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Keywords for this article are: Hypomineralised Second Primary Molars, preformed metal crowns, Hall technique

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Original Scientific Article

Non-invasive treatment approach for hypomineralised second primary molars using preformed metal crowns: results after 1-year follow-up

D. Declerck, ¹✉

Email: dominique.declerck@kuleuven.be

E. Mampay, ¹

¹ Department of Oral Health Sciences and Pediatric Dentistry and Special Care Unit, KU Leuven, University Hospitals Leuven Kapucijnenvoer, 7 bloc a, PO box 7001, 3000 Leuven, Belgium

Received: 8 June 2020 / Accepted: 6 November 2020

Abstract

Purpose

To evaluate the clinical and radiological outcome of Hypomineralised Second Primary Molars (HSPM) treated with Preformed Metal Crowns (PMC) using the Hall Technique (HT).

Methods

This prospective cohort study included healthy children presenting at the pediatric dental clinic of the University Hospitals Leuven (Belgium) with at least one primary molar affected by HSPM. The clinical and radiological situation at baseline and after a follow-up of 1 year was registered in detail using standardized criteria. After plaque removal and gentle drying, PMCs (3 M™ ESPE™ Stainless Steel Crowns) were fitted without administration of local anaesthesia nor tooth preparation. Strict outcome criteria, including gingival health condition, were applied. Informed consent was obtained for all individual participants. The study was approved by the institutional Ethics Committee.

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Results

A total of 39 PMCs with a follow-up of 12 months, placed in 15 patients (7 boys and 8 girls), were included. The mean age of the patients at the time of fitting the PMC was 4.6 ± 1.1 years (range: 3–7). None of the PMCs was lost nor failed. Clinical outcome was considered fully successful in 64.1%, radiological outcome in 93.3% of the cases; all other cases were rated as acceptable. The main reason for not being categorized as fully successful was deterioration of the gingival condition. Overall, the treatment was well tolerated and accepted by the patients.

Conclusion

PMCs fitted using the HT represent an acceptable and well-tolerated treatment option for the management of HSPM. Gingival condition should be incorporated in outcome assessment.

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Introduction

Hypomineralisation is described as a qualitative defect of the enamel characterized by a low mineral content of the affected tissue (Elhennawy and Schwendicke 2016). This clinical condition usually presents as a demarcated opacity and can be variable in severity and extent. The opacities can differ in color (white, yellow, or brown) and in extreme cases may lead to post-eruptive enamel breakdown (PEB). Molar Incisor Hypomineralisation (MIH) is a specific type of hypomineralisation of systemic origin affecting 1–4 first permanent molars, frequently associated with lesions at the level of the incisors (Weerheijm 2003). A comparable picture affecting second primary molars, but also first primary molars and primary canines, is seen in the primary dentition and is referred to as Hypomineralised Second Primary Molars (HSPM) (Da Silva Figueiredo Sé et al. 2017; Goyal et al. 2019). The etiology of these developmental defects, multifactorial in origin and subject of further research, is assumed to be comparable for both MIH and HSPM, with earlier occurrence of the provoking event in the case of HSPM (perinatal instead of postnatal) (Elfrink et al. 2008).

AQ3

The estimated prevalence of HSPM is situated between 4.9% and 9.0% of the population worldwide (Elfrink et al. 2008; Weerheijm et al. 2015; Goyal et al. 2019). The condition is often associated with post-eruptive enamel breakdown (PEB), atypical caries lesion formation, and hypersensitivity to thermal and tactile stimuli. In addition, it is well documented that obtaining effective analgesia is challenging when restoration of these teeth is required (Nazzal and Duggal 2019). However, pain-free treatment of this condition is important to avoid the potential development of dental anxiety (Jälevik and Klingberg 2012). In non-cooperative and very young children, treatment using local anaesthesia is

in most cases not achievable, which necessitates the application of (inhalation) sedation or general anaesthesia or leads to the condition being left untreated.

