‘BITE FORCE EVALUATION IN CHILDREN FOLLOWING DENTAL TREATMENT’

LATIFA ALHOWAISH

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University of Leeds

Leeds Dental Institute

Division of Child Dental Health

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The candidate confirms that the work submitted is his own and that appropriate credit has been given where reference has been made to the work of others.

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Abstract

A number of research studies have highlighted the fact that poor dental health impacts on quality of life as a whole due to a number of different elements. Dental caries is usually associated with negative consequences, such as discomfort and pain, which are known to affect growth and weight gain through effects on function, in addition to wellbeing and quality of life (George *et al*., 1999; Wendy and Sharleen, 1999). It has been suggested that a significant number of children may not be able to verbally complain of pain. This inability may be caused by their immaturity, level of cognition and language development. Children usually show difficulty in eating and loss of function which should be considered an indicator of oral problems (Anderson *et al*, 2004). Therefore functional impairment is a negative sequel of caries in children. This can be measured by different means and one of those is the evaluation of bite force which is known to be influential on mastication and chewing processes.

Bite force can be defined as “the capacity of the mandibular elevation muscles to perform a maximum force of lower teeth against the upper teeth, under favourable conditions” (Calderon *et al*, 2006). The evaluations of bite force have been proven to be constructive and thus widely utilised in dentistry (Koc *et al*., 2010), with the measurement of such conducted with the aim of determining muscular activity and jaw movements during the chewing process (Bakke,1992), with measurements also valuable in terms of masticatory efficiency (Toro *et al*., 2006; Julien *et al*., 1996).

When reviewing the literature on bite force and correlated factors, it becomes apparent that there is a lack in studies concerned with the effects of dental decay on bite force in child population specifically.

Additionally there were no studies determining the influence of comprehensive dental treatment in children on the children's maximum bite forces. Therefore, the prime **aim** of the present study was to analyse the potential effects of full mouth rehabilitation on maximum voluntary bite force of young children in the primary and mixed dentitions. Secondly, to critically assess different influencing factors on the magnitude of children's bite force in order to advance knowledge in relation to bite forces and their interplay in children.

This is a clinical exploratory study that comprised 32 children (26 with completed measurements) with a mean age of 6.45 years. 43.75 % were boys and 56.25 % were girls.

The study sample was taken from children attending the Leeds Dental Hospital/Paediatric Dentistry Department for treatment. The Maximum Voluntary Comfortable bite force was determined for each participant immediately before treatment and 3-5 weeks following completion of the required dental treatment. A single tooth bite force device was used that has been previously verified for intra-oral use in children (Mountain, 2008). The difference in bite force magnitude before and after dental treatment was analysed statistically. In addition, the correlations of key variables including, age, height, weight, BMI, gender and caries severity or dental status with maximum bite force were statistically analysed.

The mean maximum bite force for the total sample (n= 32) prior to treatment was found to be 169.32 N (SD= 66.20). The mean bite force in the male subgroup was 174.49 N (SD= 64.69) while for the females the mean bite force was equal to 165.29 N (SD= 68.93). Following comprehensive dental treatment the recorded mean maximum bite force for the children (n= 26) who attended the post treatment review appointment was 180.60 N (SD= 65.85).

Paired sample t test revealed a statistically significant increase in mean maximum bite force ($p < 0.01$) following comprehensive dental treatment that included both restorations and extractions. Correlation coefficients were determined for a number of key variables and maximum voluntary bite force in the pre-treatment stage. Child's gender failed to show significant correlation with the bite force. In contrast, child's age, body build expressed by height and weight showed a significant **positive** correlation with bite force ($p < 0.01$). In addition, poor dental status prior to treatment, expressed by the number of decayed, missing and filled teeth and surfaces, exhibited a statistically significant **negative** correlation with the bite force ($p < 0.05$). Presence of an abscess and dental pain showed similar negative impact on bite force.

The present study's findings can be important in the field of paediatric dentistry. In addition to the previously proved positive effects of treating dental caries in children, this study adds that bite force and subsequently chewing function can be improved by comprehensive dental treatment of decayed teeth. Additionally, this study showed that bite force in children is negatively impacted by a number of essential factors including, severity of dental caries as well as presence of clinical symptoms (i.e. pain and dental abscess).

Therefore, the findings can serve as an additional supportive evidence of importance of dental treatment for children as it helps improving the maximum bite force a child can exert.

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BMI	Body Mass Index.
dmft	Decayed, missing and filled primary teeth.
dmfs	Decayed, missing and filled surfaces in primary teeth.
DMFT	Decayed, missing and filled surfaces in permanent teeth.
DMFS	Decayed, missing and filled surfaces in permanent teeth.
DREC	Dental Research Ethics Committee
DS	Number of decayed surfaces
ECC	Early childhood caries
FDI	World Dental Federation, notation system.
IRAS	Integrated Research Application System
K-S	Kolmogorov-Smirnov
MHRA	Medicines and Healthcare Products Regulatory Agency
MVCBF	Maximum voluntary comfortable bite force.
N	Newtons, unit of force.
OHRQoL	Oral health related quality of life
r	Correlation Coefficient
R&D	Research and Development Forum

REC	Research Ethics Committee
SD	Standard deviation
SE	Standard error of mean
S-W	Shapiro- Wilks
SPSS	Statistic Package for the Social Sciences
TMD	Temperomandibular disorder.
WHO	World Health Organisation.
OHRQoL	Oral health related quality of life

Chapter One

Literature Review

1.0 Introduction to Literature Review

The available relevant literature has been reviewed utilising different available search engines in order to reach reasonable knowledge about what is known and what is still debatable about bite force and influential factors including dental caries in children.

1.1 The Importance of Oral Health in Young Children

Establishing and maintaining a good level of oral health is essential when striving to achieve good general health (Abanto *et al*., 2011; Acharya and Tandon, 2011; Gaur and Nayak, 2011; Paula *et al*., 2012). A number of research studies have highlighted the fact that poor dental health impacts on quality of life as a whole due to a number of different elements. Dental caries is usually associated with sequlae, such as discomfort and pain, which are known to affect growth and weight gain, in addition to wellbeing and quality of life (George *et al*., 1999; Low *et al*., 1999). Children suffering from dental-related ailments may not voice their discomfort or oral pain, but such impacts may be apparent when considering changes in sleeping patterns and eating behaviours (Low *et al*., 1999).

