Approaches to Caries Removal: What the Clinical Evidence Says

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Every day in the United States, complete caries removal in vital, asymptomatic teeth with deep carious lesions ends in unavoidable exposure of the pulp. As a result, the complexity and cost of treatment increases dramatically and many patients are left with extraction as their only viable option. This review appraises evidence which supports alternative treatments designed to preserve the vitality of the tooth and thus avoid extraction.

Evaluation of Atraumatic Restorative Treatment and Sealants under Field Conditions

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South African Dental Journal 2001 (56:309–15)

ABSTRACT

Objective: The purpose of this study was to evaluate the use of Atraumatic Restorative Treatment (ART) restorations and sealants under field conditions.

Materials and Methods: Five schools whose students demonstrated similar needs for treatment in terms of caries and sealants were chosen. The study was limited to children in grades 1–4. These grades were chosen because they demonstrated higher caries risk. One-surface lesions in both primary and permanent teeth were treated using the ART technique. The treatment included placement of glass ionomer materials—Fuji IX in the lesion and Fuji III (both GC Corporation, Tokyo, Japan) as an occlusal sealant. Both the evaluations and the placement of restorations and sealants were all completed by a dental therapist. Restorations were evaluated at 6 and 12 months after placement. Evaluations were performed to determine: (1) whether the restorations were retained and (2) whether secondary caries was present adjacent to them.

Results: Considering both primary and permanent teeth, 506 ART restorations and 552 sealants were placed. The percentages of ART restorations and sealants available for evaluation at 6 and 12 months were high (>83%). Absenteeism on the evaluation days was the primary reason participants were lost to re-evaluation. Reporting of results is limited to those teeth which were available for evaluation at both the 6 and 12 months evaluations. At 12 months, 57% of restorations in primary teeth and 84% of restorations in permanent teeth were still present. Recurrent caries was observed in 28% of the primary and 8% of the permanent teeth. Considering the evaluation of sealants at 12 months, gross visual inspection showed that only 10% were still

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present. However, caries was detected in only 1% of the teeth that had been sealed.

Conclusions: The ART technique is strongly recommended for management of small, occlusal carious lesions in both primary and permanent teeth, with better results in the permanent dentition.

COMMENTARY

John Tomes suggested in the 19th century that it was better to leave some carious dentin to ensure the continuing vitality of the pulp. By contrast, early in the 20th century, G. V. Black promoted removal of all suspicious dentin even though it might result in pulp exposure. Black's approach has predominated over the years, but it is important to remember that neither approach was based on rigorous scientific study.

The population in this study was comprised of children whose decayed missing filled teeth (DMFT) count was high in terms of decayed and missing teeth, and low in terms of filled teeth. This indicates a population at high risk for caries who were typically treated with extractions. Given the rural nature of these areas and the limited resources available, this is understandable.

The ART technique was developed by dentists tasked with meeting the dental needs of people living in just this set of circumstances. The ART technique involves the use of hand instruments to fracture away unsupported enamel to gain access to caries. Next, excavators are used to remove only the completely demineralized carious tooth tissue. Finally, a high-viscosity glass ionomer is placed into the cavity and additional material pressed into the fissure system for use as a sealant. The technique does not require the availability of anesthesia, rotary instruments, high-volume evacuators, etc.

The present study has many serious flaws relative to a well-designed and well-conducted double-blind, randomized, controlled clinical trial. Only one form of treatment was provided, so no control group was included and randomization became a moot point. Also, because there was only one operator-evaluator and only one form of treatment, no blinding or concealment was possible; i.e., both patient and evaluator were aware of which treatment had been provided, and this knowledge probably affected evaluations made by both the dental therapist and the participants. Finally, both treatment and evaluations were completed by a dental therapist whose qualifications to place these restorations and training as a researcher were not described.

However, one must be mindful of the larger purpose of this study and the stage of development of the ART technique at the time it was undertaken. The development of ART resulted from clinicians faced with a very serious clinical question: how to provide the most care to the most people when faced with very limited resources. The inclusion of the present study in this Critical Appraisal is not meant to provide high-level evidence of proof of efficacy. Rather, it is offered as an example of early, tentative steps to investigate whether all caries must be removed or some may be left in order to avoid a pulp exposure.

