Evaluation of a resin modified glass ionomer serving both as indirect pulp therapy and as restorative material for primary molars

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Key words: Resin modified glass ionomer, indirect pulp therapy, restoration survival, primary molar.
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Abstract

AIM: The successful performance of resin modified glass ionomer cement (RMGIC) as an indirect pulp therapy (IPT) dressing material and, independently, as a class II restoration material for primary molars has been adequately documented. This study investigates if an RMGIC can be successfully used in a dual capacity. **METHODS:** A total of 61, 3.5-8.5 year old children with deep proximal carious lesions in one or more primary molars, radiographically suspected of pulp exposure, were included. Exclusion criteria were: continuous unprovoked pain and an exposed or a non-vital pulp. Following adequate caries removal, RMGIC restorations were placed. The teeth were followed-up for signs/symptoms and for restoration survival according to modified United States Public Health Service (USPHS) criteria. Descriptive statistics were applied. **RESULTS:** The prospective study was completed with 86 restorations in 41 first and 45 second primary molars. Three of the 86 teeth showed pulp necrosis and the remaining 83 (96.5%) were a) asymptomatic for a mean clinical observation time of 31.9 months (SD 10.8) and b) with no radiographic signs of pathology for 25.7 months (SD 10.3). Seventy-six of these 83 (91.6%) class II-'extended' restorations were acceptable, exhibiting varying levels of occlusal wear. **CONCLUSIONS:** A single application of RMGIC was used successfully for over 2 ½ years as an IPT and restoration material in proximal caries of primary molars.

Introduction

The restoration of deep proximal carious lesions in primary molars frequently poses dilemmas, and treatment choices are influenced by our understanding of the future reparative capability of their pulps. In young permanent teeth with deep carious lesions, avoiding exposure by direct or stepwise excavation may lead to a 100% pulp survival [Leksell et al., 1996] and the favourable outcomes of preserving pulp vitality in the permanent dentition have been recently re-affirmed [Bjorndal et al., 2010]. Regarding indirect pulp treatment (IPT) in deep primary molar caries, despite the increasing popularity of this option as a taught method [Dunston and Coll, 2008] the quality of existing evidence is still regarded with some scepticism [Ní Chaollaí et al., 2009]. Past studies summarised in a review by Coll [2008] were mainly retrospective and showed clinical and radiographic success rates of 93-96 % after a minimum three year follow-up period [Farooq et al., 2000; Al-Zayer et al., 2003; Vij et al., 2004]. These rates were higher than existing rates for pulpotomy, and the outcomes seemed to favour IPT in the longer term [Coll, 2008]. Current teaching concerning methods of primary pulp therapy in dental schools in the UK and Ireland, and in the US, shows IPT with acceptances of 70% and 83% respectively [Dunston and Coll, 2008; Ní Chaollaí et al., 2009] with calcium hydroxide and glass ionomer cement (GIC) being the preferred dressing materials.

According to the relevant guidelines of the British Society and the International Association of Paediatric Dentistry [Rodd et al., 2006] and those of the American Academy of Pediatric Dentistry [AAPD, 2010], indications for performing IPT or pulpotomy in deep carious lesions of primary molars differ only in whether a pulp exposure has occurred or not. Both modalities are indicated for treating pulps that have not yet become irreversibly inflamed as determined by clinical and radiographic findings. In performing an IPT, an unspecified portion of carious dentine closest to the pulp, rather than being removed and thus risking exposure of the pulp, is covered with a biocompatible material such as a reinforced GIC. As a prerequisite, caries from cavity walls are carefully removed so that the restoration achieves an optimum external coronal seal, 'being ideally an adhesive restoration or a preformed crown' [Rodd et al., 2006]. In addition to the positive clinical outcomes of IPT, the residual discoloured infected dentine has been found to harden [Marchi et al., 2006] and its population of aciduric bacteria to drop dramatically in a matter of months [Lula et al., 2009].

Regarding the state of the primary tooth pulp, it has been histologically shown that in deep carious cavities, the pulp is found already with local inflammatory infiltration for quite some time before its exposure [Duggal et al., 2002]. This is particularly the case with interproximal as opposed to occlusal carious lesions [Kassa et al., 2009]. In interpreting these findings Kassa et al. [2009] advocated pulpotomy as the preferred clinical decision when the proximo-occlusal carious cavity appears clinically. Although they suggested further clinical investigation to validate their view, such an approach to localised inflammation anticipates insufficient pulp healing capacity in primary teeth. This is in contrast to what is acceptable for young permanent teeth [Leksell et al., 1996] and warrants investigation with prospective IPT studies. One such recent study conducted in an unspecified type of deep mandibular primary molar cavities, restored with a compomer and followed for one year, showed a 97-100% success of IPT [Orhan et al., 2010].

