Palatally impacted canine and maxillary arch width

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Abstract

Objective

The aim of this case-control study was to investigate the association between palatally impacted canines and maxillary arch width.

Method

Maxillary arch width was identified for a sample of patients with palatally impacted canines by measuring the maxillary inter-canine, inter-premolar and inter-molar widths. Maxillary arch width of patients with palatally impacted canines was compared with a control group of patients with normally erupted canines. The measurements were taken on study models of both groups using electronic digital callipers.

Results

Records of 58 subjects were assessed. Subjects in this study are orthodontic patients between 13 to 16 years of age with mean age of 14 years. Study group included 29 patients who have palatally impacted canines (PIC) and control group included 29 patients who did not present with palatally impacted canines.

Statistical method

T-tests were used to assess the significance of the difference in maxillary arch width between the two groups. T-test showed no statistically significant difference in arch width between patients with and patients without (PIC).

Conclusion

For our sample there was no association between arch width and the presence or absence of palatally impacted canines.

Declaration

No portion of the work referred to in the dissertation has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Sara El-kilani

2016

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Dedication

I would like to dedicate this MSc to:

- My mother Najat Akhlief who continuously encouraged me, believed in me and provided the best opportunities in life for me. She made it possible for me to stand where I am today.
- My dear husband Mohamed and my little angel Yara. Their love helped me through the most difficult times.
- My two sisters, Omima and Yosra and my brother Abdulrahman for their encouragement and support throughout my stay in the UK.
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Introduction

The impaction of the maxillary canine is a common clinical problem that can lead to root resorption and damage to the upper anterior teeth, and it can require surgery and complex orthodontic techniques to correct and maybe prevented by the timely loss of the upper deciduous canine.

Numerous studies have attempted to measure the incidence of maxillary canine impaction. Bass examined 9102 orthodontic patients who were referred to the Royal Victoria Hospital in Bournemouth, and found 150 patients with unerupted upper canines. He reported an incidence of 1.65% of impacted maxillary canines among the studied population. Bass believed this high incidence was due to the selective referral of the more complex cases, such as impacted canine's cases, from all around the county of Dorset and the western part of Hampshire to the consultants in hospitals (Bass, 1967).

In another study, 12000 dental records for teenagers and adult patients attending The United Oxford Hospitals were surveyed. The incidence of impacted canines among the sample was 1.5% (Rayne, 1969).

Thilander and Myrberg (1973) reported a cumulative prevalence of 2.2% of the impacted canine in Swedish school children aged 7 to 13 years. However, this slightly higher prevalence could be explained by the inclusion of a very young age group in this study. At such a young age, it is difficult to determine whether or not the canine will become impacted, as the maxillary canine tooth usually erupts at the age range 12 to 13 years and this may have led to an over estimation of the incidence of impaction of maxillary canines.

In another survey of the Swedish schoolchildren, it was found that 1.7% of the 505 children examined showed canine eruption disturbances (Ericson and Kurol, 1986). A year later, the same authors conducted a survey on a larger sample. They found a similar figure of 1.5% of potentially ectopic maxillary canines (Ericson and Kurol, 1987).

A slightly lower incidence of the impacted maxillary canine was found among the American and the Chinese populations, with an incidence of 0.92% and 0.8% respectively (Dachi and Howell, 1961; Chu et al., 2003).

With regard to the frequency of impaction among the teeth, canines are the second most frequently impacted teeth after third molars (Shah et al., 1978). Dachi and Howell (1961) noted earlier that the teeth most often impacted, in order of frequency are: maxillary third molars, mandibular third molars, maxillary canine and mandibular premolars. Similarly but more recently, Chu et al. (2003) reported that the order of the most frequently impacted teeth is: mandibular third molars (82.5%) followed by maxillary third molars (15.6%) then the maxillary canine (0.8%).

In terms of the distribution of the impacted canine among sexes, a dominance of females was shown in most studies (Dachi and Howell, 1961; Bass, 1967; BECKER et al., 1981; Peck et al., 1994). However, some studies, for instance (Rayne, 1969; Kramer and Williams, 1970), reported an equal number of male and female patients with this condition.

Development and eruption of maxillary canine tooth are slightly different from other teeth. Early in the 40s, few researchers studied the development and eruption path of the maxillary canine in order to identify the aetiological factors behind its impaction. Broadbent (1941) described the development of teeth and their supporting structures from birth to adulthood. Availability of lateral and frontal standardized cephalometric radiographs of 5000 children during various stages of life helped him to give an informative and detailed description of dent alveolar development in each stage. Regarding the development of maxillary canine, Broadbent mentioned that this tooth starts calcification around 12 months of age, and this process takes place between roots of deciduous first molar. Once the deciduous molar erupts, it leaves the developing canine behind and allows space for first premolar to develop between the deciduous molar roots. By the age of seven, crown of the maxillary canine is completed and positioned mesial to root of the primary canine. Few months later, the maxillary canine starts moving downward and forward to find its way into occlusion. Broadbent emphasized that development of normal occlusion requires development of normal supporting structures.

Dewel (1947) studied development of the maxillary canine. He was among the earliest to describe challenges facing maxillary canine as it erupts, which are “the longest period of development, the deepest area of development, and the most devious course of travel”.

More recently, Coulter and Richardson (1997) attempted to measure eruption path of maxillary canine from age of 5 to 15. Using lateral and depressed postero-anterior radiographs, they were able to assess the eruption pathway in three dimensions. They proved that the path of eruption of the maxillary canine is torturous antero-posteriorly and bucco-lingual. They also reported that between the age of 8 and 10 years, the maxillary canine normally show buccal movement away from a position lingual to root of the primary canine. When the canine fails to do so, it remains impacted in the palate. Equally important, they reported that normal development of the subnasal area is required for the downward and buccal movement of the canine. This is an important time when intervention with deciduous extractions may help normal development to re-establish.

Likewise, McSherry and Richardson (1999) measured the eruption path of the maxillary canine from the age of 5 to 15. They proved that buccal movement is significant in normal eruption of canines and that when the canine fails to move buccally between the ages of 10 and 12 years it becomes palatally impacted.

Jacoby (1983) assumes that palatal and labial canine impactions have different aetiologies based on his analysis of 46 maxillary unerupted canines treated in his clinic. He found that reduction in arch-length is associated with labial canine impaction, while excessive space in the maxillary bone is associated with palatal canine impaction. Jacoby also states that “labially unerupted” and “ectopic labially erupted canines” are a result of crowding with different degrees of reduction of arch-length. This difference is evident in the inclination of the impacted canines. The palatally impacted canines are often inclined obliquely or even impacted horizontally, while labially impacted canines presented with a more vertical angulation.

Peck et al. (1994) states that “Facial displacement of the maxillary canine is usually due to inadequate arch space. In contrast, palatal displacement of the maxillary canine is a positional anomaly that generally occurs despite adequate arch space”. However, they did not reference this observation to any previous research.

The difference between palatally and labially displaced canines with regard to dental development has been investigated by Becker and Chaushu (2000). They compared dental age with chronologic age of patients with palatally displaced canines, labially ectopic canines and a control group with bilaterally erupted or

unerupted but undisplaced maxillary canines. They found significant retarded dental development in half of the patients with palatally displaced canines, while the stages of dental development for patients with labially ectopic canines were similar to those patients in the control group. Becker and Chaushu suggest that palatal and labial ectopic canines have different aetiologies.

In a more recent study, Cernochova et al. (2010) investigated the difference in dentoskeletal characteristics between patients with palatal and patients with labial canine displacement. Using lateral cephalographs, they assessed the sagittal and vertical skeletal relationships, the inclination of maxillary central incisors and type of mandibular growth rotation. They found a statistically significant difference in dentoskeletal characteristics between the two groups.

There is higher prevalence of palatally than labially impacted canines in most studies. Nordenram and Strömberg (1966) report a prevalence of 12% of canine impaction in the dental arch, with 54% for the palatally impacted canine, 34% for the buccally impacted canine. Bass (1967) reported an incidence of only 8.6% of labially displaced canine while 90.3% of the impacted canines were palatal. Similarly, (Nordenram and Strömberg, 1966; Rayne, 1969) found that only 16% of the impacted canines were deflected labially and the remainders were misplaced palatally or in the line of the arch. The ratio of palatal to labial canine impaction is reported by Fournier et al. (1982) to be a 3:1, while Jacoby (1983) reported a ratio of 6.6:1 of palatal to labial canine impaction. In addition, a recent study by Fattahi et al. (2012) showed that the prevalence of palatal canine impaction is higher than labial canine impaction in the Iranian population.

On the contrary, Brin (1986) found a prevalence of palatal canine displacement of only 1.5% in a sample of 2440 adolescents attending school in Jerusalem. This percentage is much less than that reported in other studies. They explained their results by the fact that the study population was drown from different ethnic groups.

The scope of this study will be limited to the palatally rather than the labially impacted canine.

