Permanent Restorations on Pulpotomized Primary Molars:

An Evidence-Based Review of the Literature

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Abstract

This evidence-based study of the literature investigated the success of a final restoration material to be used in a pulpotomized primary molar. The review was based on evidence from 3 main sources: a search of several electronic bibliographic databases, a review of references from relevant studies for additional potentially relevant articles, and communications with a CDA librarian and a teaching Paedodontist. A total of 17 articles were reviewed. Of these, 7 were deemed relevant and were critically appraised according to a "causation checklist" of 16 items. The 7 studies were methodologically different in terms of test variables (such as restorative materials), sample size, controls, and factors defining success. Although two studies were randomized control trials, only one was in- vivo and even then it was not completely randomized hence none was considered to present truly strong evidence. Therefore, while traditionally the material of choice has been a stainless steel crown, no conclusions or recommendations regarding the final restoration material to be used after a primary molar pulpotomy can be made based on the evidence.

A pulpotomy is the recommended procedure to treat infected coronal pulps in primary teeth.[1] It involves the removal of the coronal pulp tissue of a primary tooth without removing the pulp tissue in the root canals. This is followed by applying pulp medicament, most commonly formocresol, over radicular pulp tissue. with a final restoration placed on the pulpotomized tooth.[2] The selection of final restoration materials include stainless steel crowns, amalgams, IRM, glass ionomer, and composite resin.[3] When deciding which restoration to utilize, variables such as aesthetics, microleakage, cost, and patient acceptability must be considered.[4] The problem lies in the fact that there is always a risk of failures such as fractures, microleakage, and recurrent caries.[1] An acceptable final restoration must allow the tooth to remain functional and without disease.[4]

This literature review was undertaken to investigate the following question: When treating a primary molar with a pulpotomy, what should be used as a final restoration? Traditionally, stainless steel crowns (SSCs) have been recommended as the restoration of choice to protect pulpotomized teeth from fracture.[2] Although very effective these restorations can be esthetically unpleasant, so it remains beneficial to consider other options. A review of the literature was thus conducted to investigate further restorative materials that may provide advantages in the restoration of pulpotomized primary molars.[2] This paper summarizes the strongest sources of evidence regarding materials used for the final restoration of pulpotomized primary molars.

Methods

A systematic method was used to identify, select and critically appraise relevant studies regarding final restorations placed on pulpotomized primary molars.

Search Strategy

Three types of searches were conducted to locate potentially relevant published articles and evidence to support recommendations for final restorations placed on pulpotomized primary molars. First, several electronic bibliographic databases were searched: MEDLINE(R) (1996 to the present), EMBASE (1980 to the present), CINAHL (1982 to the present), Ovid Healthstar (1966 to the present), Books@Ovid, Journals@Ovid, Cochrane DSR, ACP Journal Club, DARE, CCTR, AHMED (1985 to the

present), and PUBMED (1966 to the present). The following key words were used in the searches: pulp$, restor$, primary, primary molar, success rate, amalgam, zinc oxide eugenol, composite, light-cured, and calcium hydroxide. These studies were limited to studies published in English. 658 abstracts were found to match these search terms. Second, the reference lists from articles deemed relevant, as described in the next section, were examined to identify additional potentially relevant articles. 17 additional potentially relevant articles were identified by this process. Third, potentially relevant articles were sought by contacting two accommodating sources: 1) The Canadian Dental Association Librarian was contacted for her guidance and aid with a database search using the following keywords: pulpotomy, primary molar, final restoration. 2) Dr. P. Andrews, an expert in the field, was consulted to provide his opinion and suggestions for relevant articles. Dr. Andrews is a Paedodontist and an Assistant Professor at the University of Toronto, Faculty of Dentistry, and he has research interests in paediatric pulp therapy. These sources yielded no additional information or articles for this review.

Determination of Relevance

Of the 675 articles identified, an article was considered relevant if it met the following inclusion criteria:

1) The article reported primary research. Review articles and articles pertaining to pulpectomies, anterior teeth, or permanent teeth were excluded.
2) The studies examined pulpotomy procedures that had been performed on primary molars that were treated with permanent restorations.
3) The studies were direct comparison studies, RCT, non-randomized trials, case series, or retrospective analytical studies.

