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The title: Effectiveness, Costs and Patient Acceptance of a Conventional and a Biological Treatment Approach for Carious Primary Teeth in Children

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Short title: Cost Effectiveness and Treatment Acceptance of the Conventional and Biological Treatment Approaches.

Key words: Dental caries, primary teeth, conventional treatment, biological treatment, cost-effectiveness, treatment acceptance.

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ABSTRACT

Background. Over the last years conventional restorations for the treatment of active carious lesions in primary teeth have been challenged and a more biological approach has been suggested. This approach involves less invasive techniques which alter the environment of the carious lesion isolating it from the cariogenic biofilm and substrate.

Aim. To investigate the cost-effectiveness and patient acceptance of two treatment approaches for the treatment of deep carious lesions in primary teeth in children.

Methods. This was a retrospective/prospective cohort study carried out in two UK specialist hospital settings. Data on cost-effectiveness was extracted retrospectively from clinical dental records of 246 patients aged 4-9 years. A prospective study design was used to explore patient acceptance of the two treatment approaches. One hundred and ten patients aged 4-9 years and their carers completed two questionnaires on treatment acceptance.

Results. In total 836 primary teeth that had received treatment with either approach were included. More than two thirds (75.7%) of the restorations in the conventional approach were of non-selective removal to hard dentine followed by pulpotomy (24.3%). In the biological approach, most of the restorations were stainless steel crowns placed with the Hall Technique (95%) followed by selective removal to firm dentine (5%). The majority of the primary teeth remained asymptomatic after a follow-up period of up to 77 months; 95.3% in the conventional and 95.8% in the biological arm. When the treatment costs were analysed a statistical significant difference was found between the mean costs of the two approaches with a mean difference of £45.20 (Pound Sterling) ($p < 0.001$), in favour of the biological approach. The majority of the children and carers were happy with the conventional or biological restorations.

Conclusion. Although both approaches had similar successful outcomes, the biological approach consisting mainly of Hall Technique was associated with reduced treatment costs. Both approaches were accepted favourably by the children and carers.

Introduction

Although dental caries is a disease that results from an ecologic shift in the bacteria favouring aciduric and acidogenic microflora within the dental plaque biofilm, it is not an infectious disease and its sequelae, the carious lesion, does not need to be treated by removing cariogenic bacteria. (Banerjee et al., 2017). Only if a preventive strategy of managing behaviour change to achieve control of the causative factors fails, and the lesion activity is not controlled, the cariogenic biofilm will promote further lesion progression leading to pulpal inflammation, pain and dental infection in some patients (Banerjee et al., 2017).

Management of carious primary teeth is a common aspect of dental care for young children [Rodd et al., 2006]. According to Hunter and Hunter [2003], "The principal objective of paediatric operative dentistry is the restoration of damaged teeth to healthy function". Currently, two treatment approaches are proposed for the management of active carious lesion (CL) extending into dentine in primary teeth in the UK; the conventional and the biological. Conventional restoration has been the traditional approach for restoring carious primary teeth for decades [Ricketts et al., 2013; Schwendicke et al., 2013a]. It includes non-selective removal to hard dentine, formerly known as complete removal of carious tissue (CT), followed by placement of a suitable filling material with or without pulp therapy. On the other hand, the biological approach involves less invasive techniques which alter the environment of the carious lesion preventing progression by isolating it from the cariogenic biofilm. Such approaches include the Hall Technique, selective removal to firm dentine, selective removal to soft dentine and stepwise removal [Ricketts et al., 2013; Schwendicke et al., 2013a; Page et al., 2014; Banerjee et al., 2017; Coll et al., 2017].

Over the last decade there has been much debate among paediatric dentists in the UK and the rest of Europe on the merits of the conventional approach and whether to retain this treatment modality as the standard technique in restoring primary teeth, or to shift more towards a biological approach. The discussion about what might be the best treatment approach for restoring active deep CL extending into the dentine in primary teeth within the

profession was triggered by research published with contradicting views on each treatment [Innes et al., 2007; Franzon et al., 2014]. However, none of these studies explored the cost effectiveness and acceptance from a child and carers perspective when these two approaches were delivered by specialist paediatric dentists.

The cost of dental treatment is highly dependent on its complexity, material used and success rate. When different treatment approaches exist for the restoration of primary teeth, clinicians and carers` of patients want the choice of treatment to be based on techniques which are cost-effective and evidence based [Cunningham, 2000]. In addition, treatment providers such as the National Health Services (NHS), where the majority of child dental care is provided in the UK, are likely to require increased evidence on clinical effectiveness of treatments as well as information on "value of money" in the future, to inform decisions [Cunningham, 2000].

Increasingly patients are rightly more involved in their own healthcare choices than before. Treatment providers are adopting an approach that is more patient-centric in order to improve the clinical outcomes and patient satisfaction [Marshman and Hall, 2008]. As a consequence, patient-public involvement and engagement (PPIE) has become part of the research culture with growing interest among the clinicians and researchers in getting patients to express their opinions about their care experience [Marshman and Hall, 2008].