Many authors have been interested to correlate the palatally impacted maxillary canine with certain causative factors. Some studies suggest genetic basis while other studies focus more on local factors behind the occurrence of the palatally impacted canine.

It is a widely held view that genetic factors play an important role in the occurrence of the palatally impacted canine. Zilberman et al. (1990) studied family members of patients with palatally displaced canine to investigate the role of genetic factors. They examined parents and siblings of 25 patients with palatally displaced canine and concluded that family members of patients with palatally displaced canines are likely to have the same condition. They also noted that immediate, first-degree relatives show high prevalence of anomalous lateral incisors, which is four times higher than general population. Equally important, they found that late development of dentition is associated with palatally displaced maxillary canine. This finding is also reported by (Becker and Chaushu, 2000). Based on findings from these studies, it appears that genetics could attribute to the occurrence of the palatally impacted canine.

Peck et al. (1994) made an attempt to gather all the evidence that support the genetic theory. Although, in few occasions, they were not precise in reporting figures and numbers found in literature and fail to acknowledge findings to the original authors in some places, there is no doubt that genetics strongly controls the occurrence of palatal canine displacement.

Baccetti (1998) also supports the genetic theory. He found significant association between five dental anomalies; small in size maxillary lateral incisors, aplasia of second premolars, infraocclusion of primary molars, enamel hypoplasia and palatal displacement of the maxillary canine. He believes that the palatally displaced canine could be genetically linked with other types of tooth and eruption disturbances.

Another study pointing to genetics as an aetiological factor behind the occurrence of this condition is a study by Langberg and Peck (2000a). They found statistically significant reduction of mesiodistal crown size of maxillary and mandibular incisors in patients with palatally displaced canine. They added more that, since teeth sizes

match each other throughout the dentition, this means that patients with palatally displaced canine have generalized reduction in tooth size throughout the dentition. They state that this association explains the observed arch space adequacy found in patients with palatal canine displacement. They also assume that these traits share a common genetic control.

There is a large volume of published studies describing the association between palatally impacted maxillary canine and anomalous or missing maxillary lateral incisor. Miller (1963) was among the earliest to state that congenital absence of lateral incisors can affect the eruption of the canine. Few years later, Bass (1967) claimed that he is the first to report significantly high level of congenitally missing teeth in patients with impacted canine, but he failed to explain the reason behind this association.

Becker et al. (1981) investigated the incidence of lateral incisor anomalies in relation to palatally displaced canine. They found that nearly half the cases of palatally canine displacement have one or more of lateral incisor anomalies (missing, peg shaped or small size). Moreover, they attempted to explain in depth the pathogenesis of palatal displacement of maxillary canine in association with each type of the anomalies of lateral incisor.

Two years later, Becker et al. (1984) attempted to prove their assumptions by measuring root length of lateral incisor adjacent to unilaterally impacted canines and compared it with root length of lateral incisor adjacent to normally erupted canines. They show a strong association between lateral incisors with short roots and small crowns and the palatally displaced canine. They gave the same explanation as in their previous study; short root and late development of lateral incisor can cause palatal displacement of maxillary canine by lack of guidance.

Jacoby (1983) believes that the space created by missing or peg shaped lateral incisor can allow the canine to “dive” in the maxillary bone and then becomes impacted palatally. This assumption is based on his finding of excessive space in some cases of palatally impacted canine.

Brin et al. (1986) found that 43% of the palatally displaced canines were found adjacent to small, peg shaped or missing lateral incisors in a random sample of 2440 adolescents. He supports the guidance theory.

Likewise, Zilberman et al. (1990) found that anomalous lateral incisors are found adjacent to palatally displaced canines six times more frequent than adjacent to the normally erupted canines. They also showed that in the general population, 7.3% of people have anomalous lateral incisor. While in palatally displaced canine population, the percentage of people having anomalous lateral incisor is 46%.

The guidance theory was also mentioned in number of literature reviews (Bishara and Ortho, 1992; Inspection, 2000).

Although many authors documented the association between lateral incisor anomalies and palatally displaced or impacted maxillary canines, the exact mechanism and the pathogenesis of the displacement or impaction is not yet clear.

Peck et al. (1994), who strongly support the genetic theory, reported only a 3% of missing lateral incisor in patients with palatally displaced canine, while missing third molars in patients with palatally displaced canine was twice the incidence in patients with normally erupted canine. They believe that even if the high prevalence of anomalous lateral incisor in patients with palatally displaced canine was true, this is because these two conditions are part of genetically related dental disturbances that usually occur in combination.

In contrast to most of the previously mentioned studies, Brenchley and Oliver (1997) found no statistically significant association between palatally displaced canine and lateral incisor with short root or small crown. However, it is important to bear in mind the possible bias introduced by the small sample size in this study.

Adequacy of arch space has been investigated as local factor which may contribute to the aetiology of palatally impacted canine. Hitchin (1951) mentioned arch space as a possible aetiological factor in the development of palatally impacted canine. He states that “Inadequate development in size of the arch is an obvious predisposing cause…” He further explained that because maxillary canine develops high in the maxilla and it is among the least teeth to erupt, they are susceptible to deflection from their normal path during the descending from the site of development and become impacted. Although it was not mentioned explicitly, it seems that he believes that crowding is the reason behind palatal impaction of maxillary canine.

Kettle et al. (1958) also assumed that crowding can cause impaction of maxillary canine. He believes that patients with deep bite tendency and retroclined maxillary incisors, where the canine space is limited in antero-posterior direction, are more likely to have impacted canine.

Most studies that investigated the space condition in patients with palatal canine impaction showed that there is enough space in the arch for the palatally impacted canine. Jacoby (1983) found that 85% of the palatally impacted canines have sufficient space. He assumes that canine becomes palatally impacted if there is extra space in the maxillary bone because canine will be free to dive in the maxillary bone.

Zilberman et al. (1990) state that there was absence of crowding in a sample of 25 patients with palatally impacted canine.

Langberg and Peck (2000b) explained the observed adequacy of space in patients with palatally displaced canine by their finding of smaller than average teeth in this group of patients. Becker et al. (2002) found similar findings and concluded that small teeth are the reason behind the excessive arch length which is seen in palatally impacted canine patients.

The aetiology of maxillary canine impaction has always been an area of interest to many clinicians. McSherry and Richardson (1999) examined records of 20 patients with impacted canines. These records were part of the Belfast Growth Study in which lateral and depressed postero-anterior (PA) cephalometric radiographs were taken annually for children from age of 5 to 15 years. They noted a difference in growth as early as 5-6 years between children with ectopic maxillary canine and children with normal canines, this difference in growth was noted in the lateral plane of space and continued throughout the growth period. The authors failed to draw any conclusion from this finding and failed to distinguish between the two types of ectopic canines.

Jacoby (1983) mentioned that dysplasia at “maxilla-premaxillary suture” can change the path of eruption of maxillary canine and hence cause its impaction.

Brin et al. (1993) proposed that trauma to the maxillary anterior teeth during early mixed dentition can lead to maxillary canine impaction. Their assumption was based on their observation of two cases of traumatic injuries, they believe that in the two cases, trauma to the lateral incisor on one side could have affected the

eruption of the adjacent canine, while canine on the other side continue to erupt normally. But, case report is not considered as a strong level of evidence to draw conclusions from.

Mercuri et al. (2013) assessed skeletal features of patients with palatally displaced canine, buccally displaced canine and patients without maxillary canine impaction. Using lateral cephalometric radiographs, they evaluated number of cephalometric measurements in sagittal and vertical directions and they assessed few growth parameters.

They found that patients with palatally displaced canine have normal antero-posterior skeletal relationship, high prevalence of class I and lower ranks of class II and class III relationship, normal vertical skeletal relationship and normal facial divergence. They also noted a frequent absence of malocclusion in patients with palatally displaced canines.

Maxillary arch width has also been investigated as a potential aetiological factor in the process of palatal impaction of maxillary canine. Studies evaluated the relationship between the palatally displace canine and the maxillary arch width are categorized into three groups as seen in Figure 1 and Table 1.

