooth survival and initial and total treatment costs.

Results Zero/five pulp exposures occurred during SE/SW, and seven/five SE/SW teeth required endodontic therapy. Success after 12 months was 89.4% for SE and 84.9% for SW. The estimated mean time free of complications was 23 and 18 months for SE and SW, respectively, without significant differences between SE and SW (p>0.05/Cox). Initial treatment costs were significantly higher for SW (mean (SD): 507.5 (123.4) Egyptian pounds (EGP)) than SE (mean (SD): 456.6 (98.3) EGP), while total costs showed no significant difference (p>0.05).

Conclusion Within the limitations of this interim analysis, and considering the depth of these lesions (>2/3 dentine), SE and SW showed similar risk of failure and overall costs after 1 year.

Trial registration number PACTR201603001396248.

Strengths and limitations of this study

- Patients and outcome assessors were blinded, while blinding of operators was not possible.
- The study is conducted in Egypt where only limited data on this topic are available.
- Initial and long-term clinical costs were assessed.
- Both stepwise and selective carious tissue removal were performed in two visits, which may not fully reflect daily care.
- The lesions involved >2/3 dentine, and findings for even deeper lesions (>3/4 dentine) may differ.

INTRODUCTION

Management of deep carious lesions in vital teeth is challenging. The traditional management of such lesions using non-selective (complete) carious tissue oftentimes leads to exposure of the pulp.[1] The treatment of exposed pulps is either performed via direct pulp capping, which comes with limited prognosis, or root canal treatment, which may be successful but is more burdensome and costly. Especially in low-income and middle-income countries, with limited insurance coverage of dental procedures, some patients may concede to tooth extraction instead.

Stepwise excavation technique (SW) has been introduced as a more conservative approach to avoid pulpal exposure.[2] In this two-step technique, carious tissue is removed from the peripheries of the lesion until only hard dentine remains while in proximity to the pulp, soft (bacterially contaminated) carious tissue is sealed beneath a temporary restoration in the first visit. After some months, re-entry is performed with removal of the residual carious tissue, followed by a definitive restoration.

SW builds on the growing evidence that sealed cariogenic bacteria are inactivated.[3] Several clinical trials were performed with

success rates ranging from 60% to 88% over follow-up periods up to 5 years.[2 4 5] SW has the drawbacks of extended treatment time and risk of pulpal exposure in the second visit. Moreover, more recent evidence indicates that sealing limited amounts of carious dentine beneath restorations does not compromise pulp or restoration survival.[6 7] Hence, the necessity for re-entry has been questioned, and a more conservative technique named selective (SE, ie, partial or incomplete) carious tissue removal gained popularity. In this technique, only the first step of stepwise excavation is performed, and carious dentine is intentionally sealed long-term.[8 9]

In summary, both SW and SE are recommended over non-selective removal of carious dentine in deep lesions.[10] However, data comparing SE and SW for deep lesions are sparse; currently, there is one larger trial conducted in a younger Brazilian population on permanent teeth, another smaller trial on primary teeth in German children and a three-arm trial on primary and permanent teeth from Turkey comparing SE and SW.[7 11 12] These trials found SE to be superior or equally successful to SW with regard to both pulpal and restorative outcomes (although in the Brazilian trial, a significant number of patients did not complete SW, which may have increased the risk of failure). Comparative data on further outcomes like costs have only been investigated in primary and not at all in permanent teeth.

The aim of the present randomised controlled trial was to compare success, survival and initial and longer-term costs of SE and SW in permanent teeth with deeply carious permanent teeth. We hypothesised that SE would show significantly higher success than SW.

METHODS

Study design

The study is a randomised controlled, unicentre, clustered two-arm superiority trial that was held at the dental clinic complex of Misr International University, Cairo, Egypt. One hundred and fifteen participants with 132 teeth having occlusal or occlusal-proximal deep carious lesions (>2/3 dentine extension radiographically, see above) and sensible pulps, without permanent or severe pain, were included. Teeth were allocated to one of the two treatments (SE or SW), with most patients having one, but some also two teeth treated. Note that some authors define deep lesions as those extending >3/4 dentine depth, while internationally, both definitions are accepted.[1 3 5] In lesions extending >3/4 dentine depth, the risk of pulp exposure and complications may be higher.