Utilizing the criteria, 619 articles were rejected at the title stage, and an additional 24 were rejected at the abstract stage, leaving 17 articles that were retrieved and copied for review.

Validity Instrument

Of the 17 articles, 7 were deemed relevant[1-7] and were scored according to a "Checklist to Assess Evidence of Efficacy of Therapy or Prevention" developed by Leake[8] **(Table 1)**. The highest possible score was 16. A list of the 10 copied articles rejected and the reasons for exclusion appears in **Appendix 1**.

Table 1. **Checklist to Assess Evidence of Efficacy of Therapy or Prevention**

Unless otherwise indicated, for every "yes" answer to the questions below one point was scored, for a highest possible score of 16.

General Question

1. Was the study ethical?
2. Was a strong design used to assess efficacy?
3. Were outcomes (benefits and harms) validly and reliably measured?
4. Were interventions validly and reliably measured?

What Were the Results?

5. Was the treatment effect large enough to be clinically important?
6. Was the estimate of the treatment effect beyond chance and relatively precise?
7. If the findings were "no difference" was the power of the study 80% or better?

Are the Results of the Study Valid?

8. Was the assignment of patients to treatments randomized?
9. Were all patients who entered the trial properly accounted for and attributed at its conclusion?

i) Was loss to follow-up less than 20% and balanced between test and controls? (½ point)

ii) Were patients analyzed in the groups to which they were randomized? (½ point)

10. Was the study of sufficient duration?
11. Were patients, health care workers, and study personnel "blind" to the treatment?
12. Were the groups similar at the start of the trial?
13. Aside from the experimental intervention, were the groups treated equally?
14. Was care received outside the study identified and controlled for?

Will the Results Help in Caring For Your Patients?

15. Were all clinically important outcomes considered?
16. Are the likely benefits of treatment worth the potential harms and costs?

Results

Of the seven studies reviewed **(Appendix 2)**, two[1,7] compared the success of the same treatments i.e. amalgam vs. stainless steel crowns (SSCs).The first found that SSCs were more successful as judged radiographically, although far fewer teeth were restored with amalgam than with SSCs[7]. The other found no statistically significant difference between the performance of SSCs and amalgam as judged radiographically[1]. This finding may be surprising since SSCs are generally expected to fare better than other restorations. However, this study also had a much smaller sample size for amalgam. Evidence from both studies was deemed poor and both received a score of 8/16 on the checklist.

The two strongest studies assessed were Randomized Controlled Trials (RCTs). The first was a 2-year study which found, using both statistical and clinical means, composite restorations failed less than compomer[6].

The other RCT was one of two in-vitro studies reviewed. It found that bonding agents and resin-based materials provided excellent protection against microleakage while SSCs were less successful at sealing margins[3]. Traditionally, it has been thought that the full coverage SSCs provide may protect against leakage better than other restorations[2,9], a fact the latter finding contradicts. The other in-vitro study found that bonded restorations (bonded amalgam, compomer and composite resin) had higher fracture strengths than unbonded amalgam restorations[5]. Both in-vitro studies were well designed and while the latter omitted some data, it produced significant results.

Another study evaluated performance of IRM +GI vs. IRM alone and found no statistically significant difference between the two[2]. However, owing to its rather weak design, it received a score of 6/16.

The final study compared how teeth would fare after emergency pulpotomies with IRM+GI (provisional restoration) vs. SSCs (definitive restoration) [4]. The results suggested immediate placement of an SSC rather than IRM+GI improved tooth survival. However, evidence from this study was deemed insufficient because over half of the subjects treated with SSCs did not return for follow up.

Discussion

According to this review, there is insufficient evidence in the literature to make a recommendation on which final restoration to use on pulpotomized primary molars.

First and most importantly, a direct comparison between treatment options was difficult to make because only two of the studies[1,7] were comparisons of the same treatment, however, neither of these studies had a strong design (i.e. RCT) and the evidence was conflicting. In addition, 'success' was defined differently in the various studies since different outcomes were being investigated (e.g. microleakage vs. fracture strength), adding to the difficulties of making a direct comparison.