The results of this study are comparable with those of other similar studies, and together they represent a body of evidence indicating that this is an approach worthy of further study. Over the years, studies have been conducted to further our understanding of the biological explanation as to how this technique could be successful. In the last 25 years, the profession has begun to formally compare the two very different approaches to the handling of deep caries put forth more than 100 years ago.

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Changes in the Cultivable Flora in Deep Carious Lesions following a Stepwise Excavation Procedure

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ABSTRACT

Objective: The purpose of this study was to examine the cultivable microflora before and after stepwise excavation procedures in deep carious lesions.

Materials and Methods: Nine posterior teeth with deep carious lesions were examined. In eight of the teeth, the depth of the lesion was equal to or greater than two-thirds of the dentin thickness. All teeth were vital, and none had periapical lesion or signs and symptoms suggesting irreversible pulpitis. At the first appointment, the tooth was isolated using rubber dam and the external surface of the tooth was cleansed in preparation for sampling of the microflora present in the lesion. Samples of the outer carious dentin and central demineralized dentin were captured before and after the first excavation of caries. At this first appointment, complete excavation of the peripheral demineralized dentin was completed and the carious dentin in the center of the lesion was partially removed without exposure of the pulp. A calcium hydroxide liner and temporary restoration were placed. In addition, the dentin was assessed qualitatively after excavation in the first appointment and before excavation in the final appointment. The color, hardness and wetness of the dentin were recorded using a commonly accepted scale. At the second appointment, 4–6 months later, samples of the dentin were obtained before and after caries excavation as described above. The microflora samples were incubated under anaerobic conditions for 7 days and the numbers of colony-forming units (CFUs) per millimeter were counted. Finally, representative samples of CFUs were stained and the bacteria present were specifically identified.

Results: No pulp exposures occurred at either the first or second excavation appointment. Before placement of the temporary restorations, the dentin was typically described as yellowish-light brown, demineralized and soft. Prior to final excavation at the second appointment, qualitatively, the color of the dentin became darker and drier. The microflora samples taken before and after the initial excavation were very similar. Gram-positive rods were dominant (70%) and Gram-positive cocci also were present in large numbers (23%). Lactobacillus was the dominant genus. The number and nature of the bacteria present changed from the final samples taken after excavation at the first appointment to the samples taken just before the excavation at the second appointment. In the final sample, the median total CFUs were reduced 100-fold and no growth was detected in 25% of the samples.

Conclusions: The cultivable flora detected following the treatment interval had declined substantially, and the distribution of bacterial species did not represent a typical cariogenic microbiota of deep lesions, confirming the clinical findings of arrested caries progression.

COMMENTARY

This study was as much qualitative as quantitative. The comparisons described are from one sampling period to another so that each tooth serves as its own control. Although a 100-fold reduction in the median colony-forming units in the final sample seems substantial, no statistical testing is reported. The authors note that their results are consistent with similar studies and, in their view, confirm the conclusions of previous studies—i.e., that the microflora in the lesions has changed to one that does not support progression of caries.

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The idea that calcium hydroxide, instead of or in conjunction with sealing the bacteria from nutrients, may have been responsible for altering the microflora growth is not addressed.

This study, along with others, is important because it provides a basis for us to understand the physiological reason why a partial caries excavation approach could be effective.

Ultraconservative and Cariostatic Sealed Restorations: Results at Year 10

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Journal of the American Dental Association 1998 (129:55–66)

ABSTRACT

Objective: To use two modalities to evaluate the effectiveness of treating frank cavitated lesions: (1) sealed composite restorations placed over the carious lesion; (2) removal of the carious lesion and placement of ultraconservative, sealed amalgam restorations without extension for prevention. The two modalities were compared with the traditional unsealed Class I amalgam restoration, including the extension-for-prevention cavity outline form.