Follow-up is planned for 3 years; this is an interim analysis at a mean 1-year follow-up period. Success, survival, initial and total costs (including opportunity costs) were analysed. The trial was approved by the institutional review board (IRB) of Misr International University (MIU-IRB-1415-002) and was registered on https://pactr.samrc.ac.za. Note that the cost estimation was not planned a priori. Reporting of this trial follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines to ensure transparent and complete reporting.[13]

Setting, participants and recruitment

The study took place at the outpatient clinic of Misr International University. Participants were recruited between January 2016 and September 2017, according to the inclusion and exclusion criteria summarised in table 1. All participants signed written informed consents after being completely aware of the aim, settings, procedures, benefits and potential side effects of the study. The study information and consent forms were written in Arabic language to be well understood by all the participants. Patients were enrolled into the study only after signing the informed consent.

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Patient-related criteria	
► Adult patients (age: 18–50 years) of both genders. ► Able to tolerate necessary restorative procedures. ► Willing to sign the informed consent. ► Accepts the follow-up period.	► Allergy to any of the restorative materials. ► Patients undergoing orthodontic treatment with fixed appliances. ► Pregnant women. ► Patients with debilitating systemic diseases.
Tooth-related criteria	
► Posterior permanent tooth with occlusal/occlusal-proximal deep carious lesion. ► Radiographically (bitewing radiograph) extending to the inner 1/3 of dentine (D3) with a radiopaque layer between the carious lesion and the pulp chamber. ► Sensible teeth according to cold pulp test.	► Teeth with previous restorations. ► Spontaneous pain or prolonged pain (more than 15 s) after sensitivity test (cold test), which would indicate irreversible pulpitis.[22] ► Negative sensibility tests, periapical radiolucencies and sensitivity to axial or lateral percussion. ► Mobile teeth, indicating periodontal disease or trauma. ► External or internal resorption. ► Cervical carious lesions.

Sample size

Using our primary outcome, that is, success, for deep carious lesions after SE versus SW techniques, and assuming the analysis to be performed using an independent χ^2 test, the sample size was estimated as follows. A total sample of 102 teeth was needed (51 in each group), if the true success rates were 0.69 and 0.91 in SW and SE, respectively, based on previous study by Maltz *et al*,[14] with a power of 80% and 5% significance level. This number was increased to 132 to compensate for losses during follow-up over the 3-year follow-up. Sample size was calculated by the power and sample size programme PS.[15] Note that the study by Maltz *et al* differed in their protocol as to how SW was performed (see above); the identified large difference between SE and SW was partially ascribed to this protocol. This may impact on the power of our trial.

Examination

Prior to the study, four dentists were trained and calibrated for identifying eligible lesions by the primary investigator (MEL). After screening for eligibility, teeth were re-assessed by the primary investigator (MEL) for confirmation. From 134 identified patients, 115 (132 teeth) were included.

Eligible teeth were given a serial number (ID) at this initial study visit, from 1 to 132, according to the order for enrolment into the study. A preoperative digital photograph was taken, patients' demographic data, tooth number and number of surfaces were recorded and, within standard procedures and not specifically for this study, conventional periapical and bitewing radiographs obtained. Sensibility pulp testing was performed to confirm pulp vitality by refrigerant spray (Hygenic Endo-Ice; Coltene, Ohio, USA), which was applied by a cotton pellet to the buccal surface of the examined tooth. The patient would notify the operator when he/she felt pain and when this pain subsided. The duration of the pain response was recorded and compared with another control tooth.

First treatment visit

At the first treatment visit (T1), the same treatment protocol was followed for all patients and teeth. Local anaesthesia was administered and the tooth was isolated by rubber dam. Access through the cavitated enamel and outline form were obtained with a sterile high-speed diamond bur. Following international guidelines, selective removal to soft dentine was performed.[1] For the peripheries of the cavity, carious tissue removal to hard dentine was performed using a sharp sterile spoon double-ended excavator (No 51–52, Dentsply, Konstanz, Germany) and a low-speed round bur (HM 71, size #014, Meisinger). The dentinoenamel junction, cavosurface margins and gingival boxes (for proximal lesions) were inspected carefully and made sure to be clean, with at least 1.5 to 2 mm rim of peripheral sound tooth structure to provide a firm marginal adhesion for the restoration.[16] For the pulpal floor/axial wall, soft dentine was left to avoid pulpal exposure. All excavation steps were performed by the primary investigator (MEL).