In light of the above, this retrospective prospective cohort study aimed to explore the cost-effectiveness and patient and carer acceptance, response and satisfaction with the conventional and biological treatment approaches. Such a study is essential before any recommendations can be made on the best treatment modality for carious primary teeth. The study on the outcome and effectiveness of two treatment approaches has recently been reported [BaniHani et al., 2017]. This paper aimed to focus mainly on the cost effectiveness and treatment acceptance of the two treatment approaches to patient and carer. The null hypothesis of the current study is that there is no difference between the two treatment approaches, a conventional and a biological, regarding their cost-effectiveness and their acceptance to patient and carers.

Materials and Methods

Study design and ethical approval

The study was conducted in two dental hospitals in the North of England; Leeds (Leeds Dental Institute) and Sheffield (School of Clinical Dentistry University of Sheffield). Differing treatment approaches are practiced in these two dental centres. In the Leeds Dental Institute (LDI), a conventional approach is predominantly practiced, whereas a biological approach is the mainstay of dental treatment of the carious primary dentition in the School of Clinical Dentistry University of Sheffield (SCD). The conventional approaches included for the purposes of this study were non-selective removal to hard dentine with or without pulp therapy of primary teeth. In the non-selective removal to hard dentine, all CT was excavated for all parts of the cavity, peripherally and pulpally, by tungsten carbide bur and hand instruments, and only hard sound dentine was left indicated by scratchy sound produced by scraping the tooth surface with a sharp hand excavator or dental probe. Pulp therapy involved pulpotomy and pulpectomy.

The biological approaches included in the study were restorations placed using the principles of selective removal to firm dentine and the Hall Technique. Selective removal to firm dentine involved complete removal of the CT from the cavity margins leaving affected dentine pulpally that is resistant to a hand excavator.

Approval was obtained from the Dental Research Ethics Committee (DREC), University of Leeds, and the National Research Ethics Service (NRES).

The cost-effectiveness of the two treatment approaches was assessed retrospectively whereas patient and carer acceptance was explored prospectively.

The inclusion criteria for the study were:

- Patients aged 4 to 9 years at the time of dental treatment.
- Patient with no significant health problem (ASA Physical Status-1 and 2).
- Regular attender; a child who has attended at least once every 12 months.
- Patient had at least one primary tooth (molar or anterior) with active CL extending into dentine on radiographs.
- Tooth had no history of infection or swelling and no evidence of periapical pathology or pulp exposure on initial clinical and radiographic diagnosis. Teeth were asymptomatic or showed signs of reversible pulpitis.
- Pre-operative radiographs were available.

- For the cost effectiveness: treatment was performed with or without the use of local anaesthesia (LA), inhalation sedation or general anaesthesia (GA) by paediatric post graduate students under supervision of specialist staff or staff.
- For the patient and carer acceptance: treatment was performed with or without the use of local anaesthesia (LA) by paediatric post graduate students under supervision of specialist staff or staff.
- Participants (carers and children) must have signed informed written consent and assent prior to participation as well as speak and understand the English language.

Study design for cost effectiveness analysis

The study sample was selected from clinical dental records of paediatric patients who were registered at the two dental units and who had received dental treatment by either approach between 2006-2012. Clinical records were identified using the hospital`s computer system and were reviewed alphabetically by one of the authors (A.B). The cost effectiveness of the conventional and biological approaches was calculated from data collected on whether the treatment was performed with or without LA, inhalation sedation or GA, restorations placed and treatment outcome from treatment visits, recall visits, emergency appointments and post-operative radiographs, using the cost incremental ratio. Data was recorded on a standardised data abstraction proforma by a trained data abstractor (A.B). The intra-examiner reliability was measured by evaluating 15% of the cases twice and was calculated using the Kappa statistic. Intra-examiner reliability was found to equal 0.90 for all the information collected. A pilot study was carried out before the start of the main study to assess the feasibility and ease of the data collection. Neither the study protocol nor the data extraction proforma were modified in light of the pilot study. Data extracted from patients` records for the pilot study were therefore included in statistical analysis of the main study.

The total cost of each treatment approach was calculated in Pound Sterling (£) and at the patient level. It included:

- Cost of time consumed by dentists and overheads such as the dental nurse to carry out the treatment as proposed by Curtis 2012 which was found to equal £0.97 per minute.

- Cost of treatment carried out including the cost of inhalation sedation and GAs. All materials used for the treatment of carious primary teeth in the study ranging from a

cotton pledget to preformed metal crown (PMC) were noted and their cost was calculated from different sources. The sources were mainly the suppliers` official websites as well as invoices and figures of actual material costs, obtained from the purchasing department staff in the NHS. Information on cost of materials was based on manufacturer recommendations.

- Cost of treatment failures including extractions, restoration of recurrent caries, replacement of a lost filling or crown and pulp therapies.