Materials and Methods: Acceptable participants had two lesions that were obviously cavitated with bitewing radiographs showing that the lesions had progressed into the dentin but to no more than half the distance to the pulp. Three different restorative methods were used. The first is described as a "cariostatic sealed composite" restoration (CompS/C). All demineralized enamel was removed and sound enamel remaining over the carious lesion was beveled at a 45–60° angle. No attempt was made to remove carious dentin. In fact, if carious dentin was inadvertently removed, the tooth was excluded from the study. A composite restoration was placed in the cavitated area of the occlusal and a sealant placed in the remaining pit and fissure system. The second method was termed a "conservative sealed amalgam" (abbreviated as "AGS" in the paper). Here the preparation was confined to just the area of cavitation. All caries was removed, but there was no extension for prevention into the remaining pit and fissure system. Instead, these areas were sealed using Delton (L.D. Caulk, Dentsply, Milford, DE, USA) pit and fissure sealant. The third group was termed the "conventional amalgam restoration" (AGU) and was not sealed. All caries was removed and the preparation was extended into remaining pit and fissure areas. All participants ($N = 156$) received a CompS/C restoration and one, and only one, of the two amalgam restoration types. Approximately half received an AGS restoration and half received an AGU restoration. The radiographic and clinical performance of these ultraconservative sealed composite restorations placed over caries was compared over a period of 10 years.

Results: At 10 years, complete retention of the sealant was found in 16% of CompS/C and 25% of AGS. An additional 61% and 63% of restorations had at least partial retention of the sealant for the CompS/C and AGS groups respectively. Because efficacy of using a sealant rather than extension for prevention to limit future caries was a unique aspect of this study, measurements of marginal integrity were a major focus of the study. Here it is important to be clear on the terminology related to marginal integrity. In this study the term "open margin" was used interchangeably with "marginal crevice." An open margin was defined as a visible crevice detectable as a two-way catch when an explorer was moved gently over the margin. For many practitioners, this definition might differ from common usage in practice, which would be a crevice large enough to expose base or dentin. More specifically, for many in practice an open margin represents a restoration that should be replaced. However, by the study definition an open margin could also describe a restoration with a marginal defect, but one that is still serviceable. Restorations with marginal defects large enough to expose base or dentin were rated as failures.

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Open margins were reported in 8%, 9%, and 29% of CompS/C, AGS, and AGU restorations respectively at 10 years. In the two groups of sealed restorations, the percentages of restorations that did not have open margins and in which the sealant was at least partially retained were 70% for CompS/C and 84% for AGS. Only 56% of the AGU (unsealed) restorations had no open margins. Groups AGS and CompS/C restorations had significantly fewer open margins than AGU. There was no significant difference between AGS and CompS/C. Caries at the margin occurred in only one CompS/C restoration and one AGS restoration. All failures of the AGU restorations occurred as a result of caries at the margin. After 10 years, the cumulative failure rates were 14% for CompS/C, 2% for AGS, and 17% for AGU restorations. Analysis of survival curves, which consider both the number and timing of failures, for the three groups of restorations indicated that the longevity of restorations for the CompS/C and AGU groups were not significantly different, and that group AGS had significantly higher longevity than either of those two groups.

Conclusions: Bonded and sealed composite restorations placed over frank cavitated lesions arrested the progress of these lesions over a period of 10 years. Because of the high occurrence of open margins leading to caries at the margins of unsealed amalgam restorations, the remaining pit and fissure system should be sealed immediately after restoration placement of a Class I amalgam. The sealed restorations were superior to the unsealed restorations in conserving sound tooth structure, protecting margins, preventing recurrent caries, and prolonging their clinical survival.

COMMENTARY

The authors conclude that teeth restored using the CompS/C approach arrested caries over a 10-year period. Technically, no data regarding the measurement of caries progression in dentin were presented. Complaints of sensitivity also were not reported. Although this would have been a logical measure to make, techniques to radiographically measure lesion progression with acceptable precision did not exist.

At the 10-year evaluations, over 50% of the original study participants remained in the study. Keeping a large group of people in a study for over 10 years is extremely difficult. People lose interest, move from the area, etc. Locating each person and determining why he/she is no longer participating is a difficult and expensive challenge. As resource limitations make a high-quality, randomized, clinical trial of 10 years duration a rarity in dentistry, it is not unexpected that the authors did not have the resources to gather data for the missing participants. Because the loss of participants from each group is very similar, it seems reasonable to assume that loss of participants was unrelated to study results.

