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# Title:

The impact of premature extraction of primary teeth on the subsequent need for orthodontic treatment

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# Short title:

Premature extraction

## **Keywords:**

Tooth extraction, primary tooth, malocclusion, orthodontic need, premature

## Abstract

**AIM:** To investigate if premature extraction of primary teeth was associated with orthodontic need in the permanent dentition.

**STUDY DESIGN:** This was a case-control study based on retrospective dental records.

**METHODS:** As part of NHS Dental Epidemiology Programme a sample of 366, twelveyear-old children from Bradford and Airedale were examined. The survey collected data on patient demographics, dental health status including orthodontic need. Data linkage was undertaken for those children participating in the NHS Dental Epidemiology Progromme who had previously accessed the local Salaried Dental Service (SDS). For these children, retrospective dental information was collected about premature extraction of primary teeth.

**RESULTS:** From the 366 children who were surveyed, 116 children had accessed the local SDS historically. Significantly more children from ethnic minorities, low socioeconomic backgrounds and high caries rate (p<0.001) were seen in the SDS. For the 107 children who accessed SDS, an increased total number of primary teeth extractions was positively associated with orthodontic need (odds ratio:1.18, CI –1.01 to 1.37).

**STATISCTICS:** Multilevel modelling was undertaken to identify variables associated with orthodontic need.

**CONCLUSIONS:** In the study group, orthodontic need was significantly associated with the number of primary teeth extracted.

## Introduction

The long-term impact of premature extraction of primary teeth has received limited attention in the research literature. Clinical guidelines provided by professional bodies [American Academy on Pediatric Dentistry Clinical Affairs Committee-Developing Dentition Subcommittee, 2008-2009; Fayle et al., 2001] urge clinicians to restore primary teeth where feasible, to maintain the space for the permanent dentition and thus minimise crowding and malocclusion in the permanent dentition. Cohort studies have reported that space loss occurs following extraction of the primary molars [Northway et al., 1984; Hoffding and Kisling, 1978]. There are, however, fewer studies that demonstrate the effect of this space loss on the development of subsequent malocclusion and need for orthodontic treatment [Ronnerman and Thailander, 1977; Pedersen et al., 1978]. These studies have significant methodological flaws with high risk of bias and consequently their findings have to be interpreted with caution [Bhujel, 2013].

Approximately every four years the NHS Dental Epidemiology Programme undertakes a dental survey of 12-year-old children who attend mainstream secondary school in England. This national survey uses a robust sampling framework with aim of collecting information from a representative sample of 12-year-old children. As part of the 2008/2009 sample, an orthodontic need assessment was reported for the first time. The dental survey used a modified version of the Index of Orthodontic Treatment Need designed for epidemiological studies and was based on Dental Heath Component and Aesthetic Component [NHS Dental Epidemiology Programme for England; Burden et al., 2001]. The dental and orthodontic examinations were carried out by trained dentists [NHS Dental Epidemiology Programme for England].

In Yorkshire and the Humber, UK, there is a high prevalence of dental caries in young children. In Bradford and Airedale, 46% of five-year-old children have obvious dental caries into dentine and for this group at least four teeth are involved [Public Health England, Sep 2013]. In Bradford, many of the children with extensive dental caries are referred by their General Dental Practitioners to the Salaried Dental Service (SDS). These young children will

frequently undergo extraction of all their carious primary teeth under general anaesthesia. The SDS is the only local provider for dental treatment under general anaesthesia and also provides a full range of paediatric dental services including dental treatment under local anaesthesia and inhalation sedation. NHS Business Service Authority primary care data for 2010, showed two thirds of all primary teeth extracted in Bradford were carried out by the SDS.

The primary aim of this study was to investigate if Premature Extraction of Primary Tooth (PEPT) was associated with an increase in the orthodontic need. Secondary aim was to compare individual characteristics of children seen within SDS. For this study PEPT was defined as any primary tooth extracted prior to natural exfoliation by a clinician under either local anaesthesia or general anaesthesia.