Time consumed per treatment

Time consumed to carry out the conventional restoration

The conventional approach including non-selective removal to hard dentine with or without pulpotomy was timed prospectively from the moment the child sat on the dental chair till the end of the dental treatment for 10 postgraduate students and staff. All treatments were timed using an electronic timer by the researcher (A.B)

Half of the candidates performed non-selective removal to hard dentine restored with resin composite (n= 15 teeth) whereas the other half did pulpotomy followed with PMCs (n= 15 teeth).

The average time for both procedures was approximately 30 minutes if one primary tooth was restored. Whereas if two primary teeth were to be restored, the average time of dental treatment provided to the two teeth was found to be around 40 minutes.

Time consumed to carry out the biological restoration

Hall Technique was timed prospectively for four postgraduates and staff over two visits for different patients (n= 12 primary molars). Separators were usually placed on the patient's first visit to the SCD followed by placing PMCs using the Hall Technique on latter visits. Each clinician placed three PMCs using Hall Technique. All treatments were timed using an electronic timer by the researcher (A.B).

Insertion of separators consumed 10 minutes on average whereas placing PMC using Hall Technique consumed approximately 12 minutes if one primary molar was sealed with the Hall Technique and 22 minutes if two primary molars received the Hall Technique at the same visit.

Regarding the selective removal to firm dentine (n=5 primary teeth), it was found the procedure consumed 30 minutes on average if one primary tooth to be restored and 40 minutes if two primary teeth were restored at the same visit.

Study design for patient acceptance of treatment received

The study sample was identified from paediatric patients and their carers who attended for the treatment of the child's carious primary teeth at the two dental hospitals with either approach from 2013-2015.

Potential participants were approached by the researchers (A.B for LDI and C.D for SCD) at the new paediatric patient consultation clinic at the two dental units to invite them to participate. Carers and children who fulfilled the inclusion criteria of the study completed a questionnaire on the acceptance of the two treatment approaches following their dental treatment. Children were assisted by the researchers reading the questions while the child pointed to the appropriate face on the scale that represented their experience. The interviewers were different from the staff that performed the dental treatments, and were trained in the reading and intonation of each question, and option responses to avoid any interference and bias. Questionnaires distributed to carers were self-administered.

In addition, dental anxiety towards dental treatment was assessed among the children in the present study using the faces version of the Modified Child Dental Anxiety Scale (Howard and Freeman, 2007). Patients completed the questionnaire prior to their dental treatment using face to face interview. Children were assisted by the researchers by reading the questions while the child pointed to the appropriate face on the scale that represented their anxiety. This was carried out to ensure that participants who received conventional and biological treatment approaches had similar anxiety level towards the dental treatment.

Study measures

Two questionnaires using a visual analogue scale were developed by the researcher (A.B) which aimed to assess the acceptance of both treatment approaches, conventional and biological, among children and carers receiving dental treatment with or without LA. The questionnaires were named "Children satisfaction with dental treatment" and "Parents` satisfaction with their children dental treatment". Some of the questions used were adapted from questionnaires used previously at the University of Sheffield [Bell et al., 2010].

Piloting and validation of the questionnaires

The questionnaires were piloted among a sample of 30 pairs of carers and their children aged 4-9 years. Participants in the pilot study were included in the main sample. Neither the questions nor the answers were modified after the pilot study. In addition construct validation was carried out for both questionnaires (n=110 for each questionnaire) after data collection to establish the psychometric properties using factor analysis and screen plot. A cut off point of 0.30 was set for factor loading.

Further evaluation of the psychometric properties of the new questionnaires was assessed using Exploratory Actor Analysis (Varimix rotated component matrix with Kaiser normalisation) and Scree plot. In addition, internal consistency using Cronbach's alpha was performed.

Children`s satisfaction with dental treatment questionnaire

The questionnaire consisted of 12 questions in total; nine closed questions and three open questions. Closed questions had 2 items aiming to explore children satisfaction with their treatment experience at the dentist, 5 items exploring acceptance of the dental treatment they received: dental injection, drilling, placing rubber dam on, having PMC or a filling placed. Finally there were 2 items exploring children`s communication with the dental team. Responses to closed questions were given through 3 or 4-point scales aided by a prompt/explanation card with appropriate faces. Responses to open questions were gathered and grouped into themes.

Parents` satisfaction with their children dental treatment

The questionnaire consisted of nine questions in total; six closed questions and three open questions. The closed questions aimed to explore carer`s satisfaction with their child`s experience at the dentist (2 items), parent`s acceptance of the conventional and biological treatment their child received (1 item) and carers' communication with the dental team (3 items). Responses to closed questions were given through 3 and 5-point scales and responses to open questions were gathered and grouped into themes.

Sample size calculation

Data obtained from the pilot study were used to calculate the power and sample size of the retrospective cohort study using PASS (Power Analysis and Sample Size) software (version

11.0.8; PASS, NCSS, LLC). The total number of teeth obtained in the conventional and biological approaches in the pilot study was 92 and 50 teeth, respectively. In addition, 96% of the teeth in the conventional approach remained asymptomatic in place till the last follow-up visit compared to 100% for the teeth in the biological approach. Based on this data, it was found that a minimum of 192 teeth were required in each treatment approach in order to achieve 80% power to detect a difference between the group proportions of 0.04 using the two-sided Z test with pooled variance and significant level at 0.05.