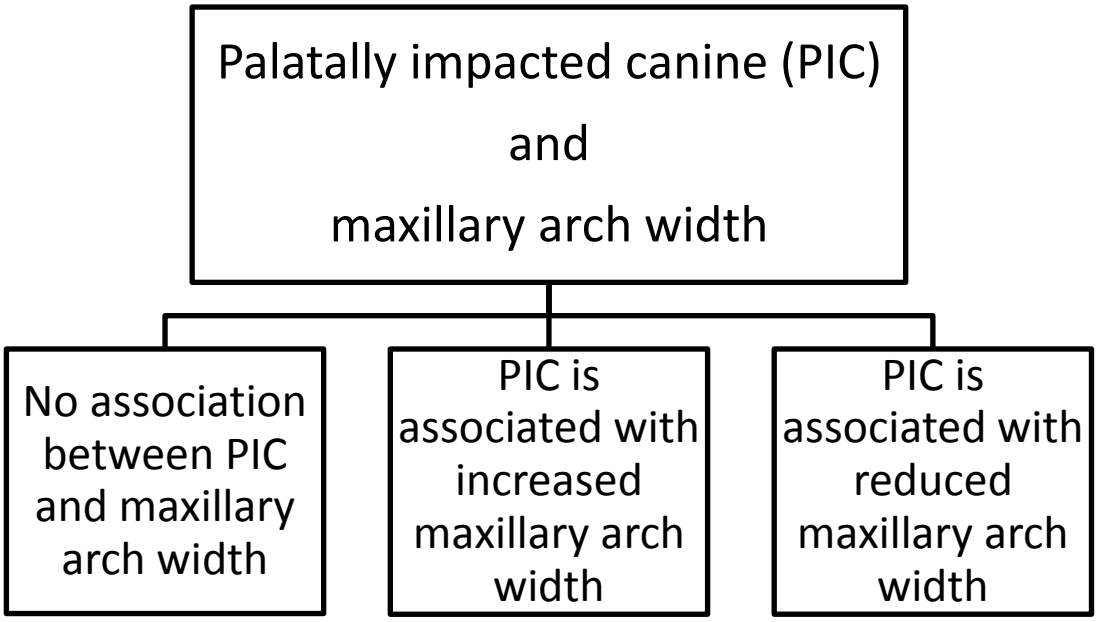

Fig 1: Studies evaluated the association between the palatally displaced canine and the maxillary arch width.

Table 1: Literature evaluated maxillary arch width in relation to palatal impaction of canines.

No association between PIC and maxillary arch width	PIC is associated with reduced maxillary arch width	PIC is associated with increased maxillary arch width
(Langberg and Peck, 2000a) (Saiar et al., 2006) (Anic-Milosevic et al., 2009) (Fattahi et al., 2012) (Yan et al., 2013)	(Kettle et al., 1958) (McConnell et al., 1995) (Schindel and Duffy, 2007)	(Al-Nimri and Gharaibeh, 2005)

Langberg and Peck (2000a) evaluated the maxillary dental arch width in a group of patients with palatally displaced canines and compared these measurements with a control group of patients with normally erupted maxillary molars. The two groups were matched by age and gender.

They found no statistically significant difference in inter-premolar and inter-molar widths between the two groups. They believe that maxillary arch width is not the aetiology behind development of palatally impacted canine. They also concluded that the occurrence of the palatally displaced canine is genetically controlled.

Saiar et al. (2006) investigated the role of maxillary skeletal width in occurrence of palatally displaced canines. They measured the maxillary skeletal width and nasal cavity width using postero-anterior cephalograms. They also measured the maxillary inter-molar arch width on study models of patients with palatally displaced canines, and they compared these measurements with a control group matched by age, gender and type of malocclusion.

They found no statistically significant difference in maxillary skeletal width, nasal cavity width and inter-molar width between the two groups. They concluded that maxillary skeletal width does not contribute to the development of palatally impacted canine.

Anic-Milosevi et al. (2009) investigated dental and occlusal features associated with palatal displacement of maxillary canine. They measured maxillary inter-premolar and inter-molar widths from the study models of patients with palatally displaced canine and compared these measurements with a control group matched to the study group by age and ethnicity. They found no statistically significant difference between the two groups regarding the maxillary arch width.

Fattahi et al. (2012) measured the maxillary arch width, length and palatal height index in a sample of Iranian patients with impacted maxillary canine. The subjects were divided in to two groups, palatal and buccal canine impaction groups, with a mean age of 20 years in both groups. Measurements from both groups were compared with control group of patients without maxillary canine impaction. The control group was matched with the two study groups according to age, gender, crowding and type of malocclusion. The arch width was measured at inter-canine, inter-premolar and inter-molar regions.

They found that arch width of patients in both groups, palatal and buccal canine impaction groups, were similar to each other and similar to the control group. These findings suggest that maxillary arch width is not related to the impaction of the maxillary canine.

Yan et al. (2013) analysed the pre-treatment cone-beam computed tomography scans of patients with and patients without maxillary canine impaction to find out the aetiological factor behind the occurrence of maxillary canine impaction in Chinese patients. The study sample consisted of patients with palatal canine impactions, patients with buccal canine impaction and patients in the control group without canine impaction, the groups were matched by age and gender.

They reported narrowing in anterior arch width (dental and skeletal) in patients with buccally impacted canine but not in patients with palatal canine impaction. They found increased prevalence of anomalous lateral incisors in the platally impacted canine group.

They concluded that buccal canine impaction in Chinese patients is a consequence of anterior transverse deficiency, while palatal canine impaction is associated with small or missing lateral incisor. They also explained the high prevalence of buccal canine impaction in Chinese population by the fact that

maxillary underdevelopment or narrowing of maxilla, which are common among Asians, contribute to the buccal impaction of maxillary canine.

Despite all the previously mentioned studies showed no association between maxillary arch width and palatal canine impaction, there are some studies that report different findings.

It is difficult to reach to a conclusion regarding the association between maxillary arch width and the occurrence of palatally impacted canine, especially with the contradicting results of different studies.

There are some studies reported association between maxillary arch width deficiency and palatal impaction of maxillary canine. Kettle (1958) was among the earliest to report that maxillary canine impaction occurs more often in cases with narrow upper arch and constricted inter-canine width.

McConnell et al. (1995) who found a deficiency in the maxillary arch width in patients with canine impaction. However, no attempt was made to distinguish between buccal and palatal canine impaction during the statistical analysis of data.

Schindel and Duffy (2007) investigated the association between maxillary transverse discrepancy and maxillary canine impaction in patients in the mixed dentition with mean age of 9 years. The study group consisted of patients with maxillary transverse discrepancy, while the control group were patients without transverse discrepancy. The maxillary transverse discrepancy was measured as the difference between the maxillary and mandibular inter-molar widths. They evaluated the position of maxillary canines from the panoramic radiograph in both groups.

They concluded that patients with transverse discrepancy are more likely to have impaction of maxillary canines (43%) than patients without transverse discrepancy (14%).

On the other hand, there is one study showed association between maxillary arch width excess and palatal impaction of maxillary canine. Al-Nimri and Gharaibeh (2005) investigated dental and occlusal features in patients with unilateral palatally impacted maxillary canines. The study group was matched with a control group of patients with normally erupted canines. Maxillary arch width was assessed in both groups by measuring the inter-premolar and inter-molar widths on dental casts.

They found that patients with palatally impacted canines have significantly increased inter-premolar and inter-molar widths in comparison with patients with normally erupted canines. They assumed that maxillary arch width excess can contribute to the palatal impaction of the maxillary canine.

This assumption was supported by the fact that palatal impaction of the canine is common among European, because they have large, well developed upper arches. They mentioned that maxillary arch width excess in patients with palatally impacted canine is the reason behind the non-extraction, non-expansion treatment of most of these cases.

They also noted an association between the palatal impaction and class II division 2 malocclusion. They believed that this supports their previous assumption that arch width excess in patients with class II division 2 malocclusion may contribute to the palatal impaction of maxillary canine.

As mentioned previously, contradicting results of these studies made it difficult to clarify the association between maxillary arch width and palatally impacted canines; this indicates a need for a structured study that avoids major sources of bias.

Knowing more about the relationship between maxillary arch width and the palatally impacted canine will enable clinician of recognising the associated risk factors for the palatally impacted canine and hence facilitate early diagnosis and interception to prevent the occurrence of this condition.

Objectives

Aims

1. To measure the maxillary arch width in a group of patients with palatally impacted canines by measuring the maxillary inter-canines, inter-premolars and inter-molars widths.
2. To compare the maxillary arch width of patients with palatally impacted canines with a control group of patients with normally erupted canines.

Null hypothesis

There is no difference in the maxillary arch width between patients with palatally impacted canines and patients with normally erupted canines.

Outcome measures

1. Maxillary inter-canine width: distance between cusp tips of maxillary permanent canines. In case the canine is impacted measurement will be taken from primary canine. If no primary canine an estimate point on the alveolar ridge where the canine cusp tip would be will be used.
2. Maxillary inter-premolar width: distance between distal triangular fossae of maxillary second premolars.
3. Maxillary inter-molar widths: distance between central fossae of maxillary permanent first molar.

Materials and methods

Study design

To investigate the association between the presence of palatally impacted canine and the risk factor maxillary arch width, a case-control study design was used.

Ethics application

Application form will be made using the Integrated Research Application System (IRAS), and then will be submitted to the National Health Services Research Ethics Committee (NHS REC).

Approval from the Research and Innovation Department (R&D approval) at the research site (Countess of Chester Hospital) will be sought.

Data collection will extend from Jun 2015 to Sep 2015, and then analysis of data and write up of the project will extend from Oct 2015 to Aug 2016.