The restorative procedure used two steps for all groups; in the first visit, a glass ionomer (GI) restoration was placed; in the second step, this was either only cut back to serve as a liner for a composite resin restoration (in SE) or completely removed to allow the second excavation step (SW), followed by reapplication of a GI base and a resin composite restoration. This was done to prevent operator bias during the first visit and to keep a patient-blinded trial design, but was also clinical routine at Misr International University, especially as many participants needed a triage phase first given their poor oral hygiene, and so on.

Hence, after the first carious tissue removal step, a cavity conditioner (GC Dentine Conditioner, GC, Tokyo, Japan) was applied into the cavity, then rinsed by air/water spray, and the cavity gently air dried. For occluso-proximal cavities, a Tofflemire matrix band no 1 with a universal Tofflemire matrix retainer was placed (Tofflemire, New York, USA). A highly viscous GI (Fuji IX GP FAST, GC) was packed and contoured into proper form and allowed to set. Further finishing was performed by a high-speed handpiece using stones (Meisinger) under water coolant. A protective coat (GC Equia Coat, GC) was applied and light cured for 20 s using LED light curing unit (Elipar S10, 3M ESPE, St Paul, Minnesota, USA) with an intensity of 1200 mW/cm^2.

Second treatment visit

After 3–4 months, patients were recalled for their second treatment visit (T2). This short interval was chosen to decrease the risk of loss of the temporary restoration or patient drop-out, but may increase the risk of pulp exposure in the second step compared with longer intermediary times.[17]

Teeth were re-examined clinically and radiographically. If any symptoms of failure (irreversible pulpitis, pulp necrosis or periapical pathosis) were diagnosed, the patients were referred for retreatment (endodontic treatment or extraction) in the respective departments.

If the examined tooth was vital, the tooth was allocated to one of the two arms of the study as described below. If allocated to SE, the GI was cut back pulpally and/or axially, to act as a base leaving a sufficient bulk of 2 mm for the final restoration.[18] For proximal preparations, a sectional matrix system (Palodent Plus, Dentsply) was used. Selective etching of enamel was performed using 35% phosphoric acid gel (Scotchbond Universal Etchant, 3M ESPE) for 15 s, rinsed for 15 s with water, gently air dried with water-free/oil-free air for 5 s and excess moisture blot-dried using absorbent tissue. A single layer of universal adhesive (Single Bond Universal, 3M ESPE) was applied to the entire cavity preparation using an applicator brush, rubbed in for 10 s, air dried for 5 s and light-cured for 20 s as described above. The overlaying resin composite (Filtek Z350 XT, 3M ESPE) was applied in 2 mm thick increments, which were light-cured for 20 s as

described. The restoration was contoured and finished while polishing was achieved using one-step polishing system (Dimanto, Voco, Germany).

For SW, re-entry for the carious lesion was performed by total removal of the GI and the residual carious lesion until firm dentine remained. The cavity was partially filled again with the highly viscous GI to serve as a base. The final composite resin restoration was provided using the same restorative procedures as described for SE.

If a pulp exposure occurred during the excavation, the exposed and surrounding areas were rinsed with water to remove debris. A cotton pellet moistened with 5.25% sodium hypochlorite was placed over the exposure for 1 min to control pulp haemorrhage and to disinfect the area.[19] The cotton pellet was removed and haemostasis confirmed. Calcium hydroxide (Dycal, Dentsply) was applied onto the exposure site and allowed to set for 3 min before restoring the cavity using a GI base and composite resin as described.

If failures occurred, as described, patients were referred for in-house retreatment. Endodontic retreatment was performed by manual instrumentation and lateral condensation obturation. All endodontically treated teeth received indirect restorations; porcelain fused to metal crowns.

Data collection and follow-up examination

Patients were recalled for follow-up once more after a mean 9 months (T3; a total of a mean 12 months from the first visit T1). Note that originally, T3 was planned 9 months after T1, but this was extended to 12 months. Assessment of clinical and radiographic criteria for success was performed by two blinded, calibrated outcome assessors for each tooth. In addition, the following data were collected by a dentist who had not been involved in the treatment at all visits, including possible retreatment visits in case failures occurred: (1) Materials used. (2) Travel times for the patients. (3) The time needed for each visit. Data collection used standardised forms for each visit.

