THE SUCCESS OF PREFORMED METAL CROWNS IN PRIMARY MOLARS USING THE HALL TECHNIQUE VERSUS THE CONVENTIONAL METHOD: A RETROSPECTIVE STUDY IN A POSTGRADUATE SETTING

By

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TITLE

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ABSTRACT

Background:

Preformed metal crowns (PMCs) have been used *conventionally* for decades in managing multi-surface carious primary molars in children. However, the *Hall Technique* (HT) is a controversial novel method, used in the United Kingdom (UK) since 2006. The HT was introduced in the United Arab Emirates (UAE) in 2014.

Aim:

The aim of this study was to evaluate the clinical and radiographic success of conventional and HT PMCs in a pediatric dentistry postgraduate dental setting in Dubai, UAE.

Methods:

A retrospective study, using HBMCDM (MBRU) pediatric dentistry patients' electronic case-notes and radiographic images, was carried out on a random sample of carious primary molars treated with either conventional or HT PMCs (from 1st July 2014 to 1st March 2017) to assess for clinical and radiographic success/failure. A Kaplan-Meier curve was used to assess PMC survival.

Results:

187 PMCs (110 HT and 77 conventional) in 65 children (34 females and 31 males) at six, 12 and 18 months were assessed for success or failure. The success rate of the HT-PMC at 6 months, 12 and 18 months was (100%, 99.1% and 98.8% respectively) while the success rate of the conventional –PMCs for the same period was (98.7%, 96.1% and 95.2% respectively), both were comparable and in concurrence with previously published studies. Four PMCs failed; one HT-PMC (a result of PMC perforation) and three conventional PMCs (because of loss of crown/retention and abscess formation). Both methods showed comparability in term of proportions of success and average time of failure ($p = 0.362$).

Conclusion:

PMCs placed conventionally or by the HT in a postgraduate pediatric dentistry setting have similar clinical and radiographic success rates at 18 months' follow-up.

DEDICATION

I would like to dedicate this thesis with all the hard work to:

My father, the man who has supported me in every step clearing stones in my path. Thank you dad for giving me the strength to reach for the stars and achieve my dreams. My beloved mother, she taught me to be who I am today, she who carries all burdens of life on her tiny shoulders and never complains.

To my husband my half soul Thamer for his endless love, support, encouragement.

and making my dreams come true. I love you endlessly.

To my angels Hamza, Nabeel & Salman for their support and patience.

To my beloved sister Abeer who has been always there for me and my brother Dawood love you.

Last but not least to my brother Hamza may peace be rest upon you I love and I miss you.

You will never be forgotten.

DECLARATION

I declare that all the content of the thesis is my own work. There is no conflict of interest with any other entity or organization.

Name: Halah Binladen

Signature:

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ABBREVIATIONS

(AAPD): American Academy of Pediatric Dentistry

(ADA): American Dental Association

(ART): Atraumatic restorative treatment

(CDHS): Children ‘s Dental Health Survey

(*dmft*): decayed, missed, filled teeth for primary teeth

(DMFT): Decayed, Missing and Filled teeth for permanent teeth

(Ds): 1st primary molars

(EAPD): European Academy of Pediatric Dentistry Board

(EBD): Evidence-based medicine

(ECC): Early Childhood Caries

(Es): 2nd primary molars

(FA): fluorapatite

(FCT): Formocresol pulpotomy treatment

(GCC): Gulf Cooperation Council

(GCP): Good Clinical Practice

(GDP): Genera dental practitioners

(GIC): glass ionomer restorative cement

(HA): hydroxyapatite

(HBMCDM): Hamdan Bin Mohammed College of Dental Medicine

(HT): Hall technique

(IAPD): International Association of Pediatric Dentistry

(IPC): indirect pulp capping

(LB): Lactobacillus

(MBRU): Mohammed Bin Rashid University

(MS): Mutans streptococci

(NHS): National Health Service

(NRCT): non-restorative caries treatment

(OVD): occlusal vertical dimension

(PMC): preformed metal crowns

(RCTs): randomized controlled clinical trials

(SD): standard deviation

(SDCEP): Scottish Dental Clinical Effectiveness Program

(S-ECC): Severe Early Childhood Caries

(SPSS): computerized Statistical Package for Social Sciences

(SS): stimulated saliva

(SSCs): Stainless Steel Crowns

(UAE): United Arab Emirates

(USA): United States of America

(WHO): World Health Organization.

APPENDICES

Appendix I. Ethical Approval Forms

Appendix II. Data collection pro forma

1.00 INTRODUCTION

Dental caries is the most common chronic condition affecting children globally[1]. It is an oral health problem that develops over many years affecting growth and development as well as the social adaptation in young children[2]. In the United Arab Emirates (UAE), dental caries is one of the most public unmet health needs in children[3]. It is estimated that less than 18 percent of UAE children aged five years were caries free[4], and the rate of untreated caries has not shown improvement over the past two decades. Despite the recent evidence in understanding the factors that cause the disease, it is still a long-standing health problem to dental clinicians. Effective dental caries management involves not only coping with children's behavior, while simultaneously promoting prevention and providing a definitive treatment until tooth exfoliation occurs. Carious primary molars, in particular, have significant importance; they have a primary role in maintaining mastication and proper space in the dental arches for the premolars to optimally erupt.

The treatment of choice of two surfaces and larger carious lesions of posterior primary molars is full coverage preformed metal crowns (PMC), widely known as "Stainless Steel Crowns (SSCs)"[5]. This procedure has a significant clinical superiority than intra-coronal restorations in terms of longevity[5][6]. Classically, or what is described here as the conventional method, the traditional preparation of the tooth to receive a PMC is done by: the administration of local anesthetic; adequate removal of tooth structure from the mesial, distal and occlusal surfaces; and complete removal of caries before the PMC is luted with glass-ionomer cement. The clinical failure rate of PMCs is, on average, four times less than that of Class II amalgam restorations[6][7]. Although the technique for placement of PMCs is less sensitive than the

placement of intra-coronal restorations, the placement of PMCs by means of traditional tooth preparation still has its potential problems in pediatric patients[5]. Some children may display uncooperative behavior due to the invasive procedure. Additionally, the treatment may require to be rendered under sedation or general anesthetic, which comes at an increased cost and risk to the child and his caregiver. New alternative intervention for caries management and restorative treatment has been utilized by many pediatric dental practitioners to provide easier dental care for the pediatric population[8].

The Hall technique is an alternative conservative treatment for carious primary molars developed by Dr. Norna Hall in the 1980s. It is a minimally invasive approach where dental caries are treated without the use of local anesthetic and drill[8]. The biological method of treating caries is utilized rather than the conventional caries removal method. The appropriate crown size is selected then cemented with glass ionomer luting cement. The crown is then fully seated by asking the child to bite firmly on a cotton roll, followed by a firm finger pressure by the thumb and four fingers supporting the mandible/maxilla to prevent slipping or displacement. The use of PMCs to seal over caries lesions on primary molars arrests carious lesion with the intention of preserving the tooth until exfoliation[8]. The Hall technique was preferred over traditional restorative techniques by children, caregivers and dentists[9]. According to those who promote it, the Hall technique provides dentists with a simple, definitive treatment that can be provided quickly to limit anxiety experienced by the patient[9]. In addition, the Hall technique improved treatment options as it was deemed more acceptable by patients and their caregivers[10]. It increased access to care, decreased rates of untreated caries and offered a restoration that will allow natural tooth exfoliation due to restoration longevity. Although it has been shown that sealing carious primary molars with PMCs and glass ionomer cement is successful, additional studies were needed to confirm the technique's effectiveness compared with that of traditional

PMC placement. This technique is not widely used in the Middle East, and there are limited studies to support its use in this region.

In the UAE particularly Dubai, The Hamdan Bin Mohammed College of Dental Medicine (HBMCDM), heart of the Mohammed Bin Rashid University (MBRU), started using the Hall technique around April 2013 as one tool in the dental armamentarium against caries in the primary molar. The use of the Hall technique has been taught in our mainstream postgraduate pediatric dentistry course [(4)(11)] and used in parallel to the use of the conventional method. Anecdotally, it appears that the Hall Technique was providing our postgraduate dentists with a simple, less anxiety-producing and definitive treatment that was delivered in a child-friendly manner. However, in the UAE there is no evidence of clinical studies that have been done to support the Hall technique or its success and effectiveness in treating child patients. Hence the purpose of this thesis was to perform a retrospective study, conducted from patients' data, to evaluate the clinical and radiographic success rate of PMCs used to restore carious primary lesions that were placed by both traditional and Hall Techniques in a postgraduate pediatric dentistry setting.

2.00 LITERATURE REVIEW

This chapter is divided into four sections. The first section provides a brief overview of dental caries in infants and young children (Early Childhood Caries), prevalence, and etiology including predisposing and contributing factors with special reference to dental health education. The second section, describes the different ways of managing early childhood caries, and the hierarchy of evidence that supports the different ways in managing caries in primary teeth according to the guidelines. The third and main section, provides a detailed overview on conventional and The Hall Technique and the latter's history, indications procedure and how occlusion is corrected. The fourth and final section, describes the studies that are against the Hall Technique and the need for conducting this study, that will aid in providing evidence and patient based studies that use this new concept of caries management.

2.10 Dental caries in children

2.11 Early childhood caries/severe early childhood caries (ECC/SECC)

Dental caries is a significant worldwide health problem; it is considered the most common chronic childhood disease and despite the advances in management[(12)], it is still a health need that remains unmet in many countries [(13)]. From an early age, often age 6 and under, dental caries can be present as either Early Childhood Caries (ECC) or Severe Early Childhood Caries (S-ECC) as stated by the American Academy of Pediatric Dentistry –AAPD[(14)].

Early Childhood Caries (ECC) is a chronic, communicable infectious disease affecting the

primary teeth[15]. It begins early in life, after the eruption of primary teeth and progresses rapidly in the teeth of children who are at high risk, and often left untreated[16]. It is defined as the presence of; one or more decayed (cavitated or non-cavitated), missing (due to caries) or filled tooth surfaces" in any primary tooth in a child 71 months of age or younger" as stated by AAPD (2014)[14][5][15]. If caries , embrace the smooth surfaces of primary teeth in an age younger than three years' it is considered as S-ECC[14]. From ages three through five, one or more cavitated, missing (due to caries), or filled smooth surfaces in primary maxillary anterior teeth or a decayed, missing, or filled score of 4 (age three), 5 (age four), or 6 (age five) surfaces constitutes S-ECC as stated by Ismail in 1999[17][15][16]. S-ECC can be associated with pain, infection and later on tooth loss if left untreated[16]. The European Academy of Pediatric Dentistry Board (EAPD, 2008) defined childhood caries as the occurrence of any sign of decay on any tooth surface during the first 3 years of life[18].

In the past, different terminologies were used for ECC in infants and young children [7,8,9]. Fass (1962) was the first to describe a particular pattern of dental caries in a young child as "nursing bottle mouth" [19]. The pattern of caries he described took the form of severe and rampant caries, which includes the maxillary incisors followed by the maxillary and mandibular first molars except for the mandibular incisors, which were infrequently affected. Furthermore, other terms had been used to describe this very condition such as, "baby bottle tooth decay," "night bottle mouth" and "nursing caries" [20].

However, these terminologies didn't include breast feeding and a sweetened pacifier, which are additional causes of early childhood caries in infants if used inclusively [7]. Recently, several studies have found that caries in infants and preschool children may occur in the absence of bottle feeding. Several reports suggested that milk might be less cariogenic than other sugar-containing liquids [8]. It has been shown that enamel dissolution is inhibited due to phosphor-

proteins found in milk. Moreover, in-vitro studies on milk revealed that it has the ability to re-mineralize artificially demineralized enamel[21]. Tinanoff and O'Sullivan used the term that had been previously introduced in the United States of America (USA) as *"Early Childhood Caries"* [9]. This term has been widely accepted by most dental clinicians and educators [22]. It replaces all other terms as it describes the problem and a possible cause[23].

Early dental caries can be diagnosed during or just after eruption of primary teeth during the first years of life and if not preventively managed, may result in ECC [14]. It is a severe dental disease that has negative influences on the child's oral and general health. It may interfere with sleeping patterns and results in pain and difficulty while eating and drinking which thereby affects the quality of life for young children[24][21]. It may also adversely affects growth and development in height and weight[21][25]. Children who experience caries early in life during the primary dentition phase are at a greater risk of developing further carious lesions in their permanent dentition [26][12].

2.12 Pattern of ECC

ECC has a particular clinical pattern according to its etiology[27][15]. If it starts early in life, it starts as simple. Then if neglect on the oral hygiene occurs, it progresses to moderate then to severe. The initial lesion fosters the labial surfaces of maxillary incisors, then additionally to the lingual and buccal surfaces of maxillary and mandibular molars. It usually begins with the maxillary primary incisors surfaces as a dull white demineralized band 'white spot', appearing along the gum line [28][29]. As the lesion progresses, cavitation starts and caries begins to spread to the maxillary molars. The pattern of involvement follows the sequence of eruption of primary teeth. Due to breast or bottle feeding, the lower mandibular incisors are protected by the tongue

which extends anteriorly over the mandibular teeth[30][31]. The milk or other fluids will pool the maxillary incisors and occlusal surfaces of posterior teeth. In the severe form, the caries activity will progress extending along the crown circumference forming a black collar leading to hard tissue loss and crown fracture leaving the teeth with only root stumps. In very severe cases the mandibular incisors can be affected[31].

2.13 Prevalence of ECC

Dental caries is a major community health problem and remains the most dominant chronic dental disease in both children and adults, despite the fact that it is generally preventable[26]. In 2010 dental caries was considered the most prevalent worldwide public health disease[12], with primary caries being the tenth most prevalent disease[32]. Kowash (2014) stated that prevalence of ECC has been reported to vary between 3% and 94% worldwide[15]. This variation has been demonstrated clearly in different studies. More specifically, it was linked to several factors such as: 1) the age and accessibility of children studied; 2) socioeconomic status; 3) ethnic and cultural factors and 4) criteria used for diagnosis[28]. The prevalence of ECC in one country cannot be compared with another. Richardson *et al.* (2001) reported that even results from one ethnic group cannot be extrapolated beyond that group, even within the same country[20].

2.13.1 Global prevalence

Many studies have been conducted to find the prevalence of ECC. Despite the fact that, there is decline in the prevalence of dental caries in children in the western countries, caries in preschool

children remains epidemic in both developed and developing countries [33]. In England, the Children's Dental Health Survey (CDHS) of 2013 revealed that a third (31%) of 5-year-olds were identified as having obvious decay experience in their primary teeth with 28% of them having decay into dentine[20]. In Italy (Sardinia) and Switzerland, there was a major decline in DMFT of dental caries[3]. The mean DMFT (Decayed, Missing and Filled teeth for permanent teeth) in 12 years old children declined from 4.3 - 3.1 in 1989 to 0.8 - 1.5 in 2004[3]. In Switzerland the mean DMFT of 12-year-old children decreased from 7.9 in 1964 to 0.84 in 1996[3]. The reason for this decline was attributed to the use of different forms of fluoride such as toothpaste, mouth rinse, fluoride foam and gels[3].

Furthermore, in the USA, dental caries is stated to be the most common chronic childhood disease of children aged 5 to 17 years and is five times more common than asthma and seven times more common than hay fever[34][31]. Over 23% of 2-5 year-old children in USA have at least one cavity or restoration, and that proportion increases to 67% among 16-19 year-olds [35]. While, untreated tooth decay in primary teeth among children aged 2-8 was twice higher for Hispanic and non-Hispanic black children[35].

In Brazil, few studies on caries prevalence in primary teeth have been developed over the last years[36]. Interestingly, in Feira de Santana, Brazil (2007), the prevalence of dental caries among 186 children aged 12 to 30 months was 6.4% due to water fluoridation[37]. While in Bauru and San Paulo, Brazil, dental caries prevalence in three to six-year-old preschool children comprised 77.28%[36]. Using The World Health Organization (WHO) criteria, a 2007 cross-sectional survey of a sample of 2014 Chinese preschool children aged 3-5 years found a prevalence of 55% of children with regular dental caries and 14% of children with rampant dental caries.

In the Middle East, the prevalence of caries is reported to be from 22% to 61% among pre-school children [24,38,39]. The extent of the disease varies among; socioeconomic groups, gender, and age of individuals [40]. In 2006 a mean primary tooth decayed(*d*), missed(*m*), filled(*f*) teeth(*t*) (*dmft*) of 4.6 was reported for 6-year-old children living in Kuwait (3) . In Saudi Arabia, on the other hand, a 2013 systematic review of population-based dental caries among children found that dental caries and its severity were estimated to be approximately (80%) for the primary dentition with a *dmft* mean of 5.0 [41]. Wyne *et al.*[42] reported a caries prevalence of 74.6% with a mean *dmft* score of 6.9 in a random sample of preschoolers in Riyadh, with a piped water fluoride level of 0.24 ppm.

2.13.2 Prevalence in the UAE

In the UAE (Al-Ain) according to Al-Hosani and Rugg-Gunn (1998), the prevalence of ECC in five-year-old children was 93.8 %. Later on, Hashim and her colleagues [43] reported a high prevalence of S-ECC in children 5-6 years old in Ajman, UAE. The overall prevalence of S-ECC was 31.1%. The prevalence of S-ECC was higher among children of low-income families, those who had a high snack consumption level, and those who utilized dental services only when they had a problem. Information on dental caries among children in the UAE over the past 20 years has been collected from Pathfinder surveys; however, these did not represent all seven Emirates. Reports on the experience of dental caries in primary dentition were mainly from Abu Dhabi. In 1998, a mean *dmft* of 7.7 was reported in 5-year-olds in Abu Dhabi [3]. These reports suggested an increasing trend of dental caries in the primary dentition of children in the UAE (3,44). A national study conducted during 2001 and 2002 in 5-year-old UAE children by Al-Nadeef (2010) found that only 17% of children were caries-free and the *dmft* index was 5.1,

ranging from 3.8 in Ajman to 6.6 in Dubai. More than 52% of children had a *dmft* score of more than 4. The major findings of this study suggest that caries is highly predominant within the primary dentition of 5-year-old children and remain mostly untreated [45].

A recent literature review done by Al-Bluwi in 2014 showed that dental caries is a considerable public health problem in young children (age 12 years and below) in the UAE[3]. Al-Bluwi concluded that "the prevalence of dental caries in the UAE is high with no evidence of decline. The (WHO) 2000 goals are still unmet for UAE children" (the WHO goal is that 50% of 5–6 year old's would be free of dental caries in 2000 [13].

2.14 Etiology and pathogenesis

The etiology of early childhood caries is a combination of several factors. The frequent consumption of fermentable carbohydrates, breast or bottle feeding, especially at night is one factor. Oral colonization by cariogenic bacteria (especially *Mutans streptococci*) is another factor in association with poor oral hygiene[31]. At suitable times, carious lesions are initiated and induced as the result of the interaction of cariogenic microorganisms, fermentable carbohydrates, and susceptible tooth surface. Using a bottle to put a child to sleep along with a high sugary diet are the strongest predictors of ECC [76]. The interplay between bacteria that produce acid and the many host factors including teeth and saliva, dental caries forms over time.

2.14.1 Tooth factor

Different aspects affect tooth susceptibility to dental caries, these include: immunological

factors, reduced saliva, immature enamel and defects of the tooth tissues. In addition, tooth susceptibility to dental caries differs from one surface to another and from one subject to another which can be attributed to several factors such as: morphology of teeth, vulnerable sites that favor plaque accumulation and stagnation and the position of the tooth[20] (46–48). Enamel pits and fissures, proximal enamel smooth surfaces, cervical margins and exposed root surfaces due to gingival recession, and restored areas with deficient or overhanging margins (recurrent caries) are more vulnerable sites for dental caries.

The main components that make up the tooth are: Inorganic components (96% in enamel, 70% in dentine), organic elements and water. If these components are affected by environmental features such as water quality, diet, and nutrition[49]; the composition of tooth surface will have the tendency to be affected by dental caries. According to numerous cross-sectional and longitudinal studies, "developmental defects of enamel (DDE)" predispose individuals to the development of carious lesions due to the structural defects of the tooth surface, which facilitate the adhesion and colonization of cariogenic bacteria [50–52]. The eruption of teeth into the mouth is accompanied by hypo-calcified enamel. As enamel continues to mature over time following tooth eruption, teeth are said to be less prone to decay[53]. The enamel matures incorporating orally available ions together with fluoride. Therefore, susceptibility to caries directly after the eruption of the tooth is high until final maturation.