With the above taken into account, the UK Child Dental Health survey 2003 emphasised that, despite its preventability, caries prevalence, which had previously illustrated a decline, had plateaued in the primary dentition. The subsequent section will describe, in detail, how dental caries affects several aspects of children's life.

1.2 Caries and its Negative Impacts on Children

The term ‘dental caries’ can be described as dental tissue breakdown or destruction, essentially caused by acids, with such by-products of bacterial metabolism present in dental plaque biofilms. Importantly, as is known, the tooth crown’s outer surface is covered with enamel, which is most vulnerable to plaque bacteria colonisation; thus, when plaque covers dental tissue, there is a high risk of carious lesion development, as highlighted by Robinson (2009).

Regrettably, dental decay—technically referred to as caries—is recognised as being one of the most common diseases impacting on young children, despite the fact that such a condition can be avoided and is preventable. Furthermore, despite the wide availability of fluoridated toothpastes and oral rinses, decayed/missing/filled teeth (dmft) levels remain high in a number of regions across the UK (Olley *et al*., 2011). It has been confirmed in information published by the British Association for Community Dentistry that, between 1997/1998 and 2005/2006, the dmft index of children aged five years was stable at 1.47, with 40% of such children recognised as having at least one carious tooth (Pitts *et al*., 2007; Tickle *et al*., 2007). In contrast, however, the care index illustrates a decline from 15% to 11% during the same period, as noted by (Pitts *et al* 1999; Pitts *et al* 2007). In the survey conducted by the NHS in 2007/2008 and published 2009, it was reported that dmft ranges between 0.48 to 2.50 in 5 years old children in England. The care index during the same period ranged between 4% - 33% with an average of 14% in all areas of England (NHS Dental Epidemiology Program for England, 2009).

For the primary dentition, dental caries is recognised as being a predominant public health concern, with such an issue recognised as significant in the UK (Olley *et al*., 2011). Upon the election of the Conservative Party in May 2010, a health manifesto was provided, detailing the aim to implement improvements across the area of NHS dentistry with the objective to reduce remedial treatment costs. In this regard, an initial proposal aimed to provide preventative care encouragement, provide advice for young children, and re-establish access to NHS dentistry (Conservative Party, 2009; Olley *et al*., 2011). Nowadays, children's dental health is commonly impacted by restricted access to care, with the high costs of such treatment combined with economic issues amongst the most highly considered issues in the field of public health (Cunnion *et al*., 2010).

In 2011, Olley *et al*. examined and assessed the services provided to a high-risk group of children in the UK, with the authors subsequently establishing that oral health support received by those considered at a high risk of dental caries was inadequate, with the need for oral health programme improvements recognised as fundamental. In this same vein, Petersen (2008) recognises that dental caries is a significant problem across the globe, with children from poor socio-economic backgrounds deprived of much-needed service. Accordingly, it is recognised that there is an apparent inequity of oral health services provided to the public.

The risk and prevalence of caries amongst children are believed to be linked with a number of risk factors. For instance, it has been found that childhood caries is linked with the group of cariogenic microorganisms, *Mutans Streptococci*. Moreover, the oral levels of such bacteria—which are usually acquired from the maternal parent—are known to be elevated in the case of those children with tooth decay (Tinanoff, 1997).

It is understood that ECC (Early Childhood Caries) is a particular category where the caries level is severe and normally affecting young children (Cunnion *et al.*, 2010). It is further noted that ECC may be recognised as a type of caries affecting primary teeth, i.e. milk teeth, which can disturb either a single tooth or more, with lesions—both non-cavitated and cavitated—seen in children of 6 years old and under (Marrs *et al.*, 2011).

There is the belief that a number of different elements can cause one child to be more vulnerable to suffering from dental problems than others, with Piper *et al*. (2012), for example, taking into account young children's caries index, nutrition, preventative behaviours and social status. Notably, the authors concluded that there is a negative link between caries index, i.e. dmft, and feeding behaviours. This particular research has shown that the long-term utilisation of baby bottles at night is one of the most important factors in regard to caries development in early childhood. Leroy *et al*. (2011) considered the potential risk factors of caries amongst a sample of preschool children. The results proved that those children found to have visible plaque during preliminary screening were more likely to experience caries. Such a result establishes that an additional factor in the development of caries in children is visible plaque accumulation.

In another study carried out by Chankanka *et al*. (2011), it was found that, amongst other caries-risk factors, low socio-economic status is linked with a greater risk of caries in children. Correspondingly, Sufia *et al*. (2011) noted a strong link between lower socio-economic levels and rural residence and the prevalence of caries. Furthermore, Cunnion *et al*. (2010) stresses that children from specific ethnic and racial minorities and those from poor economic backgrounds are more likely to acquire dental diseases and their impacts.

Currently, the ability and accuracy to establish the prevalence of caries and the incidence of such are recognised by Tickle *et al*. (2008) as being well established, although they highlight that dental disease has a number of significant, negative impacts on not only young children but also their families and these are poorly studied. Importantly, a number of impacts can be experienced if dental caries—which is recognised as an infectious disease—are left untreated (Cunnion *et al*., 2010), including dental abscess, facial cellulitis and sepsis, all of which are recognised as severe and serious problems that could result from tooth decay.

In 2009, Casamassimo and colleagues detailed a report which considered the mortality and morbidity linked with early childhood caries and which further described the effects of such in the context of the 'morbidity and mortality (M&M) pyramid'.

This framework is remarkably broken down into four different categories: whilst the base (first layer) considers the costs linked with childhood caries, such as pain subsequently causing absence from school or work, as well as the morbidity of caries treatment, including lip- or cheek-chewing and local anaesthetic overdose, the second layer considers the morbidity in a family context, such as disturbance in the child's sleeping patterns and academic performance, as well as the costs and pain associated with childcare and travel, and parental stress. The third level of the pyramid considers financial costs, including emergency treatments, whilst the model's apex details death as a direct consequence of serious odontogenic, untreated infections.