Sequence generation, allocation and blinding

The randomisation unit was the tooth. Sequence generation was performed using Microsoft Excel (Microsoft, Washington, USA) by an independent contributor. Block randomisation was performed with 1:1 allocation ratio using random block sizes of 34, 30, 30, 30 and 8. Randomisation sequence and block sizes were concealed from the primary investigator and other operators. Participants who came back for their second visit (T2) with vital teeth and showing no signs of failure had each tooth allocated remotely via phone prior to further treatment (n=113). Teeth which experienced failures before T2 were also allocated to a group as described, but received retreatments as mentioned earlier. The same applies for patients and teeth, which did not return for T2 (drop-outs), with teeth being allocated to a group in an intention-to-treat (ITT) analysis. Such analysis hence serves to explore the bias introduced by attrition. In a per-protocol (PP) analysis, drop-outs were excluded for the analysis, which mainly impacts on success and survival rates as well as treatment costs. In the main manuscript, only ITT data and analyses are presented; PP data and analyses can be found in the online supplementary appendix 1.

Outcomes and outcome measures

The primary outcome of this clinical trial was success, expressed as a binary variable indicating whether the restored tooth maintained its pulp vitality and restoration integrity after 12 months (T3), without the need for endodontic or restorative treatment or extraction.[14 20] Success was evaluated by a positive response to cold pulp testing, absence of spontaneous pain, no tenderness to percussion, absence of sinus tracts or swelling and absence of periapical radiolucency as determined by periapical radiographs. If at least one of these signs/symptoms was detected, indicating irreversible pulpitis or pulp necrosis, failure was defined. Teeth which had been endodontically or restoratively treated by another healthcare facility or by another dentist were considered as failure, too.

Cost quantification

Consolidated Health Economic Evaluation Reporting Standards (CHEERS) guidelines were followed for estimating and reporting costs.[21] Estimations of direct medical, direct non-medical (travel) and opportunity costs were performed using the societal perspective (accounting for costs generated by the patient attending the dental clinic and receiving dental treatment instead of being at work). The follow-up period, that is, 12 months, was used as the time horizon (which is why no discounting was applied).

Direct medical costs were estimated as follows; the costs for dental staff (one operator and one nurse) were calculated according to the basic salaries for staff and nurses in Misr International University. Other resources like depreciation of the dental unit, disinfection and sterilisation costs, electricity and water consumption were estimated based on the university reports. Cost of materials was estimated in Egyptian pounds (EGP) via the purchase committee supply lists of the Faculty of Dentistry in Misr International University based on the market prices in 2016/2017 and 2017/2018. Initial treatment costs were calculated by adding material costs to cost for dental staff and overhead costs. Total treatment costs were then calculated by adding retreatment costs occurring in the referred departments.

In this trial, direct non-medical costs were travel costs. For each patient, travel distance (km) and time (min) were estimated from his/her home address to the university using Google maps (Google LLC, California, USA). These data were used to generate transportation costs by using Uber bus rates (Uber Technologies, California, USA), as no national mileage estimate is available for Egypt.

Opportunity costs were estimated by using the mean weekly wages for Egypt in 2017 published by the Central

Agency for Public Mobilization and Statistics (https://www.capmas.gov.eg) and multiplying them by travelling and treatment times, including follow-up visits and retreatment visits in case of failure or need for restoration repair.

Total costs included treatment, travel and opportunity costs. In this clinical trial, participants attended the same number of visits for both SE and SW, as described; the second visit for SE was hence associated with this specific trial, but not necessarily the intervention SE. To gauge the impact of this, modified total costs were estimated in a sensitivity analysis, omitting transportation costs and opportunity costs for the second visit from the SE group.

Statistical analysis

Statistical analysis was performed using SPSS V.20.0. Kaplan-Meier plots were used to display survival stratified for treatment arms, and χ^2 and independent-sample t-test (two-sides), with Bonferroni correction for multiple testing, used for pairwise statistical evaluation. Multilevel multivariable Cox regression analyses, accounting for clustering of teeth receiving identical interventions within one patient, and generalised linear modelling were applied. Mean HR and regression coefficients as well as their 95% CI were used to determine associations between treatment and different covariates (age, gender, arch, tooth type and number of surfaces). Significance level was set at $p<0.05$.

Patient and public involvement

Patients or the public were not involved in the design or planning of the study.