2.14.2 Substrate (fermentable carbohydrate) factor

Fermentable carbohydrates play a crucial role in the initiation and development of dental caries[54]. Sugars (such as sucrose, fructose, and glucose) are cariogenic in nature to different

extents. Sucrose for instance, transforms non- cariogenic/anti-cariogenic foods to cariogenic forms. It decreases the levels of *S. Sanguinis* and increases the proportions of *Mutans Streptococci* and *Lactobacilli* [55–57]. This disruption in the microbial community balance will lead to acid production [58]. This imbalance, favors the growth of cariogenic species by converting a healthy biofilm to a diseased one, thus enhances demineralization [5]. Furthermore, oral cleansing of carbohydrates is lowest throughout sleeping times, when salivary flow decreases and the interaction between plaque and substrates rises, favoring the progression of cariogenic species [59]. Regular bottle feeding especially at night, which contains sugary liquids, similar to breastfeeding; highlights that dietary patterns play a role in the onset of the disease [60].

Studies found that at an early age, the prevalence of caries is linked to diets containing a high frequency of sugar consumption/snacking [61,62]. The consumption of sweet foods, mainly between meals, can result in a continued drop in pH levels. Demineralization of the teeth occurs shortly thereafter due to the inadequate time for the pH to return back to normal levels [55]. In addition, children aged 2-10 years who consumed soft drinks often, as opposed to children with high water consumption patterns, were found to be 1.8 times more likely to experience dental caries [63]. These children who frequently consume fruit juices and carbonated beverages have often been diagnosed with ECC [64]. Fruit juices are intrinsically acidic as they are naturally rich in sugar (fructose). Additionally, carbonated beverages possibly have an acidic pH and sugar sweetening formulas (commonly fructose) [65]. As they both lead to a significant decrease in plaque pH, fruit juices, and carbonated drinks play a great role in initiating the carious process [66].

2.14.3 Formation of dental plaque/biofilm factor

Dental plaque is a colorless, soft and sticky coat that adhere on the tooth surface[67]. The

presence of visible plaque has been reported to be one of the risk factors of early childhood caries in children [68,69]. Variations in salivary pH are the result of the metabolic nature of bacteria residing in the biofilm [70,71]. Acting on susceptible and vulnerable teeth, the organic acids produced by cariogenic plaque bacteria (which act in the fermentation of carbohydrates) results in the formation of caries [72,73]. The existence or absence of visible plaque has been a key factor in determining caries risk groups. A study done by Alaluusua and Malmivirta (2002) revealed that 91% of children in their study were correctly classified into caries risk groups, based on the plaque visibility [74].

2.14.4 Time factor

There are some important factors that comprise the etiological circles of the dental caries: host or the tooth, dental or bacterial plaque, substrate – carbohydrates and saliva, and altogether co-react with the time factor as stated by Begazati *et al.* (2015)[75]. Time considered one of the major factors that lead to caries initiation and progression if neglect occurs. The small quantities of sugar and other fermentable carbohydrates frequently consumed throughout the day (long period of time), as opposed to in large quantities and occasionally, will lead to an increased risk of caries development. More important is the ability of sugar to be cleared quickly from the mouth rather than the amount of sugar consumed [76]. Sticky foods like bread or raisins remain in the oral cavity for a longer period of time and increase the prospective for decay[43]. An increased risk of caries is also strongly related to recurrent acid attacks, which do not give adequate time for teeth to recover. Over all, poor oral hygiene will lead to plaque accumulation and frequent bottle feeding especially at night for a long period of time will initiate ECC and subsequently if neglect occurs S-ECC develops.

2.14.5 Cariogenic micro-organisms

Tooth demineralization in children is mainly the result of exposure to a cariogenic diet as well as an early infection with cariogenic bacteria. Recent clinical investigations have reported that Mutans streptococci (MS) can even colonize in the mouths infants during pre-dentation stage [(77)]. The main source from which infant acquire cariogenic bacteria vertically is through mother and horizontally through other members of family or nannies (via saliva-sharing activities)[(15)(78)(14)]. The main cariogenic microorganisms are MS, particularly *Streptococcus mutans* and *Streptococcus sobrinus*, and *Lactobacillus (LB)* [(79)]. These pathogens effect tooth surfaces by acids production. The production of acid will disintegrate tooth enamel at a faster rate than the processes of biofilm neutralization and when the oral cavity environment is below the ideal pH value (less than 5.5)[(47)]. Substantial change in the plaque biofilm pH is resultant of bacteria that metabolize dietary fermentable carbohydrates (sugars) and subsequently produce acids that contribute to the formation of dental caries [(80)]. At rest, the pH of plaque biofilm is typically neutral [(81)]. The breakdown of the structure of the tooth takes place when fermentable carbohydrates are ingested; when this occurs, the plaque biofilm pH drops and undergoes a rapid decrease to create an acidic environment [(80)].

For that, a child's teeth must be infected and colonized by MS and LB whose potential acidic environment may lead to ECC. Through Poor feeding practices, studies have shown that children from the age of 6 months can be victims to the colonization of their oral cavity by MS[(82)]. The main microorganisms involved in the instigation of dental caries are MS and LB [(83)]. The possibility of MS colonization appears to be higher in infants who drink sweetened beverages rather than milk from a bottle[(80)]. Studies have shown that MS is four times higher in children who consume beverages having sucrose in their bottle than the level of those who drank milk

from a baby bottle [84]. Lactobacilli are commonly associated with both disease advancement and as an indication of fermentable carbohydrate content [85].

Studies in addition have shown that as opposed to their counterparts who are caries-free, children with S-ECC display significantly different microbiota, which is characterized by lactobacilli comprising a large proportion of the biota[86,87]. The significant role of Lactobacilli in the progression and intensity of caries is related to the high incidence of Lactobacilli in caries lesions as well as its ability to persist in the acidic environment it produces [85].

2.15 Factors effecting ECC

2.15.1 Diet

Although ECC is an infectious disease, the role of diet is crucial in the acquisition of the infection and development of the disease[88]. Frequency, timing and amount of sugar consumption are dietary factors that are strongly associated with ECC [29]. Several investigators have reported that the most important factor influencing cariogenicity is the frequency at which food is eaten[29]. It is the major cause of development of dental caries in both adults and preschool-aged children[88][75]. The increase in caries is associated with increased sugary snacks between main meals [75]. Recently, a study highlighted that the daily consumption of high sugar-containing soft drinks has resulted in an increased prevalence of caries as mentioned before[29]. In addition, children with chronic diseases that frequently consume liquid medication high in sugar, have increased caries index[29].

A major concern about dietary practices is the overconsumption and over-reliance on foods high in sugar and fats; not only is this dangerous for dental health but it's also a risk factor for

diabetes and heart disease. As previously demonstrated, dental caries is correlated to and is caused by, alongside other factors, the frequent consumption of food and drinks containing fermentable carbohydrates[89]. Dietary control is an important preventative measure. The Oral Health Promotion Health Needs Assessment (2014) [90] recommends that the amount and the rate of sugar consumption should be changed. It should be limited to mealtime and added sugars should be restricted to a maximum of four times a day. The food pyramid is designed to encourage a healthy diet by assisting people in eating a balanced diet consisting of different types of foods in correct portions [91]. It is crucial for pediatric dentist to offer dietary advice that highlights the risks of highly acidic & sugary foods.

In addition, dietary advice, includes drinking acidic products and fizzy drinks with a meal, drinking fast and without holding in or swishing the beverage around your mouth, using a straw, and completing the meal with cheese or milk as it will help neutralize the acid in the mouth [92]. It should also be noted that milk and water could counterbalance the acid consumption of food and drinks[93].

2.15.2 Saliva

Saliva plays a role in creating a proper ecological balance to maintain ideal oral health. The functions of saliva include: lubrication and protection of oral tissues, buffering action and clearance, maintenance of tooth integrity, antibacterial activity, taste, and digestion(94). The buffering capacity, secretion rate, ion composition (calcium and phosphate), and cleansing action of saliva help counteract the etiological factors that leads to the development and progression of carious lesions[95]. In addition, the specific and non-specific oral immune systems in the saliva

affect the cariogenic bacteria to a great extend[95]. Saliva contains electrolytes such as sodium, potassium, calcium, magnesium, bicarbonate, phosphate, as well as, immunoglobulins, proteins, enzymes, mucins, urea, and ammonia[95,96]. These components assist in the modulation of the bacterial attachment in oral plaque biofilm, balance the pH and improve the buffering capacity of saliva and assist in the processes of remineralization and demineralization. The low pH in plaque can be inversed by the salivary buffering capacity, permitting oral clearance and thus inhibiting demineralization of enamel.

In addition, Flow rate and viscosity of saliva have a significant impact on caries development [97]. Maintaining a neutral pH in the mouth hinders bacterial growth, which in turn aids in the reduction of caries development[98]. Salivary gland upon food consumption, secretes stimulated saliva (SS) an ideally mineral-rich and highly buffered solution. This solution acts as a stabilizer for the pH of the biofilm [99]. Based on its constituents, salivary function is very paramount as it regulates properties such as lubrication, helps in elimination of unwanted substances, assists in the breakdown of food substances, governs the neutralization of acids or bases, and aids in the defense against demineralization [97].

Theoretically, saliva can affect caries in four general ways [94]: mechanical cleansing which reduces plaque buildup, the presence of calcium, phosphate, and fluoride reducing enamel solubility, buffering and neutralizing acids created by cariogenic organisms or hosted directly from the diet, and by antibacterial action.

2.15.3 Medical conditions and caries

There are many medical conditions that are associated with caries, and other condition that caries may be detrimental to. These conditions vary according to etiology. They may have direct effect

on caries initiation or indirect effect on salivary flow. Patient with Cystic Fibrosis may have high caries index. This is due to diet rich in sugar to compensate the defect in their exocrine gland secretion[100]. Patients with cystic fibrosis require many sugar-rich drinks to provide them with necessary energy. This diet is thought to carry a high cariogenic potential[100]. However, Chisholm *et al.* stated that salivary levels of sodium, chloride, calcium, phosphorous, protein, glycoprotein, urea and uric acid are elevated in patients suffering from cystic fibrosis Which might explain the reduced rate of caries in CF children [100].

Congenital Heart Disease is another condition associated with high caries index. This is due to the chronic use of liquid medication that contain high sugar content [101]. In addition, in children with this severe systemic condition oral care is considered suboptimal[101]. These affected children require special dental care because of their high susceptibility to infectious endocarditis, associated with bacteremia induced by invasive dental procedures[101][102]. It's important for a pediatric dentist to consider extraction of carious teeth rather than performing invasive procedures such as: pulpotomies, PMC crowns as well as Hall crowns for these patients[103][104]. Children with muscular dystrophy will require similar management due to inability of these patients to maintain their oral hygiene[103]. Hemophilic patient in contrast, require preserving the carious teeth rather than extraction to prevent hemorrhage[103].

Furthermore, some children suffer from diseases that reduce the salivary flow (xerostomia). Such patients suffer from high caries due to the diminished anti-cariogenic activity of saliva. Chronic renal failure, on the other hand, occurs in a number of inherited disorders, inhibit caries through high salivary pH[100].

Children with Down Syndrome have fewer carious lesions than children without this developmental disability according to some studies[102]. This is due to several factors: delayed

eruption of primary and permanent teeth, missing permanent teeth, small sized teeth with wider spaces between them, and supervised diet to prevent obesity which aids in the reduction of the consumption of cariogenic foods and beverages.

In general, children with medical disabilities require special oral healthcare due to inability to maintain their oral hygiene and increased intake of liquid medications that may be high in sugar. These medically compromised children require regular dental visits to highlight dietary counseling in order to maintain good diet and emphasize parenteral supervision of oral hygiene to prevent caries initiation.

2.15.4 Consequences of caries / ECC

Untreated dental caries may result in dental pain that disturbs children's regular activities, such as eating, talking, sleeping, and playing[(75)]. Children who experience caries early in life during the primary dentition phase are at a greater risk of developing further carious lesions in their permanent dentition [(55)]. Therefore, this can result in the loss of the child's front teeth at an early age. Children affected by ECC may also experience various delays in physical development such as in height and weight [(105)]. The painful consequence of ECC may very well result in a loss of appetite, eventually causing malnutrition[(106)]. Moreover, when extraction is required, psychological trauma from dental procedures can have a direct impact on the child. Furthermore, teasing by friends, peers, and even family members may lead to poor self-esteem [(75,107)]. An unlucky pattern occurs when the number of untreated caries is plenty and when there exist hurdles in the path to obtaining appropriate treatment. Because of the lack of treatment, a child's situation worsens and treatment becomes more troublesome[(108)]. Many studies show that when

caries lesions remain untreated, the risk for developing new carious lesions is five times higher [109].

Consequences of ECC in children can reach beyond the dental area effecting their general health[110]. Following pulp necrosis, septicemia (infection) may occur and spreads to the pulpal-periodontal region and can progress to facial cellulitis or Ludwig's angina[111][112]. The condition is potentially fatal, with a mortality rate of 8-10 %, the risk being greater in those with medically compromised children. Finucane (2012) listed a recent editorial stating the deaths of two American children as a result of complications related to odontogenic infections[112].

2.15.5 Socio-demographic factors and caries

Social factors are conclusively one of the strongest determinants of caries experience [113]. The children of low-income families tend to visit the dentist less regularly, often having their first visit to the dentist at a later age and only when there are prominent dental issues and concerns. In addition, these children begin brushing their teeth at a later stage in life and do so less frequently [114]. At an early age, socio-economic status plays a leading role in the development of dental caries[115]. A study conducted in Leeds, England (2004) which intended to inspect the relationship between deprivation, ethnicity, dental health and related behavior in 2,677 five-year-old children, concluded that caries prevalence was increased with higher levels of deprivation [116].

Interestingly, when the parental education is low, but the income is high, sometimes the risk of having ECC in children is higher than when both the parental education level and income are

low [24]. In the UAE, and especially in Abu Dhabi, although the family income of the population is high and dental services are free, the prevalence of caries is one of the highest in the world [44,117]. This may be attributed to behavioral and cultural beliefs existing within the UAE. Al-Hosani and Rugg-Gunn [24] found that children with higher caries scores in Abu Dhabi come from higher income families. They justified that children with high income parents have easy access to high-sugar foods and drinks. Dental status has also been directly linked with deprivation [118] and single parent families [119].

2.15.6 Fluoride

Fluoride is an essential factor that has pre-eruptive and post-eruptive effects on caries prevention. Fluoride prevents decay of a tooth by binding to the hydroxyapatite crystals in enamel[120]. The incorporated fluoride makes enamel more resistant to demineralization and, thus, resistant to decay[120]. Fluoride can be applied topically or systematically. Topical fluoride applications include a fluoride toothpaste or mouthwash or varnish. Topical fluoride is now preferred to the systemic intake such as by tablets or drops as a way to protect the teeth from decay[121].

The use of fluoride toothpaste by brushing the teeth twice a day is the most important measure that decrease caries prevalence in children[93][122]. Preventive programs advice tooth brushing with fluoridated tooth paste twice daily in combination with fluoride varnish at least twice a year for children with low caries index and 4 times for children with high caries index[93]. A routine use of fluoride varnish alone is not enough to prevent the development of ECC in children. Since ECC is a multifactorial process [123], it requires several preventive measures one of which is Fluoride application topically and systematically.

The systemic intake of fluoride through water fluoridation was introduced in the USA in 1940s at the level of 0.7-1.2 mg fluoride ion/L (ppm F) [124]. Drinking fluoridated water has been considered as the most common way to deliver systemic fluoride as it has been shown to be the most efficient way in reducing the intensity and prevalence of dental caries in entire populations [125]. It is the most rational method of delivering fluoride to all members in a community [126]. The rationale behind the fluoridation of community drinking water is to balance the concentration of fluoride in order to prevent fluorosis as well as dental caries. The Department of Health and Human Services in the USA has recently recommended to lower the limit of fluoride to a maximum of 0.7 ppm F [127]. Children living in a fluoridated area have a 50% less risk and less prevalence of caries than those living in a non-fluoridated area [63].

2.16 The dynamics of caries arrestment

Many factors affect caries progression and arrestment: diet, fluoride, salivary secretion and patient compliance or dentist intervention where fluoride dentifrices is being used and fluoride is being made available in the oral cavity [128][129]. The dynamic effect of fluoride on the carious process will slow down the progression of caries lesions by enhancing enamel remineralization and reduce demineralization. This effect is by demineralization of an incipient lesions or arresting the carious lesion if it is deep [129]. For enamel remineralization or caries arrestment to occur, it requires components that act on the oral biofilm. If the biofilm is removed, partially or totally from the tooth surface, mineral loss may be stopped or reversed toward mineral gain[128][129]. In other words, the lesion may be arrested, and this can occur at any stage of lesion formation. The mechanism of caries arrestment occurs, when the PH is not less than 5.5, hydroxyapatite (HA) is dissolved at the same time that fluorapatite (FA) is formed as stated by

Cury and Tenuta in 2009[129]. This will result in decrease of enamel dissolution, since a certain amount of Calcium and Phosphate, which was lost as HA, is recovered by enamel as FA[129]. This mineral gain has been considered as a decrease in demineralization because the mineral redeposited is different from that lost. This will aid in changing the lesion and enhance the deposition of secondary and tertiary dentine [130].

Diet, fluoride, saliva, child and parent motivation to change the behaviors may affect in ECC initiation or prevention. A proper understanding of caries cause and factors affecting it, gives the pediatric specialist a good idea in providing proper methods in preventing and managing the disease.

2.20 Clinical management of caries in young permanent and primary teeth

In the past, the management of dental caries was based on the belief that caries was a progressive disease that required surgical and restorative intervention to protect the remaining tooth structure from destruction and eventually tooth loss[131][132][14]. Now it is recognized that therapeutic treatment of dental caries alone does not stop the disease process, and restorations have a finite lifespan [14]. Some carious lesions may not progress thus no treatment is required. Therefore, the AAPD (2014) stated that 'current management of dental caries includes identification of an individual's risk for caries progression, understanding of the disease process for that individual, and active surveillance to assess disease progression and manage with appropriate preventive services, supplemented by restorative therapy when indicated.'

Decisions for therapy are often based on clinical judgment, whether a tooth is diagnosed as cavitated by clinical or radiographic examination[22]. The AAPD (2014) declared that decisions

should include at least clinical criteria of visual detection of enamel cavitation, visual identifications of shadowing of the enamel, and radiographic recognition of enlargement of lesions over a period of time. Along with other information, periodic recalls aid in determining caries activity and progression [(22)(14)].

Caries may be treated by a biological and/or therapeutic approach [(133)]. All treatment options offered should have a preventive program that enhances remineralization and inhibits the caries process, as prevention is better than cure. However, dental caries if left untreated will lead to discomfort and toothache that may alter growth as well as cognitive development of children [(134)(133)]. Dental treatment in young age as stated by Sharma *et al.* (2015) makes a very significant difference to the psychological and social aspects of patient's life in addition to their attitude toward dental treatment [(133)].

2.21 Prevention approaches

Key factors in the prevention or control of oral disease are oral biofilm plaque control and practice of the daily removal of bacteria from the teeth, tongue, and adjacent oral tissues as much as possible [(135)(136)]. Mechanical removal of oral biofilm through tooth brushing and flossing is the most widely accepted means of plaque control[(137)]. As plaque biofilm is a contributor to the formation of dental caries, plaque needs to be removed on a daily basis to prevent caries formation [(123)(68)]. It is critical to complement daily brushing with flossing since toothbrush bristles are not effective in removing proximal plaque. Fissure sealants are also important preventative measures. Dietary control is another important preventative measure[(136)]. As previously mentioned, dental caries is related to and is caused by, alongside other factors, the

frequent consumption of food and drinks containing fermentable carbohydrates [89]. The Oral Health Promotion Health Needs Assessment (2014) [90] recommends that the amount of sugar consumed and the rate at which it is consumed should change. The consumption of sugary foods should be limited to mealtime and added sugars should be restricted to a maximum of four times a day[138].