Power and sample size of the prospective cohort study was calculated using the interclass correlation coefficient (ICC). Acceptance rates of 10% and 40% in the two treatment approaches respectively were assumed, in addition to a significance level of 5% and power of 90%, a sample size of 49 participants was indicated per treatment. A dropout rate of 15% was anticipated; therefore the sample size was increased to 55 participants (carers and their children) from both participating specialist dental centres.

Data Management and Data Analysis

Data was entered into SPSS (Statistical Package for the Social Sciences) version 22. Data analysis for the cost effectiveness was carried out at patient level and probability values ≤ 0.05 were considered statistically significant. T-test was used to compare the mean cost of the two treatment approaches. The cost effectiveness of both approaches was calculated using the incremental cost ratio as below:

$$Incremental\ cost\ ratio = \frac{\text{average cost of conventional approach per patient} - \text{average cost of biological aooproach per patient}}{proportion\ of\ teeth\ remained\ asymptomatic\ in\ conventional - proportion\ of\ teeth\ in\ biological}$$

To account for the clustering in the data, multi-level models were used to analyse the data in the study. Univariate general linear model using SPSS version 22 was fitted to assess the association of the independent variables with the "total cost of treatment" as dependent variable. The independent variables included treatment approach, treatment received (complete CT removal, pulpotomy, Hall Technique, and IPC), age of patient, gender, and initial diagnosis of the tooth (one surface cavities vs two surface cavities).

All data collected on parental and child acceptance of the conventional and biological treatment were presented in terms of proportions. All responses to the open questions were

grouped into themes and analyzed in terms of proportions. Cronbach's alpha was used to assess the internal consistency of the newly developed questionnaires.

Results

Baseline characteristics

The clinical records of 1,200 patients were reviewed from LDI and SCD with 246 case notes fulfilling the inclusion criteria; 114 were for the conventional approach and 132 for the biological approach. In total, the cost effectiveness of 836 carious primary teeth with two different treatment modalities were analyzed; 428 and 408 teeth were from the conventional and biological approaches respectively. Description of the study sample is outlined in Table 1. The median age of the children was 5.8 ± 1.52 years (range 4-9 years) with more than half of the patients being females.

In addition, 110 children and their carers completed questionnaires on treatment acceptance with either approach and dental anxiety; 55 were from LDI and had received restorations with a conventional approach and a same figure were from SCD and were treated with the biological approach. The median age of the children was 7.0 ± 1.4 years (range 4-9 years) with more than half of the patients being male (50.9%).

Treatment characteristics

Conventional and biological approaches were carried out on 51.2% and 48.8% of the teeth in the sample, respectively. More than two thirds (75.7%) of the restorations in the conventional approach were of non-selective removal to hard dentine followed by pulpotomy (24.3%). In the biological approach, the majority of the restorations were placed with the Hall Technique (95%) followed by selective removal to firm dentine (5%).

Of the 836 teeth; 46.4% (388) had the Hall Technique, 38.8% (324) had non-selective removal to hard dentine, 12.4% (104) had pulpotomy and only 2.4% (20) received selective removal to firm dentine.

Resin composite was the restoration of choice for most of the teeth with non-selective removal to hard dentine (71.6%) while PMC was placed for most of the teeth with selective removal to firm dentine (75%). All teeth that received pulpotomy and Hall Technique had

PMCs placed immediately after the dental treatment. Teeth were followed for a period up to 77 months (median = 12 ± 11.6).

Of the 110 patients in the prospective cohort study, 43.6% had non-selective removal to hard dentine, 44.5% had PMC placed using Hall Technique, 6.4% had pulpotomy, and 5.5% received selective removal to firm dentine. Resin composite was the restoration of choice for teeth with non-selective removal to hard dentine. PMC was placed for all the teeth which received pulpotomy and selective removal to firm dentine in the study. All patients in the conventional approach received LA prior to the treatment compared to 8 patients in the biological approach.

Cost effectiveness of the two treatment approaches

Of the 836 teeth followed up for the study, 95.3% of the teeth in the conventional approach and 95.8% of the teeth in the biological approach remained asymptomatic in place at the final follow-up visit after a median follow-up of 13 and 9 months, respectively ($p= 0.722$). Using a mixed-effect logistic regression model no significant association was found between remained asymptomatic outcome and the approach used for treatment, age of the patient, gender, initial diagnosis, and number of carious surfaces or tooth type. These results have recently been reported [BaniHani et al., 2017]. However, the total cost of the conventional restoration in the current study was almost two times the total cost of the biological restoration with a mean cost of £168.68 per patient (Table 2). The mean cost of the biological restoration was £78.97.

Using the incremental cost ratio, the conventional approach carried out with or without LA, inhalation sedation and GA had a cost £89.6 more than the biological approach and was only 0.5% less effective in retaining primary teeth asymptomatically in place ($p< 0.001$). The results were relatively similar when cost effectiveness was calculated for the two treatment approaches performed with or without LA with the conventional restorations costing £47.43 more and 1.3% less effective in maintaining primary teeth asymptomatically in place.