Subjects

The study group will include pre-treatment records of patients having either unilateral or bilateral canine impaction, with no distinction between the two types. The control group will include pre-treatment records of patients with normally erupted maxillary canines. These records are study models and two radiographs taken at right angle to confirm the palatal position of the impacted canine. The two groups will be matched by age, gender, ethnicity and type of malocclusion to avoid some known confounding factors.

Sample size calculation

Size of the sample was calculated to detect a true difference in the maxillary arch width of 1mm. The assumptions are: a significance level of 0.05, a power of 80% a ratio of control per experimental subjects of 1:1 and a standard deviation within each subject group of 3mm, which was reported by previous studies. The calculated sample size was 24 patients in each group and this was consistent with previous literature.

Sample selection

The sample will be randomly selected from pre-treatment records of patients have received orthodontic treatment at Countess of Chester hospital.

The study group will be selected from population of patients with palatally impacted canines by stratified randomization.

The population will be classified in to eight strata according to gender and type of malocclusion (male class I, male class II div1, male class II div2, male class III, female class I, female class II div 1, female class II div 2 and female class III). For each stratum there will be the three age groups (13-14years, 14-15years and 15-16years). Then by proportional allocation, subjects will be selected from each stratum. The control group will consist of orthodontic patients with normally erupted maxillary canines, and this group will be matched by age, ethnicity, gender and type of malocclusion to the previously selected study group.

Inclusion criteria

The study group consists of orthodontic patients with either one or both maxillary permanent canines impacted. Palatal impaction will be confirmed with two radiographs taken at right angle. The control group will consist of orthodontic patients with normally erupted maxillary permanent canines.

The age of patients in both groups will range from 13 to 16 years.

Exclusion criteria

Subjects with any syndrome, cleft lip and palate will be excluded from the study.

Statistical method

I will use t-test to assess the difference in maxillary arch width between the two groups.

The independent samples t-test is used when two separate sets of independent and identically distributed samples are obtained, one from each of the two populations being compared.

Procedure

Maxillary inter-canine, inter-premolars and inter-molars widths will be measured Con study models of both groups. The measurements will be carried out using electronic digital callipers with LCD screen (PRECISION GOLD) which measures with accuracy of up to0.02mm.

Confidentiality

The study will require access to the dental records of patients who received treatment at the orthodontic department. Only members of the direct dental team will have access to the identifiable records.

Data will be extracted for analysis at which point it will be anonymized. The data extracted will include patient age, gender ethnicity and type of malocclusion.

Consent

Patients will not be asked to give explicit consent for the use of their data; the data will be gathered retrospectively. As the patients included in the study had finished their orthodontic treatment, it would be difficult, logistically, to seek consent from each of the patients. I will ensure that there is no breach of confidentiality; only members of the direct care team will be involved in accessing the records to extract the data. All dental patients that attend the department are informed that their anonymised data may be used for research purposes.

Each set of patient data will be given a unique study ID which will be used throughout the study. Publication of the results will not include any identifiable data.

Results

This case-control study is evaluating the relationship between maxillary arch width and palatal impaction of maxillary canines. Records of 58 subjects were assessed. Subjects in this study are orthodontic patients between 13 to 16 years of age with mean age of 14 years. Study group included 29 patients who have palatally impacted canines (PICs) and control group included 29 patients who have some sort of malocclusion but they have normally erupted canines.

The two groups were matched according to age, gender and the incisor relationship. As shown in Figures 2 to 4, the PIC group and the control group are equivalent in terms of age, sex and type of malocclusion.

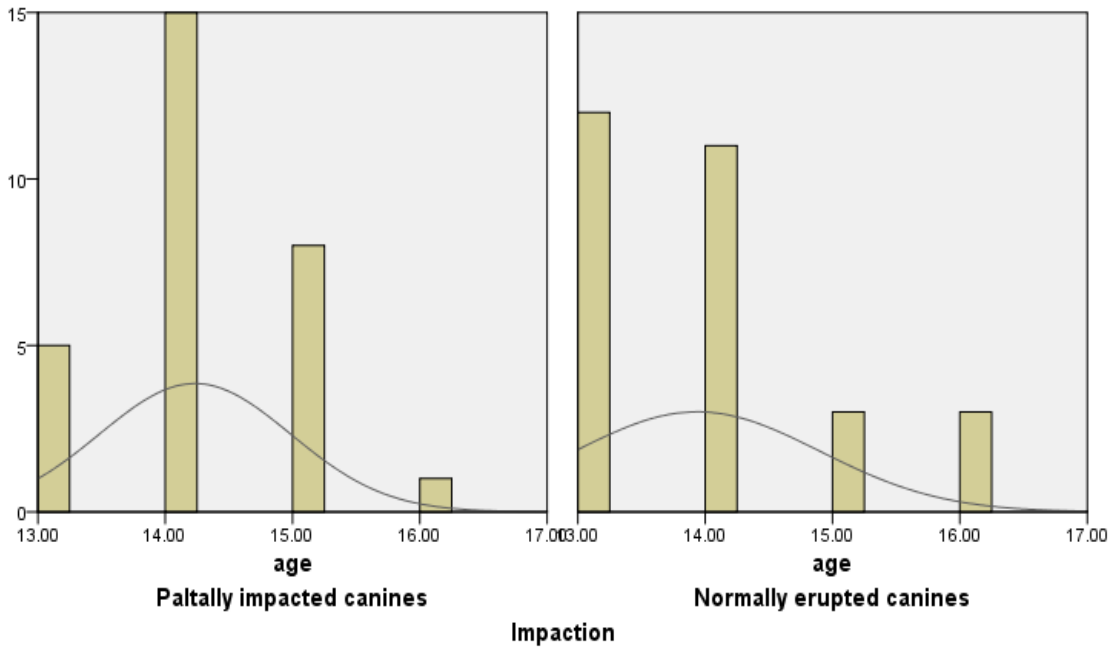

Fig 2: Age distribution among the two study groups.

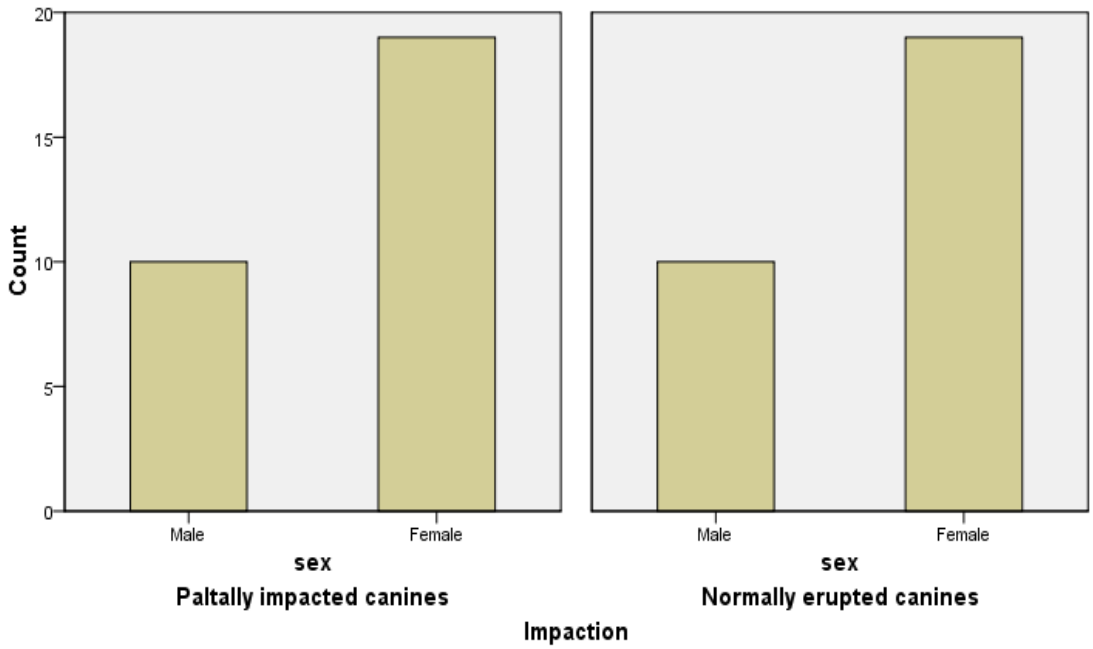

Fig 3: Sex distribution among the two study groups.