Conventional and resin modified glass ionomer cements (RMGIC) have been independently used both as a restorative and a pulp dressing material in primary molar IPT. They both have the biocompatibility and adhesive ability required to seal the carious dentine left in the deep aspect of the cavity [Murray et al., 2002; Sidhu, 2010] and, in addition, they release clinically effective amounts of fluoride [Kotsanos, 2001]. The clinical performance of RMGIC as a restorative material has been proven superior to its conventional form in several studies in primary molars reviewed by Chadwick and Evans [2007], and at least as good as amalgam [Qvist et al., 2010]. These studies, however, have presented evidence that RMGIC is suitable for up to moderate size two-surface restorations tested for two or three years, or, in the case of Qvist et al. [2010] for even longer periods. However, up to now, there has been no evidence regarding its performance in large (possibly extended slightly to the buccal or lingual surface) class II restorations of primary molars. Such large cavities are usually very deep and require some additional form of pulp treatment; here the favoured restorative option remains that of a preformed metal crown (PMC) cemented with a GIC.

Furthermore, in past IPT studies, PMCs have been the most frequently selected final restoration choices. They have provided a better seal following pulp treatment than large amalgams [Al-Zayer et al., 2003] and recommendations have been made that they should be preferred in restorations with more than two-surfaces or after pulpotomy in primary teeth [AAPD, 2010]. Alternatively, following the satisfactory long term performance of large, 'extended' class II RMGIC restorations reinforced with composite in an open sandwich approach in permanent teeth [van Dijken et al., 1999; Andersson-Wenckert et al., 2004], similar restorations were tried in primary teeth following vital pulpotomy [Atieh, 2008]. They exhibited a 92.5% success rate after two years, which was not statistically different from the 95% success rate of the PMCs for the same period of time [Atieh, 2008].

Given that RMGIC has been accepted as a suitable material for IPT and, independently, as a restorative material for moderate class II cavities in primary teeth, it was tempting to examine whether it could perhaps serve both purposes satisfactorily, with a possible simplified technique advantage as well as the aesthetics of a tooth-coloured restoration. Therefore, this study aimed at investigating the clinical and radiographic success rate of a RMGIC used both as an IPT material and as a final restoration in deep and large, class II cavities of primary molars.

Material and Methods

The clinical part of the study was conducted prospectively in the setting of a part-time privately operated specialty clinic and was institutionally approved by Aristotle university dental faculty ethics committee. All the incoming children between November 2004 and May 2007 were eligible to enter the study, provided they fulfilled the following inclusion criteria, justifying the choice of IPT or pulpotomy [Rodd et al., 2006; AAPD, 2010]:

- They were, otherwise healthy, co-operative dental patients aged 3.5-8.5 years old.
- They clinically presented with at least one large class II primary molar carious lesion not extending pre-operatively to the buccal and/or lingual surface.
- There was either no history of pain, or pain provoked by stimuli which fully subsided in the short term without/after the administration of pain relievers.
- Clinically, there were no signs of pathological mobility or soft tissue inflammation of pulpal origin.
- Radiographically:
  - Carious dentine was so close to the pulp that no normally radiopaque dentine appeared between that and the adjacent pulp horn.
  - There was no evidence of furcation or apical bone pathology.