The management of HSPM is challenging. As an interim solution, the application of glass ionomer can be used to reduce pain and sensitivity (Nazzal and Duggal 2019). One of the longer term treatment options for the restoration of HSPM is build-up of the affected teeth using composite resin. However, evidence indicates reduced bonding strength of the composite resin to hypomineralised enamel, compromising its long-term success (William et al. 2006a). In more severe cases of HSPM, it is therefore better to provide full coverage of the affected tissue using preformed metal crowns (PMCs). This technique is also advised for the management of MIH-affected teeth when the defects are extending over multiple surfaces and when there is pronounced hypersensitivity of the teeth and/or PEB (Nazzal and Duggal 2019). The use of PMCs for the treatment of MIH was investigated by several authors and shown to be a successful treatment approach (William, Messer, and Burrow 2006a, b; Lygidakis et al. 2010).

The conventional technique of placing PMCs includes the preparation and shaping of the tooth, and requires the application of local anaesthesia for providing analgesia during treatment. A possible alternative, mentioned in publications discussing treatment options for primary molars with HSPM, is the 'Hall technique' (HT). This technique consists of the placement of PMCs without prior tooth preparation and has been investigated extensively for the management of carious primary molars (Attari and Roberts 2006; Innes, Ricketts, and Evans 2007a, b; Innes et al. 2011; Ludwig et al. 2014). Advantages include ease of the technique, no need for analgesia, short application time, less critical moisture control, and excellent cost-effectiveness (Attari and Roberts 2006; Schwendicke et al. 2018). This reference should be corrected. It should be 'Schwendicke et al. 2019' instead of 2018. This change has also been made in the reference list. (Schwendicke et al. 2018). Moreover, the Hall technique is well accepted by children and their parents (Foster Page et al. 2014). All of these make it a good option for the management of HSPM without the need to resort to sedation or general anaesthesia.

Up to today, no reports have been published on the use of PMCs in HSPM. Therefore, the aim of this study is to evaluate the clinical and radiological outcome of HSPM treated with PMCs using the HT.

Materials and methods

Study design

This study was designed as a prospective cohort study of primary molars affected by HSPM and treated with PMCs using the HT. Patient characteristics including sociodemographic data, general health information, and reported oral health habits were collected at baseline and updated at each check-up. Clinical and radiological information was registered at baseline and after 12 months, to be repeated yearly.

Study subjects

Healthy children presenting at the pediatric dental clinic of the University Hospitals of Leuven (Belgium) with at least one primary molar affected by HSPM were eligible for inclusion in the study. Patients were referred by their dentist or consulted on their own initiative. Following inclusion criteria were applied: (1) age between 2 and 10 years; (2) no relevant medical antecedents (ASA-score 1) (Mayhew et al. 2019); (3) degree of hypomineralisation between score 2 (white, creamy demarcated, yellow or brown demarcated opacities) or 3 (post-eruptive enamel breakdown) (Ghanim et al. 2015); (4) caries experience grades 0 to 5 (distinct cavity with visible dentine) (based on ICDAS-score) (Ismail et al. 2007); (5) no pain or only pain provoked when drinking cold drinks, eating sweets or brushing, no spontaneous pain. Teeth affected by HSPM presenting with pain of dental pulp origin, an ICDAS-score of 6, signs of infection (clinical and/or radiological) or physiological resorption of more than 1/3rd of the length of the roots were excluded. This was also the case for patients with a history of allergy to the materials used (Kulkarni et al. 2016). In case caries was present on other teeth than those affected by HSPM, the patient was not excluded and treatment of these teeth was provided according to the EAPD guidelines (Kühnisch et al. 2016). Patient recruitment started in November 2018. This paper reports the results of all subjects with a follow-up of at least 1 year or until failure occurred.

Baseline data collection

Patient characteristics including gender, age, general health condition, and main complaint were collected at baseline using a standardized data collection form. Clinical data collection consisted of level of oral hygiene (using the Simplified

Oral Hygiene Index [OHI-S] (Greene and Vermillion 1964), periodontal condition (using the Gingival Index [GI] (Löe 1967), presence of caries [using ICDAS scoring system (Ismail et al. 2007)], and degree of hypomineralisation (Ghanim et al. 2015); measurements were performed on all teeth. The clinical examination took place in a dental chair, with artificial illumination and using a dental mirror and probe. The information was supplemented with intra-oral clinical pictures. Radiological examination was performed according to the guidelines of the EAPD (European Academy of Paediatric Dentistry) (Espelid et al. 2003) and following the principles of ALARA (As Low As Reasonably Achievable) and ALADA (As Low As Diagnostically Acceptable) (Berkhout 2015; Poorterman 2015). Radiographs were used to evaluate the interproximal bone level ($\leq$ or > 2 mm below the cemento-enamel junction), presence of caries (none, $\leq \frac{1}{2}$ of the dentine, $> \frac{1}{2}$ of the dentine) or signs of infection at the level of the furcation. Overall, dental caries experience in the primary dentition, based on both clinical and radiological findings, including initial lesions, was calculated using the dmf index (Klein and Palmer 1938). Based on all collected information, it was decided which teeth to include in the study. All patients received standard oral hygiene instructions during this visit.