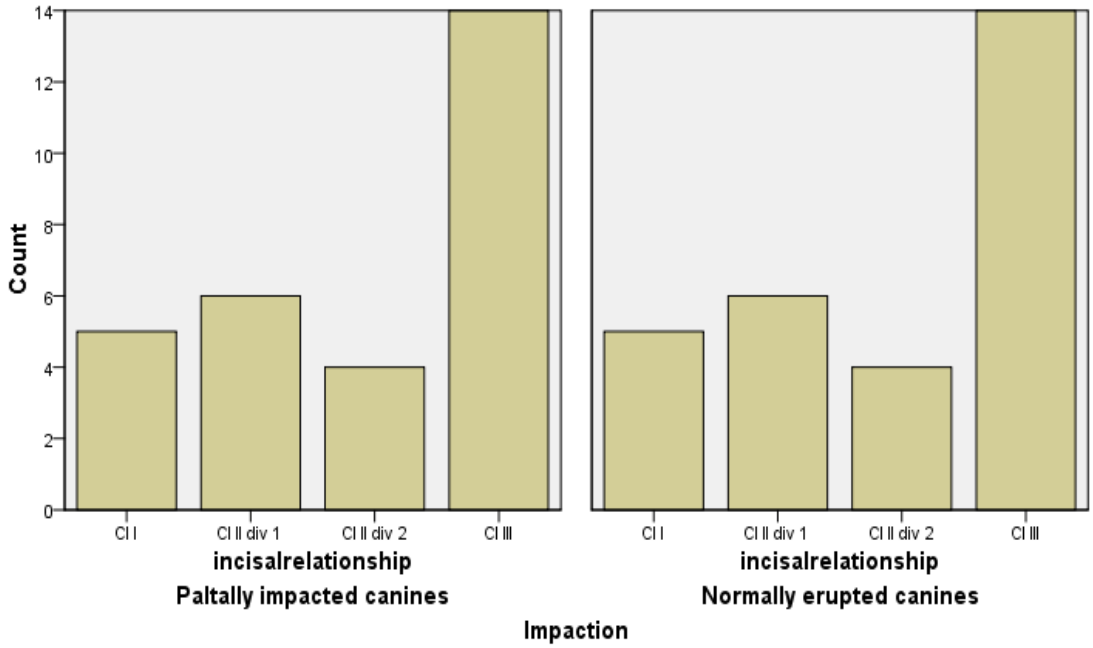

Fig 4: Distribution of incisor relationship in the two study groups.

Summary statistics for arch width values is presented in Table 2.

Table 2: Summary statistics for maxillary arch width values.

	Descriptive	PIC group	Control group
Inter-canine width	Mean	26.917	27.114
	Std.Deviation	1.9612	2.3421
	Minimum	21.6	26.3
	Maximum	29.4	36.5
Inter-premolar width	Mean	32.234	32.517
	Std.Deviation	2.4138	3.3857
	Minimum	26.3	24.1
	Maximum	36.5	39.9
Inter-molar width	Mean	42.603	42.438
	Std.Deviation	2.9078	3.3802
	Minimum	36.2	36.4
	Maximum	48.0	50.4

Data were assessed for normality. Values for the maxillary arch width were normally distributed among both groups, so independent samples T-test was used to analyse the relationship between maxillary arch width and palatal impaction of maxillary canines.

The independent samples T-test did not show any significant differences between the PIC group and the control group in terms of inter-canine, inter-premolar and inter-molar arch widths. The results obtained from T-test are summarised in Tables 3 to 5.

Table 3: Independent samples T-test for inter-canine width.

Inter-canine width	n	Mean	SD	T-test	P value
PIC group	29	26.9172	1.96124	0.866	0.730
Control group	29	27.1138	2.34212		

Table 4: Independent samples T-test for inter-premolar width.

Inter-premolar width	n	Mean	SD	T-test	P value
PIC group	29	32.2345	2.41384	0.146	0.77213
Control group	29	32.5172	3.38569		

Table 5: Independent samples T-test for inter-molar width.

Inter-molar width	n	Mean	SD	T-test	P value
PIC group	29	42.6034	2.90781	0.395	0.16552
Control group	29	42.4379	3.38024		

Discussion

A primary objective of this study was to determine the relationship between maxillary arch width and PICs. As mentioned in the literature review. It is difficult to reach to a conclusion regarding the association between arch width and PICs with contradicting results of previous studies.

In this study, maxillary arch width was measured on pre-treatment study models of patients who have PICs and on models of a control group of patients who have normally erupted canines. The arch width was measured with digital callipers and this method was proven to produce the most accurate and reproducible results (Zilberman et al., 2003).

The study group was matched to the control group by age, gender and type of malocclusion in attempt to reduce the possible effects of known confounding factors. Age difference can influence the results as younger subjects would have smaller arches. Studies showed that maxillary arch width increases significantly between 9 and 15 years of age (Knott, 1961). Subjects in this study were 13 to 16 years of age. Including subjects younger than 13 years could have caused false diagnosis of canine impaction as impacted canines have some capacity to self-correct with time (Stewart et al., 2001).

Gender was also equally distributed among the two groups since male arches tend to grow wider than female arches (Lee, 1999).

Likewise, type of malocclusion was similar in both the study and the control groups. It is known that patients with class II division 2 malocclusion tend to have wider upper arches and scissors bite tendency and this could have introduced bias.

Results of this study did not show any significant differences in maxillary arch width between patients who have PICs and patients who have normally erupted canines. These results are consistent with most of previous work in this field.

The mean values for inter-canine width (ICW), inter-premolar width (IPW) and inter-molar (IMW) in the present study are comparable to values reported in previous studies which used similar methodology and found no association

between arch width and PICs (Fattahi et al., 2012; Anic-Milosevic et al., 2009; Langberg and Peck, 2000a).

Results of the present study are also in agreement with previous studies that used different method for assessment of maxillary arch width from the method used in this study. Saiar et al (2006) used postero-anterior cephalogram and Yan et al (2013) used CBCT to assess maxillary arch width. They both found no association between arch width and PICs.

In contrast, results of this study differ from some published studies that found an association between PICs and maxillary arch width deficiency. Kettle (1958) mentioned that maxillary canine impaction occurs more commonly in narrow upper arches, without mentioning the location of maxillary canine impaction, buccal or palatal.

McConnell et al (1995) reported a significant maxillary arch width deficiency in patients with impacted maxillary canines. It seems possible that these results are due to inclusion of subjects with buccally impacted canines who probable had crowded and narrow upper arch.

Likewise, Schindler and Duffy (2007) found an association between potentially impacted canines and transverse discrepancies in patients in the mixed dentition. This rather contradictory result could be attributed to measuring the arch width in patients who are on average 9 years of age who still have underdeveloped arches. They also diagnosed 53% of canines as being impacted based on panoramic radiographs only taken at the same age, this could have overestimated the figures of potentially impacted canines.

On the other hand Al-Nimri and Gharaibeh (2005) found an association between PICs and increased maxillary arch width. This result may be explained by the fact that study group was not matched properly to control group. There were more patients with class II division 2 malocclusion in the PICs (44%) than in the control group (15%). This difference in distribution is expected as this type of malocclusion is associated with 33.5% of PICs (Basdra et al., 2000). This unequal distribution may have caused the relative increase in arch width in PIC group compared with control group.

Comparing results of the present study with average values obtained from growth studies reveals great similarities between figures. The average values for inter-

canine and inter-molar widths from growth studies are presented in Tables 6 to 9 (Ward et al., 2006; Bishara et al., 1997; DeKock, 1972; Sillman, 1964).

Table 6: Average values from Ward et al (2006) study.

Age	ICW	IMW
15y	32.9mm (+/- 3.3)	49.9mm (+/-2.4)

Table 7: Average values from Bishara et al (1997) study.

Age	ICW		IMW	
15y	M	F	M	F
	35.1mm (+/-2.7)	33.1mm (+/-1.6)	53.4mm (+/-2.9)	50.1mm (+/-2.6)

Table 8: Average values from DeKock (1972) study.

Age	IMW	
	M	F
14y	58.9mm (+/-2.1)	54.9 (+/-2.0)
15y	59.3mm (+/-2.1)	54.9mm (+/-2.0)
16y	59.3mm (+/-2.1)	54.8mm (+/-2.0)

Table 9: Average values from Sillman (1964).

Age	ICW		IMW	
	M	F	M	F
14y	36mm	35mm	45mm	42mm
16y	37mm	35mm	45mm	43mm

Direct comparison between results of the present study and results from growth studies would not be valid since in this study we combined arch width values for male and female patients and combined different age groups in one study group which is different from growth studies in which separate value were given for male and female subject at different age groups.

Findings from the present study have important implications for interceptive treatment for the palataly impacted canines. Few studies evaluated the effectiveness of maxillary arch expansion during the early mixed dentition as an interceptive treatment for the PICs (Baccetti et al., 2009; Sigler et al., 2011). In both of these studies maxillary inter-molar widths were measured and compared with a control group; they found no statistically significant difference in arch width between the PIC group and the control group. Thus expansion of the arches is not justified and it does not guarantee elimination of impaction.

Other interceptive treatment modalities for PICs were described in literature. Among these was extraction of primary canines (Newcomb, 1959; Ericson and Kurol, 1988; Naoumova et al., 2014) and distalization of maxillary molars using a cervical-pull headgear (Baccetti et al., 2008).

The present study shows that there is no association between arch width and the presence or absence of palatally impacted canines. This may also provide further support for the previous hypotheses regarding the aetiology of palatally impacted canines. A future study with more focus on the family history of subject with PICs is therefore suggested to test the genetic theory of canine impaction. Further work is also required to establish whether anomalous lateral incisors are responsible for palatal impaction of canines directly by lack of guidance or indirectly as a part of genetically inherited traits.