During recent times, there has been much debate surrounding the link between children's wellbeing and health with oral/dental status (Thomas and Primosch, 2002; Clarke *et al*., 2006). The impacts associated with oral infections have received wide recognition and documentation in the case of adults and periodontal infections, with children receiving lesser attention in terms of odontogenic infections secondary to early childhood caries (Beck *et al*., 2000; Lix *et al*., 2000; Garcia *et al*., 2001; Mojon, 2002; Casamassimo *et al*., 2009).

Unfortunately, however, there has not been a study carried out as meticulously in regard to establishing the systemic health-dental caries relationship, with greater attention previously afforded to the systemic health-periodontal disease association (van Gemert-Schriks *et al*., 2011).

With this in mind, it should be recognised that dental caries is a chronic, multi-factorial infectious disease, and so it is common sense that a link similar to that of periodontal diseases is likely. Notably, a degree of synergism is recognised owing to the fact that a number of systemic health conditions are linked with oral symptoms that subsequently cause an increased risk of dental disease. Such a belief has motivated researchers and academics to state that oral conditions are systemic health risk factors (van Gemert-Schriks *et al*., 2011).

Ngoenwiwatkul and Leela-Adisorn (2009) carried out a cross-sectional study, taking a sample of 212 primary school children, and assessed and accordingly concluded the link between nutritional status and decay prevalence. Obviously, a weight and body mass index was used as the measure to suggest overall child health, with each child also interviewed.

Through the research, a mean dmfs of 12.4 was found, with 45.8% of the sample found to be in the low percentile category. Furthermore, the investigators further stated that multiple logistic regression emphasises that each additional decayed surface (dmfs) enhances the overall likelihood of being underweight by 3.1%. This research clearly highlights the negative consequences of caries in regard to a child's weight.

Moreover, a sample of 4 year old children in Brazil was taken by Feitosa *et al*. (2005), with the psychological effects of caries analysed through the study. The researchers conducted a comparison between children with and without caries. Accordingly, it was found that 72.7% of those children with caries had experienced toothache, with almost half (49.4%) experiencing associated difficulties, i.e. problems chewing food. Furthermore, a large portion (68.8%) of the sample was recognised as being negatively affected in terms of their quality of life.

Similarly, Abanto et al. (2012) reported a significant negative impact of dental caries on parents' quality of life. Additionally, Vania et al. (2011) studied the effect of early childhood caries in a group of children in the age range of 3-6 years. The authors compared the weights of caries-affected children with caries-free group and found that the number of children in the caries group with underweight was significantly greater than those in the caries-free children.

They further explained that the underweight finding in those children could be caused by chewing alteration as a result of dental pain or because of dental tissue breakdown making chewing more difficult and subsequently avoidance of food by the affected child.

Daily activities can be affected by the presence of dental caries in children as reported by Moure-Leite *et al* (2011). The majority of 5 year old children in their study suffered from toothache which led to difficulty in eating, sleeping disturbance and affected their school performance and attendance. A similar finding was reported by Gaur and Nayak (2011) who reported that 40% of children with tooth decay complained of pain. Food avoidance was also reported in this study.

Additionally, the negative effects of early childhood caries on the quality of life of both children and their families were evaluated by Acharya and Tandon (2011).

The researchers stated that dental health had a clear and definite effect on the quality of life of children and their parents. The parameters that were most affected were the nutrition or eating pattern as well as sleeping pattern. In 2010, Cunnion *et al*. implemented the PQOL—a recently devised self-report measure—with the aim of examining the impacts of dental treatment in regard to life quality. The investigators found that the wellbeing of both the child and their family were negatively affected by poor dental health, with the opposite—that comprehensive dental care improved a number of aspects relating to life quality—also found to be evident.

To summarise, it can be stated that there is general consensus concerning the notion that caries and poor oral health negatively affect the daily activities, psychological wellbeing and overall quality of life of a child. Such a finding emphasises the need for action to be taken in order to ensure such negative impacts are overcome, with young children and their families experiencing a greater quality of life.

1.3 Positive Impacts of Dental Treatment in Children

Various research studies have been conducted with the aim of examining the potential positive impacts associated with caries treatment in children especially with the utilisation of general anaesthesia (George *et al*., 1999; Low *et al*., 1999; Acs *et al*., 2001; Filstrup *et al*., 2003; Versloot *et al*., 2006; Malden *et al*., 2008).

It has been reported by Gaur and Nayak (2011) that, six months after treatment, numerous statistically significant improvements were found in children affected with early childhood caries ($p = 0.002$). Moreover, such children were also found to have a better quality of life, established in mind of certain parameters, including eating habits and sleeping patterns.

In this same way, Gaynor & Thomson (2011) implemented a pre-test/post-test design with the aim of assessing the effects of dental treatment under general anaesthesia on the oral health-related quality of life of children (OHRQoL). Thus, the conclusion was drawn by the investigators that, under general anaesthesia, dental treatment can provide significant enhancements in the context of OHRQoL, the most notable of which can be seen in terms of emotional wellbeing and oral symptoms.

Moreover, in a prospective multi-site study, Cunnion *et al*. (2010) related similar positive impacts following dental interventions in the case of children with caries. The authors stated that the parental ratings of children's oral health and physical, psychological and social wellbeing were positively impacted.

In addition, a study was carried out with the aim of analysing the impacts associated with comprehensive dental treatment on the weight of young children suffering with caries.

The findings showed that children with caries weighed significantly less. It was also found that ‘catch-up growth’ may be experienced following comprehensive dental treatment, as recognised by George *et al*. (1999).

Low *et al*. (1999) carried out a study concerning the negative impacts associated with dental health, assessing the health-related quality of life of a sample of 77 young children. The children’s parents were questioned on a number of different variables, namely eating preferences, pain, and the social behaviours of the child both prior to and following oral intervention. When drawing their conclusions, the researchers stated that children’s wellbeing was positively impacted following treatment, with notable improvements witnessed in regard to oral pain, quality of nutrition, quantity of food consumed, and sleep patterns.