### **Materials and Methods**

#### Data set

This was a data linkage study based on two existing data sets, the NHS Dental Epidemiology Programme for 12-year-old children for the region of Bradford and Airedale and clinical records from Bradford and Airedale SDS. The dental parameters collected by the NHS Dental Epidemiology Programme were predetermined and this study simply used this data but was unable to influence how the data was collected. Following discussions with Bradford Research Ethics Committee, the data linkage between the 12-year-old dental survey for Bradford and Airedale and SDS dental records was classified as a service evaluation. The dental survey was carried out in the academic year 2008/2009. From NHS Dental Epidemiology Programme in Bradford and Airedale, there were 5,588 children aged 12 years old attending mainstream education. A representative sample of 600 children was randomly selected according to an established NHS Dental Epidemiology Programme protocol. From this sample, the need for attendance at school on the day of the survey and positive consent from parents and children themselves, led to 366 children being examined. The sampling framework is detailed in figure 1. For each of 366 children, their name, date of birth and address were matched against dental records held by SDS. Paper dental records from archiving and electronic records (provided by Kodak R4® by Practiceworks) were examined to identify if any of these children had attended SDS. Where a positive link was identified (n=116), further data was collected from the SDS records about PEPT. Where the child's name and date of birth did not match, then they were considered not to have accessed dental care in SDS. Patient identifiable information of subjects was only used to match patient demographics from 12-year-old dental health survey to SDS dental records. Following the matching process and to assure anonymity of the children involved, each subject was given a unique identification number. Table 1 describes the data collected from the dental survey and SDS dental records.

All 12-year-old children who participated in epidemiological survey conducted by NHS Dental Epidemiology Programme in 2008/ 2009 in Bradford and Airedale district were eligible for this study. These children had orthodontic need assessment undertaken by two dentists using the modified Index of Orthodontic Treatment Need. The training of all dental examiners followed national guidance with dentists receiving training in the orthodontic index but no calibration was undertaken. Children who had premature extraction of permanent tooth/teeth were excluded from the study sample.

#### Statistical analysis

All data was entered onto an SPSS spreadsheet (Statistical Package for the Social Science) version 21.0 (SPSS Inc, Chicago, U.S.A.). Quantitative data were summarised using means and standard deviation if normally distributed and medians and inter quartile range if skewed. Data was examined for normality using the Shapiro-Wilks test. Categorical data was summarised using frequencies and proportions. The Pearson's Chi- Square statistics ( $\chi^2$ ) was used to compare the two groups (children seen in SDS and those not seen in SDS) in terms of gender, ethnicity, dental health component and aesthetic component of the Index of Orthodontic Treatment Need. The Mann-Whitney U test was used to compare age at the time of extraction, DMFT and overall Index of Multiple Deprivation in the two groups since the data was not normally distributed. A significance level of p <0.05 was used.

For children with history of PEPT, further evaluation was undertaken between how these extractions were carried out, namely a comparison between general anaesthesia and local anaesthesia. The Pearson's Chi-Square statistics ( $\chi^2$ ) were used to compare the gender, ethnicity, tooth type (maxillary or mandibular teeth or first primary molar or second primary molar) distributions and whether extractions were carried out under local anaesthesia or general anaesthesia. The Mann-Whitney U test were used to compare the total number of teeth lost by PEPT and age at extraction since the data was not normally distributed.

### Multilevel modelling

For the 107 children who were seen in SDS, a multilevel model was developed using MLwiN (v2.1) software, to identify factors associated with orthodontic need. A multilevel logistic regression model was used to identify factors associated with orthodontic need in children seen within SDS. The outcome variable for the model was the dental health component of Index of Orthodontic Treatment Need (need or no need).

The predictor variables selected were based on clinical knowledge and these included gender, ethnicity, age at the time of PEPT, specific tooth type and the total number of teeth extracted as a result of PEPT. Associations between the various predictive factors and orthodontic need were quantified by odds ratios, 95% confidence intervals and p values.