Conclusion

For our sample there was no association between arch width and the presence or absence of palatally impacted canines.

The practical application of this research is that attempting maxillary arch expansion during the mixed dentition in attempt to prevent palatal impaction of canines might not be justified especially if there was no crossbite to indicate the need for expansion.

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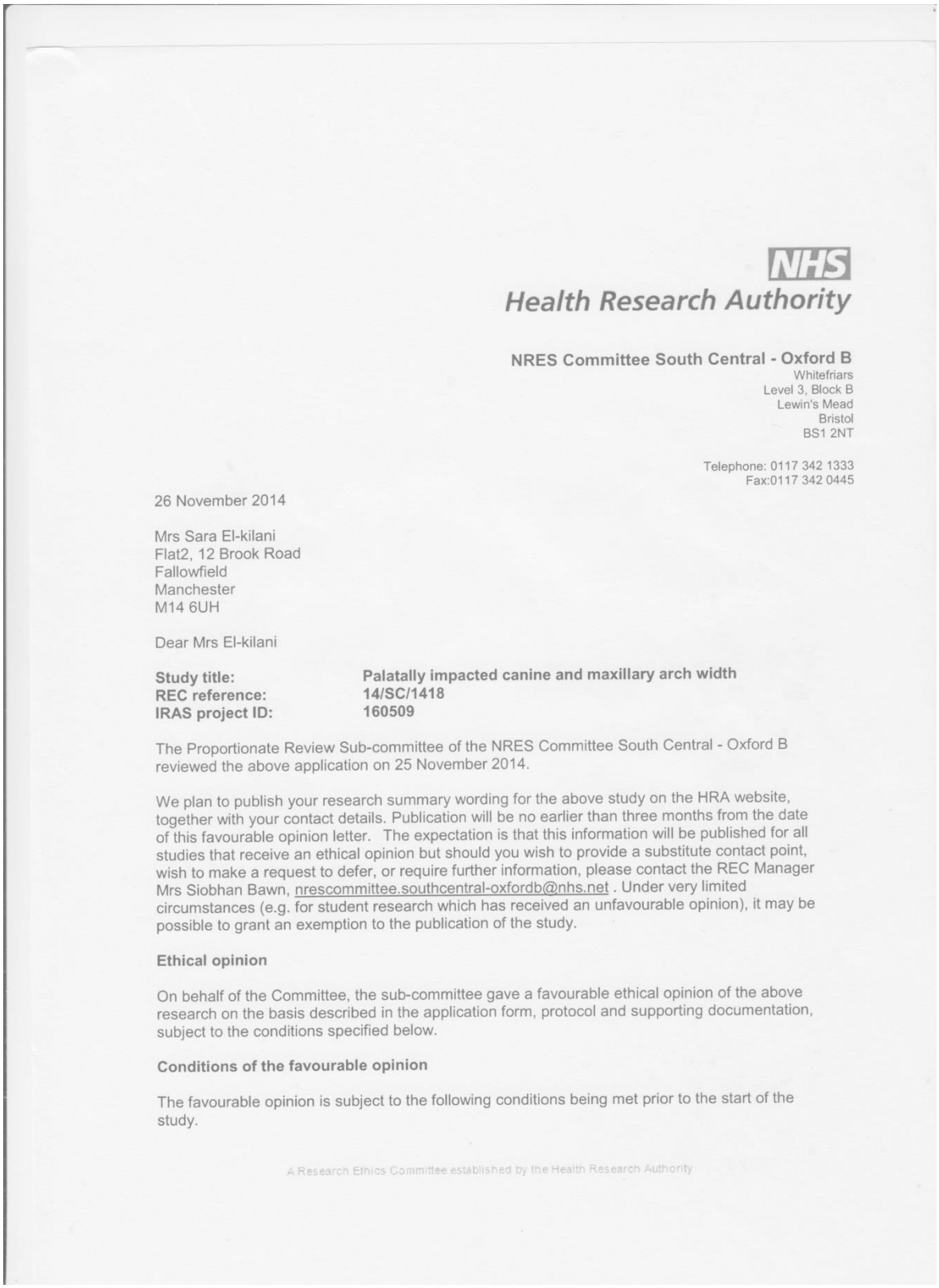
Appendix 1: National Health Services Research Ethics Committee (NHS REC) approval.



NHS
Health Research Authority

NRES Committee South Central - Oxford B
Whitefriars
Level 3, Block B
Lewin's Mead
Bristol
BS1 2NT

Telephone: 0117 342 1333
Fax:0117 342 0445

26 November 2014

Mrs Sara El-kilani
Flat2, 12 Brook Road
Fallowfield
Manchester
M14 6UH

Dear Mrs El-kilani

Study title:	**Palatally impacted canine and maxillary arch width**
REC reference:	**14/SC/1418**
IRAS project ID:	**160509**

The Proportionate Review Sub-committee of the NRES Committee South Central - Oxford B reviewed the above application on 25 November 2014.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Siobhan Bawn, nrescommittee.southcentral-oxfordb@nhs.net . Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

A Research Ethics Committee established by the Health Research Authority

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

Ethical issues raised, noted and resolved in discussion:

Social or scientific value; scientific design and conduct of the study

The Committee queried the statistical analysis of the study and requested further information with regard to the statistical analysis plan.

Mr Chadwick advised the statistical analysis of the study models is appropriate for comparing arch width, a linear measure of distance.

The Committee were satisfied with this response.

Recruitment arrangements and access to health information, and fair participant selection

The Committee requested clarification consent had been obtained for use of the moulds and not just for the use of images.

Mr Chadwick informed the Committee the study models (moulds) are part of the patient records in orthodontics. They are included in the Consent Form that refers to records.

The Committee were satisfied with this response.

Informed consent process and the adequacy and completeness of participant information

The Committee noted the study is looking at children's teeth models and queried whether the child or their parent/carer had completed the consent forms.

Mrs Sara El-kilani confirmed all patients who have received Orthodontic treatment at the Orthodontic department at the Countess of Chester Hospital were asked to sign a Consent Form before their records being taken. The Consent Form is signed by the parent if the patient is a child.

The Committee were satisfied with the confirmation.

Suitability of research summary

The Committee confirmed this.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance letter]	1	24 October 2014
IRAS Checklist XML [Checklist_18112014]		18 November 2014
Letter from sponsor [sponsor letter]	1	24 October 2014
Participant consent form [Consent form]	1	18 November 2014
REC Application Form [REC_Form_18112014]		18 November 2014
Research protocol or project proposal [Protocol]	2	15 October 2014
Summary CV for Chief Investigator (CI) [CV for the student]	1	18 November 2014
Summary CV for supervisor (student research) [CV for the academic supervisor]	1	18 November 2014

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form

available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

With the Committee's best wishes for the success of this project.

14/SC/1418 **Please quote this number on all correspondence**

Yours sincerely

PP JBaun

Dr Kim Cheetham
Vice-Chair

Email: nrescommittee.southcentral-oxfordb@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: Ms Lynne Macrae
Mrs Sheila Williams
Mr Stephen Chadwick

NRES Committee South Central - Oxford B

Attendance at PRS Sub-Committee of the REC meeting on 25 November 2014

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Kim Cheetham (Vice- Chair)	Retired Consultant Paediatrician	Yes	
Dr Richard Philip Craven	Senior lecturer in physiology	Yes	
Dr Pamela Laurie	Retired Consultant Anaesthetist	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mrs Siobhan Bawn	Co-ordinator

NHS
National Research Ethics Service

RESEARCH IN HUMAN SUBJECTS OTHER THAN CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

After ethical review – guidance for sponsors and investigators

This document sets out important guidance for sponsors and investigators on the conduct and management of research with a favourable opinion from an NHS Research Ethics Committee. Please read the guidance carefully. A failure to follow the guidance could lead to the committee reviewing its opinion on the research.

1. Further communications with the Research Ethics Committee

1.1 Further communications during the research with the Research Ethics Committee that gave the favourable ethical opinion (hereafter referred to in this document as "the Committee") are the personal responsibility of the Chief Investigator.

2. Commencement of the research

2.1 It is assumed that the research will commence within 12 months of the date of the favourable ethical opinion.

2.2 The research must not commence at any site until the local Principal Investigator (PI) or research collaborator has obtained management permission or approval from the organisation with responsibility for the research participants at the site.

2.3 If the research does not commence within 12 months, the Chief Investigator should give a written explanation for the delay

2.4 If the research does not commence within 24 months, the Committee may review its opinion.

3. Trial Registration

3.1 The registration of the clinical trial in a publicly accessible database is a condition of the favourable opinion for the following types of study:

- Clinical trial of an investigational medicinal product (CTIMP) (Please note, there is a separate copy of this document for CTIMPs).
- Clinical investigation or other study of a medical device,
- Combined trial of an investigational medicinal product and an investigational medical device,
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

For all other types of study, registration is strongly recommended for reasons of transparency but it is not currently mandatory.