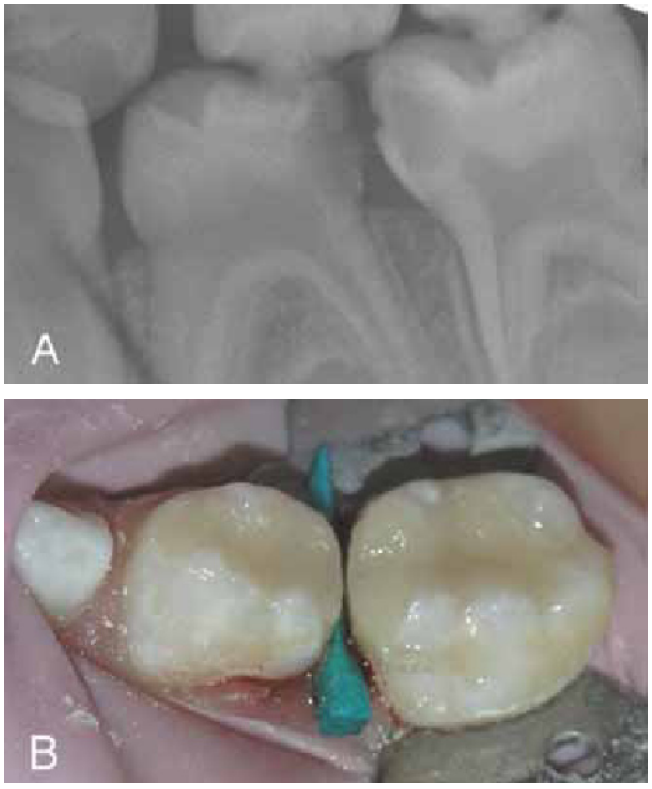
The following exclusion criteria were set. During the operative procedures, if the cavity extended more than 1mm on the buccal and/or lingual walls, or if a carious pulp exposure with obvious bleeding occurred, the tooth was excluded.

A total of 101 primary molar teeth in 67 child patients fulfilled the inclusion/exclusion criteria before operative procedures were undertaken. Oral hygiene instructions were given prior to the restoration appointments. For each participant, at least one parent/guardian was informed of the conservative approach to restoring his/her child's deep cavity/cavities and asked to sign a consent form. The protocol was such that all children were to be seen twice annually for check-ups and fluoride varnish treatment. New radiographs were to be taken at the 12 and 24 month recalls, as these were caries-risk patients. In order to minimise drop-outs, the patients' parents were sent notices and/or contacted by phone, and many of them were given compliance inducements such as free check-ups.

Inclusion/exclusion criteria were applied and dental treatment was performed by one experienced paediatric dentist (NK). Local analgesia and rubber dam isolation was used as part of quadrant dentistry delivered at pre-scheduled appointments. The cavity preparation involved high and low speed, and in most cases, hand instruments. Low speed was delivered last, taking care to remove all carious peripheral dentine, from the cervical box in particular, with a No. 4 or 5 tungsten carbide bur. After that, most, but not all, of the carious dentine over the pulp was removed, with care being taken to try to avoid a pulp exposure. All teeth had pulpal walls with incomplete caries removal but in some, approximation to, but not actual exposure of a pulp horn was supposed from the altered colour of the dentine over it, as seen clinically.

The RMGIC used was Vitremer™ (3M-ESPE, St Paul, USA). This was used within the matrix banded and wedged cavity following the instructions of the manufacturer, i.e. 20 sec primer application on the cavity walls, light air-drying, 20 sec LED source light curing, restorative material placement via a syringe tip followed by 40 sec light curing (Fig. 1). Following the removal of the rubber dam, heavy occlusal contacts were checked and a finishing gloss applied to the restoration. It is worth mentioning that cavity design was retentive in its occlusal part as this has been reported to aid retention of the restoration without relying solely on the chemical bond of the glass ionomer to the dental tissues [Hubel and Mejare, 2003].

Figure 1. *A. Radiograph of deep proximal carious lesions in first and second lower molars intended for IPT. B. The finished restorations before wedge removal.*



The teeth were followed-up for IPT success and for restoration survival. Criteria of successful IPT were: Clinically, an absence of symptoms or signs such as pathologic mobility and fistula/soft tissue oedema; Radiologically, absence of furcation bone and periodontal space pathology or internal/external pathological root resorption. Criteria for restoration survival were based on the van Dijken et al. [1999] modification of the United States Public Health Service (USPHS) criteria, further modified by removing colour match and separating interproximal contact from anatomical form (Table 1). Descriptive statistics were used.

Results

The parents of two children with three eligible teeth did not consent to participation in the study. Pulpal exposure occurred during cavity preparation in eight teeth. These received an alternative treatment to IPT and were excluded from the study during operative procedures. Four of the patients with these teeth each had another tooth remaining in the study. Three patients with four eligible teeth did not return to any recall. Two of those had moved away from town and the other was unwilling to come. The dropout rate in terms of teeth was 4.44% (4/90) and in terms of patients 4.92% (3/61). Thus, 58 patients with 86 eligible carious lesions remained in the study, in 18 of which close approximation of a pulp horn was inferred by the altered dentine colour over it (Table 2). One cavity had been restored in each of 37 patients, two in each of 15 patients, three in each of five patients, while one patient had four molars in the study. Mean age at restoration placement was 6.3 years (SD 1.60). Some patients had additional deep, non-class II two-surface cavities, 14 in all; these were treated in a similar manner as IPT, but were not included in the study (Fig. 2).