RESULTS

Recruitment and follow-up of participants are summarised in the flow diagram shown in figure 1. From 134 patients that were screened for eligibility, a total number of 115

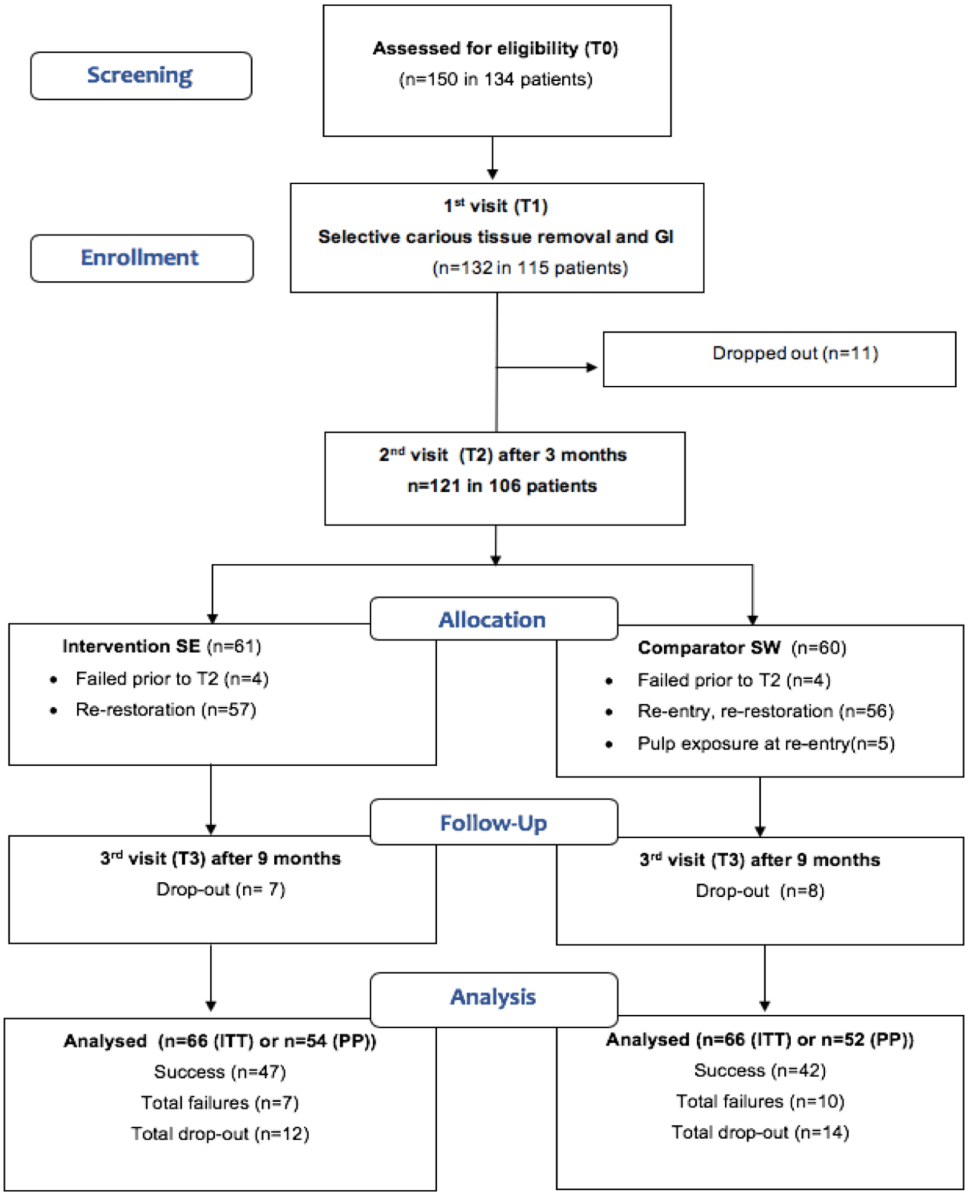

Figure 1 Flowchart of the study. GI, glass ionomer; SE, selective; SW, stepwise carious tissue removal.