Results from the CompS/C group should reassure practitioners who have concerns relative to unintentionally sealing in decay. If these substantial lesions could continue 10 years without obvious progression, it seems very unlikely that incipient lesions inadvertently sealed would not fare as well.

Although the CompS/C group marks an important milestone in our understanding of caries progression, it should not be overlooked that the AGS group, where decay was removed, an amalgam restoration placed, and the remaining pits and fissures sealed, demonstrated fewer failures and significantly higher longevity.

This randomized clinical trial study is one of the landmark studies supported by the National Institutes of Health (NIH), particularly because of its unusual 10-year duration. This study confirmed what Handelman reported over 30 years ago: when a carious lesion is sealed, the lesion does not progress.

According to the Microsoft Academic Search, this paper has been cited 65 times and it was on the list of "Most-Cited Articles as of July 1, 2012" on the American Dental Association (ADA) Web site. It was also one of the major studies cited in a 2010 American Association for Dental Research (AADR) research symposium on "To Seal, Remineralize or Restore: What is the Evidence?" At the symposium, researchers discussed current evidence on pit and fissure sealants, stepwise excavation, and incomplete caries removal

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studies. Dr. Edwina Kidd cited four randomized, controlled trials of this approach. In two of them, the investigators reentered the lesions to see what had happened under the restoration, and the results looked promising. Dr. Kidd further surmised that dental professors have been teaching our students incorrectly to remove all infected tissue from cavities. Such a protocol is old tradition and not based on scientific evidence. She went as far as saying "I've been teaching unsubstantiated rubbish for 30 years."

Another presenter, Dr. James Summitt, agreed. He cited multiple studies that suggest sealing over a lesion can arrest its progress. However, there are other studies suggesting that sealing does not stop caries. In particular, one led by Jan Poorterman of the Academic Centre for Dentistry Amsterdam found caries progression in 70% of sealed occlusal lesions.

Although the issue is far from being settled, the randomized clinical trials are the most reliable because of their higher order in the evidence-based hierarchy. Practicing clinicians should base their treatment modalities on severity and activity of the lesion, caries risk assessment of the patient, and potential for sealing and/or using bioactive dental materials, among other variables.

One major stumbling block to this approach is the current insurance model that reimburses procedures instead of diagnosis. Caries risk assessment would be an important link in the decision process. However, based on our current reimbursement model, caries risk assessment will not be reimbursable. Few dentists will perform this procedure if they are not being compensated for their time.

Even Dr. Mertz-Fairhurst lamented such situation in her 1992 guest editorial in the *Journal of Dental Research* titled "Pit-and-Fissure Sealants: A Global Lack of Science Transfer?"[5] Some dentists are still concerned that they may inadvertently seal over caries, despite clinical studies showing caries arrestment by sealants.

SUGGESTED READING

Handelman SL. Effect of sealant placement on occlusal caries progression. Clin Prev Dent 1982;4:11–16.

Kidd E. When do we need restorations? How much carious tissue should we remove for a filling? J Dent Res 2010;89(Spec Iss A): Symposium 3.

Mertz-Fairhurst E. Pit-and-fissure sealants: a global lack of science transfer? J Dent Res 1992;71:1543–4.

Poorterman JH, Weerheijm KL, Aartman IH, Kalsbeek H. Radiographic dentinal caries and its progression in occlusal surfaces in Dutch 17-year-olds: a 6-year longitudinal study. Caries Res 2003;37:29–33.

Summitt J. Black's principles viewed in today's light. J Dent Res 2010;89(Spec Iss A): Symposium 3.

Complete or Ultraconservative Removal of Decayed Tissue in Unfilled Teeth (Review)

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Cochrane Database of Systematic Reviews 2006, Issue 3. Art. No.: CD003808. DOI: 10.1002/14651858.CD003808.pub2

ABSTRACT

Objective: To test the null hypothesis of no difference in the incidence of damage or disease of the dental pulp or progression of decay and longevity of restorations irrespective of whether the removal of decay had been minimal (ultraconservative) or complete.