In general, there were several weaknesses common to all studies. Randomized controlled trials are a feasible option for providing good quality evidence when comparing final restorations for pulpotomized teeth, however, only one such in-vivo study was available. Furthermore, many of the factors which can influence the performance of a restoration were not satisfactorily controlled for. These include the type of cavity-sealing material used, the extent of the cavity and execution of the treatment (which can be influenced by such factors as operator expertise), amount of time the tooth is expected to be in the mouth before exfoliation and the health of the patient. Most of the in-vivo investigations included radiographic findings (e.g. presence of pathologic root resorption as a means to distinguish between success and failure) ostensibly because ultimately one is trying to prevent further disease propagation. However, although halting the disease is the primary goal

of treatment, it is not the only factor in play when making a clinical decision. Aesthetics, chair-time (an especially important factor when dealing with children), and cost of treatment are all important issues that help determine the most suitable treatment and unfortunately, none of the studies controlled for any of these factors.

In conclusion, additional studies with stronger designs need to be conducted on this subject. Cohesive RCTs with clearly defined inclusion criteria that compare all commonly available final restorations would be an asset in elucidating which material is most successful. 'Success' in future studies should also include as many clinically important outcomes as possible. Even with strong studies however, it would be quite difficult to pinpoint a restorative material that is considered the most successful in all situations. The reason for this is that different restorative materials may be the most appropriate to use in different situations. For example, one may decide to use composite resin if aesthetics are required but may decide against it in another situation where moisture control is a problem. While SSCs have been the preferred treatment for many years, there remains no clear evidence in the literature that shows superiority of this restoration over the others.

References

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Appendix 1. **List of articles excluded and reasons for exclusion**

Articles	Reason for exclusion
1) Primosch et al, 2005	Pulpectomized teeth were studied
2) Sadrian & Coll, 1993	
3) Barr et al, 1991	
4) Moskovitz Moti et al, 2005	Only temporary restorations were analyzed
5) Guelmann et al, 2002	
6) Tsai et al, 1993	Glutaraldehyde preparations were compared; final restorations were not studied
7) Killian and Croll, 1992	A description of the procedure for SSCs; not a study
8) Attin et al, 2001	Primary molars were not pulpotomy treated
9) Waterhouse et al, 2000	Pulp therapy techniques were studied, not final restorations
10) Hickel et al, 2005	Review article

SSCs = Stainless Steel Crowns

1) Primosch R., et al. A retrospective assessment of zinc oxide-eugenol pulpectomies in vital maxillary primary incisors successfully restored with composite resin crowns. Pediatric Dentistry 2005; 27:470-477

2) Sadrian R and Coll JA. A long-term follow up on the retention rate of zinc oxide eugenol filler after primary tooth pulpectomy. Pediatric Dentistry 1993;15:249-252.

3) Barr ES, Flaitz CM, Hicks MJ. A radiographic evaluation of primary molar pulpectomies. Pediatric Dentistry 1991;13:4-9.

4) Moskovitz Moti, et al. Success rate of root canal treatment in primary molars. Journal of Dentistry 2005;33:41-47

5) Guelmann M, Fair J, Turner C, Courts F. The success of emergency pulpotomies in primary molars. Pediatric Dentistry 2002 May-Jun;24(3):217-20.

6) Tsai TP, Su HL, Tseng LH. Glutaraldehyde preparations and pulpotomy in primary molars. Oral Surgery Oral Medicine Oral Pathology 1993;76:346-350.

7) Croll TP, Killian CM. Zinc oxide-eugenol pulpotomy and stainless steel crown restoration of a primary molar. Quintessence Int. 1992 Jun;23(6):383-388.

8) Attin T, Opatowski A, Meyer C, Zingg-Meyer B, Buchalla W, Schulte Monting J. Three-year follow up assessment of Class II restorations in primary molars with a polyacid-modified composite resin and a hybrid composite. Am J Dent 2001;14:148-152.