Flistrap *et al*. (2003) investigated early childhood caries in relation to quality of life, and subsequently reported that children suffering from caries will notice positive impacts on their quality of life following dental treatment. In this same regard, Acs *et al*. (2001) considered the results of dental treatment of young children under general anaesthesia, and highlighted that significant improvements in a number of different aspects of quality of life were recognised by parents, such as less pain, better sleeping pattern, and improved habits and eating behaviours.

Markedly, Klaassen and colleagues (2009) carried out a randomised controlled trial, which examined the oral health-related quality of life of children in regard to dental disease treatment. The study provided a hypothesis, which stated that “dental rehabilitation under general anaesthesia would improve such quality of life”. The results confirmed a positive influence and accepted the predicted hypothesis.

Moreover, the positive impacts of dental treatment under general anaesthesia on quality of life variables were assessed by White *et al*. (2003), with parents subsequently emphasising that there was marked improvement in a number of ways, particularly in terms of pain relief as well as masticatory ability.

In addition, a systematic literature review was carried out by Jankauskiene and Narbutaite (2010), analysing research concerned with changes in various aspects of children's OHRQoL after dental treatment under general anaesthesia. The conclusion was drawn that such treatment delivered immediate positive impacts on the emotional, physical, oral and social health of the child, although the researchers further noted that, as a result of differences between OHRQoL evaluation measures, accurate comparisons were not feasible, and thus there is the need for the long-term OHRQoL of children to be assessed in future studies.

1.4 Management Strategies of Caries in Children

Decision-making and treatment-planning in the situation of children with carious teeth is a complicated, multi-dimensional process requiring in-depth examination and consideration in various regards (McWhorter, 2010). The risk status of children in terms of caries, the practical treatment options available and accessible, and the behaviour and attitude of the child in regard to dental treatment are all variables known to affect the ultimate decision made in terms of treatment option.

In an attempt to evaluate the caries risk of a child, the evaluation of the dental condition, medical status and radiographic examination of the patient are needed, with the behaviour and cooperation of the child recognised as important considerations dictating the way in which treatment will be provided (McWhorter, 2010).

There is currently an on-going debate in the paediatric dentistry field concerning whether or not restorative/intervention dental treatment is necessary in the case of primary dentition (Levine *et al*., 2002; Tickle *et al*., 2008; van Gemert-Schriks *et al*., 2008). For example, a retrospective study was designed by Levine *et al*. (2002) with the aim of assessing the results of the non-restoration of decayed primary molars amongst children who receive regular prevention care through their dentist.

The likely outcome of those carious primary teeth diagnosed but left without treatment was established, with the conclusion drawn that, amongst the sample study, most unrestored carious deciduous teeth continue to be symptomless until exfoliated, which provided some support for the belief that the traditional management of caries in children should not be considered the gold standard in dentistry.

In contrast, however, a longitudinal, randomised, controlled study was carried out by van Gemert-Schriks *et al*. (2008) with the aim of establishing the impacts of numerous dental treatment approaches on the oral health of 380 children with a mean age of 6.1 years, with each child randomly assigned to four different groups: comprehensive dental treatment, extraction only, fillings only (Atraumatic Restorative Technique), and no treatment. Importantly, the presence of odontogenic infections (abscess/fistula) between the baseline assessment and at the two years recall was compared through statistical analysis.

Accordingly, it was found that the number of children with odontogenic infection decreased in the comprehensive dental treatment and extraction only groups, whilst the number in children without any treatment increased significantly.

With these findings taken into account, the research indicates that comprehensive dental treatment in regard to primary dentition is advisable whenever practical. Notably, this particular conclusion is in stark contrast with that of Levine *et al*. (2002), and also illustrates clearer evidence in favour of comprehensive treatment as opposed to no treatment for asymptomatic primary teeth.

In the view of the British Society of Paediatric Dentistry, there are various caries management approaches in regard to the primary dentition, although such strategies depend on a number of different elements, such as the level of cooperation, the medical condition, the child's age, and the child's ability to accept dental treatment. Some examples of treatment approaches include operative treatment, commonly comprising the restoration of all carious restorable teeth, and the extraction of non-restorable carious primary teeth. However, the dental extraction of non-restorable teeth is occasionally unavoidable (Fayle *et al*., 2001).

Preventive strategies are also vital when managing a child with caries. The European Academy of Paediatric Dentistry published a policy document on the prevention of early childhood caries (EAPD, 2008). The recommendation in this document relied on evidence from the most recent systematic review on caries prevention in childhood. The policy document recommended that to help prevent ECC, oral health assessment as early as the first year of life is highly advisable. Brushing of primary teeth must start as soon as the first tooth erupts using a fluoride tooth paste. There is good evidence from systematic reviews (Ammari *et al*, 2007; Twetman, 2008) showing that fluoride toothpaste gives the highest preventive effect against early childhood caries.

It has also been documented that fluoride toothpaste is the most cost-effective home care preventive measure (Marinho *et al*, 2003; Twetman *et al*, 2003). In addition to fluoride toothpaste, professional application of fluoride varnish at least twice yearly and depending on patient's caries risk, is recommended to prevent ECC. Diet advice, that mainly discourages frequent intake of sweetened drinks as well as on demand bottle feeding, is a vital element in caries prevention advice (EAPD, 2008). Prevention is often all that a child needs if they are caries-free. However, in children with active carious lesions preventive approaches are not sufficient.

Operative dental treatment balanced with preventive programs are often required to re-establish dental-health and appropriate function (Fayle *et al*, 2001). The restoration of all decayed teeth, with the utilisation of conventional fillings, is also one option when managing caries in children, although conventional restoration is widely debated, as highlighted earlier.

In this way, there seems to be a unique inclination towards minimising the invasive management approach and increasing the preventive non-restorative management techniques (Northway *et al*, 1984; Curzon and Pollard, 1997; Tickle *et al*, 1999a; Fayle *et al*, 2001; Levine *et al*, 2002; Ericson *et al*, 2003; Tickle *et al*, 2003).

One of the most important and valuable approaches in the management of dental decay of non-restorable primary tooth is tooth extraction, which generally causes a number of undesirable effects, including the shifting of adjacent primary teeth or space loss (Northway *et al*, 1984; Fayle *et al*, 2001). As a result, insufficient space within the dental arch for the erupting permanent teeth is one reason for malocclusion (Fayle *et al*, 2001).