Materials and Methods: Six major literature databases were searched for randomized controlled trials, quasi-randomized trials, and non-randomized trials.

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The population of interest was previously untreated primary or permanent teeth. The intervention of interest was minimal (ultraconservative) caries removal, which was compared to complete caries removal. The major outcomes of interest were: (1) exposure of the pulp; (2) the presence of symptoms consistent with pulpal inflammation or necrosis; (3) progression of caries under the restoration; and (4) the time until the restoration was lost or replaced. Other outcomes reported in the studies used were also recorded and used for descriptive reports. Three review authors independently identified eligible papers and performed the data extraction. The quality of the studies considered for inclusion was assessed. Evaluations were based on the degree to which the study complied with norms of good study design and handling of the data: One of the issues was randomization. A second was concealment of the treatment assigned from evaluators and/or participants. The completeness of follow-up, in terms of the percentage of participants returning for evaluations, was also assessed. Another issue considered was whether analysis of the data considered the intent to treat as opposed to just those participants still available for recall at the end of the study. Assuring that intervention and control groups were equivalent at the start of the study was also evaluated. These assessments were used as a basis for rating studies as being at low, moderate, or high risk of bias.

Results: The search identified 529 articles that potentially met the inclusion criteria for the systematic review. After screening all articles via the titles and abstracts, 49 papers were selected to be evaluated further for inclusion. From these, it was determined that only four papers met all inclusion criteria. The studies reported in those papers involved 339 patients who had 604 teeth treated. The four studies included were: Leksell and colleagues (1996), Magnusson and Sundell (1977), Mertz-Fairhurst and colleagues (1987), and Ribeiro and colleagues (1999). All four studies were randomized controlled clinical trials. In the Magnusson and Sundell study, some of the participants received multiple restorations, but randomization was done at the patient level and analysis was done at the tooth level. In contrast, Leksell and colleagues randomized at the tooth level, but again some patients had multiple restorations. While the other three studies used a parallel group design, the Mertz-Fairhurst and colleagues study used a split-mouth. Two of the studies, Magnusson and Sundell, and Ribeiro and colleagues were conducted using primary teeth. All caries was removed in the control groups of each study. However, the partial caries removal method for the treatment groups varied substantially among the four studies. Leksell and colleagues, and Magnusson and Sundell used a stepwise excavation approach. At the initial caries removal appointment, Leksell and colleagues removed "most" of the caries, applied calcium hydroxide, and placed a zinc oxide-eugenol provisional. Re-entry was planned 8–24 weeks later. Caries removal in the Magnusson and Sundell study was described only as partial and not further defined. Similar to the Leksell and colleagues study, Magnusson and Sundell applied calcium hydroxide and placed a zinc oxide-eugenol provisional. A second appointment to re-enter and remove further caries was planned for 4–6 weeks later. In the Ribeiro and colleagues study, much less caries was removed than in either the Leksell and colleagues or Magnusson and Sundell studies. Rather than a stepwise approach, a single appointment was used and the tooth was restored with composite. Finally, in the Mertz-Fairhurst and colleagues study, very little caries was removed. Treatment group teeth were restored with composite while control group teeth were restored with amalgam.

First Primary Outcome: Exposure of the Pulp

Two studies, Leksell and colleagues, and Magnusson and Sundell, collected data on this outcome. Both of these studies used a stepwise approach to caries excavation, and both had some patients for whom multiple restorations (clustered data) were placed. The data were examined and it was found that the clustering of data had no important effect on the results. The data were as follows:

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Outcome: Pulp Exposure

	Treatment Group		Control Group
	Initial Visit	Re-entry Visit	
Leksell and colleagues study	0%	17.5%	40.0%
Magnusson and Sundell study	0%	14.5%	52.7%

The risk ratio for exposure for incomplete caries removal at the initial visit versus complete caries removal in the control group was 0.02, representing a 98% reduction in the risk of exposure at the initial visit. The risk ratio for the second visit relative to complete caries removal was 0.35, representing a 65% reduction in risk.