2.22 The classical surgical management

The management of carious lesions in primary teeth has been modified to different treatment strategies [122]. There has been an enormous debate in which strategy is considered effective in managing these deep caries lesions [139]. The most preferred strategy is the conventional approach. It involves local anesthesia, complete caries removal, tooth preparation, with or without pulp therapy and placement of a restoration or PMCs [12]. This is considered best practice by both the AAPD and the British Society of Pediatric Dentistry (BSPD). Mass *et al.*, 1999 and Fuks *et al.*, 2000 stated that there is strong evidence in the literature that supports the restoration of primary teeth by following principles of good restorative and excellent success rates have been reported[140].

The aim of the restorative treatment is to limit the damage from caries and preserve the tooth structure as much as possible [141]. In addition, it eliminates areas that are susceptible to caries by stopping the progression of tooth demineralization and restoring the integrity of tooth structure. For that, it will prevent the spread of infection into the dental pulp and shifting of teeth due to loss of tooth structure.

On the contrary, restorative therapy will lessen the longevity of teeth by making them more susceptible to fracture and recurrent lesions if the restoration fails and iatrogenic damage to

adjacent teeth if massive preparation was required. Furthermore, pulpal exposure could occur during caries excavation that will lead to future pulpal complications and tooth loss [141].

Conventional restorations require local anesthesia, complete caries removal with a high-speed hand-piece, then a slow hand-piece and/or an excavator to clear carious dentine from the pulpal wall. A matrix band or T-band and a wedge then applied to facilitate the application of the restoration, isolation and proper contouring[139]. There are two common types of restorative materials that are used intra-coronally to restore the tooth structure resin composite restoration and amalgam restoration (the latter is not used as often nowadays)[142].

2.22.1 Resin based composites

Resin-based composite is an esthetic restorative material used for posterior and anterior teeth. Resin-based composites have the benefits of allowing the practitioner to be conservative during tooth preparation[143] [144]. The carious tooth structure can be removed and restored while avoiding the traditional "extension for prevention" removal of healthy tooth structure[144]. However, resins require longer time for placement and are more technique sensitive than amalgams[143]. In cases where isolation or patient cooperation is compromised, resin-based composite may not be the restorative material of choice[144]. Furthermore, resin restoration tend to show higher failure rates in a child with active ECC[145]. This is due to the fact the patient presents with the etiological factors of the caries disease, such as a high rate of visible biofilm, uncontrolled diet and restricted access to fluoride as mentioned by Alencar *et al.* (2016).

2.22.2 Amalgam restorations

Dental amalgam has been used since 1880's for restoring teeth[143]. Amalgam is an easily applied restorative material, durable, relatively low cost, and a reduced technique sensitivity compared to other restorative materials[143][144]. However, esthetics and tooth colored restoration have led to decrease its use. The American Dental Association (ADA)'s Council on Scientific Affairs has concluded that "based on available scientific information, amalgam continues to be a safe and effective restorative material" and that "there currently appears to be no justification for discontinuing the use of dental amalgam"[144].

To achieve adequate resistance and retention, amalgam restorations often require removal of healthy tooth structure[144]. For that, glass ionomer or resin restorative materials retain a healthier tooth structure and might be a better choice for conservative restorations[143][144]. The decision to use amalgam should be based upon each individual patient need[143][144]. SSCs may be the better choice in patients with poor compliance and questionable long-term follow-up especially children that suffer from ECC and S-ECC.

2.22.3 Preformed metal crowns

Preformed metal crowns or 'PMCs' also known as stainless steel crowns (SSCs) are prefabricated metal crown forms that are adapted to individual primary molars and cemented with a biocompatible luting agent to provide a definitive restoration' as stated by AAPD (2014) and the BSPD[14][5]. Typically, PMCs are placed after traditional mesial, distal and occlusal preparations [146]. Indications for the use of conventional treatment with PMCs in primary teeth include high-risk patients, extensive carious lesions that include two or more surfaces and after pulpotomy or pulpectomy treatment. Additionally, defective restorations and developmental

defects such as enamel hypoplasia or hypocalcification are indications for PMC placement. Furthermore, PMCs can be used in teeth which are used as an abutment for space maintainers, teeth exhibiting tooth wear and in-patients treated under general anesthesia [5]. However, PMCs are contraindicated in situations where: the tooth is near exfoliation, in a tooth with poor prognosis due to irreversible pulpal involvement; children allergic to nickel, pre-cooperative (inability to bite on rigid metal due to very young age to understand) or children where parents are unhappy with the aesthetics[147].

PMCs are the most efficient and durable restoration for large carious lesions that involves two or more surfaces on primary molars [146]. Several retrospective studies revealed a markedly increased longevity of stainless steel crowns in comparison with multi-surface amalgam restorations[6][5][7]. Five retrospective studies revealed a 26% of five-year failure of Class II amalgam restorations in comparison to 7% failure of PMC restorations[6] [5] [7]. The clinical failure of PMCs is on average four times lower than that of Class II amalgams [146]. Hence the popularity of the PMC is based on its longevity.

The BSPD and the IAPD in 2008 [148] summed up and listed the indications of PMC placement in the following situations:

- Two surface caries,
- Dental anomalies such as amelogenesis imperficta, dentinogenesis imperficta and enamel hypoplasia,
- Following pulpotomy and pulpectomy,
- Restoration of fractured molars,
- Teeth exhibiting severe erosion, abrasion or attrition,
- Patients with high caries index.

- As abutment teeth for space maintainers,
- Special needs patient,
- Infra-occluded molars,
- Patient undergoing restorative care under general anesthesia[148].

2.23 Novel concepts

There is currently a range of new biological methods for treating carious primary molars. They span from sealing-in caries, stepwise caries removal [122], partial caries removal or non-restorative caries treatment (NRCT).

2.23.1 Non-restorative caries treatment (NRCT)

In the NRCT method, the cavity is opened exposing the biofilm of the carious lesion. These lesions are typically opened with a high-speed bur to remove over-hanging enamel, making the cavity accessible for plaque removal[125]. No carious dentine is removed from the pulpal wall and no local anesthesia is placed[139]. Fluoride varnish is applied to the cavity to stimulate remineralization. The biofilm will be altered by the continuous disruption/cleaning by a parent and child, which will arrest the carious lesion[149] [139], thus transferring the responsibility of care from the dentist to the parent/patient.

2.23.2 Atraumatic restorative treatment (ART)

The ART approach involves the use of hand instruments only such as spoon excavator to remove carious lesion, then restoring the cavity and sealing any adjacent enamel fissures with a conventional glass ionomer restorative cement (GIC)[(150)(144)]. GICs demonstrate sustained fluoride release, pulpal biocompatibility, and chemical adhesion to tooth substance as stated by Alencar *et al.* in 2016. This minimally-invasive procedure is largely accepted by children as it is pain-free. In addition, ART is gaining more acceptance in developed countries for the management of ECC[(150)(144)]. ART is better accepted by small children, as it can be applied in locations where there is no electricity or running water, its use can increase the prevention and as an interim therapeutic restoration of carious lesions in uncooperative children[(153)(146)].

The use of GIC for caries stabilization is very beneficial as an intermediate approach in many children whilst their cooperation and compliance is assessed[(140)]. However, GIC is not recommended for proximal lesions and high failure rates have been reported when used in multi-surface lesions[(140)].

2.23.3 Stepwise/ Indirect pulp capping

The stepwise technique requires partial removal of decayed tissue in two steps for teeth diagnosed with reversible pulp inflammation that are at a high risk of pulpal exposure if total removal of decayed tissue done in one step [(151)]. In the first session, complete caries removal of the softened and infected dentine tissue from the walls surrounding the cavity and the pulp leaving part of the infected dentin at the bottom of the cavity (pulpal wall) [(151)]. The cavity later,

may be filled with calcium hydroxide-based material, although this is not essential, and sealed with temporary restorative material (GIC), remaining for a period of 2 to 9 months, or even 12 months, before being reopened to allow tertiary dentin to be formed. Then, in the second session, potential removal of all the remaining decayed tissue in the cavity, followed by definitive restoration [(151)(152)]. This approach is thought to facilitate arrest and demineralize the lesion to induce development of tertiary dentin [(152)], thereby reducing the risk of pulpal exposure and postoperative complications after the second excavation step.

Several studies questioned the need to re-enter if the sealed residual lesions is clinically and microbiologically arrested [(152)]. Some clinician recommended the shift to selective (one-step) partial excavation, to prevent weakening of tooth structure, sealing carious dentin under a definitive restoration is much more recommended [(152)]. Sealing the lesion is thought to deprive residual bacteria from dietary carbohydrates and has been found to exert significant antibacterial effects, thus arresting the lesion [(152)]. Recommendation prefers single step partial caries tissue removal with the use of material for indirect pulp protection followed by the use of a definitive restorative material, without the need for further intervention[(145)].

Numerous long term studies have shown the success of indirect pulp capping (IPC) procedure[(153)(154)]. These studies compared the treatment of deep carious lesion in primary teeth with IPC material over Formocresol pulpotomy treatment (FCT) between 2000 and 2004, unless there was an unintended pulp exposure when using a slow speed round bur before IPC[(155)]. The IPC has shown a higher success rate than pulpotomy in primary teeth[(153)(154)(155)]. The overall success rate of IPC was 88% in Baltimore *et al.* study (2013) that was slightly lower than similar studies, including Falster *et al.* (90%), Farooq *et al.* (93%), and Vij *et al.* (94 %)[(155)]. Farooq *et al.* study in 2000 were the first study that evaluated the success rate of indirect pulp therapy (IPT) of deep carious lesion in primary molars over Formocresol pulp therapy (FPT)[(154)(155)]. IPT

was performed on 55 teeth, while 78 teeth had a (FP)[154]. The study intended in addition to evaluate the success of these therapy on teeth with history of reversible pulpitis pain and their effect on exfoliation(154). Overall IPT success was 93% versus 74% for FPT[154]. Molars with pain compatible with a diagnosis of reversible pulpitis were successfully treated by IPT 85% versus 76% for FPT[154]. FP-treated molars exhibited earlier exfoliation 38%, while all IPT molars exhibited normal exfoliation as stated by Farooq *et al.* (2000)[154]. Therefore, indirect pulp treatment of primary carious teeth is more preferable to pulpotomy when the pulp is normal or has a diagnosis of reversible pulpitis as stated in the AAPD pulp therapy guideline in 2015[153].

Furthermore, a recently updated Cochrane systematic review of eight trials of 934 patients (1,372 teeth) that compared biologically-orientated strategies (stepwise, partial and no-caries removal), with complete caries removal for managing caries in both primary and permanent teeth[8]. 1,191 teeth were analyzed and the review concluded that biological orientated strategies had clinical advantages over complete caries removal in the management of dentinal caries in symptomless primary vital teeth [8].

2.23.4 The Hall technique

Sealing-in caries or the "biological" approach include those with no caries removal, such as the "Hall" technique and fissure sealants over caries [9][93]. The new Hall technique of placing a preformed metal crown (PMC) without conventional preparation is considered by its advocates as effective as the conventional method [9][8][156]. It is more acceptable to parent, children and general dental practitioners than the conventional restorative approach[9][157]. One of its

advantages was that there was no discomfort in 89% of the cases of PMCs crowns placed by the Hall technique compared to 78% of the conventional restorations [157].

The Hall technique can essentially be as an extension of the indirect pulp cap (where the pulp has carious tissue left over it but is sealed in) as stated by Innes *et al.* (2017) and Welbury (2017)[158][159]. The Hall technique utilizes all the three principles of the biological approach as stated by Welbury (2017) [158]. The use of glass ionomer cement will bond to enamel and dentine, the bacteria denied of substrate and sealed into tooth die and do not cause caries progression, and finally the crown that is used will produce an effective marginal seal[158]. The clinician's judgment is the key to success for this biological approach[160]. It gave a leading edge of being part of the child-friendly approach in dentistry. Because of its more recent introduction, the Hall technique will be discussed further in this chapter.

2.30 The hierarchy of evidence

Evidence-based medicine (EBD) requires the integration of clinical judgment, recommendations from patient's value and the best evidence available[161]. A number of well-respected experts have come together to produce evidence based guidance[161][138]. Scientific evidence to guide clinical practice by helping clinicians promotes oral health and prevent oral disease in patients. It is intended to be used throughout primary dental care[138].

The fundamental principle of evidence-based medicine is the recognition of a hierarchy of evidence[138]. Evidence from systematic reviews, randomized controlled clinical trials (RCTs), case–control or cohort studies, observational studies, and expert opinions are used to make disease-specific practice recommendations[162]. The highest ranking is for the systematic review

and the lowest is for expert opinion. The decisions basing the strength of the evidence relies on the method that was used [161]. The method with a less bias on other words less error[161].

Each piece of advice or any suggested intervention displayed in a model is supported by evidence of varying levels of strength[138]. If the level of evidence is weak it does not mean that the intervention does not work but simply that the current evidence supporting it is not of the highest quality[138]. The grades of evidence given typically are as follows as stated by the UK's National Health Service (NHS) prevention tool kit book (2014):

Grade Strength of evidence

- **I** Strong evidence from at least one systematic review of multiple well-designed randomized control trial/s.
- **II Strong** evidence from at least one properly designed randomized control trial of appropriate size.
- **III Evidence** from well-designed trials without randomization, single group pre-post, cohort, time series of matched case-control studies.
- **IV Evidence** from well-designed non-experimental studies from more than one center or research group.
- **V** Opinions of respected authorities, based on clinical evidence, descriptive studies or reports of expert committees[138].

The different types of evidence from strongest to weakest are: systemic review or meta- analysis, randomized controlled trial (RCT), non-randomized clinical trial including cohort studies and case control followed by least is expert opinion. Systematic reviews are generally considered the highest in strength. They provide the best evidence for all question types as they are based on the

findings of multiple studies that were identified in comprehensive, systematic literature searches[161]. Furthermore, a large, well conducted RCT may provide more convincing evidence than a systematic review of smaller RCT[161]. However, expert opinions are based on the clinician observation and not a study. It is important for clinician to understand the hierarchy of evidence and guidelines to base their expertise on choosing the best management option on patient.

There are two randomized control trials[9], a Cochrane systematic review[7], and a number of observational studies[12][146] that were published to support the use of Hall technique. Up to date, there are no studies that have reported adverse effects with the treatment using Hall technique [163]. For that, It is very important for clinicians to change and accept the new paradigm (such as fitting crowns to primary molar teeth with no local anesthetic or tooth preparation), but also a new way of thinking that goes along with it (sealing in caries is safe and beneficial, and restoring primary teeth is worthwhile[162][163]. It is better for clinician to have several procedures from which to select the optimal choice for a specific tooth, child, and surrounding circumstances than to limit themselves to a traditional view[163].

Figure 2.1: The hierarchy of evidence from strongest to weakest.

2.40 The specific management of primary molar caries according to guidelines

Guidance on prevention and management of dental caries in children is designed to assist dental practitioners in improving and maintaining the oral health of their child patients[93]. A clear guidance conducted from several information and studies to show what, when and how to do things. It includes advice on how to assess a child (according to caries risk assessment) to deliver the appropriate prevention and treatment options available in managing caries. In addition, recall, referral and how to manage child's neglect[93].

There are several guidelines that had been applied to support the different ways of managing primary molars with deep asymptomatic caries with reversible pulpitis. Pediatric practitioners follow different guidelines: Examples are the AAPD, BSPD, the European Academy of Pediatric Dentistry (EAPD) and the Scottish Dental Clinical Effectiveness Program (SDCEP). Such

guidelines help practitioners make decisions regarding restorative dentistry, including the necessity to treat a carious tooth and the appropriate restorative dental materials to be used for children and adolescent patients[144]. The different treatment modalities were mentioned briefly in the previous section as traditional and alternative biologic approaches. The SDCEP in 2014 stated that in addition to traditional restorative procedures, evidence supports alternative approaches based on altering the environment of the plaque biofilm to be effective in managing caries in the primary dentition.

All the guidelines support the use of PMCs For primary molars with extensive multi-surface carious lesions (ECC) with signs of reversible pulpitis [93][164][144][165]. PMC is durable, has a long lifespan, adequate in protecting the remaining tooth structure and preventing marginal leakage[164]. However, 'achieving optimal marginal adaptation is difficult with PMCs due to a limited ability to adjust their prefabricated shapes and dimensions; thus, luting cements are crucial in obtaining a suitable marginal seal and reducing the micro-leakage around the crown margins' as stated by AAPD in 2014[164].

PMCs had been used since 1950s[147]. These crowns were traditionally called SSCs. They are crowns that are composed of nickel chromium. The composition is mainly constituting of: 65-74% of iron, 17-19% of chromium and 9-3% nickel [147]. In patient allergic to Nickel, it's contraindicated for them to be treated with PMC as mentioned previously [147].

Children are not always easy to care for because of differing levels of co-operation. In addition to that, primary teeth have different morphology short bulbous crown, thin enamel and dentin with large pulp chamber[140], to choose whether to prepare the asymptomatic tooth or directly seal in caries depends on a proper case selection and child's cooperation.

In addition, whether the PMC applied by the conventional traditional way or alternatively by the

Hall technique means, aesthetics is a potential issue to both parents and children[147][166]. Page *et al.* revealed in his study how few parents were concerned that the presence of crowns in their kids may indicate child neglect[12]. Another study by Bell *et al.* surveyed parents and children view about PMCs placed by conventional and Hall technique and found out: 8% of children felt the crown placed "okay", 16% were concerned about the appearance and 5% of parents additionally were concerned by the appearance[147]. For this reason, it is very important to explain the procedure for parents and children and let them view the crown in situ prior to the procedure[147][166].

2.41 Conventional PMC placement

The conventional crown preparation has been outlined in details in popular textbooks in pediatric dentistry [143]. Conventional crown preparation requires good level of patient cooperation and maturity as local anesthesia is administrated. Preparation requires sufficient occlusal reduction of approximately 1.5mm. Also, mesial and distal preparations are cut at a sufficient angle to avoid the creation of ledges or steps at the gingival finishing line. In addition, preparation should be done with care to avoid damaging the neighboring tooth. All line angles should be rounded to allow sufficient space for the crown to fit. The appropriate size of crown is selected that is a tight snap fit and cemented with luting cements such as GIC, zinc oxide polycarboxylate and zinc phosphate cements. Care should be taken into account when placing the crown on the primary second molar where the permanent molar is un-erupted to avoid distal overhang that will prevent the permanent molar from eruption[143][5].

Over the past two to three decades, PMC have shown a higher success rate than any other restorations in primary molars[143]. PMC are by far the most durable restoration for primary molar; they seldom require replacement. Covering the whole tooth surface with prefabricated metal crown prevents tooth from further carious attack[143].

Many studies support the durability and the effectiveness of PMC crown. Wong and Day in 1999 randomly analyzed one restoration per patient within 361 records of three dentists working in NHS practice[5]. They found evidence that PMCs performed better than alternative restorations within the conditions of NHS practice[5].

Conventional treatment for primary teeth is an invasive approach as it involves removing part of the tooth structure to access the caries lesion especially in interproximal sites [12]. Moreover, conventional restorations such as amalgam and composites have a limited life span and may require in some cases repetition, pulp involvement, and eventually tooth loss[12][140]. The conventional restorative approach requires some degree of patient's maturity and cooperation which might not be present in some children. Page *et al.* (2013) stated that 'failure of restorations in primary teeth is more common in younger age groups, perhaps because, in children, the anatomy of primary teeth, small mouths, and age-appropriate limited cooperation can make the placement of restorations challenging'. It is evident that such restorative procedures are taxing to all involved; the child, the dentist and the care-provider. This had increased the search for alternative methods of treatment.