To recap, there is no professional consensus on the best management approach to sufficiently treat the carious primary dentition. A number of factors are usually considered prior to treatment decisions. In addition to clinical considerations, socio-economic status, parent's views and attitudes as well as their attendance patterns must be considered (Tickle *et al*, 1999a; Tickle *et al*, 1999b; Tickle *et al*, 2003). Moreover, treatment decisions are also guided by available funds, materials and number of qualified personnel. These factors are especially important for countries and communities with weak economies. Unfortunately, despite the fact that oral problems constitute a crucial public health issue in disadvantaged countries, oral health care is frequently underestimated within a total health-care system (van Palenstein *et al.*, 1999).

In summary it should be recognised that a number of aspects should be apparent in the case of ideal dental health care, including the avoidance of pain and discomfort for children, the prevention of new carious lesion development, and the reduction of early loss of primary teeth wherever possible, and the treatment and arrestment of present cavities (van Gemert-Schriks *et al*., 2011).

1.5 Bite Force and its Clinical/Research Application

The evaluations of bite force have been proven to be constructive and thus widely utilised in dentistry (Koc *et al*., 2010), with the measurement of such conducted with the aim of determining muscular activity and jaw movements during the chewing process (Bakke, 1992), with measurements also valuable in terms of masticatory efficiency evaluation (Julien *et al*., 1996; Toro *et al*., 2006).

Bite force is recognised as being one of the essential elements involved in the chewing function, and is regulated by the '*dental, muscular, nervous and skeletal systems and exerted by the jaw elevator muscle*' (Ow *et al*., 1989). Notably, the jaw muscle strength establishes the force available in crushing or cutting food. In this regard, Rentes *et al*. (2002) considered bite force measurement in the potential to assess physiological parameters, namely occlusion and their influences.

Moreover, during prior studies, bite force has been utilised in order to assess prosthetic devices amongst adults, and also to provide reference values for research conducted in the field of prosthetic device biomechanics (Patterson, 1998; Koc *et al*., 2010). In this same way, bite force has been examined as a tool able to examine the removable dentures amongst young children, and to thereby assess their overall efficiency in acting as replacements for missing natural teeth (Serra *et al*., 2007).

In 2010, Koc and colleagues conducted an in-depth literature review on bite force, and subsequently noted that bite force measurement is recognised as being a diagnostic tool in the cases of stomatognathic system disturbances, namely temporomandibular joint disorders.

Previously, in 2001, Sonneson *et al*. took note of maximum bite forces, utilising this information to examine the link between craniofacial morphology, temporomandibular dysfunction and head position. Children who were due to receive orthodontic treatment made up the study sample.

In 2006, a research study was carried out concerned with investigating adult cases of bruxism, with bite force assessments used through the study approach (Calderon *et al*., 2006). An earlier study was carried out in 1973 by Lindqvist and Ringqvist, who took bite force measurements so as to investigate bruxism-related factors in the case of children.

In regard to adult dentistry, implant success is assessed in consideration of various factors, namely chewing ability, biting ability, and functional recordings, which provides one aspect of bite force determination clinical use (Rismanchian *et al*., 2009; Luraschi *et al*., 2011; Muller *et al*., 2012).

In 2012 Carlsson analysed the approaches implemented during the evaluation of masticatory function in the case of dental implants patients. He considered the doctoral theses of six Swedish researchers, three of whom wrote their papers during the early era of osseo-integrated implants, with the remaining three on the same subject from recent years. Moreover, the available recent literature centred on implant patients' masticatory efficiency was also searched, with the earlier approaches implemented for implant success evaluations found to be mainly questionnaires focused on assessing the chewing efficiency of patients, both prior to and following treatment.

However, research carried out later on utilised other techniques, such as dietary selection, occlusal perception, and numerous innovative approaches utilising custom-made equipment in order to monitor changes in jaw movement and bite force. The researcher subsequently drew the conclusion that newer approaches were valuable within the field of prosthodontics including bite force evaluation.

Patients' satisfaction with implant-supported over-dentures and masticatory efficiency were two areas investigated by Bakke *et al.* (2002) with the use of bite force as a variable within the assessment. As a result, research stated that implant-supported over-dentures had the capacity to improve maximum bite force and the subsequent chewing ability. In this same vein, Rismanchian *et al*. (2009) noted that the utilisation of bite force evaluation acted as a guide for implant effects in terms of enhancing chewing efficiency and thus patient satisfaction of the treatment outcome.

Furthermore, a cross-sectional multi-centre research was carried out by Muller and colleagues (2012) with the aim of assessing the differences between bite force and chewing efficiency across a sample of edentulous patients with varying degrees of implant-supported prostheses. One of the approaches used for the evaluation was the recording of bilateral maximum bite force. There is a tendency, especially in dental implantology, to utilise bite force evaluation to assess treatment success and failure.

To summarise, the above mentioned studies provide evidence that supports the value of utilising bite force measurements in different fields of dentistry.

1.6 The Contribution of Bite Force to Masticatory Efficiency

'*Masticatory function can be described in terms of the objective capability of a person to fragment solid food or as the subjective response of an individual to questions regarding food chewing*' (van der Bilt, 2011).

With the above taken into account, it can be stated that there are numerous elements known to impact masticatory performance, including age, bite force, gender, the loss and type of restoration of post-canine teeth, malocclusion, total area of teeth in contact, oral motor function, and salivary glands function (van der Bilt, 2011). Bite force and the functional tooth units were clarified as being the main bases for masticatory function and its performance (Julien *et al*., 1996; Hatch *et al*., 2001).

Bite force is recognised as one of the factors indicating the masticatory system's functional state resulting from jaw elevator muscle action, modified by cranio-mandibular biomechanics (Koc *et al*., 2010). It has been highlighted by Hatch *et al*. (2001) that bite force has a strong link with masticatory performance, although the effects of such are not recognised as being as strong as the number of functional teeth. Furthermore, it has been established by Julien *et al*. (1996) that, in addition to functional occlusal contact area and body build, maximum bite force explained approximately 72% of the variation in masticatory performance and efficiency among adults and children.