Second Primary Outcome: Symptoms Consistent with Pulpal Inflammation or Necrosis

Data from all four studies were reported. In the Leksell and colleagues study, at 1 year no symptoms were reported for either the control or treatment groups. Magnusson and Sundell reported 2 out of 55 participants who had partial caries removal reported symptoms consistent with inflammation, and 3 complete caries removal patients with necrosis compared to only 1 in the partial caries group. Mertz-Fairhurst and colleagues reported no complaints of necrosis or inflammation from either group. One complete caries removal participant experienced pulpal necrosis in the Ribeiro and colleagues study.

Third Primary Outcome: Time until the Restoration Was Lost or Replaced

The Mertz-Fairhurst and colleagues study was the only one to collect data on this outcome. During the first 2 years of the study, no restorations were lost or replaced.

Conclusions: The authors of the review stated four conclusions:

- Partial caries removal in symptomless primary or permanent teeth significantly reduces the risk of pulp exposure.
- Partial caries removal seems preferable to complete caries removal in deep lesions, in order to reduce the risk of carious exposure.
- There was insufficient evidence to know whether it is necessary to re-enter and excavate further in the stepwise excavation technique. Relative to those that did re-enter, studies without re-entry reported no adverse consequences.
- With only four included studies, studies at high risk of bias, and differences in lesion severity, firm conclusions cannot be drawn and there is need for continued research in this field.

COMMENTARY

The meta-analysis of the data for the first primary outcome, pulp exposure, is the most informative aspect of this systematic review. Only two studies, Leksell and colleagues, and Magnusson and Sundell, reported data that could be included in this analysis. Considering both studies and combining the number of exposures from both the initial and second visits for the incomplete caries removal group, the risk of exposure using a stepwise approach was 0.16 (18 exposures out of a total of 112 participants). A risk of zero would represent no risk of exposure and a risk of one would represent a 100% risk of exposure. Similarly, considering the number of exposures in the complete caries removal groups of both studies, the risk of exposure was 0.46 (57 exposures out of a total of 125 participants). Participants in the complete caries removal group were 2.8 (0.46/0.16) times more likely to experience a pulp exposure.

Although a meta-analysis of data adds substantially to the value of any systematic review, not all data from differing studies can be combined. It must make sense to combine data from different studies; e.g., both studies have recorded the same clinical outcome in similar ways. In the present systematic review, the clinical approach to incomplete caries removal varied among the four studies and more specifically between the two studies for which data were combined. Accordingly, one must consider whether it was appropriate to combine the data and perform a meta-analysis. Both studies can easily and accurately be

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understood as having divided treatments into two categories, complete and incomplete caries removal. In that sense, combining the data was appropriate. Similarly, both studies measured exposures as present or absent. However, one study (Magnusson and Sundell) considered only primary teeth and the other only permanent teeth. In one sense, combining data from primary and permanent teeth in this meta-analysis improves the relevance of the study to general practice. However, the risks for the two age groups do differ (see data table for "Outcome: Pulp Exposure"). The risk ratio for the two approaches when used on primary teeth in the Magnusson and Sundell study was 3.6 (0.527/0.145). In the Leksell and colleagues study, it was 2.3 (0.400/0.175). The differing results may result from study-related issues, such as normal variation between samples, different operators and evaluators, and/or different approaches to incomplete caries removal. Or, it could be due to differences in primary and permanent teeth. If the results are strictly a function of primary versus permanent teeth, the combined data probably underestimate the effectiveness of this approach with primary teeth and overestimate it for permanent teeth. Most importantly, whether viewing the results either separately or in combination, it is clear that the risk of exposure was substantially increased when a one-visit, remove-all-caries approach was used.

Only qualitative data were provided for the second primary outcome. Although all four studies provided data on this outcome, there were too few instances of pulpal inflammation or necrosis to provide a basis for statistical analysis. The data support the following conclusions: first, in terms of pulpal inflammation and necrosis, not exposing the pulp greatly increases the chances for success. Second, for teeth in which the pulp was not exposed, both approaches appear to result in a fairly low rate of incidence of inflammation or necrosis. In other words, the key to improved success is not exposing the pulp.