IPT success rate. Regarding IPT, three teeth were diagnosed clinically as failed. Two presented with inter-radicular inflammation within two months and one with a buccal fistula after 13 months (at his first observed recall). The remaining 83 teeth were a) free of signs and symptoms for a mean clinical observation time of 31.9 months (SD 10.8, range 19-59) and b) free of radiographic signs of pathology for 25.7 months (SD 10.3, range 14-55). Therefore, success rate for IPT was 96.5% (83/86).

Restoration survival. Regarding survival of the restorations, at the end of the study all restorations were in place with none showing mobility. Their rating appears in Table 3. Marginal integrity and anatomical form combined were unacceptable in seven restorations. Only one out of four interproximal tooth fracture defects exposing dentine presented with visible dentinal caries. Surface texture was not ideal but lay within the acceptable range. Eleven teeth were found to have an 'open' interproximal contact while 15 second molars had no contact due to loss of the adjacent first primary molar. For reasons explained in the discussion, the teeth with 'open' interproximal contacts were not considered failed restorations.

An almost general clinical observation was some reduction of restoration height. Although not determined, it appeared to range from just noticeable up to about 1 mm (Fig. 3). In three restorations, all over 34 months old, the dentine was slightly exposed and these were considered as unacceptable according to the modified USPHS criteria. In all other cases, this wear did not appear to constitute a cause for restoration replacement or repair, since it did not lead to impairment of function or aesthetics for primary molars. Therefore, restoration survival for the mean 31.9 months clinical observation time period was 91.6% (76/83).

Table 1. *van Dijken et al. [1999] modified USPHS clinical criteria after further modification for posterior teeth RMGIC restoration survival by removing colour parameters and separating interproximal contact from anatomical form.*

Category	Score		Criteria
	acceptable / unacceptable		
Anatomical form	0		Restoration is continuous with existing tooth anatomy
	1		Slightly under-contoured restoration; axial enamel walls partly visible
		2	Restoration heavily under-contoured; dentine exposed; occlusion affected
		3	Restoration is missing partially or totally; replacement required
Marginal integrity	0		Explorer does not catch; no crevice is visible
	1		Explorer catches but does not penetrate crevice
		2	Obvious crevice at margin; dentine may be exposed
		3	Restoration or tooth is fractured; restoration is mobile
Interproximal contact	0		Proximal contact is present
	1		No resistance to floss but no open proximal space
		2*	No proximal contact
	3		Absence of an adjacent proximal surface
Recurrent caries	0		No caries at restoration margin
		1	Caries at restoration margin
Surface texture	0		Smooth, similar to polished enamel
	1		Slightly rough or pitted
	2		Rough, cannot be refinished
		3	Coarse surface pitting, irregular grooves

*For the purposes of the present study an 'open' proximal contact was not considered unacceptable for reasons explained in the discussion

Table 2. *Number of primary molar teeth receiving IPT and remaining in the study. Numbers with an asterisk include one failed IPT treatment each.*

Teeth	Maxillary	Mandibular	Total
1st molars	24*	17*	41
2nd molars	20	25*	45
Total	44	42	86

Figure 2. *Bitewing radiographs showing primary maxillary right second #55, maxillary left first #64, mandibular right #84 and left #74 first molars of one patient pre-treatment (A & B) and 3 years 5 months post-treatment (C & D). Additional non-class II very deep lesions of maxillary and mandibular right second molars #55 and #85 were treated similarly but not included in the study. The maxillary right first molar #54 and mandibular left second molar #75 were initially extracted.*