### Results

#### Children characteristics

From the 366 children examined in the survey, 116 (31.6%) children had accessed SDS during their childhood prior to the dental health survey and are shown in figure 1. The demographics of 366 children surveyed were divided into two groups, as 'seen in SDS' and 'not seen in SDS' and they are reported in table 2. Children seen in the SDS were significantly more likely to come from a non-white ethnicity, to be younger at the time of the dental health survey examination, to come from a more deprived background (increased overall Index of Multiple Deprivation score) and to have a higher level of dental caries.

One hundred sixteen children were seen in SDS, nine children (7.8%) had extraction/s of a permanent tooth or teeth and thus were excluded from the study. Therefore the study group comprised of 107 children. Sixty-six children (56.9%) had a history of PEPT with 29 children had extractions under general anaesthesia and the remainder, 37 children had extractions under local anaesthesia. Forty-one children (35.3%) were seen in SDS but had no history of PEPT. Descriptive summaries of child level data for need and no need for orthodontic treatment for 107 children seen in SDS are shown in table 3.

When comparing the groups who had treatment under general anaesthesia and local anaesthesia, age at the time of extraction was significantly different between these two groups (p<0.001) with a median age of 75 months (IQR 66-81) for general anaesthetic compared to 89 months (IQR 79.5-103) for local anaesthetic. The number of primary teeth extracted was also significant (p<0.001), with a median of eight teeth (IQR 7-12) for general anaesthetic compared to two teeth for local anaesthetic (IQR 1-4). Therefore children who were treated under general anaesthesia were younger and had a greater number of premature extractions. There were insignificant differences in the specific tooth types or from which arch of the mouth the extractions were carried out.

## Multilevel modelling

There were 376 primary teeth extracted (teeth were set at the lower level) from 107 children (children were set at the higher level) of which 41 children did not have history of PEPT. The multilevel logistic model indicated that, there was significant variation at a patient level (p=0.001). From the variables investigated the only significant independent predictor of orthodontic need was the total number of PEPT (table 4). Increased total number of teeth extracted as a result of PEPT led to a significant increase in orthodontic need (odds ratio of 1.18 (CI-1.01 to 1.37). The odds ratio reported an 18% increase in orthodontic need in the permanent dentition for every primary tooth lost as a result of PEPT. Other predictors such as gender, ethnicity, age at the time of extraction, whether it was maxillary tooth or mandibular tooth, the specific tooth type were not significantly associated with orthodontic need.

## Discussion

The findings in the population studied showed that PEPT was associated with an increased need for orthodontic treatment in the permanent dentition. However due to the study design and methodology, which were outside the authors control, care is needed with interpreting the findings to a wider population.

Bradford and Airedale offered a unique setting to study PEPT as a result of a high prevalence of risk factors for dental caries. This district has high levels of dental caries in primary dentition for five year olds compared to the national average [Public Health England, Sep 2013]. Many of these young children were treated by extractions as shown by the two fold increase in prevalence of missing teeth as compared to the national average of 12 % [NHS Dental Epidemiology Programme for England, Oct 2009]. Furthermore, over the last 20 years the only provider of dental treatment under general anaesthesia in the district has been the SDS. Consequently if a child had undergone extractions under general anaesthesia then this was likely to be identified by reviewing their SDS clinical records.

Children with premature extraction of first permanent molars were excluded from this study as this is a confounding variable. Extraction of lower first permanent molars is associated with intra-arch, inter-arch and skeletal problems and consequently these permanent extractions may be associated with orthodontic need [Abu Aihaija et al., 2000; Normando and Cavacami, 2010]. A retrospective study found in cases where first permanent molars were extracted, half developed favourable occlusion without orthodontic intervention [Jalevik and Moller, 2007].