In addition, the majority of the patients in the current study were found to have six primary teeth treated on average with either approach (17.2%) followed by four (16.7%) and three teeth (15.6%). The mean cost of treatment provided to patients with six restored primary teeth was compared for conventional versus biological approaches using independent sample t-test.

A statistically significant difference was found among the two approaches with a mean cost of difference of £70.34 in favour of the biological approach ($p < 0.001$).

The effect of independent factors on the cost of the two treatment approaches

Only age of the patient and treatment approach were found to affect the total cost of treatment provided using univariate general linear model of analysis after adjusting for the independent factors namely age of patient, gender, initial diagnosis of the tooth (one surface versus two or more surface cavities) and treatment approach (conventional versus biological) ($p < 0.001$ and $p = 0.004$, respectively). Higher cost was seen with the conventional approach in the younger age group of children.

Children and carers acceptance of the conventional and biological approaches

Description of children and carers' responses to `children acceptance of dental treatment` and `parents' acceptance of dental treatment` questionnaires in both treatment approaches are summarized in Tables 3-6. In the conventional approach, two thirds (70.9%) of the children were positive about the conventional restorations they received and the majority (90.9%) were very happy with their experience at the dentist. Likewise, the majority (>94.5%) of the carers were pleased with the conventional restorations their children received and happy for their children to have the treatment again.

For the biological approach, more than half (58.2%) of the children in the study were positive about the crowns placed with the Hall technique or selective removal of caries they received and two thirds (67.3%) were happy with their experience at the dentist. In addition, most of the carers were happy (89.1%) with the biological restorations their children received and would be happy (96.4%) for their children to have the treatment again.

The majority (80%) of the children in the study were not worried about going to the dentist in general. No statistical significant difference was found between the total Faces version-MCDAS scores among children received the conventional versus the biological approach ($p = 0.841$) suggesting that children who attended for the conventional and biological treatment approaches had similar anxiety levels. The mean score of Faces version-MCDAS for the sample was 12.4 (± 5.13); 12.1 ± 4.64 and 12.4 ± 5.6 for the conventional and biological approaches, respectively. None of the participants were extremely dentally anxious (score of ≥26)

Discussion

The current study is one of the first to investigate the cost effectiveness and patient acceptance of these two treatment approaches, a conventional and a biological, from two perspectives; child and carer, for the treatment of deep CL in primary teeth in children.

The methodology adopted for the study was robust in that the cost of every single material and piece of equipment used was taken into consideration and entered into a detailed cost analysis investigation. In addition, two new questionnaires using a visual analogue scale were developed by the researcher bringing new elements into the literature. The questionnaires aimed to assess patient and carer acceptance, response and satisfaction with both approaches.

The strength of the present study was that the two treatment approaches were carried out to their highest standards as they were administered by specialist paediatric dentists at two specialised dental hospitals in the UK. Teeth in the conventional and biological approaches were restored after taking into consideration any possible pulp inflammation, longevity of the restorative materials and principles of cavity design [Duggal et al., 2002]. Moreover, specialist paediatric dentists are trained at putting the child at ease and reducing the discomfort and anxiety associated with dental treatment. This child friendly environment would nurture a positive dental attitude among the paediatric patients and the accompanying carers.

This study`s principal finding was that although the number of teeth that remained asymptomatic at the last follow-up visit did not differ significantly among the two treatment approaches, the biological approach was more cost effective. The present study's results were in agreement with the limited data available in the literature. Schwendicke et al (2013b, 2014) reported that selective excavation (one-step incomplete) was more effective and less costly than stepwise (two-step incomplete) and complete caries excavation for all posterior teeth over the lifetime of a male German patient initially aged 15 and 18 years with a remaining life expectancy of 60 years regardless of an individual's caries risk using tooth-level Markov-model. Currently, no data is available in the literature on the cost-effectiveness of the hall technique

The conventional restorations in the present study had cost nearly two times the cost of the biological restorations. There are several factors that would have contributed to these findings. The conventional approach in the present study included a slightly smaller number of patients (114 compared to 132 patients), however, a greater number of teeth were treated

among this group of patients (428 teeth compared to 408 teeth). Therefore, greater number of treatments were carried out in the latter intervention with more restorative material being used. Unlike the biological approach, conventional restoration consumes more dental materials such as LA, rubber dam, liner/base, restoration materials and pulpotomy materials especially if Mineral Trioxide Aggregate (MTA) has been used as a pulpotomy medicament, which is a relatively expensive material. In the current study, 20% of the teeth that received pulpotomy had MTA as a pulpotomy medicament costing nearly £60 per pulpotomy. The cost of MTA pulpotomy was found to be six times the cost of ferric sulphate pulpotomy.

The Hall Technique was found to cost the least among the four treatment groups. The latter constituted the majority of the treatments included in the biological approach (95.1%) contributing to the lower cost seen within this treatment approach in this study. In addition, more patients in the conventional approach had their dental restoration under GA (7 patients) and inhalation sedation (one patient) compared to one patient who received biological restorations under GA with average cost of £837 and £703 for treatment under GA and inhalation sedation per patient, respectively.