Table 2 Baseline characteristics of the teeth in both groups

	SE (n=66)	SW (n=66)
Age (years)		
Mean (SD)	29.9 (7.5)	28.6 (6.1)
Gender (n (%))		
Male	23 (34.8)	18 (27.3)
Female	43 (65.2)	48 (72.7)
Arch (n (%))		
Upper arch	32 (48.5)	23 (34.8)
Lower arch	34 (51.5)	43 (65.2)
Tooth type (n (%))		
Premolars	31 (47.0)	27 (40.9)
Molars	35 (53.0)	39 (59.1)
Number of surfaces (n (%))		
One surface	21 (31.8)	26 (39.4)
Multi-surface	45 (68.2)	40 (60.6)

SE, selective; SW, stepwise carious tissue removal. No significant differences were observed (p>0.05).

Table 3 One-year results of the trial

	SE (n=66)	SW (n=66)
Pulp exposures	0	5*
Endodontic treatment	6	6* (one after exposure)
Extraction	1	0
Total complications	7	10
Success (%)	89.4	84.9
Initial treatment costs in EGP (mean (SD))	**456.6 (98.3)**	**507.5 (123.4)**
Total treatment costs in EGP (mean (SD))	586.8 (396.1)	636.8 (379.3)
Total costs in EGP (mean (SD))	886 (528.92)	926.96 (500.56)
Modified total costs in EGP (mean (SD))	**826.37 (505.37)**	**926.96 (500.56)**

Bold: significant differences (p<0.05).
*One case showed endodontic complications after direct pulp capping and is hence also included in the 'endodonic treatment' category.
EGP, Egyptian pounds; SE, selective; SW, stepwise carious tissue removal.

patients (age: 18–47 years, mean±SD: 29±6) of both genders with 132 teeth were recruited in this study. Data for age, gender, dental arch, tooth type and number of surfaces (baseline characteristics) are presented in table 2 and showed no statistically significant differences between groups (p>0.05).

All 132 teeth received the same initial treatment and were restored with GI (T1). During the first 3 months (T1-T2), eight teeth (6%) in eight patients showed signs of failure (three pulp necrosis, four irreversible pulpitis and one patient had postoperative pain and had her tooth extracted at another dental clinic). Ten patients with 11 teeth (8.3%) were lost to follow-up.

At T2, five pulp exposures (8.9%) occurred in SW, and none in SE.

In the following 9 months (T2-T3), 4 further teeth (3 in SE, 1 in SW) experienced pulpal complications. Moreover, a total of 15 teeth (11.3%) in 13 patients were lost to follow-up between T2-T3.

In the ITT analysis, success after 12 months was 89.4% for SE and 84.9% for SW (table 3). In SE, a total of seven failures occurred; four prior to T2 as described before, one pulp necrosis with periapical pathosis and two pulpitis between T2 and T3; all received endodontic treatment. For SW, there were a total of 10 failures; 4 prior to T2, 5 pulp exposures at T2 and 1 pulp necrosis with periapical pathosis between T2 and T3; again, pulpal complications received endodontic treatment.

Pulp exposures were considered as failures and received direct pulp capping. After 9 months, four of the five teeth (80%) maintained vital pulps while one tooth (20%) lost its vitality with periapical pathosis.

A Kaplan-Meier plot is shown in figure 2. The estimated mean survival time (time free of complications) after SE was 23 versus 18 months after SW, without significant difference between the two treatments.

Initial treatment costs were significantly higher for SW than SE, while for total costs there were no significant differences. Modified total costs were significantly higher in SW than SE, though (table 3).

Regression analysis showed molars, and multi-surface restorations were more prone to complications than premolars and single-surface restorations (table 4) while treatment strategy, age, gender and dental arch did not have a significant association (p>0.05). Initial treatment costs were significantly higher for SE than SW and for multi-surface restorations, while total treatment costs were only significantly higher for molars and multi-surface restorations. Modified total costs were significantly higher for SW than SE. PP analysis showed nearly identical results to ITT analysis (online supplementary appendix tables S1, S2 and S3).