Recently, Lepley *et al*. (2011) conducted a prospective cross-sectional study, subsequently highlighting that occlusion and maximum bite force respectively are the most important factors impacting masticatory performance, as established through their sample comprising 30 adults.

Importantly, it was found that, in the premolar region, better masticatory performance was achieved as a result of a larger volume of bite force ($r = -.0362$, $p = 0.027$). Undoubtedly, when examining the functional status of the masticatory system, maximum voluntary bite force is acknowledged as fundamental, and has been used in such evaluation in relation to occlusal factors (Bakke *et al*., 1990; Wang *et al*., 2010), function of natural dentition (Miyaura *et al*., 1999; Gibbs *et al*., 2002), dental prostheses (Helkimo *et al*., 1976; Slagter *et al*., 1992), implantology (Carlsson and Lindquist, 1994; Fontijin-Tekamp *et al*., 2000; van Kampen *et al*., 2002), maxillofacial and orthognathic surgery (Throckmorton *et al*., 2000; van den Barber *et al*., 2004), disorders of neuromascular nature (Granger *et al*., 1999; Weijnen *et al*., 2000) and temporomandibular dysfunction (Bakke *et al*., 1989; Ahlberg *et al*., 2003).

It has been acknowledged that bite force markedly impacts masticatory performance in those patients with natural dentitions, full dentures and over-dentures (Fontijin-Tekamp *et al*., 2000; Hatch *et al*., 2001). In this regard, strong correlations of up to 0.8 have been noted between bite force and mastication efficiency; therefore, bite force can explain more than 60% of the variance in the context of masticatory function level (van der Bilt, 2011).

In terms of definition, ‘chewing’ has been described as ‘a function that is developed and matures with time through learning experiences’; thus, it is seen to be a fundamental aspect of the overall food intake process, with bite force further recognised as being a prominent determinant of chewing function and efficiency, ‘exerted by the jaw elevator muscles, skeletal and dental systems’. Accordingly, such systems’ status will have a significant impact on the bite ability, and subsequently on chewing performance (Rentes *et al*., 2002).

It is recognised by various researches, including Lemos *et al*. (2006), that bite force and chewing performance both affect the development of masticatory function; therefore, it is accepted that establishing such variables during times of development and growth, as well as their respective links with dental arch morphologic characteristics, is fundamental, which can be achieved by gathering comparative data to ascertain whether or not such a system is progressing as it should. The link between chewing performance and maximum bite force in children was investigated by Lemos *et al*. (2006), who took account of the morphologic characteristics of occlusion and body mass index.

In this study, 36 children, aged an average 9.06 years, formed the sample, with bite force subsequently established as having a negative relationship with the chewing test material particle size. This suggests that a greater degree of bite force induces enhanced chewing performance ($r=0.410$, $p<0.05$). Moreover, it was established through the regression analysis that the equations explain 29%–38% of the variation in the particles as a result of the bite force variable. Ohira *et al*. (2012) assessed masticatory performance and maximum bite force in a sample comprising young Japanese children aged 4-6 years. The investigators examined the overall effectiveness associated with a four-week chewing exercise, and how such an approach could enhance mastication performance through bite force. There were no statistically significant differences between the maximum bite force and masticatory performance in both study and control groups at base line. However, there was a significant increase in bite force as well as mastication efficiency in the chewing exercise group. In addition to this finding, Ohira and colleagues confirmed a close association of the maximum bite force and mastication performance.

When considering mastication, age is recognised as a directly linked factor. Numerous cross-sectional research studies have been carried out in an attempt to evaluate the age factor in respect to masticatory ability, with the latter found to improve with age (Shiere and Manly, 1952; Agerberg *et al*., 1981; Julien *et al*., 1996). More specifically, more remarkable improvements in masticatory performance are found between individuals aged 12–15 years old, which may be rationalised through considering the adolescent growth spurt, which is characterised by a prominent increase in size of the body as well as an increase in total muscle mass (Tanner, 1962).

Thus far, research has not yet managed to draw a sound conclusion in terms of the link between mastication performance and gender (Barrera *et al*., 2011). In this regard, Toro *et al*. (2006) highlighted a negative finding, stating that there were no statistically significant differences amongst boys and girls aged 6–15 in regard to their capacity to masticate food; however, Julien *et al*. (1996) emphasised that young males demonstrated greater efficiency when masticating artificial food when compared to females (Julien *et al*., 1996).

To conclude, it is recognised that there is much support that bite force has a remarkable impact on masticatory efficiency. A higher bite force is believed to induce greater chewing performance (Fontijn-Tekamp *et al*., 2000; Okiyama *et al*., 2003; Lemos *et al*., 2006). Moreover, a number of other variables in addition to muscle efficiency and force generated during mastication are acknowledged as being factors of chewing performance (Okiyama *et al*., 2003), such as the number and area of occlusal contacts, and the level and degree of lateral excursion throughout mastication (Wilding, 1993; Bourdiol and Mioche, 2000; Ownes *et al*., 2002).

It is widely supported that masticatory and chewing functions have the capacity to impact dietary selection, which is notably linked with quality of life (Ikebe *et al*., 2005). The gradual dentition deterioration witnessed in adult patients is believed to be linked to the declining intake of calories rich foods, carbohydrates, fibres, numerous vitamins and minerals, and protein (Krall *et al*., 1998; Teoh *et al*., 2005), thus suggesting that a decreased intake of nutrients may result subsequent to lower chewing performance (English *et al*., 2002). Such an issue might be more significant amongst young and growing children than aging adults; accordingly, precautionary and curative dental measures could ensure children's general and oral health are improved, as stated by Lucas *et al*. (2002) through their view that the status of the mouth affects mastication and swallowing.

In summary, it can be postulated that bite force has a significant impact on mastication function which similarly has a notable influence on the nutritional status on any individual.