Intervention

When patients needed more than one tooth to be treated, several appointments were planned each with an interval of 1 week. In case of a closed interdental space, a separation elastic (Dentalastics[®] separators, Dentaaurum mbH & Co. KG, Ispringen, Germany) was placed between the tooth that needed the PMC and the neighbouring tooth one week before the scheduled treatment. PMCs (3 M[™] ESPE[™] Stainless Steel Crowns, 3 M, St. Paul, MN, USA) were fitted using the Hall Technique. After plaque removal and gentle drying of the tooth, the PMC was fitted without the administration of any local anaesthetic or any tooth preparation. The PMC was fitted and cemented using a self-curing, radiopaque, fluoride-releasing, resin-modified glass ionomer luting cement (Ketac[™] Cem Plus Luting Cement, 3 M[™] ESPE[™], St. Paul, MN, USA).

At each occasion, the level of oral hygiene and gingival condition (measured around each of the PMCs that was placed), occlusion (contact one sided or both sides), size of the PMC that was selected, and the adaptation and position of the margins (sub-, equi-, or supra-gingival) were registered. For each of these

variables, the criteria described above were applied.

Follow-up visits

Patients received a dental check-up half-yearly. The check-up after 12 months (and yearly thereafter) was scheduled at the university dental clinic. At each of these appointments, clinical and radiological information was collected independently by two pediatric dentists, and in case the oral hygiene was insufficient, standard oral hygiene instructions were repeated.

When scores differed, the situation was discussed until consensus was reached. A calibration exercise took place, explaining the scoring systems to be applied; for the radiological evaluation, this was illustrated using available radiographs. Since, in each clinical case, a discussion moment was used to reach consensus, no calculation of agreement was undertaken.

Each follow-up visit consisted of a detailed clinical and, when indicated, radiological examination, as described by Sharaf and Farsi 2004. At each occasion, information was collected using the criteria described above on oral hygiene, gingival health, occlusal contacts, adaptation of crown margins, presence of signs of wear of the PMC, and clinical signs of infection. Radiographs were taken according to the principles of ALARA and ALADA, and the following information was extracted: position of the interproximal bone level, marginal adaptation of the crown, presence of caries, or signs of infection at the level of the furcation.

In addition, information was gathered from both the patient and the parents regarding their assessment of the difficulty of the procedure and the overall outcome of the treatment. For this purpose, a structured questionnaire was used with ratings based on a Visual Analogue Scale (0–10). For children, a series of line diagrams of faces with expressions of increasing distress were used, derived from the Faces pain scale (Tsze et al. 2018). To evaluate the aesthetic aspects of the treatment, separate Visual Analogue Scales were used for children and parents (0 being aesthetically most unpleasant to 10 meaning no aesthetic problem at all).

Determination of success and failure

Each PMC treatment was categorized as clinical and/or radiological ‘success’,

‘acceptable’, or ‘failure’. Criteria applied in the present study are shown in Table 1. A PMC was considered ‘fully successful’ when clinical as well as radiological findings were categorized as ‘success’; when either category indicated a ‘failure’ the overall score of ‘failure’ was attributed. In all other situations, treatment outcome was rated as ‘acceptable’.