2.42 Alternative methods to the conventional PMC restoration

2.42.1 The Hall technique (HT)

As highlighted above, the HT is used to seal caries. It was reported by Innes *et al.*, 2006 as a minimally invasive approach whereas dental caries is treated without the use of local anesthetic and drill[(167)(104)(166)(152)]. Sealing caries with PMC will isolate caries from oral environment, the bacterial biofilm in the caries will change, resulting in losing its cariogenic potential so that the lesion does not progress[(168)(158)]. Like other treatments aimed to manage carious lesions by sealing them in, the Hall crown works by leaving the lesion without fuel and making the environment unfavorable for its progression[(162)]. The aim of arresting the lesion to prevent irreversible inflammation of the dental pulp[(158)]. Clinical trial has shown the Hall Technique effectiveness and acceptance by a majority of children, parents and clinicians[(168)]. There are many ways that helps in preventing demineralization process, including: removing the biofilm; increasing saliva (quantity and mineralization potential); adding fluoride; reducing sugar frequency through diet change; and, in addition, physically blocking cariogenic biofilm from its substrate as fissure sealants and the Hall technique[(162)(163)].

The first step of HT requires assessment. It is important to assess child, the tooth shape and contact points if broad or tight. Due to that, the technique requires two appointments: the initial appointment placing orthodontic separators if no space is present between the tooth, the second, three to five days to remove the separators and place the crown[(168)]. The separators are applied by using a floss to stretch the separator and place in between the contact points. Care must be taken to ensure that the separator has not slipped completely below the contact point[(166)]. 'HT PMCs should not be fitted at the same visit to opposing (occluding) teeth but can be fitted on contralateral teeth in the same or an opposing arch' as stated by Hyde (2015).

Second step at the fitting day, the clinician has to make sure the airway of the child is protected by using gauze swab, and the child is sitting more upright when trying and seating the crown. Select different sizes of crowns aiming to fit the smallest size of crown that will cover all the

cusps, and approaches all the contact points, with a slight feeling of 'spring back'[104][166][168]. Separators are removed with a probe, the appropriate crown size is selected then cemented with glass ionomer luting cement [139]. The crown is then fully seated by asking the child to bite firmly on a cotton roll after a firm finger pressure by the thumb and four fingers supporting the mandible/maxilla to prevent slipping or displacement [10]. This process arrests the carious lesion with the intention of preserving the tooth until exfoliation [10][104]. Figure 2.2 shows the steps of placing PMC's by the HT means.

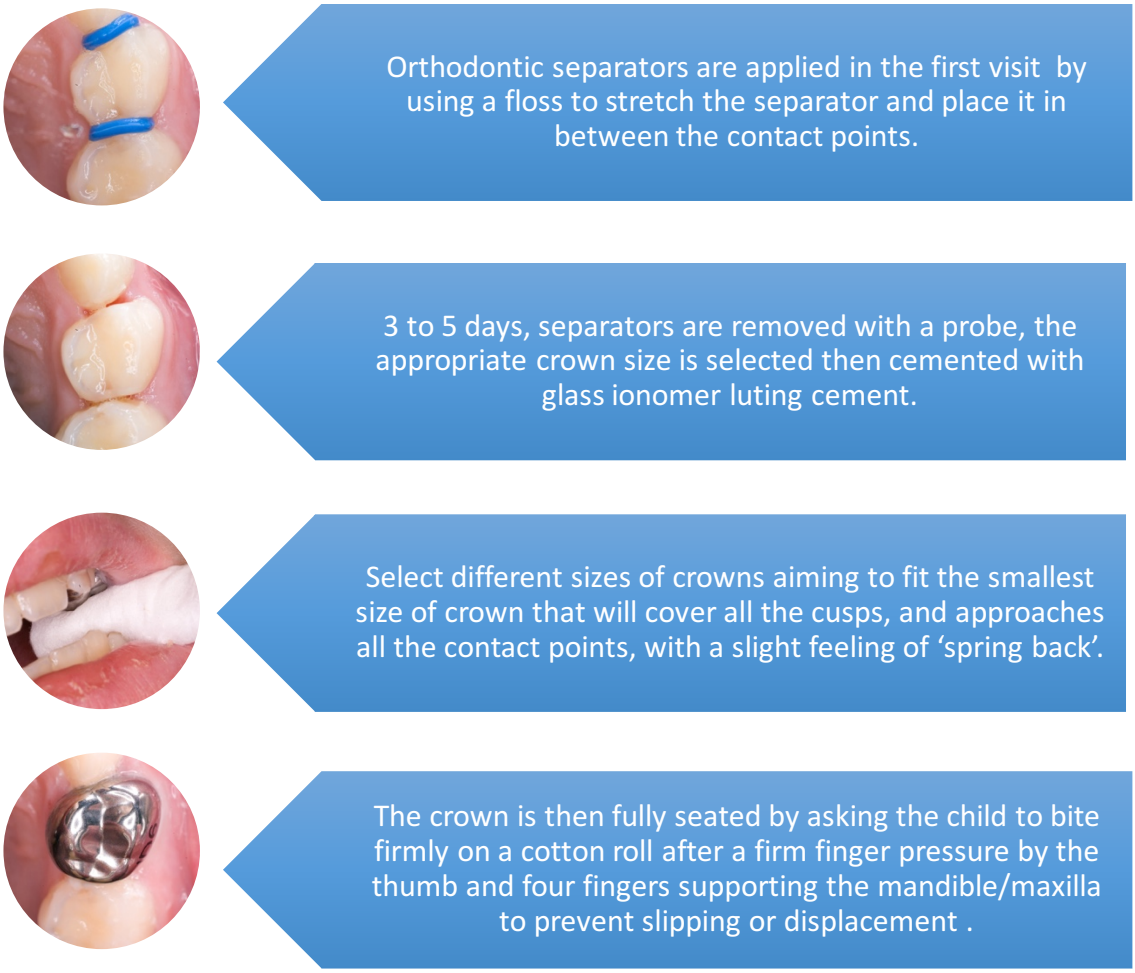


Figure 2.2: The steps of placing Hall Technique crowns.

2.42.2 History of the Hall technique

The concept of the HT took the pediatric dentistry world by surprise in 2007 [(4)], However, its history stretches further back than that. In the late 1980s, Dr. Hall, a general dental practitioner (GDP) from Scotland, started using the yet unnamed "Hall Technique" as an approach for treating dental caries [(167)]. She sealed multi-surface carious primary molars with PMCs using glass ionomer luting cement [(167)] and she found out that it is easier to seal a carious lesion into a tooth using a restorative material such as composites or glass ionomers especially in occluso-proximal cavities rather than doing a restoration[(158)]. A retrospective audit of Dr. Hall's work was then conducted to measure the success of her technique. It was concluded that her outcomes were similar to those with conventional restorations[(158)(167)(146)(140)(160).] It has been ten years since the first paper on HT was published in the *British Dental Journal* and almost 20 years since the HT came to be mentioned[(162)]. Since then, growing understanding that caries is essentially a biofilm driven disease rather than an infectious disease, explains why the HT, and other 'sealing in' carious lesion techniques, are successful as stated by Innes *et al.* in 2017[(162)(160)].

The BSPD in 2001 encouraged treatment of primary molar teeth with caries involving two or more surfaces by using PMCs however the BSPD was guarded regarding the utilization of the HT [(8)(12)(169)]. Additionally, HT was recommended where there was a carious primary molar with no clinical or radiographic signs of pulpitis or sepsis [(10)] and a 'clear' band of dentine that can be seen between the caries lesion and the pulp, on a bitewing radiograph[(160)(170)(10)(171)]. However, the latter has not been formally validated[(172)]. Resembling all clinical interventions, the HT requires, after fulfilling certain selection criteria outlined by Innes *et al.* (2009)[(10)], the following:

- A careful and appropriate case selection,

- A high level of clinical skill,
- Excellent patient management
- Long term monitoring for its success.

Indications	Contraindications
• **Class I lesion, non-cavitated, if patient unable to accept fissure sealant, or conventional restoration.** • **Class I lesion, cavitated, if patient unable to accept partial caries removal technique, or conventional restoration.** • **Class II lesions, cavitated or non-cavitated.**	• **Teeth with signs or symptoms of irreversible pulpitis, or dental sepsis.** • **Teeth with clinical or radiographic signs of pulpal exposure, or periradicular pathology.** • **Teeth with crowns so broken down with caries, they would normally be considered as unrestorable with conventional techniques.**

Table 2.1: The HT indications and contraindications (Adapted from Innes *et al.* 2009) [10]

As mentioned in the table 2.1, the Hall crowns is not suitable for every child with carious primary molars; therefore, proper case selection is significantly important[140][161][162]. The very anxious or the very young child might not be able to cope with biting on a rigid metal crown

through potentially tight contact points as stated by Duggal and Bani Hani in 2015[140]. In addition, to cases that primary molars indicates signs and symptoms of irreversible pulpitis[140].

The HT was anticipated to increase patient's co-operation, and operation ease as local anesthetic is not used [160][173][174]. In addition, performing dentistry early in life with less traumatic experience by sealing in caries, intends patients to return for more complex treatment later on in life [174]. According to Welbury (2017) "it contains the following properties[163]:

• Overall easier for the child (and parent) to cope with

• Quicker to complete

• Not requiring local anesthetic

• Proven efficacy by randomized controlled trials

• Easy to teach to students and general practitioners".

2.42.3 Occlusion following the Hall technique

The HT does not involve any preparation for placing the PMC. This leads to an increase in occlusal vertical dimension (OVD) and minimal increase in child's open bite. Innes *et al.* in 2006 and 2009 stated that occlusion returned back to normal within few weeks with no TMJ pain or problem tend to occur, and this was later confirmed by van der Zee and van Amerongen (2010)[157][140]. However, there were only a few studies supporting the change in occlusion and how it re-establishes after placing Hall crowns[175], and due to their importance, they will be outlined below.

In 2010, van der Zee and van Amerongen recruited 48 school children living in the rainforests of Suriname and assessed their occlusion and monitored how many days it took for the open bite to

be re-established after placing Hall PMCs. Their article was the first evidence that supported occlusal equilibration by scoring the over-bite before and after placement of the Hall crowns. The result concluded that the occlusion returns to normal within 15 to 30 days [157]. They measured the most prominent incisal point of maxillary and mandibular cuspids/ canine before, directly after placement of the Hall crowns and after the treatment within 2 to 4 weeks. They concluded that the reduction of overbite seems to be caused by intrusion of the Hall technique treated tooth and its antagonist tooth. This was later confirmed in another study [161]. In this recent prospective study, 10 children's occlusions following placement of a Hall crown being fitted, clinical photographs, study model and intra-oral measurement follow-ups were carried out at two weeks, six weeks and six months. There was a mean increase in the OVD of 1.1 mm immediately following crown placement and reduced to 0.3 mm after two weeks[158]. It appeared that the compensation was mainly but not completely from the intrusion of the crowned tooth with some *intrusion* of the opposing tooth with no evidence of damage to the permanent successor[158]. In addition, there was no evidence that PMC placed without prior tooth reduction will have any influence at all on future spacing considerations in the developing dentition[159].

2.42.4 The international response to the development of the Hall technique

The HT for primary molars have been shown to have wide spread acceptance from many dentists in the UK and the world in addition to some pediatric dentists in the USA [176]. As the technique started to gain acceptance worldwide by clinician, parents and children, some were still against its concept. A letter to the Editor of Pediatric Dentistry Journal published in 2015 by Croll *et al.* viewing their concerns about the new perception of restoring primary carious teeth with Hall technique [176]. Croll and his colleagues asked different questions regarding:

- The Hall technique success,
- Marginal micro-leakage,
- What was the histopathological implications of leaving caries in situ and does it affect the underlying tissue,
- The rational and the ethics of the procedure and if it is medico-legally acceptable.
- Children with medical condition such as bacterial endocarditis would this procedure still be acceptable to them[176]. This letter is accusing the users of Hall technique that they are using a profitable short, quick fix on caries-infected children than performing the conventional standard preparation[176].

Earlier back, another study in vitro was done by Yalcinkaya and Cehreli in 2014 investigating marginal fit and micro-leakage using three different luting cement for both conventional and HT PMC. The study concluded that PMC placed using the HT displayed higher micro-leakage scores than those applied using the conventional technique, regardless of the cement material that were used[149]. In-vitro studies, while needed cannot always be extrapolated into clinical significances as they do not fully resemble the actual clinical situation and may give uncertain results. Furthermore, HT requires no crown preparations; for that, clinicians may have had difficulty in choosing the appropriate crowns that fully fit the tooth[149]. When the interaction of the material and technique was assessed, resin cement presented as the best choice for minimizing micro-leakage in both techniques[149].

Furthermore, Hashim (2012) questioned the validity of the RCT study that was done by Innes *et al.* and did not advocate its use in clinical practice. The study compared Hall technique with other restorative material and identified two issues: control restoration and outcome assessment[177]. Within the control restoration, Hashim concluded that it is unethical to compare PMC using the Hall technique with multi surface glass ionomer[177]. The author said that in this

RCT the Hall technique was not compared to the golden standard control group (i.e. conventional PMC crown preparations). The other issue, was that there was no radiographic assessment regarding the outcomes in some of the patients which risked the validity of the study[177]. Moreover, Croll and his colleagues in 2015 stated several subjective concerns to clinicians who treat patients using the HT[178]. Their major concern was about leaving infected tooth in situ and sealing it questioning whether clinicians do the same to their own children[178]. Another matter declared was that the Hall crowns might affect the eruption sequence causing ectopic eruption or delay in eruption, external and internal resorption or it might cause gingival inflammation[178]. The writers did not keep in mind that the crown that is been used for Hall is the same PMC used for conventional technique and that the effect of crown on the underlying tissue is similar. Another concern was stated: a question about the use of antibiotic regimen for the Hall technique procedure for immune-deficient patient or patient with a history of infective endocarditis[178]. This concern was merely based on the opinion of Croll *et al.*, as it was clearly stated in HT manual that the Hall technique was contra-indicated in immunocompromised children and in patients that were at risk of infective endocarditis[156].

The articles that opposed the HT did not contain a strong evidence base, as they were based on opinion[179] and laboratory based studies. Thus, to date, there are no published studies that showed failure of HT or contradicted its use. Indeed, quite the opposite was reported[8][146][139][162][163]. Welbury stated in his recent article (2017) that clinicians need to be more advocates of HT not only to acknowledge the sound scientific principle, but to trust its efficacy and use it more[163].

2.42.5 Case selection and exercising clinical judgment

Clinicians require appropriate case selection, good clinical judgment and radiographic assessment to indicate or contradict the use of Hall technique. The use of less invasive procedures has advantages related to the preservation of pulp vitality and dental tissue as well as preserving the deciduous tooth in the dental arch prior to exfoliation. Moreover, it aids in the treatment of uncooperative children, reduce appointment time and change children's behavior with regards to dental care. However, not all carious primary molars can be treated using the Hall technique. This was clearly stated by those who advocated its use[104]. It is important to stress that the HT is an alternative to conventional preparation and not as a primary treatment for all patients [163].

2.42.6 The Hall technique and child friendly dental treatment

Children deserve better. 'Dentists need to be better trained in the diagnosis of the state of pulp in response to proximal caries in primary molars as stated by Duggal and Bani Hani (2015) [140]. In addition, children have limited ability to cope with restorative dental treatment and require a pediatric specialist to manage them ethically appropriate[158]. The welfare of a child is a paramount; caries that may cause pain and infection should not be left[159]. The HT gives clinician an extra way of management to achieve treatment relatively. This new technique has made a huge difference to children, parents and clinician in the way of management of caries in primary dentition[158][159]. It gave another biological solution to this major national and worldwide problem[158][159]. Evidence have shown the effect of HT in benefiting the child and show no harmful effect[158][159]. It is the duty of every dentist to provide the appropriate dental

treatment to children and their parents to reduce the caries burden[140][158][159]. Dental schools must teach all students their ethical responsibilities, their duty towards their profession, to the patients and society No profession will ever gain prominence if the sole objective of those professionals is self-centered development and financial motives[140].

2.50 PMCs in the UAE and our college HBMCDM

A recent study showed that dentists in the Gulf Cooperation Council (GCC), of which the UAE is part of, were aware of the HT, however clearly not in favor of using it[180]. PMCs are used in the UAE mostly by pediatric dentists[180]; however conventional preparations are usually adopted when carious primarily molars are used to treat children. In our college, HBMCDM, we had and still are practicing the use of PMCs using the internationally agreed conventional methods of preparation when appropriately indicated. However, in the presence of the new academic evidence emerging around the Hall technique, our college, an academic institution, could not ignore the evidence and openly started using the Hall technique since piloting it in April 2013, and formally adopting it as a treatment modality later in July 2014. While some studies have retrospectively audited the use of PMCs both methods, no studies have done so in the UAE to date. Thus, it was felt appropriate to study our own work by comparing the Hall technique PMC to a traditionally placed PMC by radiographically and clinical means.

2.60 Aim of the study

The aim was to conduct a retrospective study to evaluate the clinical and radiographic success of PMCs used to restore carious lesions in primary molars that were placed by means of both the traditional technique and the Hall technique in a postgraduate dental setting.

2.70 Null hypothesis

The Null Hypothesis was that was no clinical and radiographic difference between the Hall technique using PMCs (to seal-in caries) and the conventional approach (complete caries removal) in a postgraduate pediatric dentistry setting.

3.00 MATERIALS AND METHODS

In this chapter the study logistics will be presented, including the study design, criteria and statistical analysis.

3.10 Study design

This study is a Cohort retrospective study using HBMCDM (MBRU) pediatric dentistry patients' electronic cases notes and radiographic images to review all primary molar teeth dated from 1st July 2014 to 1st of March 2017 that had been treated with either conventional preparation/PMC or Hall Technique PMC in children.

3.20 Permission and ethical approval

A research protocol was conducted and reviewed locally by the MBRU Pediatric Dentistry Department. Later on, the Research Protocol was submitted to the Research and Ethics Review Committee of MBRU, and approval was obtained (see Appendix 1) to conduct the study.

3.30 Study population/ location

The study sample comprised all the dental records (written digital documents and radiographic images) of pediatric patients that visited MBRU clinical arm, Dubai Dental Clinic who received

either conventional preparation/PMC or Hall Technique PMC for treating their carious lesions.

3.40 Study inclusion and exclusion criteria

3.41 Criteria of inclusion

- Primary molars receiving PMCs (regardless of the technique) that had carious lesions large enough that the clinician felt a Class I or Class II restoration was unlikely to be successful for the life expectancy of the tooth, yet not so extensive that the patient was experiencing or clinically demonstrating any signs or symptoms of irreversible pulpitis.
- Carious lesion in a primary molar with no clinical or radiographic evidence of pulpitis, necrosis or abscess, as well as follow up of at least 6 months or until failure occurs.
- Children who had received treatment consisting of PMC placement by means of either traditional preparation or Hall Technique according to the Hall Technique manual's selection criteria.

3.42 Criteria of exclusion

- Patients with medical conditions that render the Hall technique contra-indicated such as patients at risk of infective endocarditis.
- Teeth with clinical signs or symptoms of irreversible pulpitis, or dental sepsis at the initial assessment.
- Teeth with radiographic signs of pulpal exposure, or interadicular/ periradicular pathology at the time of initial assessment.

- Teeth with extensive breakdown in their crowns due to caries that would preclude them from being considered as restorable with conventional or Hall technique.
- Teeth that underwent a pulpotomy or pulpectomy.

3.50 The outcome measures

We graded the restoration success based on previously used clinical and radiographic criteria originally used and defined (Innes *et al.*, 2007) [(9)]:

- Successful; documented information from the patient records (notes and radiographs) that:
  - The restoration appears satisfactory, no intervention required.
  - There are no clinical signs or symptoms of pulpal pathology.
  - No pathology visible on radiographs or
  - The tooth exfoliated naturally.
- Failure: documented information from the patient records (notes and radiographs) that:
  - 'Minor' failure – wear of the PMC, or reversible pulpitis, or loss of the crown (without irreversible pulpitis which could be managed by repair or replacement of the crown).
  - 'Major' failure – signs or symptoms of irreversible pulpal damage, dental abscess and un-restorable tooth. Also if tooth was extracted.

3.60 Sample type and size

A convenience sample of all the children who attended MBRU who received traditional PMCs or HT crowns in the said period were studied. A sample of 187 teeth was collected from all the

children who satisfied the inclusion criteria; their data was collected from July 2014 to March 2017. Six participants who received 13 PMCs from the start were not included due to inadequate follow-up time.