9) Waterhouse PJ, Nunn JH, Whitworth, JM. An investigation of the relative efficacy of Buckley's Formocresol and calcium hydroxide in primary molar vital pulp therapy. British Dental Journal 2000;188:32-36

10) Hickel R, Kaaden C, Paschos E, Buerkle V, Garcia-Godoy F, Manhart J. Longevity of occlusally-stressed restorations in posterior primary teeth. American Journal of Dentistry 2005;18:198-211.

Appendix 2. **Studies investigating success of various final restorations in pulpotomized primary molars**

Author, date	Population (Age, sex, location)	Test treatment (Number studied)	Control Treatment (Number studied)	Time after treatment for evaluation	Measure of Failure	Outcome	Critical appraisal comments	Conclusion, Strength of evidence and classification
Cehreli et al, 2006[6] RCT	84 children of both sexes, 6-10 years old; 200 primary molars	Of the 200 pulpotomized molars assessed, 100 restored with composite (TPH) and 100 with compomer (Dyract)	No control-compared composite vs. compomer success	Study lasted 24 months but evaluations at 0, 3, 6, 12, 18 and 24 months	Failure assessed radiographically and defined as one or more of the below: 1) Periapical or interradicular radiolucency 2) Internal or external pathologic root resorption 3)Uneven root resorption 4)Calcific metamorphosis in the radicular pulp canal	Overall, composite had 97.6 % (80/82) success rate while compomer ha 80.9% (72/89) success rate. No occlusal restorations failed; 3% of 2-surface restorations on composite failed and 22.1% of 2-surface restorations on compomer failed.	Score: 11/16 Limitations: Not double-blinded Only teeth, not subjects randomized Factors such as cost, chair-side time not considered.	Provided natural exfoliation of teeth is expected within 2 years, restoration of pulpotomized primary molars can be done with composite (TPH); use of compomer (Dyract) is not recommended. CTF Rating: I B
Guelman, et al, 2004[3] RCT	In vitro study, extracted pulpotomized primary molars with at least 3 sound walls and ½ to 2/3 root remaining	60 teeth in 5 equal groups: compomer, GI, amalgam, SSC, IRM. Thermocycling, then immersed in	Control was IRM, 12 teeth	Thermocycling for 500 cycles, time unspecified	Three sections were made each .5mm from the edge of the restoration and one in the center. Then a scoring system	Bonding agents and resin based restorations provided the best total margin protection. SSCs cemented with GI were unable to	Score: N/A[a] Good study design and good execution with significant results. However, since	Bonding agents and resin-based restorations will provide the best total margin protection against microleakage, specifically superior

		dye (24 hrs), then progressively ground and examined for microleakage.			was used to show amount of leakage.	form a hermetic seal. *Statistically significant results. Other groups were not leakage-resistant.	it was in-vitro, did not mimic oral cavity mechanisms as closely as in-vivo studies.	to SSCs. However, this was an in vitro study. CTF Rating: N/A[a]
El-Kalla et al, 1999[5] Non-randomized in-vitro trial	In-vitro study; 80 pulpotomized primary molars with at least 2/3 of root remaining.	Number unspecified. Treatment groups were teeth restored with: bonded amalgam, compomer, Z100 composite which are all bonded systems.	Unbonded amalgam was used as control. Number unspecified	Time unspecified	Fracture strength being investigated so following 1000 thermocycles between 5-55°C, teeth tested to failure using Instron compressing machine	Unbonded amalgam had statistically significant lower fracture strength than the bonded systems. There was no statistically significant difference between the bonded systems i.e. bonded AM, compomer or composite. However, large standard deviations from mean in all 4 groups.	Score: N/A[a] Fairly good design- molars were matched as much as possible according to cavity class, molar type and size. Although results were statistically significant, they were undermined by large standard deviations. In-vitro study therefore can only speculate	According to study, bonded systems tested have higher fracture strength than unbonded control. In-vitro however so can only speculate on clinical performance. CTF Rating: N/A[a]