Table 1

Outcome criteria applied for the determination of success and failure

	Success	Acceptable	Failure
Clinical outcome	Crown present no gingival bleeding (GI = 0) <u>no clinical signs of infection</u> It's better to start this in the next line, because it is a separate reason and is not connected with 'bleeding (GI = 0)'. Better to start 'No' with a capital N to make it more visible it is a different reason.	Crown present Gingival bleeding (GI ≠ 0) <u>No clinical signs of infection</u> It's better to start this in the next line, because it is a separate reason and is not connected with 'bleeding (GI = not 0)'.	Crown loss <u>infection due to pulp necrosis</u> It's better to start this in the next line, because it is a separate reason and is not connected with 'crown loss'. Better to start 'Infection' with a capital I to make it more visible it is a different reason. <u>infection of periodontal origin</u> It's better to start this in the next line, because it is a separate reason and is not connected with 'pulp necrosis'. Better to start 'Infection' with a capital I to make it more visible it is a different reason.
Radiological outcome	No caries development nor progression <u>Interproximal bone level < 2 mm below CEJ^a</u> It's better to start this in the next line, because it is a separate reason and is not connected with 'progression'. <u>no signs of</u>	No caries development nor progression <u>Interproximal bone level > 2 mm below CE</u> It's better to start this in the next line, because it is a separate reason and is not connected with 'progression'.	New caries lesion or progression of existing lesion <u>signs of infection at the level of the furcation</u> It's better to start this in the next line, because it is a separate reason and is not connected with 'existing lesions'. Better to start 'Signs'

^aCEJ = cemento-enamel junction

	Success	Acceptable	Failure
	<div>infection at the level of the furcation It's better to start this in the next line, because it is a separate reason and is not connected with 'CEJ'. Better to start 'No' with a capital N to make it more visible it is a different reason.</div> <div>.....</div>	<div>J^a no signs of infection at the level of the furcation It's better to start this in the next line, because it is a separate reason and is not connected with 'CEJ'. Better to start 'No' with a capital N to make it more visible it is a different reason.</div> <div>.....</div>	<div>with a capital S to make it more visible it is a different reason.</div> <div>.....</div>
^a CEJ = cemento-enamel junction			

Data management and analysis

All data were entered in a database using Excel (Microsoft[®] Excel[®], 2016). Descriptive statistics were used to summarize the information at patient and at tooth level.

Ethical aspects

Before inclusion in the study, the purpose of the investigation was explained in detail to the parents and the patients, taking into account the age of the child, and informed consent was obtained. The study was approved by the Ethics Committee for Research from the University Hospitals and KU Leuven (Belgium) under protocol number B322201837979. The study was conducted in accordance with the Declaration of Helsinki.

Results

At baseline, 18 subjects were eligible for inclusion. Three patients were not included due to lack of patient co-operation, long distance for the patient to attend the dental clinic for the follow-up appointments, and cancellation of all appointments without an explanation. In this report, 39 PMCs with a follow-up of at least 12 months, placed in 15 patients (7 boys and 8 girls), were eventually included. The mean age of the patients at the time of fitting the PMC was 4.6 ± 1.1 years (range: 3–7). The most frequent finding reported by parents at intake was enamel breakdown (60.0%). Table 2 presents an overview of clinical and

radiological findings at baseline. Most patients presented with excellent oral hygiene (no debris, 80.0%) and sound gingival condition (no bleeding, 86.7%). Teeth that were included in the study presented in 74.4% of the cases with post-eruptive enamel breakdown (hypomineralisation degree 3). The largest proportion (43.6%) was without signs of caries (ICDAS-score 0), while 38.5% showed localized enamel breakdown due to caries (ICDAS-score 3). Radiographs were available for 14 out of 15 patients (93.3%), one child not allowing the procedure; in most cases, bite-wing radiographs (92.9%) were taken. Due to sub-optimal positioning, information on interproximal bone level or evaluation of the furcation area could not be extracted from the images for 8 teeth (see Table 2). At baseline, the interproximal bone level was situated ≤ 2 mm below the cemento-enamel junction in the 31 teeth that could be assessed radiologically. None of the teeth presented with signs of infection. Regarding overall caries experience, 26.7% was caries free (dmft score = 0). Mean dmft and dmfs scores were, 1.1 ± 1.0 and 1.5 ± 1.2 respectively (each with a range from 0 to 3); both indices had a median score of 1.