3.70 Data collection

The data were collected by accessing the digital files from Dentimax™ and Dental4Windows™ patients record systems and recording clinical and radiographical data from baseline, and 6, 12 and 18 months respectively in a proforma (Appendix 2). The review period was 32 months between July 1, 2014, and March 1, 2017. A pilot study was conducted to check the feasibility of the data collection sheet. A total of 10 crowned teeth were recorded to check for inter-and intra-examiner reliability. 10 records were assessed twice with a one-week gap for inter-examiner reliability and the results were 100% reliable. The same 10 records then were audited and assessed separately with another assessor to check for intra-examiner reliability and the result were 100% reliable. For that, no statistical analysis was computed due to the constant results between the two examiners.

The variables that were included in the data collection sheet were file number, gender, age, tooth number, treated, by Hall PMC (given a code 1) or conventional PMC (given a code 2), initial radiograph, crown present or crown lost, tooth naturally shed or extracted, clinical symptoms and radiographic pathology at 6, 12, 18 months' follow-up (Appendix2).

3.80 Statistical analysis

The data were collected using the data sheet, transferred to computer-spread sheets and analysed using computerized Statistical Package for Social Sciences (SPSS, version 20, Chicago, SPSS Inc). Descriptive statistics were performed for the general description of the data. A Kaplan-Meir survival curve was used to evaluate the HT and conventional PMCs survival. The level of statistical significance was set at 5%.

3.90 Ethical issues

The proposal of this study was submitted and approved by the research and ethics committee of MBRU. This study was conducted in full conformance with principles of the Good Clinical Practice (GCP) and within the laws and regulations of Dubai. All data collected was anonymous and no patients' identifiers were used.

3.100 Assessors

The main assessor was Dr H Bin Laden with Dr I. Hussein and Dr M. Al-Halabi and Dr M Kowash as secondary assessors. Calibration for measuring success and failure criteria of the PMCs radiographically and completion of the proforma, was carried out to increase inter and intra examiner reliability (kappa test: No statistic is computed because the two examiners results are constant). A pilot trial was conducted to allow assessment for feasibility.

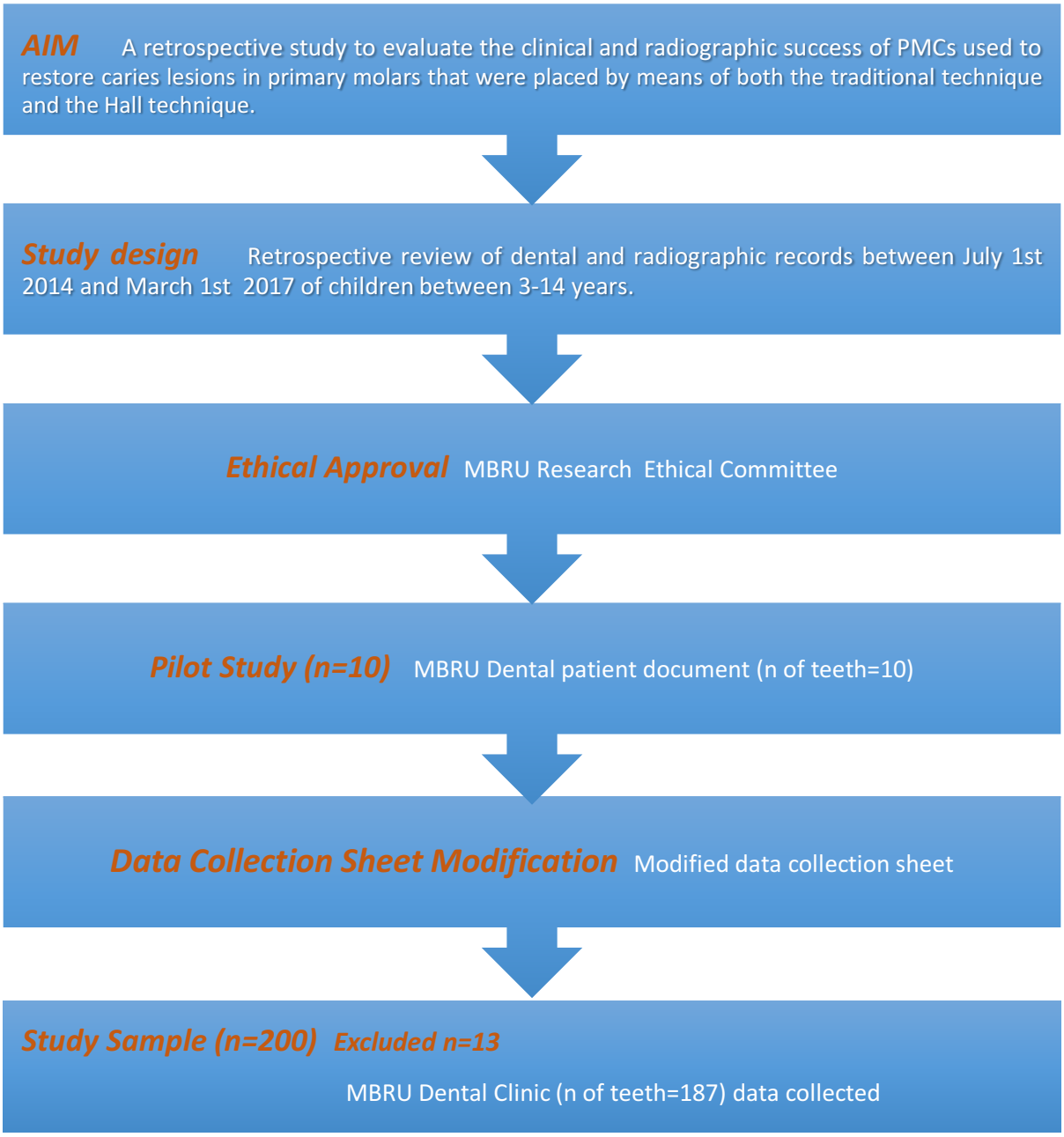


Figure 3.1: Study methodology summary flowchart

4.00 RESULTS

In this chapter, the study results are presented, in the following order: the demographics, baseline characteristics, six, 12 and 18 months follow up results and the overall survival curve of the PMCs provided.

4.10 Demographic characteristics of the study

4.11 Study population

Our pool of patients for this study was those who had attended with their carers /parents to our college, the HBMCDM. The records of 71 children (n=200 teeth) who had received PMCs were randomly audited both clinical notes and radiographs between 1st July 2014 and 1st March 2017. Several children were treated by means of PMC conventional preparation alone, others by HT and the rest were treated by the combination of both. Six participants who received 13 PMCs were excluded, owing to inadequate initial and follow up documentation. This left us with 65 children with 187 PMCs. Amongst the 65 children, the number of children who had been treated by the PMC conventional preparation and PMC HT were 20 (31%) and 33 (51%) patients respectively. The remaining 12 (18%) children received the combination of both treatments (as seen in Figure 4.1). These children were followed up for an average of 12 months (range; 6-18 months).

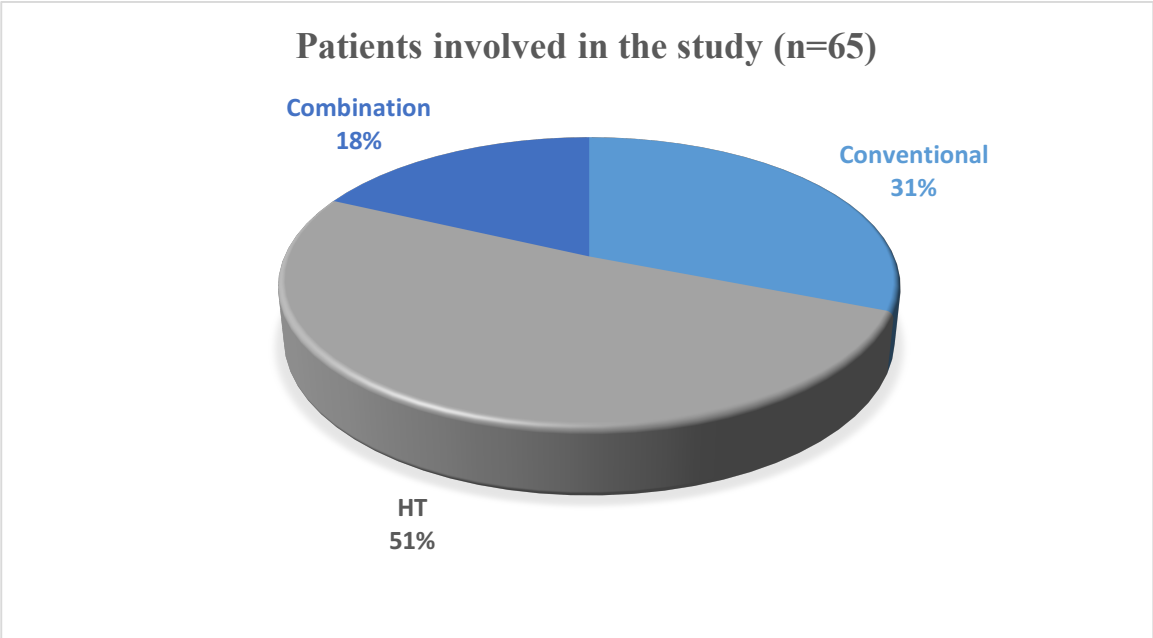


Figure 4.1: Patients involved in the study

4.12 Gender distribution and PMCs

The total of 65 children, who were treated by means of HT and PMC conventional preparation to treat carious lesions in their primary molars were composed of 31 males (47.6%) and 34 females (52.3%). The males in the study received 88 PMCs (47.1%); while females received 99 PMCs (52.9%) (as seen in Figure 4.2).

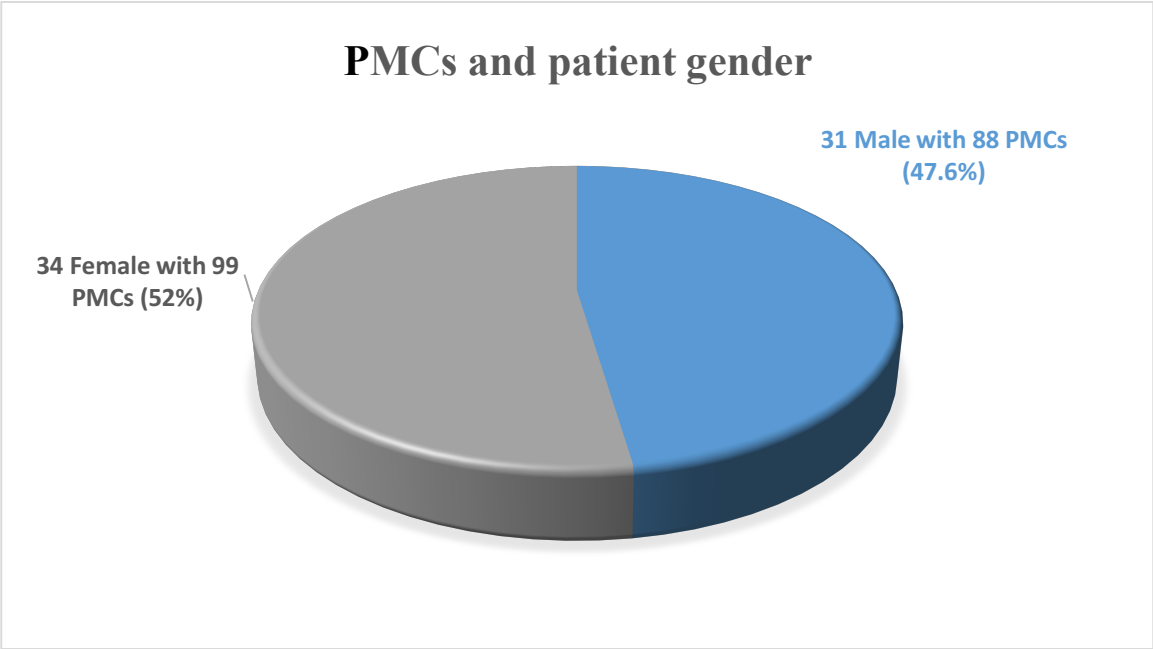


Figure 4.2: PMCs (HT/conventional) and patient gender

Out of the total of 187 PMCs, 99 PMCs (52.9%) were used in females, of which 67 PMCs (61%) were by HT means while 32 PMCs (41.5%) were conventionally prepared. Male patients involved in the study received 88 (47.1%) PMCs; of which 43 (39%) were HT and 45 PMCs (58.4%) were prepared conventionally (as seen in Table 4.1 and figure 4.3).

Initial base-line information	Hall n(%)	Conventional n(%)	Total n(%)
Male	43(39.09)	45(58.4)	88(47.1)
Female	67(60.9)	32(41.6)	99(52.9)
Total	110(100)	77(100)	187(100)

Table 4.1: Male and female PMCs distribution at baseline.

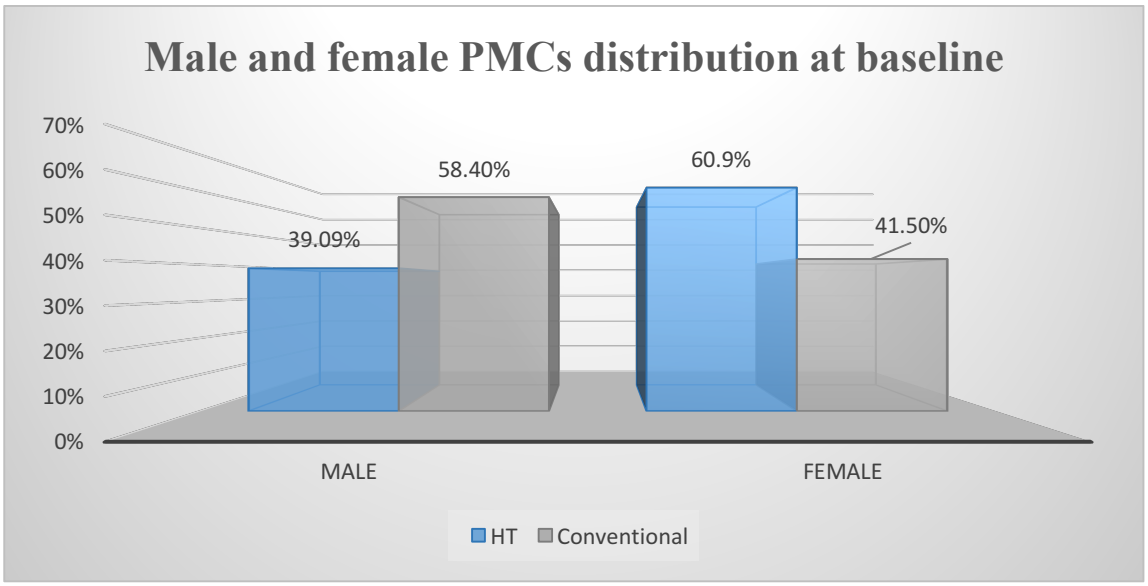


Figure 4.3: Male and female PMCs distribution at baseline.

4.13 Age distribution

The mean (standard deviation/SD) age of the study children at the time of treatment was 6.44 (1.48) years for those treated utilizing the HT and 6.45 (2.0) years for those treated with a conventional preparation. The distribution of the HT/conventional PMCs according to age is shown in Figure 4.4. The results showed that the largest proportion of HT PMCs was placed in patients aged five years (30.9%), while 22.1% of conventional PMCs were placed in children aged six and eight. A 14-year-old child was included in the sample. From the clinical and radiographic documentation, it was found that this patient had a congenital missing 2nd premolar and the primary second molar was retained with a conventional PMC means.

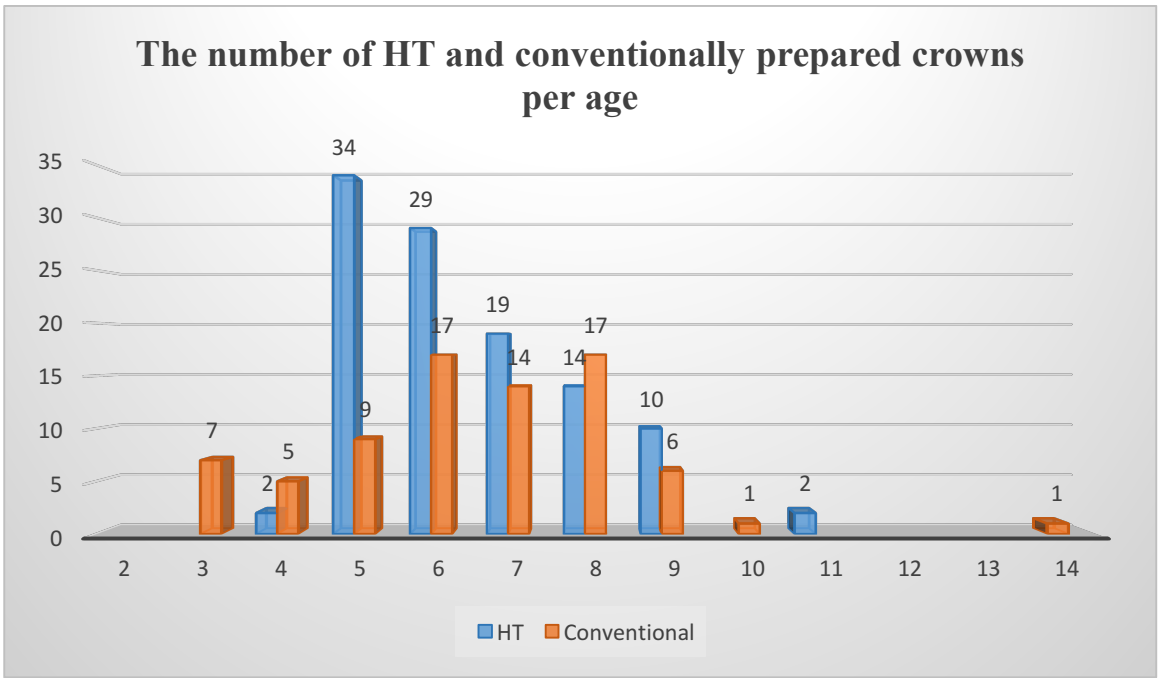


Figure 4.4: Distribution of PMCs (HT and conventional) per age.

4.14 Number of teeth restored with the HT and conventional PMCs

A total of 187 teeth, that fulfilled the criteria of inclusion, were included in this study. These were randomly collected from the case notes of patients treated, between the 1st of July 2014 to the 1st of March 2017. 110 (59%) PMCs were restored by means of the HT and 77 (41%) were restored by means of conventional preparation (Figure 4.5). The treatment was carried out to treat primary carious molars with no pulpal involvement.

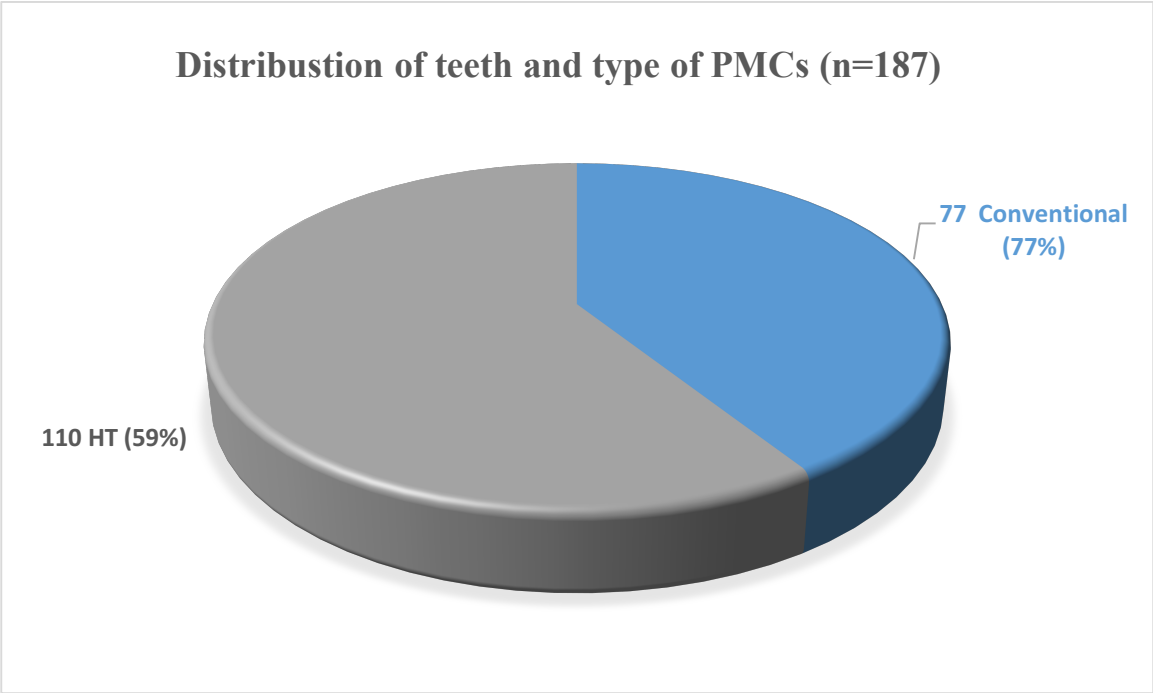


Figure 4.5: Total number of teeth restored with PMCs according to type of PMC (HT or conventional).