For the fourth primary outcome, only the Mertz-Fairhurst and colleagues study contributed any data regarding this issue. Accordingly, the systematic review offers us nothing further than could be gleaned from reading the article itself. The Results section does not include any report of data for the third primary outcome, progression of caries under the restoration. One is left to assume that if evaluators in the Mertz-Fairhurst and colleagues study had detected caries under any of the restoration, this would have been cause to replace the restoration.

The studies included in the review were regarded as being at high risk of bias. Regarding random assignment of treatment, the use of multiple restorations in the same patient was common to three of the four studies. As described earlier in this Critical Appraisal, the Mertz-Fairhurst and colleagues study used a split-mouth design. However, each participant did not receive one of each of the three restorative approaches. Instead, every participant received a sealed composite restoration. In this approach, (1) the damaged enamel was removed and sound enamel beveled; (2) no carious dentin was removed; (3) a bonded composite restoration was used to restore the cavitation; and (4) a sealant was placed in the remaining pit and fissure system. A second restoration was placed for every participant. For half of the participants, this was a sealed amalgam restoration. In this restoration, (1) a conservative preparation involving only the cavitated area was made; (2) all caries was removed; and (3) a sealant was placed in the remaining pit and fissure system. For the remaining half of participants, a traditional amalgam restoration was placed. Here, all caries was removed and the preparation was extended into the remaining pit and fissure system; i.e., extension for prevention. This design represents somewhat of a hybrid between a split-mouth design and an independent, parallel group design. Given appropriate statistical testing, this does not represent a problem.

However, using the same treatment for multiple teeth from the same patient is a problem. Practitioners generally recognize the uniqueness of patients and the impact each has on the final results of treatment. Study design and statistical analysis need to take this into consideration, but in two studies, the researchers did not. One study randomized each participant to a

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specific treatment, provided multiple restorations of the same type, and analyzed the results as though they had occurred from several different people rather than the same person. Another study randomized several teeth from the same participant to receive different treatments, and then reported the results for individual teeth as though they had occurred from several different people. Both approaches ignore the impact the individual has on the result, and both are potentially problematic. In the present systematic review, analysis of this clustering effect did not appear to affect the outcome, but did reduce the precision.

Concealment of the treatment rendered or blinding is always a concern as source of bias. Sometimes the issue of bias may seem of theoretical concern only. But bias is real and can have a clinically important effect on the outcome of a study. For the four studies included in this review, the steps taken to conceal treatment from the researchers and the participants were not clear. Lacking clear information that an effective concealment strategy was used, the most conservative approach is to assume the studies are somewhat suspect in this regard. For the Mertz-Fairhurst and colleagues study, each of the three restorative approaches was easy to recognize: (1) composite versus amalgam; and (2) amalgam with sealant versus amalgam without sealant. Thus, it is clear that concealment was not part of this study.

To clarify the potential for bias, assume that the evaluators believed strongly in the study hypothesis; i.e., that caries could be arrested by sealing the lesion from external sources of nutrients. As a result, every bonded composite restoration might be graded a bit more leniently and every amalgam restoration a bit more harshly. Obviously, such an occurrence would have a real effect and would distort the results. When one considers all of these potential sources of bias, deciding that the studies reviewed were at high risk for bias is very reasonable. As a result, our confidence in their results is lessened.

Two studies, Mertz-Fairhurst and colleagues, and Ribeiro and colleagues, used a single-visit, incomplete-caries-removal approach. In terms of symptoms consistent with pulpal inflammation and/or necrosis, participants in these studies did not appear to fare more poorly than those in the other two studies. However, the incidence of symptoms in both the complete and incomplete caries removal groups for all four studies was so low that drawing any firm conclusions is not possible.