1.8 Previous Studies Reporting Bite Force Values in Children

In both adults and children, bite force has received much attention in studies across the globe (Lindqvist and Ringqvist, 1973; Helkimo *et al*., 1976; Kampe *et al*., 1987; Tortopidis *et al*., 1998; Rentes *et al*., 2002; Tsai and Sun, 2004; Kamegai *et al*., 2005; Sonnesen and Bakke, 2005; Usui *et al*., 2007; Castelo *et al*., 2010; Mountain *et al*., 2011). Each research study had a specific objective and associated research questions concerned with human bite force. However, there is a lack of research centred on bite force in young children, with most studies focused on children with bruxism habits (Lindqvist and Ringqvist., 1973), dental malocclusion (Sonneson and Bakke, 2005) or temporomandibular disorders (Sonnesen *et al*., 2001). Importantly, only one research, carried out in the UK, examined bite force in the case of children with primary dentition (Mountain *et al*., 2011).

In the subsequent section, bite force means and ranges, as detailed in studies with children, will be appraised, although the elements known to impact maximum bite force will be considered in another section.

In 2011, the magnitude of maximum voluntary bite forces was determined by Mountain *et al*., utilising a sample of 205 children aged 3–6 years at school in a major UK city. The data recorded provided a comparatively wide intra and inter-individual disparity, with three bite force measurements ranging from 12.6 N to 353.64 N, and providing a mean of 196.60 N. Furthermore, in 2004, Tsai assessed the levels of bite force concerning dental status in children with deciduous dentition. The sample comprised 676 Taiwanese children aged 3–5 years. It was found that the maximum bite forces recorded ranged between 147 N and 176 N.

In the USA in 1996, Braun *et al*. carried out a research focused on recording bilateral bite force in a sample of 457 individuals aged 6–20 years. In terms of the maximum bite forced found, the mean was 78 N amongst those aged 6–8 years, and 178 N amongst those aged 18–20 years.

Moreover, bite force was evaluated in a randomly selected group of Finnish children aged 5–17 years, with all 98 individuals assigned to one of five different groups according to age. Notably, the mean maximum bite force recorded in the case of permanent or deciduous molars was 245.3 N in girls and 251.1 N in boys aged 5 years (Helle *et al*., 1983). Moreover, in the case of 7 year olds, bite forces measured had a mean of 312.9 N in girls and 312.8 in boys. In 2005, Kamegai and colleagues assessed the bite force measurements of 2,549 northern Japanese children aged 3–17 years, with all sample subjects divided into groups according to age. Notably, the mean force ranged from 186.2 N in the case of 3–5 year olds, and up to 545.3 N amongst 15–17 year olds.

In 2007, Usui *et al*. conducted a study with the aim of ascertaining the link between bite force and a number of different parameters, taking a sample of individuals aged 8–25 years old, all of whom were patients attending an orthodontic department with malocclusion. The means of the bite force values were found to be 20.9 Kgf (204.9 N) amongst those aged 8.6 years, but were as high as 40.7 Kgf (399.1 N) in participants aged 25.4 years. Bite force of 201 preschool children in the age range of 4-6 years was determined by Su and colleagues 2009. The average age of their studied sample was 5.2 years. Mean maximum bite force has been reported to be 5.69 Kg and that is equal to 55.79 Newtons.

In addition, a study by Rentes *et al*. (2002) determined bite force in children in the deciduous dentition stage, although their sample was only small, comprising 30 children subdivided into three groups according to their primary occlusion. The age range of the subjects was 3–5.5 years, all of whom were due to commence dental treatment. In this research, the mean maximum bite force was expressed separately in regard to occlusion category, with the normal occlusion group providing a mean maximum bite force of 213.17 N.

Later, in 2010, Castelo *et al*. assessed the bite force of a sample of 67 children aged 3.5–7 years, and examined the impacts of numerous variables on the magnitude of bite force. The mean maximum bite force established through the normal occlusion and primary dentition group was 280.46 N. Moreover, the isometric bite force of the first permanent molar in a sample of 12 year old children was recorded, with the recorded mean of maximum bite force 43.4 Kg (425.6 N) in the right first permanent molar area and 43.7 Kg (428.5 N) in the left permanent molar region amongst a sample of 79 individuals (Linderholm *et al*, 1971). Additionally, when taking a sample of 36 children aged 9.06 years on average, the maximum bite force was recorded with the values correlated alongside masticatory ability (Lemos *et al*., 2006). The researchers stated that the mean maximum bite force across the subjects was 410.07 N.

It may be acknowledged that the numerous researches examining maximum bite force amongst children remains limited; thus, there is the need for additional studies to be carried out in consideration of bite force amongst children, focuses on different factors and the links of such, particularly in the UK context.

1.9 Bite Force and Influential Factors

The direct measurements of the bite force are obviously influenced by various factors; thus, a number of different investigators have established numerous bite force values. Essentially, the significant variation in the value of bite force depends on various factors linked with the physiological and anatomical characteristics of the subjects (Koc *et al*., 2010).

When analysing the evidence-based literature, various attempts to establish a link between independent variables and bite force can be seen, with such parameters including age, body size and facial morphology, dental status expressed by caries level, gender, malocclusion, muscles thickness and strength, periodontal support of teeth and temporomandibular disorders and pain—some of which are dependent on one other. Thus research studies concerned with individual variables were more complex.

Furthermore, as well as physiological aspects, bite force measurements are vulnerable to variations in terms of experimental approaches, such as in design and the various recording devices (Koc *et al*., 2010), as well as the degree to which participants cooperated (Hagberg, 1987), the techniques implemented by the investigator during the recording of bite force (Mountain *et al*., 2011), the head posture during the process of bite force measurement (Hellsing and Hagberg, 1990), the positioning of the recording device within the dental arch, and the degree of jaw separation when accommodating the bite force device (Bakke *et al*., 1990; Braun *et al*., 1996). The following section will provide separate summaries concerning the reported impacts of each variable in relation to the measurement of bite force.

1.9.1 Age Factor and Bite Force Measurements

In a recent review of the literature of the data available in regard to bite force and influential factors on its magnitude, Koc *et al*. (2010) took into account age, with Shinogaya *et al.* (2001) known to maintain that the normal ageing process impacts the jaw muscle force in terms of reduction. Nevertheless, there is consensus that bite force commonly increases with age until the individual is approximately 20 years old, at which point there will be stabilisation in bite force (Usui *et al*., 2007; Sonnesen and Bakke, 2005). However, upon reaching 40 years, bite force begins to decrease. Moreover, in 1990, Bakke *et al*. investigated bite force in a sample of 8–68 year old males and females, subsequently concluding that bite force increases with age until females are 25 years old and males are 45 years old, at which point a decline is experienced.