DISCUSSION

Invasive treatment strategies for teeth with deep carious lesions and clinically healthy pulps bear a significant risk for the pulpal health. Two conservative strategies can be adopted: SW or SE. The present randomised trial compared SW and SE in lesions extending >2/3 dentine depth in permanent teeth. Within this interim 1-year analysis, we found no significant differences in success or

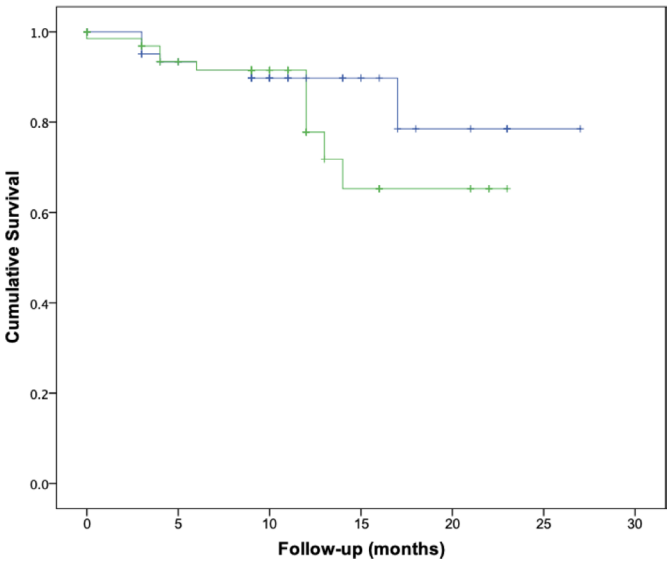

Figure 2 Kaplan-Meier curve. Blue SE, green SW.

survival between SE and SW. We hence reject our hypothesis, but want to highlight that given the limited follow-up, our statistical power may be insufficient to robustly refute it. SW generated more pulp exposures. Also, overall treatment costs were higher for SW when accounting for the specific restorative approach performed in this study (where SE was provided in two steps as well, something we discuss below). It may be speculated that given in SW, no residual carious tissue remains, and the restorative success may be superior to that of SE long-term. So far, however, our data do not provide strong justifications to perform SW instead of SE in permanent teeth, at least for lesions extending >2/3 dentine depth. Our findings should not be transferred to even deeper lesions (eg, >3/4 dentine depth).

A number of specific steps in this trial need discussion. As described, a modified, two-visit SE strategy using a GI in the first and a GI-composite-sandwich restoration in the second step was adopted (no further carious tissue removal was performed, though). This decision had mainly trial-immanent reasons, as discussed, but may be adopted clinically in some circumstances, too. For example, restorative difficulties (limited moisture control options, time constraints) or strategic reasons (triage of high risk, multi-need patients prior to the provision of composite restorations) may well justify this approach in other, routine settings, too. Notably, though, a second SE step comes with additional costs, as confirmed by our study (we will discuss this below) and also requires patients' compliance to allow provision of a composite as planned.[18]

A relatively high number of early failures (between T1 and T2) were found. The preoperative assessment of pulpal health in this study was performed by combined clinical and radiographic assessment, as such combination increases the diagnostic accuracy.[22] Notably, though, misclassification is nevertheless often occurring, especially in multi-rooted teeth where one canal may be necrotic while others can be anything from normal to degenerative. Since teeth that are responsive and appear to be healthy may have pulps that are irreversibly damaged, it is possible that some subjects in our study may not have been suitable candidates for SE or SW. This may explain the reason for the failures that occurred before T2. Until clinical assessment methods with greater accuracy are adopted to evaluate pulpal health, reported differences between pulpal complications from SE and SW should be interpreted with an understanding of the limits as well as the validity of the assessment tools available.[6]

Our study found SE and SW to not show significantly different success and survival. Our findings are somewhat in conflict with another recent randomised trial comparing SE and SW in permanent teeth, where SE

Table 4 Factors associated with initial treatment costs, total treatment costs, total costs, modified total costs and risk of complications

Item	Initial treatment costs (EGP)	Total treatment costs (EGP)	Total costs (EGP)	Modified total costs (EGP)	Risk of complications (HR)
SW (ref: SE)	**0.13 (0.07/0.2)**	0.13 (–0.23/0.28)	0.09 (–0.04/0.23)	**0.16 (0.001/0.32)**	1.49 (0.54/4.09)
Age (years)	–0.002 (–0.007/0.004)	0.00 (–0.01/0.01)	0.005 (–0.007/0.01)	0.01 (–0.002/0.025)	1.00 (0.92/1.09)
Female sex (ref: male)	–0.03 (–0.01/0.04)	0.04 (–0.12/0.22)	–0.01 (–0.15/0.13)	–0.08 (–0.26/0.1)	1.78 (0.54/5.87)
Upper arch (ref: lower)	–0.06 (–0.13/0.01)	0.003 (–0.17/0.18)	–0.06 (–0.23/0.09)	–0.07 (–0.26/0.11)	1.09 (0.36/3.24)
Molar (ref: premolar)	–0.04 (–0.13/0.04)	**0.26 (0.04/0.47)**	0.17 (–0.02/0.36)	**0.231 (0.008/0.45)**	**3.61 (1.1/11.82)**
Multi-surface (ref: one surface)	**0.1 (0.005/0.19)**	**0.4 (0.17/0.62)**	0.18 (–0.02/0.39)	0.14 (–0.08/0.38)	**5.06 (1.25/20.47)**