4.15 Tooth baseline characteristics

We described the baseline characteristics of the 187 teeth that were covered by PMCs to treat carious lesions. A total of 65 radiographic pairs (bitewings) were taken for all the children showing all the 187 mandibular and maxillary primary molar teeth used in this study. Out of the 77 PMCs prepared by the conventional means; 41 (53.2%) were carious 2nd primary molars (Es) while 36 teeth (46.7%) were carious 1st primary molars (Ds). On the other hand, out of the 110 PMCs restored by the HT; 43 (39%) of them were carious 2nd primary molars (Es) and 67 teeth (61%) were 1st primary molars (Ds) (as seen in Figures 4.6).

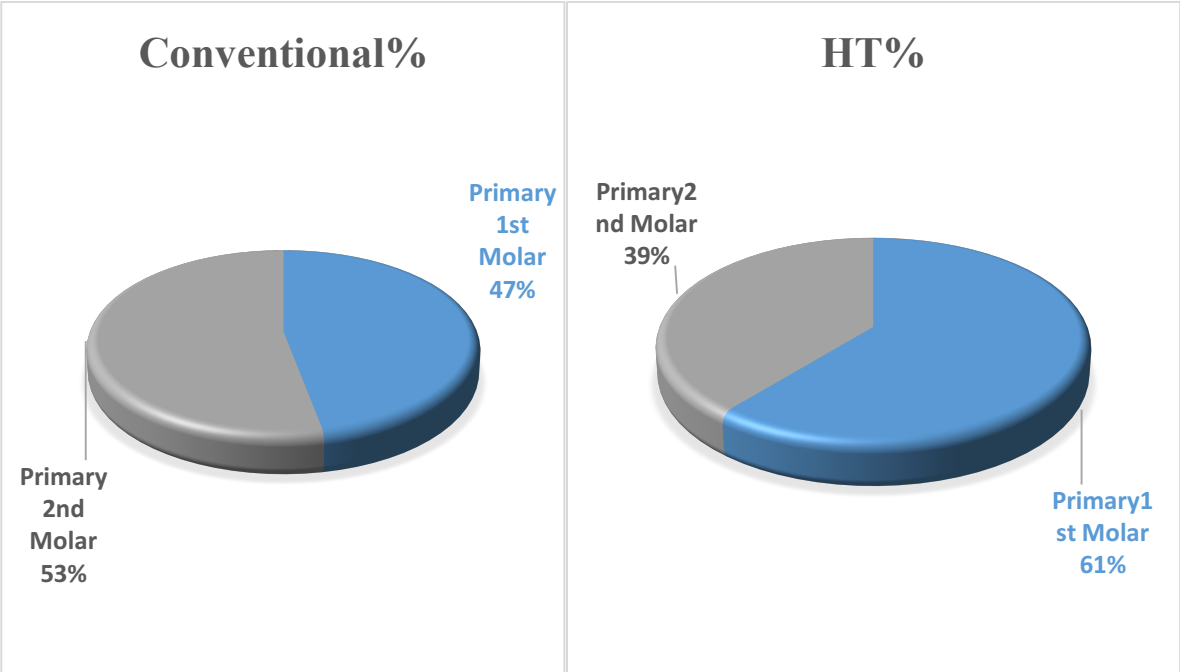


Figure 4.6: The percentage of primary 1st and 2nd molars in relation to conventional and HT preparation (1: first primary molar, 2: second primary molar).

4.20 PMC results at six-month follow up

In this section, the clinical success of the PMCs (which included presence or absence of PMC, tooth shed or not, tooth extracted or not and symptoms present or not) in addition to radiographic presence of pathology at six months are presented.

4.21 Tooth/PMC success/failure status at six months

The documentation of the 187 teeth at six month follow up revealed 100% success of all the teeth that have been treated by the HT (110 PMCs) and 98.7% for the teeth that had been treated by conventional means (76 PMCs) (as seen in Tables 4.2). The restoration success at six months was graded based on the criteria originally defined by Innes and colleagues (2007)[9]. A successful restoration was recorded as "crown present" (date of last examination recorded without tooth exfoliation, the crown being present and no further treatment required) or tooth exfoliation (date of last examination recorded before recorded tooth exfoliation) (these distributions are documented in Table 4.4). At the six-month recall, none of the treated teeth had exfoliated nor were extracted. One PMC placed by conventional preparation experienced a "minor failure" in retention and crown loss (an upper left 2nd primary molar). However, the conventionally failed crown was recorded later as "major failure" due to root resorption and no further treatment was recorded. Figure 4.7 shows the overall success and failure rate of the conventionally prepared and HT PMCs.

Crown present at 6 months	Success n(%)	Failure n(%)
PMCs	186(99.4)	1(0.52)
Crown present n(%)	**Hall n(%)**	**Conventional n(%)**
Success	110(100)	76(98.7)
Failure	0(0)	1(1.3)
Total	**110(100)**	**77(100)**

Table 4.2: The overall success and failure of HT and conventionally prepared PMCs crowns at six months.

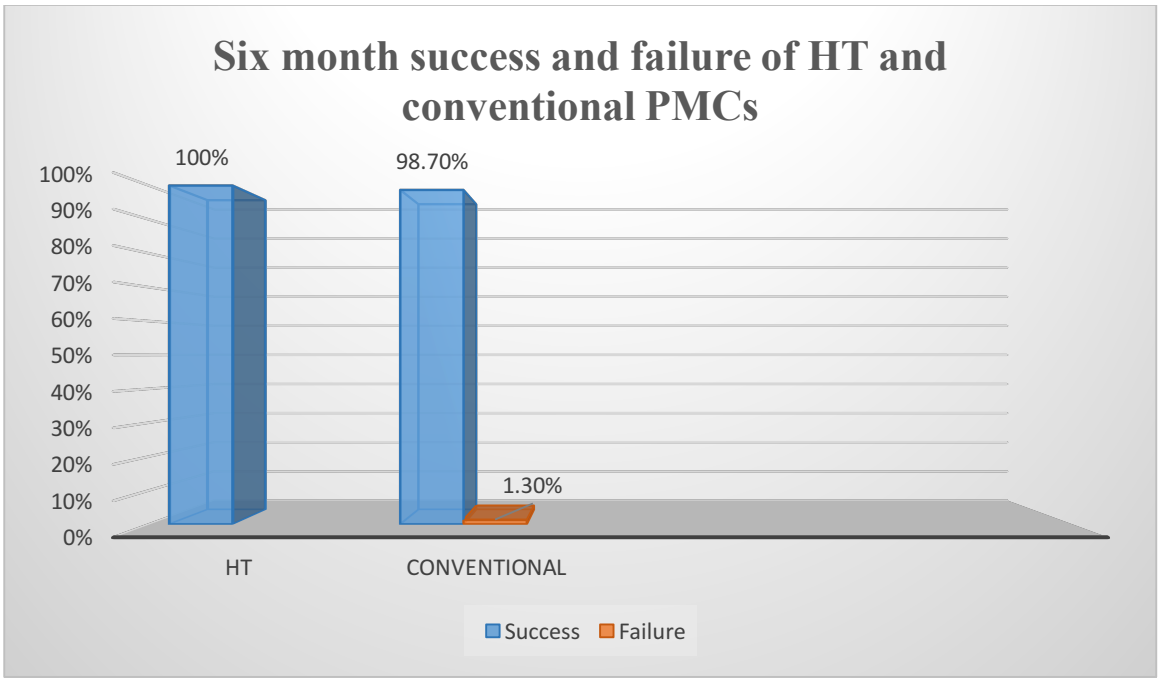


Figure 4.7: The overall success and failure of HT and conventionally prepared PMCs crowns at six months.

4.22 Radiographic results at six months

At six months, follow up of the 187 teeth, the success was measured by assessing the radiographs or documented radiographic reports of the follow up radiographs (bitewings). The presence of pathology was recorded as yes/no. Table 4.3 and Figure 4.8 show the pathology status on the radiographs that were taken to document the success and failure of PMCs at the six-month recall period. There was only one 1 PMC (0.53%) with documented radiographic pathology. This was a conventional PMC that was considered a "major failure" due improper

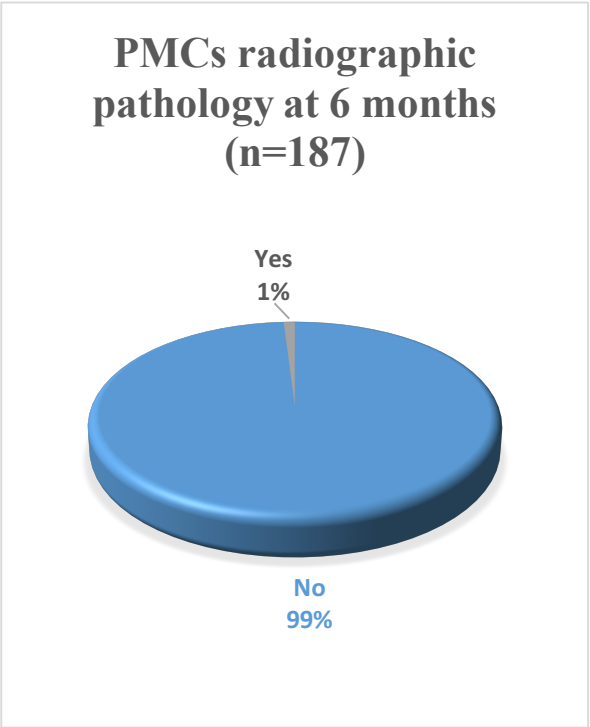
crown selection loss of crown (as highlighted above in section). This was documented in the radiographic report with no history of pain and abscess.

4.23 Symptoms presence at six months

At six months, clinical records of the follow up of the 187 teeth were noted by assessing the clinical documentation. The presence of symptoms was recorded as yes/no. Table 4.3 and Figures 4.8 show the results. None of the 187 teeth were recorded to have symptoms. The exception was the tooth that had lost its PMC as highlighted above. The lost and failed PMC due to improper crown selection and was conventionally prepared. This was documented clinically with no history of pain and abscess, but was considered a symptom.

Radiographs @ 6months	Hall n(%)	Conventional n(%)	Total n(%)
No pathology	110(100)	76 (98.7)	186(99.47)
Pathology/Failure	0(0)	1(1.3)	1(0.53)
Symptoms @ 6 months	Hall n(%)	Conventional n(%)	Total n(%)
No	110(100)	76 (98.7)	186(99.47)
Yes	0(0)	1(1.3)	1(0.53)

Table 4.3: Six month radiographic and clinical symptoms of PMCs



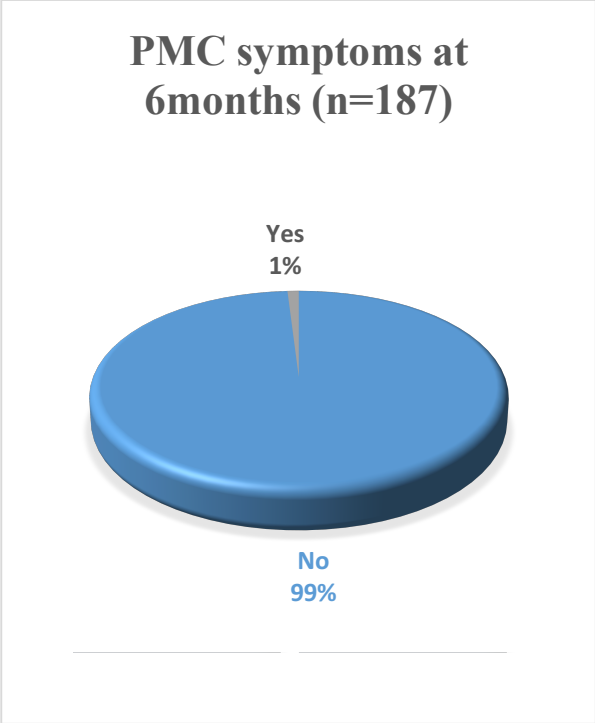


Figure 4.8: Six month radiographic and clinical symptoms of PMCs

4.30 PMC results at 12 month follow up

In this section, the clinical success of the PMCs (which included presence or absence of PMC, tooth shed or not, tooth extracted or not and symptoms present or not) in addition to radiographic presence of pathology at 12 months are presented.

4.31 Tooth/PMC success/failure status at 12 months

The overall success of the PMCs was 183 PMCs (97.8%-out of 187) at 12 months. The clinical success of the teeth (assessed by recording PMC presence or not, tooth shed or not, tooth extracted or not and the presence of symptoms) that had been treated by the HT and conventional

preparation methods were 99% and 96.1% respectively (as seen in Table 4.4 and 4.5). The restorations success at 12-month was graded with the presence of all PMCs and no loss of tooth due to extraction. All the PMCs that were placed by HT, were graded as successful at 12 months except one. HT PMC failed due to observed perforation identified during routine examination. It was considered as a minor failure too and the crown was replaced by a new PMCs placed by HT. Two PMCs placed with a conventional preparation failed because of abscess formation/infection at 11-12 months respectively and the teeth were extracted accordingly (Figure 4.9). These teeth were considered to have a "major failure" according to Innes *et al.* (2007) criteria of success and failure [9].

PMCs @12-month	Success	Failure
PMCs	183(97.8)	3(2.2)
PMCs @ 12 months	**Hall n(%)**	**Conventional n(%)**
Success	109(99.1)	74(96.1)
Failure	1(0.9)	3(3.9)

Table 4.4: The overall success and failure of HT and conventionally prepared PMCs crowns at 12-month follow up.

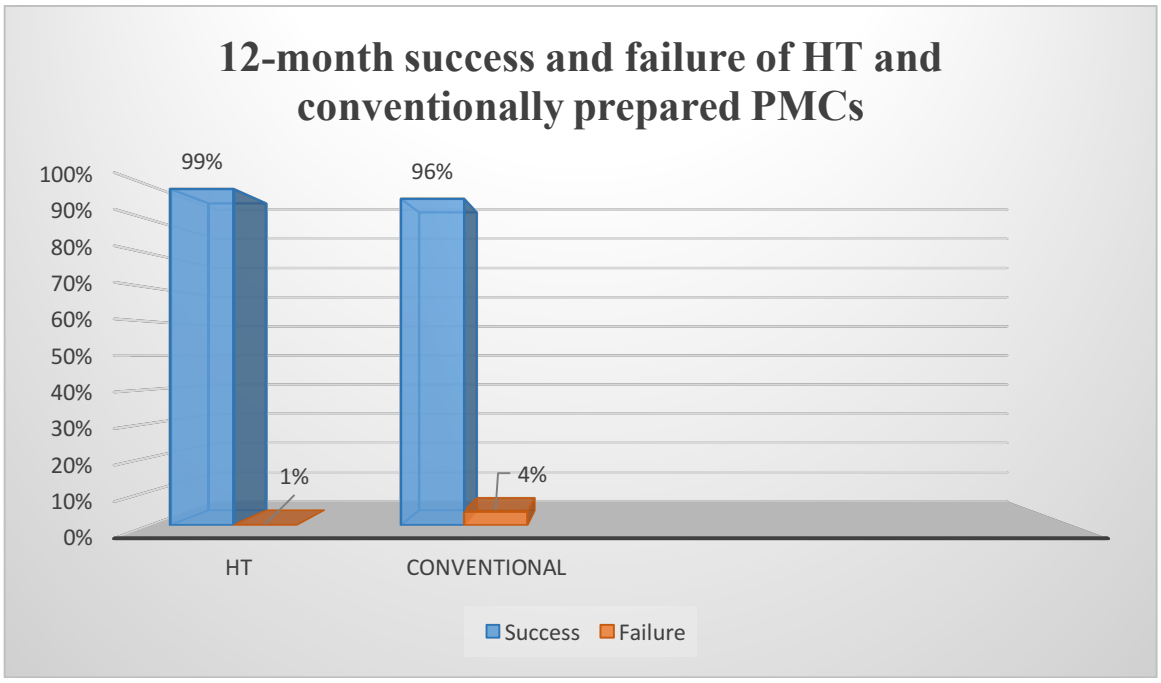


Figure 4.9: The overall success and failure of HT and conventionally prepared PMCs crowns within 12-month.

Tooth shed @ 12-months	Hall n(%)	Conventional n(%)	Total n(%)
Yes	0(0)	0(0)	0(0)
No	110(100)	77(100)	186(100)
Tooth extracted @ 12-months (n=187)	Hall n(%)	Conventional n(%)	Total n(%)
Yes	0(0)	2(2.6)	2(2.6)
No	110(100)	75(97.4)	184(98.8)

Table 4.5: Tooth shed and extraction distribution at 12-month follow up.

4.32 Radiographic results at 12 months

Table 4.6 and Figure 4.10 show number of teeth that were followed up at this point (12 months). 186 PMCs crown were followed radiographically, two conventional prepared crowns (both were lower D's) were reported as having inter-radicular pathology. As highlighted above, these two teeth were extracted.

4.33 Symptoms presence at 12 month

At 12 months, symptoms of the 186 teeth were noted by assessing the clinical documentation. The presence of symptoms was recorded as yes/no. Three teeth (1.7%) were recorded as having symptoms. As outlined above, 2 of the conventional PMCs had symptoms of pain and sepsis was documented as a "major failure". One HT PMC was perforated, this was documented clinically with no history of pain and abscess, but was considered a symptom accordingly (see Table 4.6 and Figure 4.10).

Radiographs @ 12-month	Hall n(%)	Conventional n(%)	Total n(%)
No Pathology	110(100)	74(96.1)	184(98.4)
Pathology	0(0)	3(3.9)	3(1.6)
Symptoms @ 12 months n(%)	Hall n(%)	Conventional n(%)	Total n(%)
No	109(99.1)	74 (96.1)	183(98.3)
Yes/ Failure	1(0.9)	3(3.9)	4(2.1)

Table 4.6: 12 month radiographic and clinical symptoms of PMCs

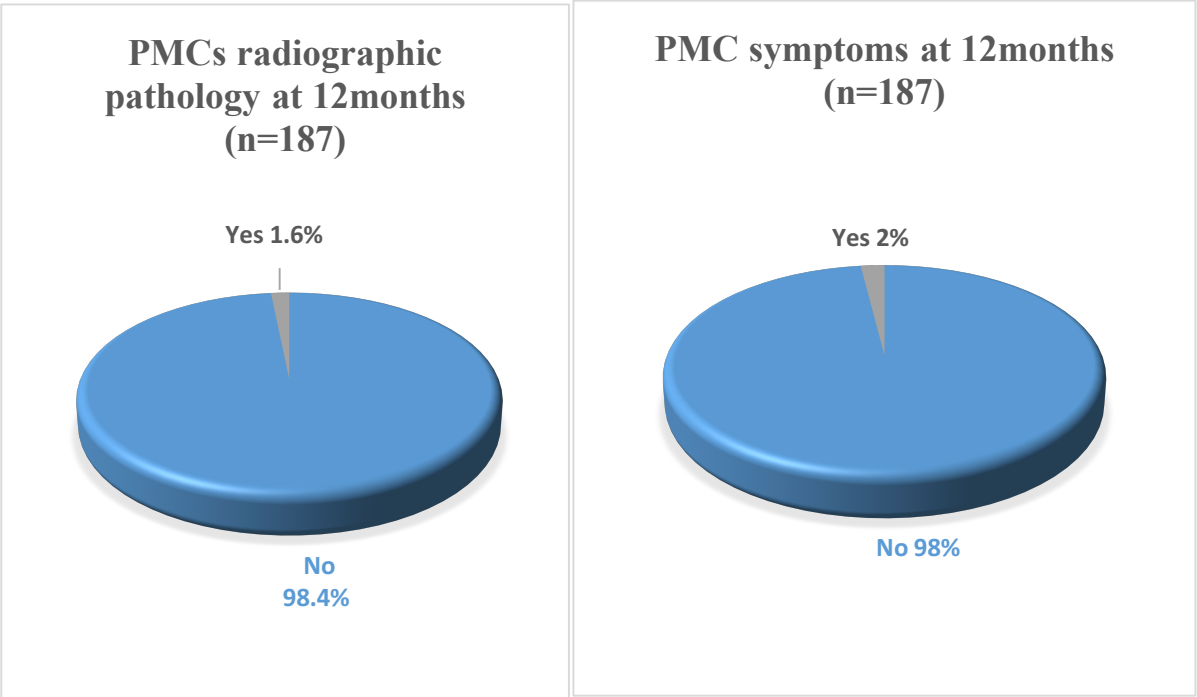


Figure 4.10: PMCs Radiographic and clinical symptoms presence at 12 months.