3. Duration of ethical approval

3.1 The favourable opinion for the research generally applies for the duration of the research. If it is proposed to extend the duration of the study as specified in the application form, the Committee should be notified.

3.2 Where the research involves the use of "relevant material" for the purposes of the Human Tissue Act 2004, authority to hold the material under the terms of the ethical approval applies until the end of the period declared in the application and approved by the Committee. In England, Wales and Northern Ireland, samples may be held after the declaration of the end of the trial, for analysis or verification of research data for up to one year. After this period legal authority to hold any human tissue under the ethical approval for this project will expire. To ensure that any continued storage is lawful, either the tissue must be held on premises with a storage licence from the Human Tissue Authority, or an application made for ethical approval of another project before the favourable ethical opinion of the existing project expires. Otherwise the tissue would need to be destroyed in accordance with the HTA Codes of Practice.

4. Progress reports

4.1 Research Ethics Committees are expected to keep a favourable opinion under review in the light of progress reports and any developments in the study. The Chief Investigator should submit a progress report to the Committee 12 months after the date on which the favourable opinion was given. Annual progress reports should be submitted thereafter.

4.2 Progress reports should be in the format prescribed by NRES and published on the website http://www.hra.nhs.uk/resources/during-and-after-your-study/nhs-rec-annual-progress-report-forms/

4.3 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss the progress of the research.

5. Amendments

5.1 If it is proposed to make a substantial amendment to the research, the Chief Investigator should submit a notice of amendment to the Committee.

5.2 A substantial amendment is any amendment to the terms of the application for ethical review, or to the protocol or other supporting documentation approved by the Committee that is likely to affect to a significant degree:

(a) the safety or physical or mental integrity of the trial participants
(b) the scientific value of the trial
(c) the conduct or management of the trial.

5.3 A Notice of Substantial Amendment should be generated by accessing the original application form on the Integrated Research Application System (IRAS). The Notice of Substantial Amendment should be electronically authorised by the Chief Investigator and the sponsor of the study before the amendment is submitted to the Committee.

5.4 A substantial amendment should not be implemented until a favourable ethical opinion has been given by the Committee, unless the changes to the research are urgent safety measures (see section 7). The Committee is required to give an opinion within 35 days of the date of receiving a valid notice of amendment.

5.5 Amendments that are not substantial amendments ("minor amendments") may be made at any time and do not need to be notified to the Committee. However, changes to contact details of the CI, sponsor or R&D contact are helpful and can be notified by letter or email.

5.6 Further guidance on amendments is available at. http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/

6. Changes to sites

Management permission (all studies)

6.1 For all studies, management permission should be obtained from the host organisation where it is proposed to:

- include a new site in the research, not included in the list of proposed research sites in the original REC application
- appoint a new PI or Local Collaborator at a research site

- make any other significant change to the conduct or management of a research site.

In the case of any new NHS site, the Site-Specific Information (SSI) Form should be submitted to the R&D office for review as part of the R&D application.

Site-specific assessment (where required)

6.2 The following guidance applies only to studies requiring site-specific assessment (SSA) as part of ethical review.

6.3 In the case of *NHS/HSC sites*, SSA responsibilities are undertaken on behalf of the REC by the relevant R&D office as part of the research governance review. The Committee's favourable opinion for the study will apply to any new sites and other changes at sites provided that management permission is obtained. There is no need to notify the Committee (or any other REC) about new sites or other changes, or to provide a copy of the SSI Form.

6.4 Changes at *non-NHS sites* require review by the REC which reviewed the application for the research. Please submit the SSI Form (or revised SSI Form as appropriate) to the REC together with relevant supporting documentation. The REC will notify the Chief Investigator and sponsor of its opinion within a maximum of 25 days from the date on which a valid SSA application has been received.

Studies not requiring SSA

6.5 For studies designated by the Committee as not requiring SSA, there is no requirement to notify the Committee of the inclusion of new sites or other changes at sites, either for NHS or non-NHS sites. However, management permission should still be obtained from the responsible host organisation (see 6.1 above).

7. Urgent safety measures

7.1 The sponsor or the Chief Investigator, or the local Principal Investigator at a trial site, may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety.

7.2 The Committee must be notified within three days that such measures have been taken, the reasons why and the plan for further action.

8. Serious Adverse Events

8.1 A Serious Adverse Event (SAE) is an untoward occurrence that:

(a) results in death
(b) is life-threatening
(c) requires hospitalisation or prolongation of existing hospitalisation
(d) results in persistent or significant disability or incapacity
(e) consists of a congenital anomaly or birth defect
(f) is otherwise considered medically significant by the investigator.

8.2 A SAE occurring to a research participant should be reported to the Committee where in the opinion of the Chief Investigator the event was related to administration of any of the research procedures, and was an unexpected occurrence.

8.3 Reports of SAEs should be provided to the Committee within 15 days of the Chief Investigator becoming aware of the event, in the format prescribed by NRES and published on the website: http://www.hra.nhs.uk/resources/during-and-after-your-study/progress-and-safety-reporting/

8.4 The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss any concerns about the health or safety of research subjects.

8.5 Reports should only be sent to the REC which reviewed the application.

9. Conclusion or early termination of the research

9.1 The Chief Investigator should notify the Committee in writing that the research has ended within 90 days of its conclusion. The conclusion of the research is defined as the final date or event specified in the protocol, not the completion of data analysis or publication of the results.

9.2 If the research is terminated early, the Chief Investigator should notify the Committee within 15 days of the date of termination. An explanation of the

reasons for the early termination should be given.

9.3 Reports of conclusion or early termination should be submitted in the form prescribed by NRES and published on the website: http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/

10. Final report

10.1 A summary of the final report on the research should be provided to the Committee within 12 months of the conclusion of the study. This should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.

11. Review of ethical opinion

11.1 The Committee may review its opinion at any time in the light of any relevant information it receives.

11.2 The Chief Investigator may at any time request that the Committee reviews its opinion, or seek advice from the Committee on any ethical issue relating to the research.

Appendix 2: Research and Innovation Department approval (R&D) at the research site (Countess of Chester Hospital).

Countess of Chester Hospital NHS
NHS Foundation Trust

The Countess of Chester Health Park
Liverpool Road
Chester CH2 1UL

Research & Innovation Department
Tel: 01244 365532
Email: sheila.williams4@nhs.net

16th January 2015

CONFIDENTIAL

Mrs Sara El-kilani
Flat 2, 12 Brook Road
Fallowfield
Manchester
M14 6UH

Dear Mrs El-kilani

Study Title: **Palatally impacted canine and maxillary arch width**
REC Ref: **14/SC/1418**
Protocol: **Version 2 (15 October 2014)**
R&D Ref: **Stud079/14**

The Research & Innovation Department is pleased to approve this project, together with the indemnity and financial assessments and hopes that it proves to be interesting and rewarding.

You are reminded that although this project has been approved by the Trust, all research must also have appropriate ethical committee approval **before** it is undertaken.

As part of research governance, the Research & Innovation Department is required to monitor the progress and outcome of research within the Trust. Therefore, whilst this project continues Mrs Sheila Williams, Research Manager will be in contact annually to request a brief update and the Research & Innovation Department would be grateful for a summary on completion of the project, (if available, a copy of any publication or an abstract of a presentation relating to this study would suffice).

Conditions of approval

In addition, please note you must inform us if your project deviates in any way from the original proposal/documentation you have submitted. Your approval is limited to the dates stated on the research application form and that you are obliged to notify the Research & Innovation Department of any adverse events that arise during the course of the project. May I remind you that you are obliged to adhere to the Research Governance Framework for Health and Social Care (2005). If it is found that this is not the case, this may result in the suspension of your project until

changes have been agreed with the Trust, or your research may be terminated pending an enquiry.

Permissions

This letter authorises you in principle to undertake research within the Trust. However, it is your responsibility to ensure that individuals appropriate to your work have no objections to your studies. This department accepts no liability for non co-operation of staffs or patients.

Auditing

I would strongly urge you to maintain an accurate and up to date site file for your documentation, as the Trust randomly audits projects to assess compliance with the relevant frameworks and legislation. If your study is chosen, you will be notified in writing not less than two weeks prior to the required submission date of documentation.

Reporting

In the interest of ensuring the Trust receives maximum benefit from co-operating with research projects such as your own, the Trust places great importance on disseminating findings and conclusions. Therefore we would welcome a short summary of the findings of this project, once completed, along with any formal publications resulting from this work.

I would like to take this opportunity to wish you well with your project. If you have any questions or I can be of any further assistance to you, please do not hesitate to contact me.

Yours sincerely

S Williams

Mrs Sheila Williams
Research & Innovation Manager

Appendix 3: Patient's consent form.

Informed Patient Consent for Orthodontic Photography

Patient details sticker

Consultant: .....

Treating clinician: .....