This was the first national dental survey which reported orthodontic need based on a modified version of the Index of Orthodontic Treatment Need. This used a simple binary outcome with children recorded as need or no need [Burden et al., 2001]. The full dental health component of the Index of Orthodontic Treatment Need composes a scale of one to five [Brook and Shaw, 1989]. The modified version recorded children with scores four and five in the category of need for orthodontic treatment [Burden et al., 2001]. Similarly, for the aesthetic

component a simple binary outcome was recorded as need or no need [Burden et al., 2001]. The full aesthetic component ranges from one to ten [Brook and Shaw, 1989]. For the modified version only scores eight to ten were recorded as need. Children in the dental survey were classified as need or no need in both the dental health and aesthetic categories. For 107 children seen in SDS, 57% children were classified as needing orthodontics based on the dental health component and 17.7% based on the aesthetic component. All children who were recorded as having orthodontic need using aesthetic component were also recorded as having need according to the dental health component. This modified criteria for orthodontic need is more stringent than the current NHS orthodontic eligibility criteria which is set at children meeting a dental health component of three if they have an aesthetic component of six or above [British Orthodontic Society, 2009]. Thus, the dental survey methodology would have missed a small number of these borderline cases. The modified dental health and aesthetic components of the Index of Orthodontic Treatment Need have previously been validated for use in epidemiological surveys [Burden et al., 2001]. The examiners were trained in the modified Index of Orthodontic Treatment Need. However calibration was not undertaken as part of this training. No data was collected on intra or inter examiner reproducibility. The internal and external validity of the orthodontic assessment may therefore be questioned.

The modified Index of Orthodontic Treatment Need used in NHS Dental Epidemiology Programme was unable to provide further details of the children malocclusion beyond the binary outcome of need or no need. Consequently the impact of PEPT on different malocclusions or changes in complexity of orthodontic treatment cannot be quantified from this data. This would have been a valuable information as it would have allowed comparison with the Pedersen et al. [1978] study. In his study, they showed that PEPT led to an increase in a number of individual malocclusion features, such as class II malocclusion, deep bite, midline displacement and cross bite as well being associated with increased complexity of orthodontic treatment with extraction of permanent tooth more likely in order to correct these malocclusion features.

There was no significant difference in orthodontic need between the children who were seen in SDS and those who did not access the service. In this small study, 66 children out of 107 children were identified as experiencing PEPT in the SDS. This study relied on retrospective collection of information from dental records which limits what information was available. For example details were only available for teeth extracted by the SDS. Therefore some children seen by the SDS may also have had further teeth extracted in general dental practice. It is also unknown how many children who were not seen in the SDS had extractions of their carious teeth at their own dentist. Finally a few children will have had teeth extracted by Oral and Maxillofacial colleagues as a result of an acute hospital admission associated with a facial swelling.

Previous literature [Owen, 1971; Ronnerman and Thailander, 1977; Clinch and Healy, 1959; Richardson, 1965; Northway et al., 1984] has shown that space loss following PEPT was more marked in a number of clinical situations such as maxillary compared to mandibular extractions, posterior teeth extractions compared to anterior teeth or when a second primary molar was extracted as compared to a first primary molar. This research did not show a significant difference in orthodontic need with respect to these clinical situations. Interestingly from the results presented in table 3, orthodontic need was related to the number of extracted primary teeth extracted not simply whether a primary tooth is extracted or not. These finding are likely to be related to the limited size of the sample in this study.

Results looking at child level descriptives led to conclusion that children seen in SDS were more likely to be non-white, were younger, had higher levels of dental disease (higher DMFT index) and more socially deprived (higher IMD score). Differing levels of dental caries based on ethnicity has been recognised at regional level in previous publications with Asian children showing increased caries experience compared to White and Afro-Caribbean children and this difference was maintained even when controlled for material deprivation [Prendergast et al., 1997; Bradford and Airedale Teaching Primary Care Trust, 2006]. Median age difference of children seen and not seen in SDS was two months at the time of dental survey examination; although statistically significant, it is unlikely to have had a clinical significance.