The significance of getting children as well as carers to express their opinions about treatment experiences is becoming increasingly important in dentistry [Marshman and Hall, 2008]. At the present, there is a growing interest among the clinicians and researchers in investigating the acceptability of the conventional and biological restorative approaches [Innes et al., 2007; Page et al., 2014; Santamaria et al., 2015]. However, none of the aforementioned studies explored children and carers satisfaction, acceptance and response to the conventional and biological approaches from two perspectives: child and carers.

The most significant finding of the current study is that the two treatment approaches, the conventional and biological, were very well accepted by children and carers for the treatment of carious primary teeth. The majority of the children, slightly more for conventional (70.9%) compared with the biological (58.2%), and their carers (>92.7% for the conventional and >89.2% for the biological) in the current study were happy with the approach used for their child. The present study's results were in agreement with the limited data available in the literature. Santamaria et al. [2015] reported that the majority of the carers were very satisfied with the Hall Technique that their children received and were happy for their children to have the treatment again. Page et al. [2014] found that most of the children had

positive opinions about the Hall Technique, reporting an even higher rate of acceptance (90%).

A common theme that arose from both treatment approaches was parental and children perceptions of communication between the dental staff and the child patient and the carers. Dentists at both dental units were acknowledged for being friendly, kind as well as for their ability to put the child at ease and reduce his/her anxiety throughout the dental treatment. Also dentists were valued for explaining the dental treatment and re-assuring the child constantly all through the dental visit. The findings of the current study reflect the importance of establishing effective communication and building a trusting relationship between dentist, child and carer, whichever treatment approach might be agreed. The dentist`s attitude, body language and communication skills are critical to create a positive dental visit for the child and to gain trust from the child and carer. In addition, the clinical staff are an extension of the dentist in behaviour guidance of the patient and communication with the carer.

Similarity was seen in the responses reported by carers and children in terms of the advantages and disadvantages of the conventional restoration in the present study except for the "Communication" which emerged as a unique theme related to the advantages of the conventional treatment. Effective communication between the dentist and the child was the key to successful treatment and it included pro-active engagement of the child by handing him a mirror to watch the dental treatment and giving the child breaks during the treatment session. Surprisingly, having a dental injection was among the advantages of the conventional approach reported by children and carers. Other reported advantages were teeth drilling, filling and having the PMC put on using the conventional approach.

On the other hand, the drawbacks of the conventional approach from child and carers' perspective in the present study were mainly found to be elements of discomfort related to the nature of the treatment. This included the discomfort associated with the dental injection, the difficulty of the child keeping their mouth open and staying still throughout the dental treatment, having the rubber dam on, tooth drilled, filling placed, and having the PMC put on using the conventional approach.

Numerous advantages and disadvantages were noted for the biological restoration by the carers and children in the study. No injection needed, the relative brevity of the procedure, and the easiness of placing the Hall PMC as well as the separator bands for Hall Technique were among the advantages of the biological restoration reported by carers. Some children

perceived Hall crowns as 'cool' and shiny (perception of specialness). Others reported the ease of placing the Hall PMC and getting stickers as a reward for their cooperation during the dental treatment among the advantages of the biological restoration. The latter highlighted the significance of positive reinforcement in children behavior management. The lack of the need to give the child a dental injection and the relative brevity of the procedure were advantages the Hall Technique have previously been reported as potential advantages of the Hall Technique [Innes et al., 2006; Innes and Evans, 2013; Page et al., 2014].

On the other hand, few common disadvantages were described by children and carers for the biological restoration largely related to elements of treatment procedure. These included discomfort and pain associated with pushing the Hall PMCs on as well as placing the separators, the taste of "the glue" associated with Hall Technique and annoyance associated with having the gauze in the mouth during the placement of the Hall PMCs. In a study by Innes et al. [2007] children were found to dislike the taste of the excess glass ionomer cement extruded from the margins of the crown in Hall Technique. Moreover, more than half of the carers in a previously reported study [Page et al., 2014] had negative views about placing the separator rings prior to the placement of Hall PMCs.

One of the concerns reported in the literature with the Hall Technique has been the occlusal interference [Innes et al., 2007]. This was not an issue in the present study. None of the children or carers complained of occlusal issues when they were interviewed either directly following the dental treatment or at 3-6 months following the dental intervention.

The literature and recently published studies (BaniHani et al, 2017) have shown the advantages and the successful outcomes of selective caries removal, or the biological approach, which is associated with lower discomfort for children. The present study has clearly shown a clear advantage of the biological approach consisting mainly of Hall Technique in terms of its cost-effectiveness. Although this study had limitations that it was carried out in two specialist centres and with an overwhelming choice of hall technique in biological approach, a cautious extrapolation of the results to a primary care provider setting can be made.

Conclusion:

Although both a conventional and a biological approach had similar outcomes for the treatment of deep carious lesion in primary teeth in children, the biological approach adopted in this study consisting mainly of Hall technique was significantly more cost-effective. The

conventional and biological treatment approaches were both highly accepted among children and carers for the treatment of carious primary teeth.