Justification for images:	Features to be photographed:
Diagnosis of malocclusion	Face and teeth
Medico-legal record	*(All views to be taken in the Orthodontic*
Treatment progress and completion	*Department throughout treatment)*

Patient Consent – There are 4 types of consent:

1. Patient Records ONLY

I understand that the illustrations, to which I have agreed, will form part of my confidential treatment records.

Patient's signature:..... Date: .....

2. To educate new patients who are considering similar treatment

I understand that these images may be used to show to patients who are considering undertaking a similar course of treatment.

Patient's signature: ..... Date: .....

3. Restricted educational use by medical staff

I also understand that illustrations may be useful for the purposes of medical teaching and research and in view of the explanation given to me, I agree that the illustrations may be shown to appropriate professional staff. If illustrations revealing my face or identity are at a later date, required for reproduction in a journal or textbook or any other medical publication, I give my consent.

Patient's signature: ..... Date: .....

4. For open public display (leaflets/ displays/ web sites)

I understand that the illustrations, to which I have agreed, may be useful for the purposes of general education and publication. In view of the explanation give to me, I agree that the illustrations may be published as part of a display or information leaflet or open access web sites, which may be seen by members of the general public.

Patient's signature: ..... Date:.....

I understand that I have the right to withdraw consent at anytime by writing to the Trust and that my choice of consent level will not effect in any way my treatment within the Trust.

Consent obtained by: ..... Date:.....

On behalf of:.....

CONSENT FORM FOR ORTHODONTIC TREATMENT

Patient surname..... Hospital number.....

Other names.....Date of birth...../...../.....

To be completed by Orthodontist

Approximate length of treatment

Months ☐

Retention

Months ☐

Indefinitely ☐

I confirm that I have explained the nature of the orthodontic treatment proposed and any appropriate options that are available.

Signature.....Date.....

Name of Orthodontist.....

To be completed by the patient and/or parent/guardian

1. Please read this form and the notes overleaf carefully.
2. Please ask for more information if there is anything you do not understand.
3. If the information is understood and you want treatment then sign the form.

I agree

- The treatment has been explained to me by the Orthodontist named on this form.

I understand

- The length, time and commitment needed for effective treatment.
- The complications, risks and drawbacks of this orthodontic treatment.
- Changes to the treatment plan may be necessary but will be explained in detail.

Parent/Guardian

I.....Name in block capitals

Hereby consent to the above orthodontic treatment

Signature.....Date.....

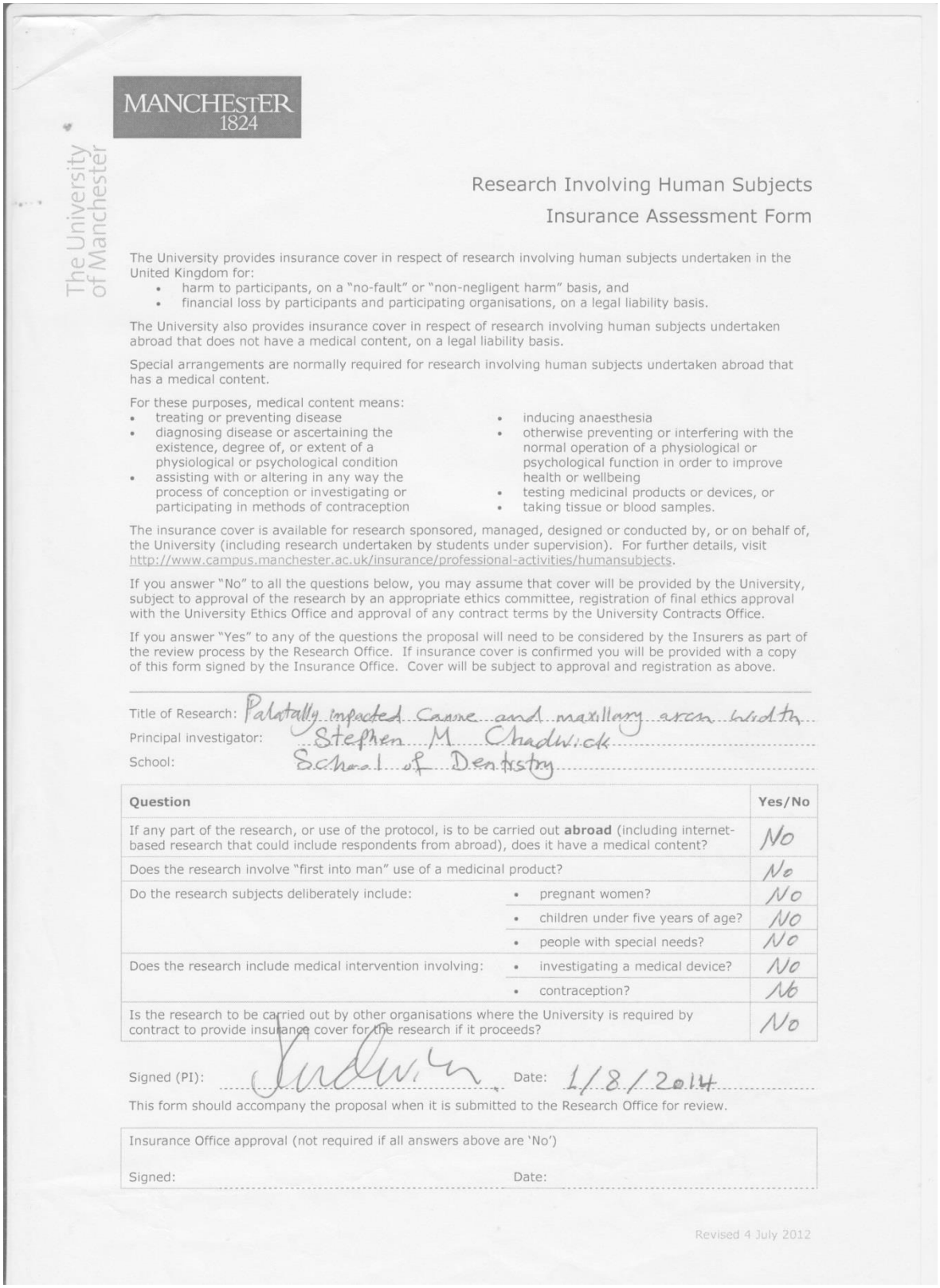
Patient

I.....Name is block capitals

Hereby consent to the above orthodontic treatment.

Signature.....Date.....

Appendix 4: The University of Manchester sponsor form.



MANCHESTER 1824

The University of Manchester

Research Involving Human Subjects
Insurance Assessment Form

The University provides insurance cover in respect of research involving human subjects undertaken in the United Kingdom for:

- harm to participants, on a "no-fault" or "non-negligent harm" basis, and
- financial loss by participants and participating organisations, on a legal liability basis.

The University also provides insurance cover in respect of research involving human subjects undertaken abroad that does not have a medical content, on a legal liability basis.

Special arrangements are normally required for research involving human subjects undertaken abroad that has a medical content.

For these purposes, medical content means:

- treating or preventing disease
- diagnosing disease or ascertaining the existence, degree of, or extent of a physiological or psychological condition
- assisting with or altering in any way the process of conception or investigating or participating in methods of contraception
- inducing anaesthesia
- otherwise preventing or interfering with the normal operation of a physiological or psychological function in order to improve health or wellbeing
- testing medicinal products or devices, or
- taking tissue or blood samples.

The insurance cover is available for research sponsored, managed, designed or conducted by, or on behalf of, the University (including research undertaken by students under supervision). For further details, visit http://www.campus.manchester.ac.uk/insurance/professional-activities/humansubjects.

If you answer "No" to all the questions below, you may assume that cover will be provided by the University, subject to approval of the research by an appropriate ethics committee, registration of final ethics approval with the University Ethics Office and approval of any contract terms by the University Contracts Office.

If you answer "Yes" to any of the questions the proposal will need to be considered by the Insurers as part of the review process by the Research Office. If insurance cover is confirmed you will be provided with a copy of this form signed by the Insurance Office. Cover will be subject to approval and registration as above.

Title of Research: Palatally impacted Canine and maxillary arch width

Principal investigator: Stephen M Chadwick

School: School of Dentistry

Question		Yes/No
If any part of the research, or use of the protocol, is to be carried out **abroad** (including internet-based research that could include respondents from abroad), does it have a medical content?		No
Does the research involve "first into man" use of a medicinal product?		No
Do the research subjects deliberately include:	• pregnant women?	No
	• children under five years of age?	No
	• people with special needs?	No
Does the research include medical intervention involving:	• investigating a medical device?	No
	• contraception?	No
Is the research to be carried out by other organisations where the University is required by contract to provide insurance cover for the research if it proceeds?		No

Signed (PI): [signature] Date: 1/8/2014

This form should accompany the proposal when it is submitted to the Research Office for review.

Insurance Office approval (not required if all answers above are 'No')

Signed: Date:

Revised 4 July 2012