The statistical methodology used in this study was appropriate as it accounted for the clustering of the data within individuals. The multilevel modelling approach accounted for the dependence of multiple data from the same child. Ignoring this dependence will result in

underestimation of standard errors and increased false positives for subgroup analysis. Predictor variables used were based on clinical knowledge. These predictors included in the model, however, explained little individual variation. Important predictors of the outcome such as time lag between extraction of primary tooth and eruption of permanent tooth and orthodontic parameters at the time of extraction such as skeletal base, centrelines, molar relationship and crowding were unavailable. This study was exploratory with no priori hypothesis therefore there was no priori sample size calculation for subgroup analysis. This could have led to important predictors not reaching statistical significance due to lack of power. However we followed Peduzzi's recommendation of 10 events per predictor during model building [Peduzzi et al., 1996].

A randomised trial with follow up until full permanent dentition or a long term prospective cohort study following children from primary dentition to full permanent dentition would provide more robust data to examine the impact of PEPT and subsequent orthodontic need. Long term follow up periods of approximately ten years makes these methodologies fraught with difficulty. For example follow up cohort studies of children receiving dental care under general anaesthesia showed less than 10% attending clinical appointment at three months following treatment [Jamjoom et al., 2001]. Innovative methodologies to maintain the cohort would be needed to ensure valid and generalisable results are achieved. This study, despite the limitations described, provides results that will help future estimations of sample size to investigate orthodontic need following extractions of primary teeth.

Analysis of the number of teeth extracted under local or general anaesthetic confirms clinical advice that treatment under general anaesthesia is more frequently prescribed for younger children with significant dental disease in multiple quadrants. The number of teeth extracted under general anaesthetic was higher than previously reported for exodontia under general anaesthesia [Albadri et al., 2006; Holt et al., 1999]. This data confirms the clinical guidance within the SDS, that where children require dental extractions under general anaesthetic all teeth with caries are extracted whether restorable or not. The odds ratio calculated from the multilevel model, extrapolate an 18% increase in subsequent need for orthodontic treatment for every primary tooth extracted. Thus reducing the number of premature extractions of

primary teeth, were appropriate and feasible, would appear beneficial in reducing subsequent orthodontic need in the permanent dentition. Restoring primary teeth can be achieved in a number of ways including the use of 'Hall crowns' which have been shown to be easier for young children to tolerate [Innes et al., 2011], conventional restorative approach using materials with proven track records of longevity, the use inhalation sedation and local anaesthesia and the provision of comprehensive dental care under general anaesthesia. Each of these procedures will take clinical time and therefore incur costs in terms of time for parent, child and dental team as well as financial costs to health care funders. These should be offset against costs associated with orthodontic treatment. Prevention of orthodontic need and malocclusion is likely to have great universal benefits to the population as a result of the inequitable access to orthodontic care from children with a more deprived background despite similar or greater impacts of their malocclusion on their Oral Health Related Quality of Life [Locker, 2007; Mandall et al., 2000; Morris and Landes, 2006].

## Conclusion

This case-control study is the first in the United Kingdom to assess the impact of extractions in primary dentition on development of malocclusion in the permanent dentition. In a population with high levels of dental caries, the total number of primary teeth extracted prematurely was significantly associated with increased orthodontic need. Each primary tooth extracted prematurely led to an 18% increase in orthodontic need in permanent dentition. When appropriate and feasible, dentists should minimise the number of primary teeth extracted extracted. This finding is in line with published clinical guidelines.