Similarly, participants in the treatment group of the Mertz-Fairhurst and colleagues study did not seem to need replacement of restorations at a rate higher than those in the control group. With just one study reporting data on this outcome and a very low incidence of replacement in both groups, no firm conclusions can be drawn. That the four studies used different approaches to incomplete caries removal is clear. Unfortunately, the varying definitions are not clear enough to help the reader understand exactly how their approaches differed. Although this review supports the conclusion that avoiding pulpal exposure in deep carious lesions leads to better outcomes, it can offer little information relative to how much/little caries should be removed.

SUGGESTED READING

Leksell E, Ridell K, Cvek M, Mejare I. Pulp exposure after stepwise versus direct complete excavation of deep carious lesions in young posterior permanent teeth. Endod Dent Traumatol 1996;12:192–6.

Magnusson BO, Sundell SO. Stepwise excavation of deep carious lesions in primary molars. J Int Assoc Dent Child 1977;8:36–40.

Mertz-Fairhurst EJ, Call-Smith KM, Shuster GS, et al. Clinical performance of sealed composite restorations placed over caries compared with sealed and unsealed amalgam restorations. J Am Dent Assoc 1987; 115:689–94.

Ribeiro CCC, Baratieri LN, Perdigão J, et al. A clinical, radiographic, and scanning electron microscopic evaluation of adhesive restorations on carious dentin in primary teeth. Quintessence Int 1999; 30:591–9.

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THE BOTTOM LINE

- The profession's present consensus that all caries must be removed, even at the risk of exposing the pulp, is based on the careful observations of G. V. Black made in conjunction with treatment of his patients. Although G. V. Black remains a giant in the dental profession, it is important to recall that things have changed over the years. Because G. V. Black's observations were made, the profession has developed materials that allow us to seal restorations against microleakage on a consistent basis.
- The use of ART restorations demonstrates the enormity of the underlying clinical problem. Is there a different approach to the management of carious lesions which can preserve teeth rather than condemn them unnecessarily to extraction? Such an approach would represent a tremendous public health benefit.
- Although the early studies of ART were not scientifically rigorous, they provided evidence that a different approach might be available and that this approach was worthy of additional study. At this point, there is good, high-level evidence available supporting the partial excavation of caries as a means to avoid pulp exposure.
- Bjørndal and Larsen and other similar studies provide us with a physiological explanation of how partial caries excavation can be successful.
- The Mertz-Fairhurst and colleagues study did not use calcium hydroxide and achieved the same result, arrest of the carious lesion, as the Bjørndal and Larsen study. The evidence supports the conclusion that the use of calcium hydroxide is not a necessary step in arresting the progression of caries.
- The Mertz-Fairhurst and colleagues study supports the conclusion that sealing lesions from the nutrients found in the oral cavity is sufficient to arrest decay. Further, the study supports the conclusion that sealing the remaining pit and fissure system reduces the incidence of new decay.
- The evidence supports the use of occlusal sealants without concern for inadvertently sealing a tooth that has incipient caries. Accordingly, the use of procedures to investigate the pit and fissure system to determine whether caries is present, as opposed to using it as means to increase sealant retention, are not necessary and result in unnecessary loss of tooth structure.
- The evidence supports leaving all caries as a viable approach. From a public health standpoint, this could save considerable time and money. However, it is important to recall that restorations in the Mertz-Fairhurst and colleagues study had significantly greater longevity when all caries was removed than when no caries was removed. Thus, any benefits from not removing caries may represent a short-term but not a long-term or overall benefit. To our knowledge, no studies exist to answer this question.
- The Ricketts and colleagues review indicates that the risk of exposure increases nearly three-fold when a one-visit, remove-all-caries approach is used instead of a stepwise caries removal approach.
- When the pulp was not exposed, there was a low rate of pulpal inflammation and necrosis. This was the result regardless of the approach used, complete or partial caries removal. Thus, the key to success is to avoid pulp exposure.
- These studies support the conclusions that:
  - The use of partial caries excavation in order to avoid pulpal involvement leads to better outcomes in terms of inflammation or necrosis of the pulp.
  - Remaining caries does not progress.
  - Annual failure rates for teeth in which caries remained were reasonable (1.4%).
  - The public health implication of preserving teeth that would otherwise be extracted is tremendous, as is the benefit for the individual patient.

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