							on clinical performance.	
Holan et al, 2002[1] Non-randomized trial	227 patients (129 boys, 98 girls); 341 primary molars; Principal author's dental office, Israel	Of the 341 pulpotomized molars: 287 (84%) restored with SSC, 54 (16%) restored with amalgam	No control – compared SSC vs. AM success	Ranges 6 to 103 months	Pulpotomy failure assessed radiographically criteria: 1) periapical or inter-radicular radiolucency 2) internal or external pathologic root resorption 3) calcific metamorphosis in the radicular pulp canal	47 (14%) of the 341 pulpotomies were failures: 36/287 (13%) of SSC, and 11/54 (20%) AM – not statistically significant Failure rates of 2 surface AM was 7/30 (23%), and the failure rate of 1 surface AMs was 2/20 (10%)	Score: 7/16 Limitations: Not randomized No controls	Pulpotomized primary molars can be successfully restored with one surface amalgam if their natural exfoliation is expected after not more than 2 years. CTF Rating: II-1 C

Guelmann et al, 2005[2] Non-randomized trial	52 patients, 59 primary molars; 2 operator pediatric dental office, Tampa, Florida	Of the 59 pulpotomized molars: 39 (66%) reinforced ZOE (IRM) only, 20 (34%) IRM + GI, all with resin based material Z100 incrementally packed	Radiographs of the 59 pulpotomized molars were compared to the contralateral non-pulpotomized control teeth to assess exfoliation rate (normal, accelerated, delayed)	Ranges 7 to 43 months	Pulpotomy failure assessed radiographically criteria: 1)furcation/ periapical osseous radiolucency 2) internal/ external pathologic root resorption	Occlusal surface restored: 100% success Proximal restorations: 83% (15/18) success IRM + GI and 69% (22/32) success for IRM only When compared to contralateral non-pulpotomized control teeth: 47 (80%) exfoliated normal physiologic resorption patterns, 2 (3%) accelerated resorption, and 10 (17%) pathologic failure	Score: 6/16 Limitations: Not randomized No controls	Success rate for resin-based restorations (78%) was inferior to prior studies using SSCs When proximal surfaces were involved, the failure rate (26%) was comparable to that reported for amalgam restorations (23%) CTF Rating: II-1 C
Gruythuysen et al, 1997[7] Dramatic result from non-randomized trial	57 children Avg age 5.5 yrs 106 molars History of behaviour management problems related to dental txt.	SSC vs. AM Number that received tx of each unspecified	None	2 yrs	Radiographic (pathologic root resorption, bone resorption) and clinical signs (pain, abscess, fistulae) leading to extraction	After 2 years, 8/25 (32%) AM had failed, 10/67 (15%) SSC had failed. This data excludes dropouts and exfoliations	Score: 8/16 Limitations: Study's primary objective was not to compare final restorations	Significant difference between SSC and AM; SSC more successful CTF Rating: II-3 C

							therefore missing important information as to how trial was executed with respect to final restorations. However, study found the only factor affecting success was final restoration. Factors such as cost, chair side time not considered.	
Guelmann et al, 2005[4] Retrospective analytical study	92 pulpotomies, 50 male, 42 female, ages 2.2-10.9, Graduate residents, Florida university	Of the 92 pulpotomies, 41 restored with ketac molar +IRM, and 43 SSC.	No control: IRM+ Ketac molar(temporary) vs. SSC(Permanent)	Ranges from 8-866 days	Failure criteria used for pulpotomy: 1)internal root resorption 2)furcation radiolucency 3)periapical bone destruction	-<50% that were tx w SSC returned for recall. Total 18 success and 3 failure for SSC and 10 success and 3 failure for IRM+Ketac Molar -high failure rate during the 1st 90	Score: 8/16 Very significant loss to follow-up rendered evidence insufficient	Immediate placement of SSC tended to improve the chances for positive outcome when emergency pulpotomies were performed. CTF Rating:

					4)pain 5)swelling 6)sinus tract	days with all material -SSC survival estimate median=410 days -IRM+Ketac survival estimate =173 days -no difference between age, gender, tooth type, and arch		II-3 I

AM = Amalgam

[a] Inapplicable since checklist and CTF ratings not designed for in-vitro studies; however, same principles used to evaluate studies