Table 2

Clinical and radiological findings at baseline, before treatment

	Patients (<i>n</i> = 15)		HSPM (<i>n</i> = 39)	
	<i>N</i>	%	<i>N</i>	%
Clinical findings				
Oral hygiene level ^a (<i>n</i> = 15)				
No debris	12	80.0		
< 1/3 of tooth surface covered with debris	2	13.3		
> 1/3 but < 2/3 of tooth surface covered with debris	1	6.7		
^a Simplified Oral Hygiene Index (OHI-S)				
^b Gingival Index (GI)				
^c ICDAS scoring system				
^d As described by Ghanim et al (2015)				
^e CEJ = cemento-enamel junction				

	Patients (<i>n</i> = 15)		HSPM (<i>n</i> = 39)	
	<i>N</i>	%	<i>N</i>	%
≥ 2/3 of tooth surface covered with debris	0	0.0		
Gingival health ^b (<i>n</i> = 15)				
No bleeding upon probing	13	86.7		
Some bleeding after some seconds	2	13.3		
Bleeding immediately after probing	0	0.0		
Heavy bleeding immediately after probing	0	0.0		
Caries status ^c (<i>n</i> = 39)				
ICDAS score 0			17	43.6
ICDAS score 1			0	0.0
ICDAS score 2			7	17.9
ICDAS score 3			15	38.5
Degree of hypomineralisation ^d (<i>n</i> = 39)				
No visible enamel defect			0	0.0
Enamel defect, non-HSPM			0	0.0
White or creamy demarcated opacities			2	5.1
Yellow or brown demarcated opacities			8	20.5
Post-eruptive enamel breakdown			29	74.4
Radiological findings				
Interproximal bone level (<i>n</i> = 31)				
≤ 2 mm below CEJ ^e			31	100.0
> 2 mm below CEJ			0	0.0
^a Simplified Oral Hygiene Index (OHI-S)				
^b Gingival Index (GI)				
^c ICDAS scoring system				
^d As described by Ghanim et al (2015)				
^e CEJ = cemento-enamel junction				

	Patients (<i>n</i> = 15)		HSPM (<i>n</i> = 39)	
	<i>N</i>	%	<i>N</i>	%
Caries (<i>n</i> = 37)				
No radiological signs of caries			28	75.7
Present, $\leq 1/2$ into dentine			9	24.3
Signs of infection (<i>n</i> = 31)				
No			31	100.0
Yes			0	0.0
^a Simplified Oral Hygiene Index (OHI-S)				
^b Gingival Index (GI)				
^c ICDAS scoring system				
^d As described by Ghanim et al (2015)				
^e CEJ = cemento-enamel junction				

All 39 PMCs were placed chairside by one single operator (EM) with the exception of 4 crowns in 1 patient that were fitted during a comprehensive treatment session under general anaesthesia (because of insufficient co-operation of the child). The number of PMCs fitted in a single patient varied between 1 and 4, with 2 crowns being the most prevalent situation (40.0%). In 97.4% (*n* = 38) of the cases, the interdental space was closed necessitating the use of separation elastics.

Most PMCs were fitted in lower second primary molars (22 crowns, 56.4%); the most commonly used crown size was E5 (14 teeth, 35.9%).

One-year data were collected after a mean follow-up period of 11.5 months (± 1.5) (range: 9–14 months). In all but one case (14/15 patients), the treating dentist (EM) and one other colleague collected the data at the follow-up visit. Table 3 summarizes clinical and radiological findings immediately after fitting the PMC and at the 1-year follow-up. Clinical results show a net decline in both the level of oral hygiene and the gingival condition between baseline and the 1-year follow-up. Where the occlusion presented some distortions immediately

after the fitting of the PMC (unilateral occlusal contact in 25.6% of cases), this completely disappeared at the 1-year follow-up. While crown adaptation was very good immediately after placement of the PMC (in 91.4% no margin detectable upon probing), the situation deteriorated in the following months leading to 58.9% of the PMCs presenting with a marginal defect detectable upon probing (in most cases limited to one single point). Both vestibular and palatal/lingual margins of the PMCs were in most cases situated sub-gingivally immediately after fitting (94.3–97.1%); at the 1-year follow-up, these percentages dropped to 71.8% for the vestibular margins and 89.7% for the palatal/lingual margins. Radiological findings show that the interproximal bone level remained quite stable, with a score of 0 (≤ 2 mm below the cemento-enamel junction) in 100.0% of all PMCs radiologically assessable at baseline and 93.8% in those assessed at follow-up. Although there was evidence of caries development ($< \frac{1}{2}$ of the dentine) in 24.3% of teeth at baseline, none of the teeth assessed at the 1-year follow-up presented with visible signs of caries. There were no radiological signs of infection detectable, neither at baseline nor after 1 year. None of the PMCs was lost. Signs of wear were present in 7 (17.9%) of the PMCs, without perforation of the crown.