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Author contributions: A.B, C.D, J.T and M.D conceived the ideas; A.B collected the data; A.B analysed the data; A.B, C.D and M.D all contributed to the writing.

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Legends:

Table-1: Baseline characteristics of the participants in the study sample including age (years), gender, teeth treated, initial diagnosis of teeth and dmft (sample size n = 246 patients and 836 teeth, conventional approach n = 114 patients and 428 teeth, biological approach n = 132 patients and 408 teeth).

Table-2: Descriptive data of the cost of treatment of the conventional and biological treatment approaches (in Pound Sterling)

Table-3: Distribution of children's responses to children acceptance of dental treatment questionnaire in both treatment approaches, the conventional and biological.

Table-4: Description of the themes that emerged from the open questions of the children's acceptance of conventional and biological treatment approaches

Table-5: Description of parents' responses to parents' acceptance of dental treatment questionnaire in both treatment approaches, conventional and biological.

Table-6: Description of the themes that emerged from the open questions of the parent's acceptance of conventional and biological treatments

Table 1: Baseline characteristics of the participants in the study sample including age (years), gender, teeth treated, initial diagnosis of teeth and dmft (sample size n = 246 patients and 836 teeth, conventional approach n = 114 patients and 428 teeth, biological approach n = 132 patients and 408 teeth).

Variable	**Conventional approach** n (%)	**Biological approach** n (%)	**Study sample** n (%)
Age at time of dental treatment			
Minimum	4.0 (14.9%)	4.0 (24.2%)	4.0 (19.9%)
Maximum	9.0 (7%)	9.0 (6.1%)	9.0 (6.5%)
Median	6.0 ± 1.52	4.0 ± 1.5	5.8 ± 1.52
Total	114 patients	132 patients	246 patients
Gender			
Male	51 (44.7%)	63 (47.7%)	114 (46.3%)
Female	63 (55.3%)	69 (52.3%)	132 (53.7%)
Teeth treated			
Second primary molar	224 (52.3%)	250 (61.3%)	474 (56.7%)
First primary molar	148 (34.6%)	157 (38.5%)	305 (36.5%)
Anterior	56 (13.1%)	1.0 (0.2%)	57 (6.8%)
Total	428 teeth	408 teeth	836 teeth
Initial diagnosis of teeth			
One surface cavity	180 (42.1%)	201 (49.3%)	381 (45.6%)
Two or more surface cavity	248 (57.9%)	207 (50.7%)	455 (54.4%)
Total	428	408	836
dmft			
Range	13	13	13
Median	8.0 ± 2.7	7.0 ± 2.6	7.0 ± 2.7

Table 2: Descriptive data of the cost of treatment of the conventional and biological treatment approaches (in Pound Sterling)

Descriptive statistics	**Conventional approach** N (£)	**Biological approach** N (£)
Total cost	19229.9	10438.4
Median	113.1 ±184.7	66.6 ± 80.9
95% confidence interval	134.4-202.9	65.05-92.898
Minimum	35.04	28.66
Maximum	875.21	900.40
Range	840.17	871.74

1 Table-3: Distribution of children's responses to children acceptance of dental treatment

2 questionnaire in both treatment approaches, the conventional and biological.

3

Question	Conventional Tx	Biological Tx
What do you think about the dental treatment you just had?		
Positive	39 (70.9%)	32 (58.2%)
Neutral	14 (25.5%)	16 (29.1%)
Negative	2.0 (3.6%)	7.0 (12.7%)
Total	55	55
How do you feel about:		
Having your teeth put to sleep to have the treatment done:		
Not bothered	42 (76.4%	2.0 (25%)
Neutral	7.0 (12.7%)	4.0 (50%)
Very bothered	6.0 (10.9%)	2.0 (25%)
Total	55	8
Sound of the drill:		
Not bothered	44 (80%)	2.0 (33.3%)
Neutral	8.0 (14.5%)	3.0 (50%)
Very bothered	3.0 (5.5%)	1.0 (16.7%)
Total	55	6
Having the rain coat on:		
Not bothered	37 (72.5%)	7.0 (87.5%)
Neutral	3.0 (5.9%)	-
Very bothered	11 (21.6%)	1.0 (12.5%)
Total	51	8
What do you think of having the silver cap put on your tooth?		
Positive	12 (85.7%)	36 (65.5%)
Neutral	-	15 (27.3%)
Negative	2.0 (14.3%)	4.0 (7.3%)
Total	55	55
What do you think of having the filling put on your tooth?		
Positive	36 (75%)	-
Neutral	8.0 (16.7%)	-
Negative	4.0 (8.3%)	-
Total	48	
How do you feel about your experience at the dentist?	50 (90.9%)	37 (67.3%)
I am very happy	4.0 (7.3%)	12 (21.8%)
Neutral	1.0 (1.8%)	6.0 (10.9%)
I am very unhappy		
Total	55	55
How friendly the staff was on our clinic?		
Were very friendly	55 (100%)	55 (100%)
Neutral	-	-
Were very unfriendly	-	-
Total	55	55