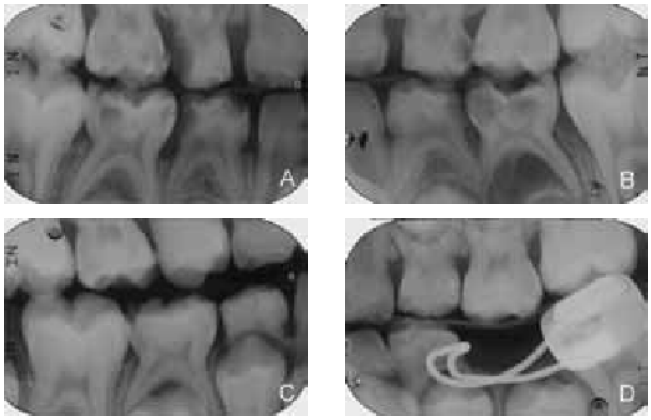
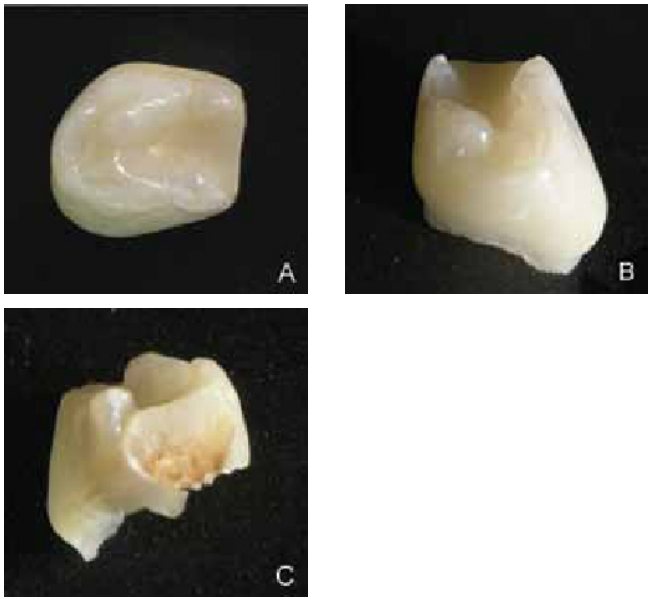


Table 3. *The modified USPHS scores for the 83 restorations placed in those teeth successfully receiving IPT.*

	0	1	2	3
Anatomical form	1	79	3	0
Marginal integrity	22	57	2	2
Interproximal contact	27	30	11	15
Recurrent caries	82	1	-	-
Surface texture	0	42	41	0

Figure 3. *An exfoliated first primary molar with a disto-occlusal RMGIC restoration at 4 year follow-up. A. Occlusal view shows good anatomical form. B. Proximal view shows acceptable occlusal wear. C. Distal view shows wear was about to expose the dentine.*



Discussion

The success rate of 96.5% for primary molar IPT is a favourable outcome for the 2 years and 8 months clinical and approximately 2 years and 2 months radiographic mean follow-up time in the present prospective study. It was produced after a simplified operative technique was performed in one appointment on very deep proximal carious lesions, radiographically suspected of pulp exposure. The present IPT success rate compares favourably to older reports on formocresol pulpotomy, as summarized in Coll's [2008] review. It is very close to the success rate of newer studies of MTA pulpotomies, which have produced significantly higher average clinical (98.5%) and radiographic (98%) success than previous pulpotomy medicaments according to evidence-based assessments [Ng and Messer, 2008].

The choice between IPT and pulpotomy is at the discretion of the clinician according to the current recommendations [Rodd et al., 2006; AAPD, 2010] and allows clinical research trials to choose one or the other treatment modality. For example, a recent randomised controlled trial (RCT) compared two pulpotomy medicaments in class I and II deep carious lesions that could well be treated with IPT [Zealand et al., 2010]. With success rates in recent reports being above 96% for either pulp treatment modality, other factors which are of importance in the practice of paediatric dentistry, such as technique simplicity and patient chair time, become important. IPT used to be taught as a two appointment procedure and it is still being investigated as such [Bjorndal et al., 2010; Orhan et al., 2010] while MTA required a second appointment for securing its proper setting [Walker et al., 2006]. Recently the one appointment treatment has been preferred for both IPT and MTA pulpotomy particularly in carious primary molar teeth [Orhan et al., 2010; Zealand et al., 2010]. In the present study, IPT and tooth restoration were not only completed in one appointment, but also as a one step procedure. In a future RCT, the time needed for each pulp treatment modality and for restoration placement could be evaluated in conjunction with the success rate of either technique, so that the two could be directly compared.

In the IPT two contradictory aims have to be accommodated, i.e. the removal of infected dentine from as close to the pulp as possible, and the avoidance of pulp exposure. This is difficult, arbitrary and requires considerable attention as well as experience. It is probably more difficult in the smaller sized primary than the permanent molars. In the present study one could argue that caries removal was too zealous, as eight teeth resulted in exposure (failing to enter the study) while, in some, close approximation to a pulp horn was visible at direct clinical view by the altered colour of the dentine over it. While in permanent teeth it might be acceptable to leave more carious dentine behind, leaving too much softened dentine to secure avoidance of pulp exposure might have compromised long term retention of the RMGIC restorations.