The mean coefficient (units of scale) or the HR and 95% CI are shown. Bold: significant (p<0.05)
EGP, Egyptian pounds; SE, selective; SW, stepwise carious tissue removal.

showed significantly higher success rate than SW (80% and 56%, respectively, after 5 years).[11] The authors attributed the higher failure rates of SW to the loss of the temporary restoration before the second visit, with many patients not completing treatment. The used material (a calcium hydroxide liner and a modified zinc oxide-eugenol cement) seemed to not be sufficient for withstanding longer restorative periods. In our study, a GI was used; we did not find any restorative failures between T1 and T2 (and also none in the following 9 months when composite was used as main restorative material). Notably, and in line with the literature, SW showed more exposures, all in the second excavation step. So far, only one of the exposed and directly capped teeth required retreatment, equaling a 1-year success rate of 80%. This is much higher than the 32% 1-year rate found in previous trial involving SW and pulp capping,[5] while this trial included only lesions extending >3/4 dentine, which will impact on the risk of pulpal complications, as described. In our case, longer-term results will allow a judgement if a pulp exposure can truly be seen as a failure, as we did, or if it can be 'repaired' successfully by direct capping (which the literature does only limitedly corroborate).[23]

A number of confounders were tested for their effect on our results. For example, we found teeth with multi-surface restorations to be at higher risk of failure, which is in accordance with previous studies.[17 24] Patient's age, gender and location of tooth in upper or lower arch had no significant confounding effect. Tooth type was a significant predictor for complications, as molars were three-folds more prone to failure than premolars. This may also be attributed to the described difficulty of pulpal diagnosis.

This is the second study assessing the initial and long-term treatment costs of SE versus SW. We found SW to be more costly initially, mainly as the second SW step required more treatment time but also as additional materials (eg, GI, anaesthesia) were needed. However, long-term and considering that SE was performed in two steps, no significant differences were found. If omitting the additional travelling and indirect/opportunity costs of the second SE step, SW was also more costly long-term, which is in line with a recent trial on primary teeth.[7]

This trial has a number of strengths and limitations, some of which we discussed before. First, and as a strength, a randomised design was chosen, increasing the internal validity of the trial. Moreover, patients were blinded, and also the outcome assessment by clinical examiners was performed blind, reducing the risk of detection bias. Second, this trial was conducted in Egypt, a setting from which only limited data on this topic are available. Our findings may be applicable to the largely under-researched healthcare settings in Africa and the Middle East. Third, and as a limitation, this is only an interim analysis, with a 1-year follow-up period. Longer term follow-up will allow to detect further events and increase the power. Especially for restorative complications and to discern possible restorative advantages of SW over SE in this regards (as described), such longer term data may be relevant.[3] Fourth, blinding of the operator was not feasible and hence not performed; operator bias can hence not be fully excluded. Fifth, and as discussed, SE included a second restorative step, which is not standard and has been discussed and addressed in sensitivity analyses. Last, our drop-out was higher than expected, and we assume that after 3 years, we may not meet the estimated minimal sample size any longer. It remains to be seen in how far this will impact on our statistical power, which will be highly dependent on the future complications occurring in both groups. Also, randomising teeth and not patients can be debated, and we needed to account for that by multilevel analysis. A clustered parallel design trial, with randomisation of patients, may have been a valid alternative.

In conclusion, within the limitations of this study, success and survival did not differ significantly between SE and SW after 1 year of this randomised trial. Total costs of SE were similar to those of SW when SE was performed in two visits. Dentists may choose either SE or SW for treating deep carious lesions, while based on our study, there is no strong justification to prefer SW over SE for lesions extending >2/3 dentine.

Trial status

The trial is running and re-examinations are performed.

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