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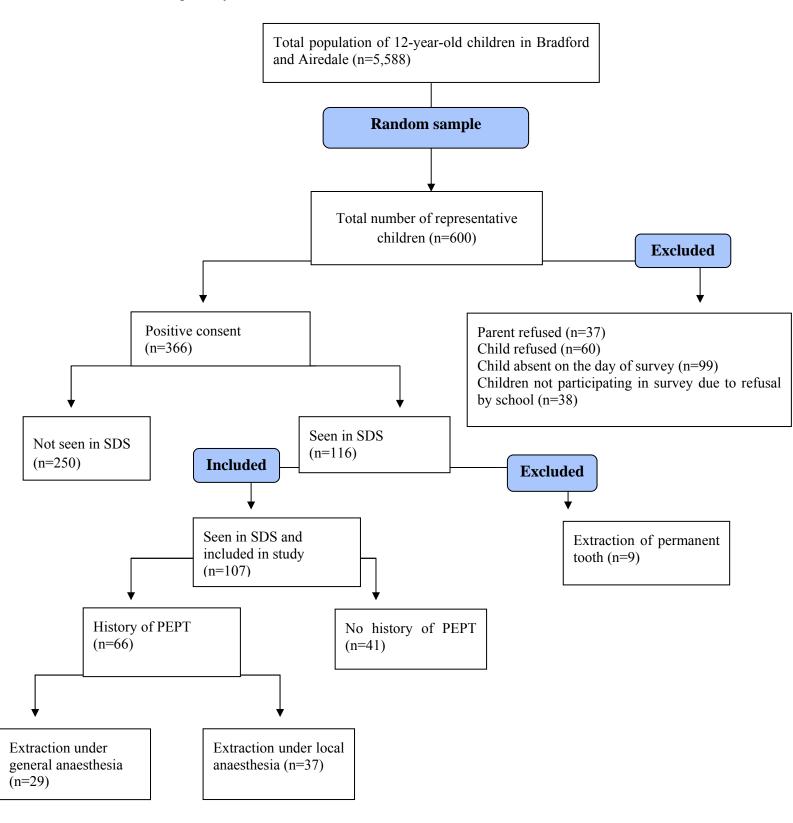
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Figure 1. Flowchart of the number of the 12-year-old children in Bradford and Airedale who were available for inclusion in this study of the orthodontic implications of premature extraction of primary teeth



SDS- Salaried Dental Service; PEPT- premature extraction of primary tooth

Table 1. Information collected from 12-year-old dental epidemiological survey and from retrospective dental notes in Bradford and Airedale Salaried Dental service (SDS).

Information from the 12 year old dental epidemiological survey	Information from dental notes in Bradford and Airedale Salaried Dental Service (SDS)		
Age	seen or not seen in SDS		
Gender	If seen in SDS:		
Ethnicity	* Whether there was a history of premature		
Home postcode	extraction of a primary tooth/teeth or not		
Date of dental survey DMFT Dental health component of modified Index of Orthodontic Treatment Need	<ul> <li>* Whether extractions were carried out under general anaesthesia or local anaesthesia</li> <li>* Date of extraction/s</li> </ul>		
			* Number of tooth/teeth extracted
	Aesthetic component of Index of Orthodontic	* Tooth notation/s for extracted tooth/teeth	
Treatment Need			

Table 2. Descriptive of patient groups 'seen in Salaried Dental Service' and 'not seen in Salaried Dental Service' by gender, ethnicity, dental health component and aesthetic component of the modified Index of Orthodontic Treatment Need, age at examination of survey, DMFT and the overall Index of Multiple Deprivation score.

	Children seen in Salaried Dental Service (n=116)	Children not seen in Salaried Dental Service (n=250)	p value	
Gender	Male, n=65 (60.7%) Male, n=145 (58%)		0.62	
n (%)	Female, n=42 (39.3%)	Female, n=105 (42%)		
Ethnicity	White, n=23 (21.5%)	(21.5%) White, n=160 (64%)		
n (%)	Non-white, n=84 (78.5%)	Non-white, n=90 (36%)		
Dental Health	No need, n=46 (43%)	lo need, n=46 (43%) No need, n=122 (48.8%)		
Component	Need, n=61 (57%)	Need, n=128 (51.2%)		
n (%)				
Aesthetic	No need, n=88 (82.2%)	=88 (82.2%) No need, n=217 (86.8%)		
Component	Need, n=19 (17.8%) Need, n=33 (13.2%)			
n (%)				
Age at the time	148	150	0.01*	
of survey in	(146-152)	(147-153)		
months				
Median (IQR)				
DMFT	2	1	0.001**	
Median (IQR)	(0-3)	(0-2)		
Overall Index of	49.25	27.86	0.001*	
Multiple	(36.06-60.95)	(17.84-48.03)		
Deprivation				
Median (IQR)				

\* p<0.05, \*\* p<0.01

Table 3. Descriptive of patient groups according to orthodontic need and no need in children seen in Salaried Dental Service (n=107) and children who were seen in Salaried Dental Service and experienced premature extraction of primary tooth (PEPT) (n=66).