How well did the dentist explain things to you?		
Very well	54 (98.2%)	52 (94.5%)
Neutral	1.0 (1.8%)	3.0 (5.5%)
Things were not explained	-	-
Total	55	55

Table-4: Description of the themes that emerged from the open questions of the children's acceptance of conventional and biological treatment approaches

Themes emerged related to conventional treatment		**Themes emerged related biological treatment**	
Theme	n= number of children	Theme	n= number of children
What do you like the most about the treatment?(48/55)		**What do you like the most about the treatment?(21/55)**	
1. **Communication**		1. **Perception of Specialness**	
Positive reinforcement	3	Cap looks cool	1
Pro-active engagement	3	Cap is shiny	10
2. **Treatment procedure**		2. **Treatment procedure**	
Having the dental injection	7	Having the crown on	4
Teeth drilling	9	Being easy to push down	2
Having the raincoat on	6	Having the elastic bands on	1
Having the dental filling	9		
Having the cap on	8		
3. **Having the teeth checked before the treatment**	3	3. **Positive reinforcement**	
		Getting stickers after finishing the dental treatment	3
What do you hate the most about the treatment? (32/55)		**What do you hate the most about the treatment? (32/55)**	
1. **Elements of discomfort related to nature of treatment**		1.**Elements of discomfort related to nature of treatment**	
Having the injection	11	Cap feels tight	1
Teeth drilling	3	Cap hurt when pushed down	16
Having raincoat on	9	Placing separators	3
Having the filling	5		
2. **Negative sensory experience**		2.**Negative sensory experience**	
Seeing the needle prior to injection	1	Taste of the glue	10
Numb feeling	2	Having the gauze in the floor of the mouth	1
Taste of the acid etch	1	Feeling associated with touching the crown	1

Table-5: Description of parents' responses to parents' acceptance of dental treatment questionnaire in both treatment approaches, conventional and biological.

Questions	Conventional Tx (n=55)	Biological Tx (n=55)
My child coped well during the dental treatment…		
Strongly agree	37 (67.3%)	36 (65.5%)
Agree	15 (27.3%)	17 (30.9%)
No opinion	2.0 (3.6%)	-
Disagree	1.0 (1.8%)	2.0 (3.6%)
Strongly Disagree	-	-
How do you feel about your child experience at the dentist?		
I am very happy	51 (92.7%)	49 (89.1%)
Neutral	4.0 (7.3)	6.0 (10.9%)
I am very unhappy	-	-
The dentist explained very well why my child needed the provided dental treatment		
Strongly agree	45 (81.8%)	44 (80%)
Agree	9.0 (16.4%)	10 (18.2%)
No opinion	1.0 (1.8%)	-
Disagree	-	1.0 (1.8%)
Strongly Disagree	-	-
The dental team were kind during my child's dental treatment		
Strongly agree	47 (85.5%)	51 (92.7%)
Agree	7.0 (12.7%)	4.0 (7.3%)
No opinion	1.0 (1.8%)	-
Disagree	-	-
Strongly Disagree	-	-
Would you be happy for your child to have the dental treatment again?		
Yes	52 (94.5%)	53 (96.4%)
Neutral	3.0 (5.5%)	2.0 (3.6)
No	-	-

1 Table-6: Description of the themes that emerged from the open questions of the parent's

2 acceptance of conventional and biological treatments

3

Themes emerged related to conventional treatment Theme	n=number of children	**Themes emerged related to biological treatment** Theme	n= number of children
Is there anything you would like to say about your child dental Tx? (n=26/55)		**Is there anything you would like to say about your child dental Tx? (n=21/55)**	
1. **Communication:**		1. **Communication:**	
Anxiety reduction	8	Anxiety reduction	13
Explanation	6	Explanation	4
Re-assurance	2	Re-assurance	3
Showing gratitude	5		
2. **Treatment procedure**		2. **Treatment procedure**	
All comments were positive	5	No L.A needed and treatment was fast	1
What do you think your child found the easiest? (n=27/55)		**What do you think your child found the easiest? (n=5/55)**	
1. **Treatment procedure:**		1. **Treatment procedure:**	
Giving injection	8	No injection needed	1
Teeth drilling	5	Having the silver cap on	3
Teeth filling	7	Getting the bands on	1
Having the cap on	3		
2. **Communication**			
Re-assurance:			
Child been involved and spoken to directly	1		
Given breaks	1		
Pro-active engagement	2		
What do you think your child found the hardest? (n=32/55)		**What do you think your child found the hardest? (n=16/55)**	
1. **Elements of discomfort related to nature of treatment**		1. **Elements of discomfort related to nature of treatment**	
Giving injection	13	Pushing in the crown	7
Having raincoat on	6	Placing the separators	3
Teeth drilling	1	Keep the mouth open and still	4
Having filling	1	2. **Negative sensory experience**	
Having cap	1	Taste of the glue	1
Keeping mouth open and still	10	Having the gauze in the mouth	1

4

1