Table 3

Clinical and radiological findings immediately after placement (at baseline) and at 1-year follow-up ($n = 39$)

	Upon placement		At 1-year follow-up	
	<i>N</i>	%	<i>N</i>	%
Clinical findings				
Oral hygiene level ^a	$(n = 39)$		$(n = 39)$	
No debris	34	87.2	4	10.3
$< 1/3$ of tooth surface covered with debris	5	12.8	23	59.0
$> 1/3$ but $< 2/3$ of tooth surface covered with debris	0	0.0	12	30.8
^a Simplified oral hygiene index (OHI-S)				
^b Gingival index (GI)				
^c CEJ = cemento-enamel junction				

	Upon placement		At 1-year follow-up	
	<i>N</i>	%	<i>N</i>	%
≥ 2/3 of tooth surface covered with debris	0	0.0	0	0.0
Gingival health ^b	(n = 39)		(n = 39)	
No bleeding upon probing	37	94.9	25	64.1
Some bleeding after some seconds	2	5.1	14	35.9
Bleeding immediately after probing	0	0.0	0	0.0
Heavy bleeding immediately after probing	0	0.0	0	0.0
Crown adaptation	(n = 35)		(n = 39)	
No marginal gap	32	91.4	16	41.0
Defect limited to one single point	3	8.6	17	43.6
Multiple defects but limited to one tooth surface	0	0.0	6	15.4
Multiple defects distributed over several tooth surfaces	0	0.0	0	0.0
Position of margin on vestibular surface	(n = 35)		(n = 39)	
Sub-gingival	33	94.3	28	71.8
Equi-gingival	0	0.0	10	25.6
Supra-gingival	2	5.7	1	2.6
Position of margin on palatal/lingual surface	(n = 35)		(n = 39)	
Sub-gingival	34	97.1	35	89.7
Equi-gingival	1	2.9	4	10.3
Supra-gingival	0	0.0	0	0.0
Occlusion	(n = 39)		(n = 39)	
Occlusal contacts on both sides	29	74.4	39	100.0
Occlusal contact only at right side	5	12.8	0	0.0
^a Simplified oral hygiene index (OHI-S)				
^b Gingival index (GI)				
^c CEJ = cemento-enamel junction				

	Upon placement		At 1-year follow-up	
	<i>N</i>	%	<i>N</i>	%
Occlusal contact only at left side	5	12.8	0	0.0
Radiological findings				
Interproximal bone level	<i>(n = 31)</i>		<i>(n = 32)</i>	
≤ 2 mm below CEJ ^c	31	100.0	31	96.8
> 2 mm below CEJ	0	0.0	1	3.2
Caries			<i>(n = 37)</i>	
No radiological signs of caries			37	100.0
Present, ≤ 1/2 into dentine			0	0.0
Signs of infection	<i>(n = 37)</i>		<i>(n = 15)</i>	
No	37	100.0	15	100.0
Yes	0	0.0	0	0.0
^a Simplified oral hygiene index (OHI-S)				
^b Gingival index (GI)				
^c CEJ = cemento-enamel junction				

Figures 1 and 2 present clinical and radiological images, both at baseline and at the 1-year follow-up, of two of the cases included in this study.

Fig. 1

Clinical and radiological documentation of one of the cases included in the study: frontal and occlusal views and bite-wing radiographs at baseline (**a** and **b**) and at 1-year follow-up (**c** and **d**) in a 3 year-old girl. **a** Baseline frontal and occlusal views show yellow–brown opacities and PEB on the lower right second primary molar. **b** Radiological images show the presence of a separation elastic (white arrow) between elements 84 and 85 in preparation of crown placement 1 week later. **c** Clinical picture at 1-year follow-up with PMC in position on element 85, healthy gingiva, and absence of signs of infection. **d** Radiological evaluation shows absence of infection in the furcation area, stable interproximal bone level, and good marginal fit of the crown.

Fig. 2

Clinical and radiological documentation of one of the cases included in the study: frontal and occlusal views and bite-wing radiographs at baseline (**a** and **b**) and at 1-year follow-up (**c** and **d**) in a 5-year-old girl. **a** Yellow–brown opacities are present on all second primary molars, with PEB on both lower second primary molars. Note also the presence of demarcated opacities on the upper right canine and both upper first primary molars. **b** Radiological images taken at baseline. **c** At the 1-year follow-up, PMCs on teeth 75–85 show no clinical signs of infection and a healthy gingival condition. **d** Radiologically, there are no signs of infection in the

furcation area, a stable interproximal bone level (≤ 2 mm below the CEJ) and good fit of the margins of the crown.