	Children with orthodontic need (n=61)	Children with no orthodontic need (n=46)	
Gender	Male, n=35 (57.4%)	Male, n=30 (65.2%)	
n (%)	Female, n=26 (42.6%)	Female, n=16 (34.8%)	
Ethnicity	White, n=15 (24.6%)	White, n=8 (17.4%)	
n (%)	Non-white, n=46 (75.4%)	Non-white,	
		n=38 (82.6%)	
DMFT	2 (0-3)	1.5 (0-3)	
Median (IQR)			
Overall Index of Multiple Deprivation	48.02 (25.37-61.94)	51.57 (40.92-60.05)	
Median (IQR)			
History of PEPT	Yes, n= 37 (60.7%)	Yes, n=29 (63%)	
Yes/no	No, n=24 (39.3%)	No, n=17 (37%)	
For children seen in Salar	ied Dental Service and had history	of PEPT (n=66)	
	Children with orthodontic need (n=38)	Children with no orthodontic need (n=28)	
Number of teeth lost by PEPT	6.5 (2-9)	4 (1-6)	
Median (IQR)			
Teeth lost under local	Local anaesthesia, n=19 (50%)	Local anaesthesia, n= 18 (35.7%)	
anaesthesia v. general anaesthesia	General anaesthesia, n=19 (50%)	General anaesthesia, n=10 (64.3%)	
Maxillary v. mandibular	Maxillary tooth, n=117	Maxillary tooth, n=58 (48.7%)	
tooth	(53.9%)	Mandibular tooth, n=61 (51.3%)	
	Mandibular tooth, n=100 (46.1%)		
Age at the time of PEPT in months	79 (67-92)	80 (72-94)	
Median (IQR)			
Tooth type lost by PEPT	Anterior, n=49 (22.6%)	Anterior, n=16 (13.4%)	
	First primary molar, n=84 (38.7%)	First primary molar, n=57 (47.9%) Second primary molar, n=46 (38.7%)	
	Second primary molar, n=84 (38.7%)		

PEPT- Premature Extraction of Primary Tooth

Table 4. Multilevel results to investigate predictor variables to influence orthodontic need in 107 children seen in Salaried Dental Service. The coefficient estimates of variables, their standard error (), odds ratio, 95% confidence interval of the odds ratio () and size of effect are given for the model.

	Variables		Null Model	Random Intercept model with covariates	Odds ratio (CI)	Size of effect on orthodontic need
Fixed effect			0.35(0.21)	0.09(1.27)		
Child level	Gender (ref Male)	Female v. Male		0.35(0.45)	1.42(0.58 to 3.45)	
	Ethnicity (ref White)	Others v. White		-0.46(0.53)	0.63(0.22 to 1.79)	
	Total teeth lost by premature extraction of primary tooth			0.16(0.08)	1.18(1.01 to 1.37)*	18%
Tooth level	Age at premature extraction of primary tooth			-0.01(0.01)	.96(0.12 to 8.59)	
	Tooth type (Maxillary or mandibular tooth)	Maxillary v. no extraction		0.11(2.27)	1.12(0.01 to 95.68)	
		Mandibular v. no extraction		0.12(2.28)	1.12(0.01 to 97.89)	
	Tooth type (second primary molar, first primary molar or anterior tooth)	Second primary molar v. no extraction		-0.12(0.41)	.89(0.4 to 1.2)	
		First primary molar v. no extraction		-0.16(0.40)	0.85(0.39 to 1.88)	
		Anterior tooth v. no extraction		0.0(0.0)	1(1 to 1)	
Random effect			2.6(0.59)	2.93(0.66)		

\* Significant value (95% confidence interval does not include 0)