4.40 PMC results at 18 month follow up

In this section, the clinical success of the PMCs (which included presence or absence of PMC, tooth shed or not, tooth extracted or not and symptoms present or not) in addition to radiographic presence of pathology at 18 months are presented.

4.41 Tooth/PMC success/failure status at 18 months

At this stage and due to loss of patients not attending their 18 month follow up, we suffered a slight drop in numbers of patients and subsequently PMCs followed up. Only 148 PMCs were followed for 18-month clinically, radiographically or both for its success or failure from the 187 PMCs. No new failures were observed at this stage of the study. Out of these 148 PMCs, two teeth exfoliated naturally, but were not considered failures. The first of these two PMCs was a primary 1st molar treated by HT means, while the other one was a primary 1st molar treated by conventional means. By adding the four previously failed PMCs (at 6 and 18 months) this made the total PMCs followed up at 18 months to be 152 PMCs; one "minor" for the HT PMCs and three "major failures" for the conventional PMCs teeth treated by conventional means were extracted due to sepsis and pain since the 12-month period (Table 4.7 and 8). The successful HT PMCs were 89 out of 90 while the conventional PMCs were 59 out of 62.

PMCs @ 18 months	Hall n(%)	Conventional n(%)
Success	89(99)	59(95)
Failure	1(1)	3(5)

Table 4.7: The overall success and failure PMCs crowns at 18-months.

Tooth Shed @ 18-months	Hall n(%)	Conventional n(%)	Total n(%)
Yes	1(1)	1(1)	2(1.4)
No	89 (99)	61(99)	150(98.6)
Total	**90(100)**	**62(100)**	**152(100)**
Tooth extracted 18month	**Hall**	**Conventional**	**Total**
Yes	0(0)	2(1.4)	2(1.4)
No	90(100)	60(98.6)	150(98.6)
Total	**90(100)**	**62(100)**	**152(100)**

Table 4.8: Tooth shed and extraction distribution at 18-month follow up.

4.42 Radiographic results at 18 months

Table 4.9 and Figure 4.11 show number of teeth that were followed up at this point (18 months). 152 PMCs crown were followed radiographically. Two conventional prepared crowns (Ds) were

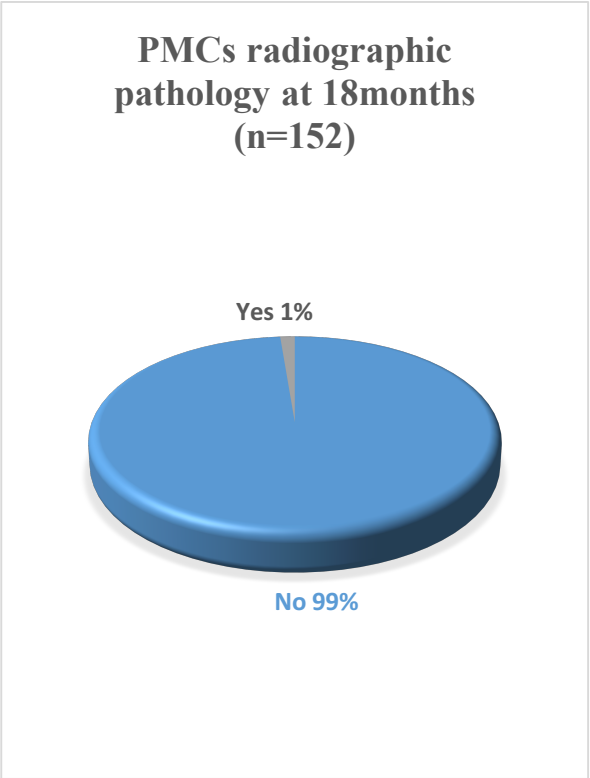
reported as having inter-radicular pathology. As highlighted above, these two teeth were extracted.

4.43 Symptoms presence at 18 months

At 18 months, symptoms of the 152 teeth were noted by assessing the clinical documentation. The presence of symptoms was recorded as yes/no. Four teeth (2.6%) were recorded as having symptoms. As outlined above, one conventionally prepared tooth the crown was lost at six months due to improper crown selection, two of the conventional PMCs at 12-month recall that were extracted had symptoms of pain and sepsis and one HT was perforated. (see Table 4.9 and Figure 4.11).

Radiographs @ 18-month	Hall n(%)	Conventional n(%)	Total n(%)
No Pathology	90(100)	60(97)	150(98.7)
Pathology	0(0)	2(3)	2(1.3)
Symptoms @ 18 months	Hall n(%)	Conventional N(%)	Total n(%)
No	89(98.8)	59(95.1)	148(97.4)
Yes	1(1.2)	3(4.9)	4(2.6)

Table 4.9: 18 month clinical symptoms of PMCs.



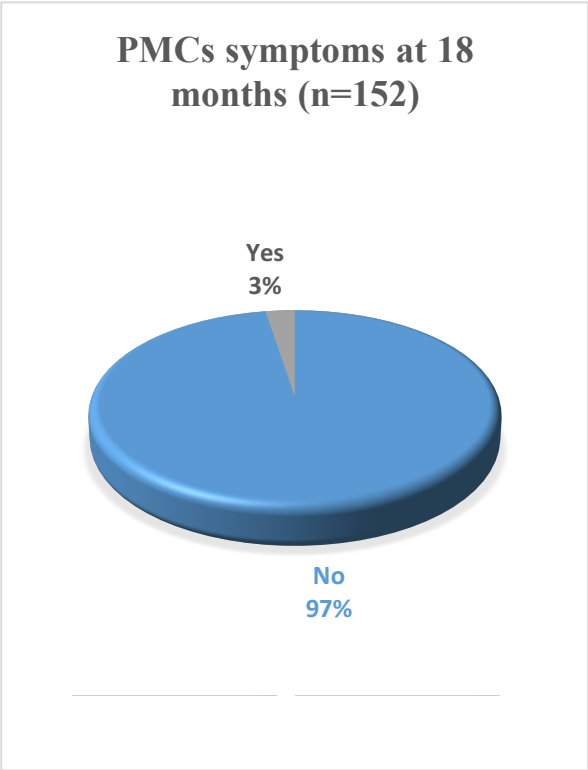


Figure 4.11: Radiographic and clinical symptoms presence at 18 months.

4.50 Summary of the overall results

The study started with 187 PMCs at baseline. We followed up 187 for six-months, 187 were followed for 12-months and finally 152 PMCs were followed for 18-month clinically, radiographically or both for their success or failure (See Figure 4.12). At the six months' point of cut off we graded 100% (110 out of 110) PMCs placed by the means of HT technique to be successful, whereas 98.7% (76 out of 77) of the PMCs placed by the means of conventional reparation were graded as successful. At the 12-month point of the study we graded 99.1% of PMCs (109 out of 110) placed by the means of HT technique to be successful, whereas 96.1%. (74 out of 77) of the PMCs placed by the means of conventional preparation were graded as successful. The observed failure of HT PMC was the result of perforation. Three PMCs placed

by the conventional preparation means failed because of crown loss (retention) and abscess (infection). These results represent the one year follow up results. At the 18 months' point of the study, as we followed up only 148 of the PMCs, the results related to the 148 PMCs (89 HT and 59 conventional PMCs) can only be reported, in addition to the four PMCs that had previously failed (making the total out of 152 PMCs; 90 for the HT PMCs and 62 for the conventional PMCs). We graded 98.8% PMCs placed by the means of HT technique to be successful (89 out of 90) at 18 months, whereas 95.1% (59 out of 62) PMCs placed by the means of conventional preparation were graded as successful. The two conventional PMCs that had failed at the previous stages were due to improper crown selection and pain and sepsis.

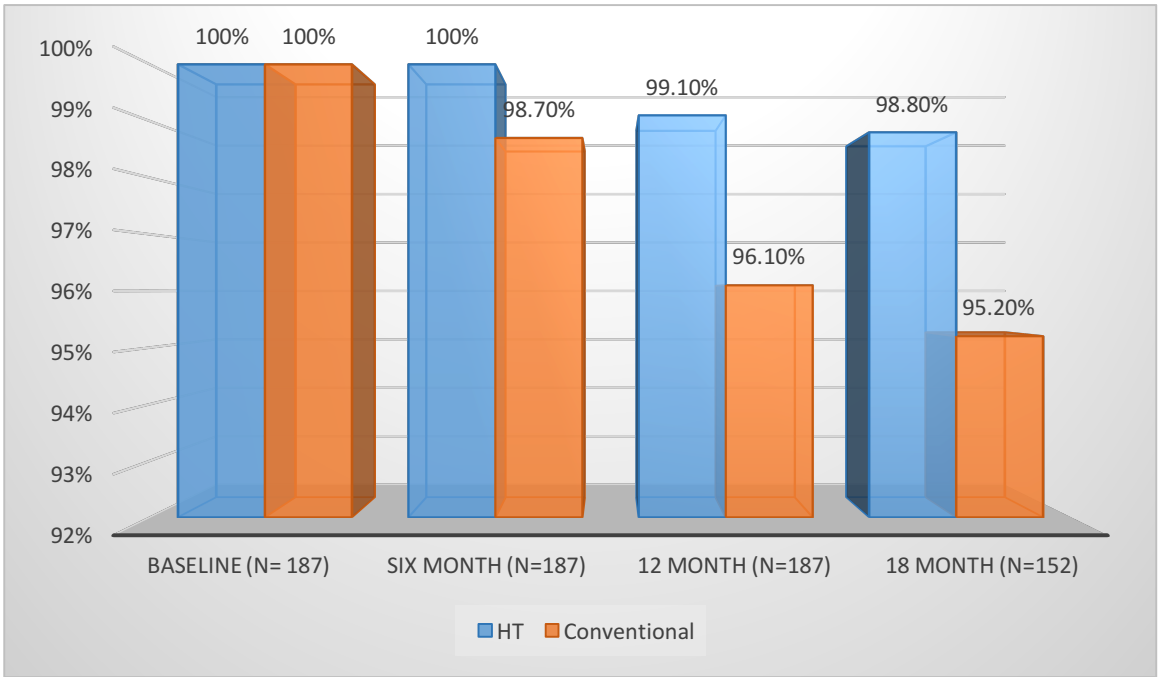


Figure 4.12: The distribution of PMC success and failure grading of the whole study period. 18 months follow up results are included but are not representative of the total sample.

	Conventional preparation (n=77)			Hall technique (n=110)		
Outcomes @	**6 months n=77(%)**	**12-months n=76(%)**	**18-months n=62 (%)**	**6-months n=110(%)**	**12-months n=110(%)**	**18-months n=90(%)**
Crown present						
Yes	76 (98.7)	74 (96.1)	59 (95)	110 (100)	109 (99.1)	89 (98.8)
No	1(1.3)	2(2.59)	3(5)	0(0.0)	1(0.9)	1(1.2)
Tooth shed						
Yes	0(0)	0(0)	1(1.6)	0(0)	0(0)	1(1.2)
No	77 (100)	76(100)	61(98.4)	110(100)	110(100)	89(98.8)
Tooth extracted						
Yes	0(0)	2(2.6)	2(3.2)	0(0)	0(0)	0(0)
No	77(100)	74 (97.4)	60(96.8)	110(100)	110(10)	90(100)
Radiograph pathology						
Yes	1(1.2)	2(2.6)	3(5)	0(0)	1(0.9	1(1.2)
No	76 (98.8)	74 (97.4)	59 (95)	110 (100)	109 (99.1)	89 (98.8)
Symptoms						
Yes	1(1.2)	2(2.6)	3(5)	0(0)	1(0.9)	1(1.2)
No	76(98.8)	74(97.4)	59 (95)	110(100)	109 (99.1)	89(98.8)

Table 4.10: The overall distribution of PMC success and failure grading.

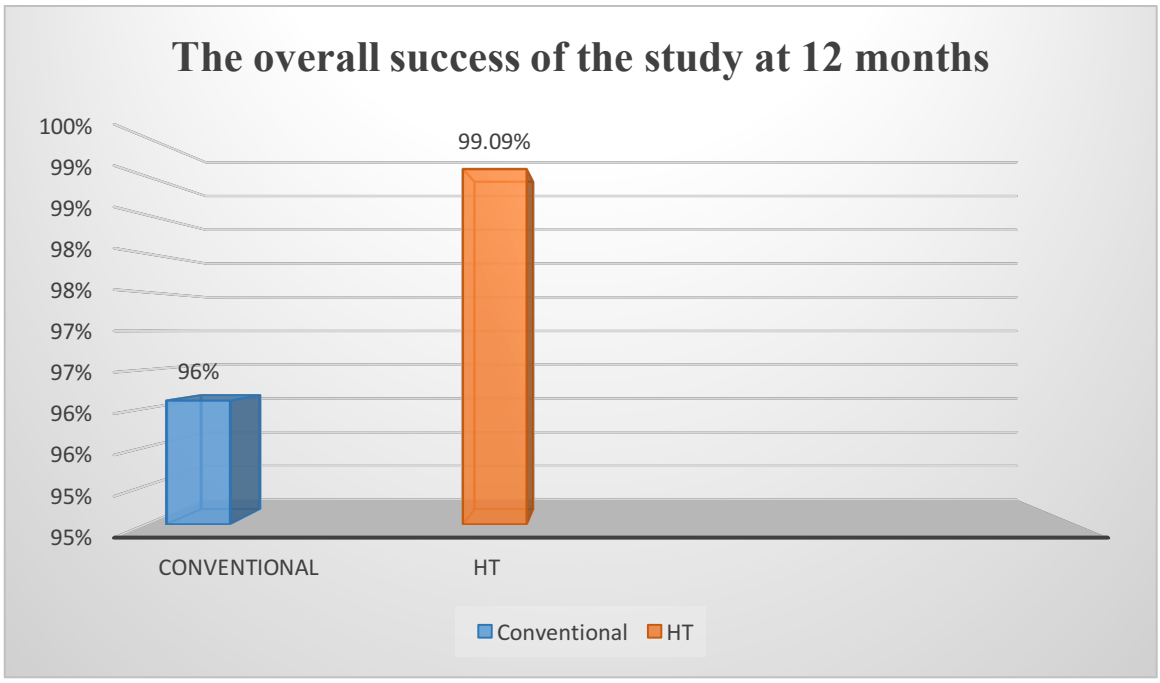


Figure 4.13: The overall success of the PMCs at 12 months (stating no significant differences between the two (the p value more than 5%)**).**

4.51 PMC survival curve

A Kaplan-Meier survival curve (Figure 4.14) for length of 18 months after crown placement until occurrence of the failure for conventional preparation and Hall Technique methods was created. The numbers of teeth still at risk of experiencing a failure at date of point were indicated (censored).

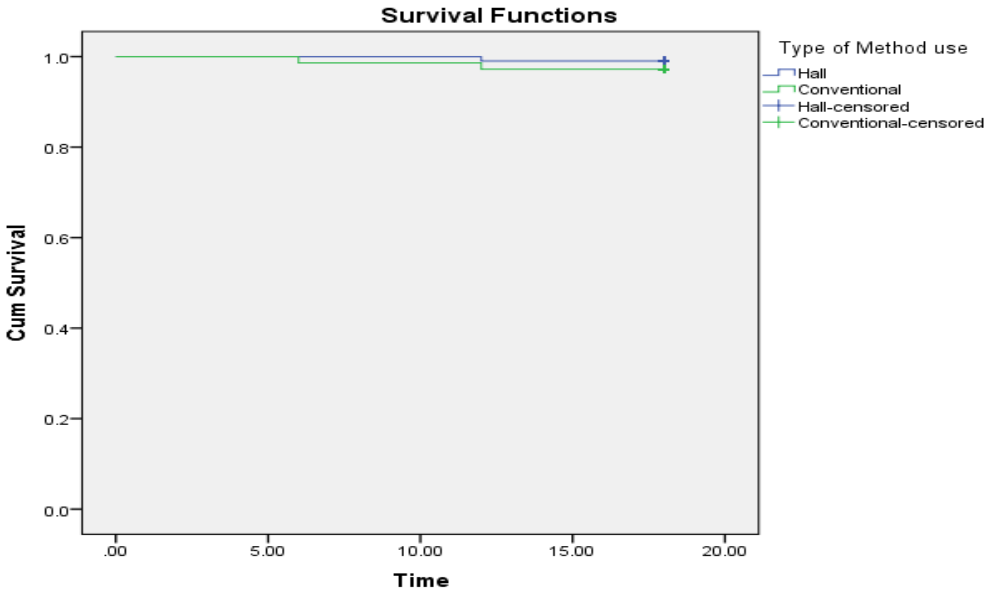


Figure 4.14: Overall survival curve.

Both methods showed comparability in term of proportions of success and average time of failure, where the p-value was 0.362 (not significant). The failure over the period of follow up was 3(3%) on the conventional preparation method with average time in 9.7 months while the failure of the Hall Technique was 1(0.2%) with average time of failure 9.9 months.

5.00 DISCUSSION

5.10 Introduction

Dental caries in an early age can affect children's oral health, nutrition and their quality of life if neglect occurs [159]. Different strategies and techniques are used to treat carious primary teeth in children[93]. Dentists in the GCC region including the UAE were shown to disagree on the restorative treatment modality for primary molar teeth[180]. The restorative technique, material used, age and the ability of children to cooperate affects the treatment plan. On one hand, traditional restorations are mainly used to treat multi-surface carious primary molars and may require a pediatric specialist, local anesthesia and the use of sedation or general anesthesia if the child is un-cooperative or medically compromised. On the other hand, the biological methods such as the Hall technique had been demonstrated to be a predictably successful restoration in children, becoming a global phenomenon[130][158]. Besides many postgraduate pediatric programs teaching this technique and including it in their curriculum, many countries now widely utilize the Hall technique as a biological approach for treatment of caries in the primary molars such as: Australia, Belgium, Brazil, Chile, Germany, India, Netherlands. New Zealand, UAE, UK and the and to a lesser extent in the US [158][159].

In summary, a review of the literature reveals that many studies had been conducted worldwide assessing the success of the Hall technique in managing carious primary molars. Many of these studies found that using PMCs done by HT was as successful as conventional restorations and considered it as part of the biological approach in sealing in caries [7][9][124][141][146][159][162][163][169][167][174][182][184]. Within these studies, there were retrospective case

note studies and randomized control studies, however no randomized control trials have directly compared the HT with conventionally placed crowns. The first study regarding the Hall technique was a simple 2-year retrospective audit of Dr. Hall's HT cases [(9)] where 111 crowns were monitored for two years; 91 (82%) were successful indicating that the HT had a high survival rates comparable to conventional restorative options being used in primary care and accepted by the general dentist [(158) (159)]. Another analysis of a larger sample was conducted retrospectively by Innes *et al.* in 2006 from1988 to 2001, showing similar results [(9)]. Furthermore, three separate randomized control trials demonstrated the effectiveness of crowns placed using the HT to seal dental caries. Although, these studies compared the Hall Technique with plastic restorations; the first study was set in a general dental practice in Scotland [(171) (182)] and the other one was in a German dental hospital where specialists and trainees provided all the care [(182)]and the third one with similar hypothesis was in Australia (Tonmukayakul *et al.* in 2015)[(183)].