Table 4 summarizes success and failure rates observed in the present study. The clinical outcome could be determined for all 39 PMCs with 25 crowns (64.1%) categorized as successful, 14 (35.9%) as acceptable and none as a failure. The most frequent reason for not being categorized as successful was deterioration of the gingival health. Radiological evaluation was only possible for 15 crowns (38.5%) with 14 crowns (93.3%) categorized as successful, 1 crown (6.7%) as

acceptable, and none as a failure. The only PMC not ranked as successful was a crown showing an interproximal bone level > 2 mm below the cemento-enamel junction. When combining both clinical and radiological findings, 10 out of 15 (66.7%) PMCs with fully available data set were classified as ‘fully successful’. Figure 3 illustrates the global outcome (combined clinical and radiological assessment) of individual PMCs (with complete data available) and this according to the period of follow-up in months.

Table 4

Clinical and radiological outcome ratings at 1-year follow-up, overall success based on combined clinical and radiological outcome

	Success		Acceptable		Failure	
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
Clinical outcome ($n = 39$)	25	64.1	14	35.9	0	0.0
Radiological outcome ($n = 15$)	14	93.3	1	6.7	0	0.0
Overall outcome ($n = 15$)	10	66.7	5	33.3	0	0.0

Fig. 3

Overall outcome rating of individual PMCs, based on a combination of clinical and radiological findings, as a function of the period of follow-up (in months)

Table 5 presents information on the perception of this treatment modality for both parents and children. Assessment of the aesthetic aspect resulted in a mean score of 8.3 (SD $\pm$ 2.6) for patients and 7.2 ($\pm$ 2.9) for parents, on a scale from 0 to 10. Patients indicated a mean score of 4.1 (SD $\pm$ 2.6) (on a scale from 0 to 10) when asked how demanding the treatment was experienced. From all steps that were needed for the placement of the PMC, the taste of the luting cement was indicated as being the most unpleasant aspect as reported by 7 patients (46.7%). Only 1 patient (6.7%) mentioned temporary difficulties with eating immediately after the treatment.

Table 5

Perception of treatment modality by parents and patients ($n = 15$)

	Patients		Parents	
	Mean	SD	Mean	SD

	Patients		Parents	
	Mean	SD	Mean	SD
Aesthetics ^a	8.3	2.6	7.2	2.9
Difficulty of treatment ^b	4.1	2.6		
	<i>N</i>	%		
Most unpleasant aspect of the treatment				
Separation elastics/pressure	4	26.7		
Crown placement/pressure	4	26.7		
Taste of luting cement	7	46.7		
Teeth do not fit well	0	0		
Others	0	0		
Difficulties encountered after treatment				
Difficulties with eating				
Yes	1	6.7		
No	14	93.3		
TMJ ^c related pain				
Yes	0	0		
No	15	100		
Toothache				
Yes	0	0		
No	15	100		
<i>SD</i> standard deviation, <i>N</i> number of children				
^a Based on a scale from 0 to 10. Zero meaning aesthetically unacceptable to 10 meaning no aesthetical complaints				
^b Based on a scale from 0 to 10. Zero meaning very easy to 10 meaning extremely difficult				
^c TMJ = temporomandibular joint				

Discussion

This study assessed the outcome of HSPM treated with PMCs using the Hall technique. After a mean observation period of 1 year, 64.1% of the PMCs were rated as clinically and 93.3% as radiologically fully successful. It is important to mention that the criteria that were used in this study were stricter than those used in most other surveys. The criteria originally define [d by Innes et al.](#) It's is only referring to the article of Innes in 2007 with the title: 'The Hall Technique; a randomized controlled clinical trial of a novel method of managing carious primary molars in general dental practice: acceptability of the technique and outcome at 23 months.'