According to histological findings [Duggal et al., 2002; Kassa et al., 2009] all the teeth of the present study should have suffered some pulp inflammation, and yet their pulps survived for an extended period. The present clinical investigation underlines the considerable capacity of the pulp of primary teeth to withstand inflammation. Findings that the structures necessary for healing and repair are maintained until advanced stages of root resorption also support this [Monteiro et al., 2009]. Although it has not yet been shown histologically if the inflammatory infiltration regresses and the pulp returns to normal, the word 'irreversible' for the inflamed state of pulp should be used with care for carious primary teeth too. Adhesion of dental materials to sound peripheral dental tissues of the cavity is now more feasible than in the past, and RMGIC has proven suitable as such a material [Murray, 2002].

At least one study [Farooq et al., 2000] stated that IPT failures were observed at an early stage, as also occurred in the present study. However, the longer follow-up is also important for assessing the longevity of the restoration, since its survival is critical for the long term success rate of IPT. Following any vital pulp treatment, the objective is that 'the restorative material should completely seal the involved dentine from the oral environment' [AAPD, 2010] and, despite the relative lack of high quality supporting evidence, PMCs seem to be superior in multi-surface cavities [Innes et al., 2007]. The question is whether alternative tooth-coloured materials can produce as good a seal as PMCs. Our findings support Atieh [2008] for alternative approaches to PMCs by presenting a 100% retention rate of the bulk restorations with a relatively small number of unacceptable proximal defects (4/83). These were associated with enamel fractures, as has previously been reported for RMGIC/composite open sandwich restorations in permanent teeth [van Dijken et al., 1999; Andersson-Wenckert et al., 2004] and call for improved cavity design in the proximo-buccal or proximo-lingual corner.

The surface roughness score of the restorations was inferior to enamel, it was however within the acceptable range for posterior teeth. This seems to be an inherent disadvantage of the GICs in general in emulating naturally polished enamel surfaces due to the microporosity of their entire mass, partly a result of the mixing process. A more intriguing finding was the observed loss of contact point for 11 teeth in the study. As seen in most cases by comparing initial with final radiographs, there were local spacing adjustments close to the exfoliation times of first primary molars (e.g. in Fig. 2 comparing the spacing mesially and distally of right first mandibular #84 and of left first maxillary #64). It is likely that these explained many of the 11 cases of contact loss between molars and for this reason 'open' interproximal contacts were not counted as restoration failures in terms of abrasive loss of the material.

An obvious general clinical observation was some reduction of restoration height. It was most probably due to occlusal wear (abrasion) and it did not seem to constitute a reason

for restoration replacement or repair for the duration of the present study with the exception of a few of the older restorations, which were unacceptable in terms of the strict criteria applied (dentine was visible). Even for these, repair by the addition of composite resin in the form of open sandwich was possible, without requiring full restoration replacement. This notable wear has not been reported before in over 20 previous studies on RMGIC performance already mentioned as having been reviewed by Chadwick and Evans [2007]. This is possibly due to the fact that the present study alone involved large class II restorations, often extending slightly to the buccal and/or lingual surfaces and thus exposed to heavier masticatory stresses. This amount of wear, occurring at a rate much faster than that of primary enamel, was not anticipated and its quantitative estimation was not included in the study protocol. This suggests a restriction on depending on these large restorations if the tooth is expected to be functional for more than about 2.5 years. Newer RMGIC materials using nano-technology have been developed, which are advertised as having superior surface wear resistance; these should be investigated. Alternatively, the open sandwich approach could be used combining RMGIC with composite resin, but this would increase patient chair time.

The lack of a suitable control, both for the pulp treatment modality and the survival of the restorations may be a limit to the value of this prospective study. In the results from other studies used for some comparisons, inclusion criteria, settings and operator experience probably differed. Additionally, this approach cannot be proposed, even for the time tested, in compromised situations such as in the operating room before its long term success is proven in an RCT.

Conclusions

IPT and restoration of primary molars with resulting class II cavities minimally extending to buccal or lingual surface can be implemented as a one step procedure with RMCIC, if exfoliation is up to 2½ years. The study added clinical evidence of the capacity of primary molar tooth pulp to withstand inflammation when favourable conditions are restored.

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