Innes and her colleagues (2007) published a randomized clinical trial (RCT) that assessed the success of HT-placed crowns in Scotland [(170)(182)(183)]. This trial differed from our study by being a prospective study with a sample random selection decreasing the selection bias. It was 2-year then five years split mouth RCT comparing HT-placed crown with other GDP placed restorations [(167) (182) (183)]. The treatment was performed by 17 general practitioners while in our study pediatric specialist and trainees provided the treatment and we compared Hall PMCs to conventionally placed ones. Innes and her colleagues conducted an outcome criterion that we based our results upon [(182)]. Ricketts *et al.* (2013) furthermore, did a systemic review of all these mentioned studies, in addition to studies that managed dental caries in permanent teeth in children [(124)]. They compared parallel group and split-mouth randomized and quasi-randomized controlled trials comparing stepwise, partial or no dentinal caries removal with complete caries

removal, in unrestored primary and permanent teeth [124], favoring sealing dental caries as a treatment option.

Only two retrospective study in the USA were performed by pediatric dental specialists and assessed the success rate of conventional- and HT-placed crowns following Innes *et al.* (2007) success criteria [146] [184]. The success was based on the crown being present with no clinical or radiographic pathology and no further treatment being required.

In this chapter, the study results are discussed, including the demographic, baseline characteristics, the overall of the six, 12 and 18 month results and the overall limitations of the study. The results of our study were in line with those of previous studies showing that the Hall technique can result in a clinically sound restoration as successful as the conventionally placed crown.

5.20 Why is this study important?

Non-invasive child friendly treatment modalities in managing dental caries in children, is no longer a dental eutopia, and there is a strong plethora of evidence coming out in support of such a school of thought. The results of this study contribute to the mounting evidence related to the assessment of the use of the Hall technique in clinical practice. This study was important because it was the first cohort retrospective study that had been conducted to assess the HT as a method of sealing caries in primary molars in a region where the HT was not widely used such as the GCC region [180], the UAE and specifically Dubai. Academic clinicians should not be in a position to ignore the evidence based biological methods of caries management. This study was therefore important because it was a pragmatic study conducted in an academic pediatric dental

department in a dental college well engrained and trained in using conventional methods and, as such, was likely to be relevant to the patient population and the provision of proper pediatric dental care. Children with minimal cooperation or very young age require different modalities and treatment options. As mentioned in the literature review the HT is a simple, less invasive technique, and does not require local anesthesia and tooth preparation to remove the carious lesion and is considered an extension to the indirect pulp capping technique [(159)(158)]. It was been reported in many studies that the Hall technique was more acceptable by children and their parents [(159)(158)], presumably because the avoidance of the dental injection eliminates a dental fear inducing stimulus. There is no doubt that dental anxiety is widespread in adults in many developed nations (prevalence was 48% in the UK in 2009) and was in many cases attributable to a negative dental experience in childhood[(180)]. It would appear to be logical to research dental clinical techniques that contribute to a positive behavior especially in children [(186)]. Interestingly, in addition to parents reporting a positive behavior of their children when they used HT compared to conventional treatment, dentists considered it an easier and a quicker procedure[(159)(158)]. The aforementioned points contribute to highlight the importance of this study and why dentist should consider the use of Hall crown as part of their treatment modality.

5.30 Discussion of the study population

Our pool of patients for this study was those who had attended with their carers /parents to our college, the HBMCDM. The records of 65 children who had received 187 PMCs were audited by assessing both clinical notes and radiographs between 1st July 2014 and 1st March 2017. Most of these children were followed up to 18 months. These were comparable to other studies.

Ludwig *et al.* (2014) in the USA had done a similar retrospective study that included 95 participants who received 184 PMCs [146]. In his study, the conventional restoration was recorded from April 2008 till April 2013; while the Hall Technique was recorded from 2010 owing to inadequate follow-up [146]. Their minimum period of follow up was 6-month [146] while our study monitored both conventional- and HT- placed crown at the same period, 6, 12 and 18-month, giving more directly comparable results. Another retrospective study was conducted in USA University of IOWA audited 293 crowns and recorded data of PMCs placed by Hall Technique means between 2008 and 2015[184]. In Innes's *et al.* RCT, 17 general practitioners recruited 132 patients over a period of two years and six months (July 2001 to January 2004) and 132 PMCs were assessed [182].

Amongst the 65 children of our study, the number of children who were treated by the PMC conventional preparation and PMC HT were 20 (31%) and 33 (51%) patients respectively. The remaining 12 (18%) children received the combination of both treatments. In comparison Ludwig *et al's.* retrospective study audited 34 (36%) children received PMCs placed according to the HT while the remaining 51(54%) were treated by the conventional means [146].

Furthermore, the gender distribution of this study's participants was 99 (52.9%) females and 88(47.1%) males from 3 to 14 years of age with a mean (standard deviation) age of our study children at the time of treatment 6.44 ($\pm$1.48) years for those treated utilizing the HT and 6.45 ($\pm$2.0) years for those treated with a conventional preparation. In comparison, Clark *et al.* studied 293 crowns in children with a mean age of child= 5.1+/-2.4, and 61% of them were males [184]. Innes *et al.* (2007) male subjects had a higher proportion than females; 69 (52.2%) males and 63 (47.7%) females were recruited from three to 10 years of age (mean 6.8years; SD1.58) [182]. Ludwig *et al.* (2014) study included children ranging from 2 to 10 years of age with a mean (standard deviation [SD]) age of these children at the time of treatment was 5.9 ($\pm$0.16) years for

those treated according to the Hall technique and 5.3 (±0.15) years for those treated with a traditional treatment [146].

5.40 Discussion of the overall six, 12 and 18-month results

Within our study, results show no statistical significant difference between either method for placing crowns. The study started with 187 PMCs at baseline. We followed up 187 for six-months, 187 were followed for 12-months and finally 152 PMCs were followed for 18-month clinically, radiographically or both for their success or failure. At the six months' point of follow up we graded 100% (110 out of 110) PMCs placed by the means of HT technique to be successful, whereas 98.7% (76 out of 77) of the PMCs placed by the means of conventional preparation were graded as successful. The failed crown was due to improper crown selection resulting in "minor failure". However, due to signs of root resorption of the tooth and the fact that no retreatment measures were done; the failure was recorded as "major failure". The retrospective study by Ludwig and colleagues, investigated the effectiveness of PMCs placed using the Hall Technique compared to those placed using the traditional method (with local anesthetic, caries removal, and tooth preparation before crown fitting) starting with a minimum follow-up period of Hall crowns at six months [146]. They reported a total of 65 out of 67 Hall crowns (97%) were successful and 110 of 117 (94%) of conventionally-placed crowns were successful owing to similar results to our study [146]. The two observed failures of Hall-technique crowns were the result of abscesses, with one causing symptoms at five months and the other identified during routine examination at 11-months. Of the PMCs placed according to the Hall technique that were graded as successful, none caused painful symptoms according to the

dental record, and no follow-up examinations were needed to evaluate symptoms. Within the conventionally placed crowns Five PMCs failed because of abscess or infection at an average time of 17 months (eight, 21, 23 and 23 months) [146].

At the 12-month point of our study we graded 99.1% of PMCs (109 out of 110) placed by the means of HT to be successful, whereas 96.1%. (74 out of 77) of the PMCs placed by the means of conventional preparation were graded as successful. One observed HT PMC failed as the result of perforation and was recorded as "minor failure". In comparison, a retrospective analysis of survival of PMCs placed in a specialist pediatric dental clinic reported that out of 1,010 PMCs reviewed at a mean time of 2.13 years, 2.1% suffered a perforation and 0.9% became de-cemented as stated by Innes *et al.* 2007 [167] [182]. This was with 55% of the PMCs being placed under general anesthetic and 98% under rubber dam; yet both of these figures are equivalent to those found in Innes *et al.* (2007) with the Hall PMCs (0.8% perforating and 0.8% de-cemented). Other studies report similar or slightly higher failure rates: 2% perforation and 14% de-cementation, 4.4% perforation and 8.4% de-cementation [184] [187] [188].

In this present study, at this follow up level, three PMCs placed by conventional means were all graded as a "major failure". The failures are due to crown loss at six-month with root resorption with no retreatment was recorded; other two recorded abscess (infection) due to irreversible pulpitis and the teeth were extracted. These results represent the one year follow up results. Clark *et al.* 2016 retrospective study in addition showed a high clinical and radiographic success for crowns placed on primary molars using the HT. At initial follow-up (mean time = 9.9 months), a success rate of 98.9% was observed both clinically (178 of 180 crowns) and radiographically (86 of 87) [184].

At the 18 months' point of our study, as we followed up only 148 of the PMCs, the results

related to the 148 PMCs (89 HT and 59 conventional PMCs) can only be reported, in addition to the four PMCs that had previously failed (making the total out of 152 PMCs; 90 for the HT PMCs and 62 for the conventional PMCs). We graded 98.8% PMCs placed by the means of HT to be successful (89 out of 90) at 18 months, whereas 95.1% (59 out of 62) PMCs placed by the means of conventional preparation were graded as successful. At this level similar result was shown in Clark *et al.* 2016 retrospective study at the 2nd follow up (mean time 20.1months); 74 of 76 (97.4%) Hall crowns were clinically successful and 37 of 39 (94.9%) were radiographically successful [(184)]. The findings in the retrospective study by Innes and colleagues showed that a three- year survival rate for PMCs placed according to the Hall technique was 73.4% [(167)(183)(182)]. A separate prospective study relying on multiple clinicians showed a survival rate of 96.2 % after a minimum of 23 months of follow-up and 92% at a minimum of 48 months of follow- up [(183)]. In our study, the operators were either pediatric dentistry faculty or residents which might have resulted in the higher success rates for both the conventional and the Hall techniques.

A Kaplan-Meier survival curve was used in our study for length of 18 months since crown placement until occurrence of the failure for conventional preparation and Hall Technique methods was created. The numbers of teeth still at risk of experiencing a failure at date of point were indicated (censored). Both methods showed comparability in term of proportions of success and average time of failure, where the p-value was 0.362 (not significant). The failure over the period of follow up was 3(3%) on the conventional preparation method with average time in 9.7 months while the failure of the Hall Technique was 1(0.2%) with average time of failure 9.9 months. The survival rate seen in Ludwig *et al.* (2014) study after 15 months was in accord with our result and previous results, and it equaled or exceeded the success of all other materials used for restoring primary molars at one to two years of follow-up [(146)].

However, in addition to the different comparisons (traditional crowns in this cohort study and plastic restorations in the previous trials), several other differences are seen between the studies. The Hall Technique protocol [105] was deviated from slightly in Ludwig *et al.* (2014) study, as tight tooth contacts were managed with proximal tooth preparation in around half of the teeth to facilitate crown placement, rather than an orthodontic separator being placed to create space. In our study, we used orthodontic separators as the only means to create sufficient space for the HT PMCs. Also, although the authors stated that restoration success was graded on the same basis as Innes and colleagues [167] [182] this was not quite the case because a lost crown was considered a treatment failure, whereas Innes and colleagues only considered this to be a 'Minor' failure when it was possible to re-cement the crown.

Innes *et al.* (2007) RCT at 48-month follow-up of 91 patients revealed "major" failures in 3% of the HT teeth and in 16.5% of the control restorations ($p = 0.0005$). Five percent of the HT demonstrated "minor" failures, as did 42% of the control restorations ($p = 0.000001$). The follow-up data between 1 and 60 months (130 patients) showed "major" failures in 2% of teeth in conjunction with the HT and in 17% of the control restorations ($p = 0.000004$). "Minor" failures were detected in 5% of the HT and 46% of the control restorations ($p = 0.000001$) [182].

Based on the information provided above, and in the sample of PMCs carried out in primary molar teeth in children in a pediatric dentistry postgraduate setting, the null hypothesis that the Hall technique using PMCs (to seal-in caries) was not as successful of a method as the conventional approach (complete caries removal) in a postgraduate setting was rejected.

5.50 Study limitations

This study had several limitations as followed:

- First, the study contained a small sample size due to time restrain and change of the file system in the HBMCDM organization restrained the operator from gaining the proper patient information from the system.
- The study was a retrospective study, and the group of traditionally placed PMCs was not an ideal control group, because the majority of these crowns were less in number than the Hall crown group because many of our conventionally placed PMCs in our college were traditionally used after pulp therapy and was excluded from our study which lead to the reduction in the number of sample in the conventional group.
- The age of the patients in our sample was not predetermined. Our sample included patients of different ages. A specific range of age might have been more accurate to eliminate confounding factors such as patient cooperation and time of tooth until exfoliation.
- Loss of participants owing to inadequate follow-up was a limitation of this study and had a proportionally greater effect on the patients whose PMCs were placed according to the Hall technique. 15 participants treated with 35 PMCs (15 participants who received 19 traditionally placed PMCs and three participants who received 16 PMCs placed with the Hall technique) did not return for regular 18month follow-up, and this increases the uncertainty of the success of the two techniques.
- The study's focus was on the clinical success of the crown as it related to loss or to pulpal or caries-related problems, and we did not specifically measure periodontal health or changes in occlusion.

6.00 CONCLUSIONS

Following a retrospective case note analysis of a sample of primary molars in children treated in a postgraduate pediatric dentistry setting, it can be concluded that:

- The Hall technique PMC is clinically and radiographically as successful as the conventionally placed PMC at 6, 12 and 18 months post operatively.
- The success rate of the HT-PMC at 6 months, 12 and 18 months was (100%, 99.1% and 98.8% respectively) while the success rate of the conventional –PMCs at the same period was (98.7%, 96.1% and 95.2% respectively), both were comparable and in concurrence with previously published studies.
- The survival rate of both methods showed comparability in term of proportions of success and average time of failure (p= 0.362). This indicated that PMCs placed conventionally or by the HT in a postgraduate setting have a similar success rate at an average time of 18 months.
- Finally, the Null Hypothesis was accepted proving that there was no clinical and radiographic difference between the Hall technique using PMCs (to seal-in caries) and the conventional approach (complete caries removal) in a postgraduate pediatric dentistry setting.

7.00 RECOMMENDATIONS

- A high-quality randomized controlled trial is recommended to compare conventional crowns and Hall Technique crowns. It will be superior in design to our study and would be needed to definitively determine the relative effectiveness of each crown placement method. However, given the low failure rates for both techniques, many patients will be required to detect a difference between the two treatments, and the need for such a study may be unjustified.
- In addition, the recommended trial might be of more significant to investigate the preferences for treatment of children their parent/carers and dentists, as well as the relative cost-effectiveness of each crown placement method.
- Furthermore, evaluation of occlusion and periodontal health with continued follow-up as a part of a prospective trial would be greatly beneficial in understanding whether the Hall technique poses any deleterious effects or not.
- Evidence has been established regarding the effectiveness of HT worldwide and now in the Middle East particularly the UAE (Dubai); this should be publicized to encourage clinicians to update their current practices and adopt the new biological perspective to use the HT, include it in pediatric armamentarium and offer it to the patient as a treatment option.

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Appendix 1

Date: 6/12/2016

Dear Dr Halah BinLaden – Paediatric Dental Resident

Re: Your research protocol

Titled: Success of Hall Crowns……

Thank you for submitting your research protocol to the Research and Ethics committee of the Hamden Bin Mohammed College of Dental Medicine, MBRU.

It was considered at the meeting held on: 23/10/2016

After appropriate revision of the protocol approval has been given. If you need specific guidance, please make an appointment to see the Chair, Prof A Milosevic, as soon as possible. The committee would like to remind you that it is a requirement of the programme that you complete a research dissertation, which comprises 15% of credits within the 3-year MSc programme.

With best wishes

Yours sincerely,

Prof A Milosevic

Chair, Research and Ethics Committee, HBMCDM

Appendix 2

INITIAL BASELINE INFORMATION				INITIAL BASELINE INFORMATION		Clinical 6month success/Failure			6month Xray		Clinical 12month success/ Failure			12 month Xray		18 month success/Failure			18 month Xray	
Patient ID	Gender m/f	age in years	Tooth No #	SSC: Hall (1) or Conventional (2)	X-ray present y/n	SSC present y/n	Tooth shed y/n	Tooth extr. y/n	Pathology y/n	symptoms y/n	SSC present yes/no	Tooth shed y/n	Tooth ext. y/n	Pathology y/n	symptoms y/n	SSC present y/n	Tooth shed y/n	Tooth Ext. y/n	pathology y/n	symptoms y/n
NAFMO000	M	5	64	1	y	y	N	N	Clinical	NO SYMPTOMS	y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
NAFMO000	M	5	85	1	y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
NAFMO000	M	5	75	1	y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
NAFMO000	M	5	55	1	y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
NAFMO000	M	5	84	1	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
NAFMO000	M	5	74	1	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
NAFMO000	M	5	54	1	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
SAMAH001	M	5	55	2	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	y	N	N	Clinical	NO SYMPTOMS
SAMAH001	M	5	54	2	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	y	N	N	Clinical	NO SYMPTOMS
SAMAH001	M	5	65	2	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	y	N	N	Clinical	NO SYMPTOMS
SAMAH001	M	5	64	2	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	y	N	N	Clinical	NO SYMPTOMS
SAMAH001	M	5	74	2	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	y	N	N	Clinical	NO SYMPTOMS
ABUGH001	F	8	55	2	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
ABUGH001	F	8	64	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
ABUGH001	F	8	65	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
ALSAJO05	F	6	55	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
ALSAJO05	F	6	75	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
ALSAJO05	F	6	65	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
ALSAJO05	F	6	84	2	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	y	N	N	18 month Xray	NO SYMPTOMS
LARAD000	M	8	65	2	Y	N	N	N	Y CROWN LOSS	CROWN LOSS							N	N		
ABUOM001	M	5	75	1	y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
ABUOM001	M	5	74	1	y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
ABUOM001	M	5	64	1	y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
ABUOM001	M	5	84	1	y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
ABUOM001	M	5	85	1	y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS
ABDAL004	M	9	85	2	Y	Y	N	N	6month	NO SYMPTOMS	N	N	Y	12month xray	Abcess	N	N	Y	18 month Xray	EXTRACTED
OBAMO000	M	6	65	1	Y	Y	N	N	Clinical	NO SYMPTOMS	y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
OBAMO000	M	6	84	1	Y	Y	N	N	Clinical	NO SYMPTOMS	y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
OBAMO000	M	6	85	1	Y	Y	N	N	Clinical	NO SYMPTOMS	y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
OBAMO000	M	6	74	1	Y	Y	N	N	Clinical	NO SYMPTOMS	y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
OBAMO000	M	6	55	2	Y	Y	N	N	Clinical	NO SYMPTOMS	y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
OBAMO000	M	6	54	2	Y	Y	N	N	Clinical	NO SYMPTOMS	y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
OBAZA000	M	7	64	2	Y	y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
OBAZA000	M	7	74	2	Y	y	N	N	Clinical	NO SYMPTOMS	N	N	Y	12month xray	Abcess	N	N	Y	18 month Xray	Abcess
HADRA000	F	6	54	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	HADRA015	Y	N	N	18 month Xray	NO SYMPTOMS
HADRA000	F	6	74	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
ABDW1001	F	9	55	1	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	y	N	N	18 month Xray	NO SYMPTOMS
ABDW1001	F	9	54	2	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	y	N	N	18 month Xray	NO SYMPTOMS
ALKHA005	M	4	55	1	y	y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18MONTH	NO SYMPTOMS
11740	M	5	55	1	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
11740	M	5	65	1	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18MONTH	NO SYMPTOMS
11740	M	5	64	1	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
11740	M	5	75	1	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
LALKM001	M	7	54	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS					
LALKM001	M	7	74	1	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS					
	M	7	65	2	Y	Y	N	N	6month	NO SYMPTOMS	Y	N	N	12month xray	NO SYMPTOMS					
AHMMU000	M	3	54	2	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS
AHMMU000	M	3	64	2	Y	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	Clinical	NO SYMPTOMS	Y	N	N	18 month Xray	NO SYMPTOMS