2007a, [b](#) considered a PMC as successful when no clinical signs or symptoms of pulpal pathology developed, no intervention was required and no pathology was visible on radiographs. When we apply this definition to the results obtained in the present study, PMCs rated as 'acceptable' should also be incorporated, leading to a 100.0% success rate. Clinical survival, usually defined as no crown or tooth loss, was comparable with results presented in studies evaluating the survival of PMCs fitted in carious primary molars using the Hall technique reporting results ranging from 97% after 15 months (Ludwig et al. 2014), 98.9% after 10 months, and 97.4% after 20 months (Clark et al. 2017) to 98% after 1 year (Santamaria et al. 2014). A similar situation was seen for radiological survival. Radiological success rates of PMCs placed using the HT in carious primary molars are less frequently reported in the literature and are situated between 97.7% after 10 months and 94.9% after 20 months (Clark et al. 2017).

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The patients included in this study were very young, with a mean age lower than 5 years. Young age impacts on the level of co-operation during dental treatment, certainly when multiple invasive procedures are needed requiring the administration of local anaesthesia. In the present study, all treatments were performed in an ambulatory setting without analgesia, except for one patient where co-operation was insufficient and treatment under general anaesthesia was necessary. Despite the young age of some of the patients (only 3 years), treatment usually went smoothly. This was confirmed by the ratings of perceived discomfort of the procedure. When the reasons of discomfort were explored in more detail, the unpleasant taste of the luting cement was the most frequently reported item. Therefore, the choice of another product for cementation of the PMCs should be considered. In addition, the use of PMCs is usually

accompanied by aesthetic concerns (Atieh 2008; Zimmerman et al. 2009), mostly from the parents rather than the child. This was also the case in the present study, but only to a limited extent. Overall, the treatment of HSPM with PMCs using the HT was well tolerated and accepted by both patients and parents.

Although the treatment approach was highly successful, it should be noted that oral hygiene levels and gingival condition deteriorated over the period of follow-up. This could be associated with the position of the margins of the PMC and/or crown adaptation, as well as with oral hygiene habits of the patient (Belduz Kara and Yilmaz 2014). According to Koleventi et al. (2018), sub-gingivally located margins of PMCs present irregularities triggering inflammation of the surrounding gingival tissues, even when the crowns fit well. In addition, the level of oral hygiene contributes to this inflammatory reaction (Sharaf and Farsi 2004). In the present study, oral hygiene was much less good at follow-up than at baseline, without a clear explanation.

A strong point of the present research is the much more detailed definition of success that was applied, including items related to gingival health (bleeding upon probing) and periodontal condition (interproximal bone level). This is not unimportant, since the margins of most of the PMCs placed using the HT are positioned sub-gingivally, as was the case in 97.1% of the PMCs included in this study. Major reasons for PMCs not being rated as successful were gingival inflammation and loss of interproximal bone, both linked to periodontal health. Whether the impact on periodontal condition is also clinically significant remains to be confirmed and requires a longer follow-up period and larger patient groups.

A challenge that arose in this study was the collection of radiological information of sufficient quality allowing a complete evaluation of the PMCs and surrounding tissues. Imaging was in some cases hampered by the young age of the patient and associated limitation in co-operation. In addition, it proved to be difficult to capture the furcation area on the bite-wing radiographs, especially when PMCs in both maxilla and mandibula needed to be visualised. This was mainly a problem at follow-up and much less at baseline. A plausible explanation for this situation was given by Innes et al. (2007b). Because there was no occlusal reduction prior to placing PMCs using the HT, the crown height is lengthened and so the area of the film near the furcation is reduced. Considering, in addition, that radiographs in the present study were taken using a size 0 (22 ×

35 mm) film, this can further explain this finding.

The results presented in this paper cover a rather small number of HSPM. It would be interesting to increase the sample size, allowing a more in-depth analysis of factors contributing to the periodontal health impact of this treatment modality. Furthermore, it would be interesting to extend the follow-up period.

Conclusion

Results of the present research indicate that PMCs fitted using the HT are an acceptable and well-tolerated treatment option for the management of HSPM, even in very young children, with the added advantage that the administration of local anaesthesia can be avoided. Follow-up studies including larger numbers and longer evaluation periods would be useful. The present study showed that gingival health should be incorporated in the assessment of treatment outcome.

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Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Compliance with ethical standards

Conflicts of interest The authors have no conflicts of interest to declare.

Research involving human participants and/or animals This research involves human participants.

Informed consent Informed consent was obtained from all individual participants included in the study.

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