Sonnesen and Bakke (2005) state that the recognised increase in bite force, which has come to be linked with growth following their consideration of a sample aged 7–13 years, may be due to dental development in regard to increased dental eruption; thus, with an increased number of erupted teeth, it is expected that there will be a greater bite force.

Furthermore, in 1996, Julien and colleagues measured bite force, contrasting masticatory efficiency in a sample of 47 children and adults. Notably, the numerous variables in the group were discussed, with the explanation subsequently provided that the contact areas in posterior teeth in occlusion were strong determinants of masticatory performance. Furthermore, it was found through regression analysis that individuals with greater contact areas performed more efficiently than their counterparts of the same gender and body build but with fewer contact areas.

Julien *et al.* (1996) also emphasised that the total available surface area cannot be considered a strong indicator of contact area, with this same notion supported earlier by Yukastas *et al*. (1965). In specific regard to the effect of age on bite force in the case of children populations, a number of research studies have considered this variable (Mountain *et al*., 2011; Usui *et al*., 2007; Lemos *et al*., 2006).

Usui and colleagues reported a statistically significant difference in mean maximum bite force between subgroups of their subjects according to age. This difference was seen in both boys and girls, being largest between group one with mean age of 8.6 years and group two with mean age of 10.8 years. The difference was much less when group two was compared with group three who had a mean age of 13 years.

Furthermore, in 2009, Su *et al*. (2009) took a sample of 201 children in Taiwan, and found an increase of mean maximum bite forces between those aged 6 years and those aged 4 years. In addition, the bite force in primary dentition in the UK was examined by Mountain *et al*. (2011), who discussed the numerous influences, subsequently highlighting no strong link between age and maximum bite force when considering their samples of children aged 3–6 years. This conclusion suggests that bite force can be enhanced by the effect of stage of eruption and body growth—not solely chronological age.

1.9.2 Gender Influences on Bite Force Values

Many studies have established gender differences in maximum bite force, with males being higher when compared with females (Linderholm *et al*., 1971; Rentes *et al*., 2002; Tsai, 2004; Ferrario *et al*., 2004; Usui *et al*., 2007; Mountain *et al*., 2011). Nevertheless, this has not been found across all studies. Obviously, larger bite force in males may be due to greater muscular potential (Bakke *et al*., 1990; Shinogaya *et al*., 2001; Koc *et al*., 2010). Moreover, anatomical variables—namely greater masseter muscle fibre diameters (Pizolato *et al*., 2007), have also been found, and may be explained in regard to gender differences. Furthermore, it is also paramount to acknowledge that gender differences are not clear amongst children, i.e. in pre-pubescent individuals. Accordingly, the link between gender and bite force may become clear when considering samples aged 18 years and older (Koc *et al*., 2010).

As well as body variable, it is acknowledged that another contributing factor may be tooth size between genders, as highlighted by Shinogaya *et al*. (2001). In the case of young children, bite force changes as a result of gender remain inconclusive.

In this regard, few research studies have highlighted important differences in terms of gender, including Tsai and Sun (2004), who examined the maximum bite force amongst a sample of 463 Taiwanese children aged 9–12 years, subsequently recognising that the values were significantly higher in males than females. Moreover, when taking a sample of younger children aged 3–6 years, Mountain *et al*. (2011) reported a mean maximum bite force of 203.90 N in males and 186.19 in females, which supports the recognition that there is a difference, although, at the 0.05 level, it was not considered to be significant. Accordingly, it was stated by the authors that gender influence on bite force is not apparent clearly in the case of young children.

Additionally, it has been stated by Su *et al*. (2009) that gender differences in regard to maximum bite force are not statistically significant, with the investigators stating this following a sample of 201 children aged 4–6 years being studied, with bite forces only marginally higher in boys. In this same vein, it has been reported by Kamegai *et al*. (2005) that greater bite forces were found amongst Japanese girls aged 3–5 years old than their male counterparts but this was not significant statistically. However, no difference was found amongst genders by Rentes *et al*., who took a sample of 30 children in the primary dentition stage and therefore their results were pooled.

In regard to gender differences, it can be stated that, although there are some differences, they are not recognised as being significant until subjects have progressed through puberty, when anatomical differences and body variables are clear. Furthermore, although gender-related differences in regard to bite force amongst adults have received much attention and documentation, child-related differences are somewhat disputed.

1.9.3 The Effect of Height and Weight on Bite Force

Height and weight are known to be linked with maximum bite forces (Linderholm *et al*., 1971; Julien *et al*., 1996; Rentes *et al*., 2002; Lemos *et al*., 2006; Castelo *et al*., 2007; Mountain *et al*., 2011). It has been acknowledged that there is a positive association, with Julien *et al*. (1996) noting that the majority of research studies have not examined the effects of body variables, with the samples commonly comprising subjects of different ages and genders, therefore resulting in exaggerated variations and limited results interpretation.

In addition, a positive link between maximum voluntary bite force and child's (3–6 years old) weight was established by Mountain *et al*. (2011), which is believed to contribute 6.9% of the recorded bite forces variation.

Furthermore, similar findings were acknowledged by Lemos *et al*. (2006), with their study explaining 17% of the recorded bite force variability in their sample of 9.06 mean age children. Moreover, although the same was found by Linderholm *et al*. (1971), the link was stated as weak. Rentes *et al.* (2002) reported similar positive correlation of bite force and body build. This was proved by correlation coefficients of (r = 0.24) for bite force and weight, and (r = 0.23) for bite force and height. Similarly, Linderholm *et al.* (1971), although reported a positive correlation of bite force with body variables but described it as a weak correlation.

On the other hand, Su and colleagues (2009) used regression analysis to test for the association of maximum bite force in 201 preschool children with a number of variables including height and weight. No significant association was reported between bite force and either height or weight of the child. Toro *et al*. (2006) reported a dramatic increase in bite force with increase in body size and was clearest when comparing children at 10 years old with 11 years old, which is the stage of "pubertal growth spurt". It can be interpreted as an increase in body variables (Weight/Height) means greater muscle mass and therefore greater bite force magnitudes.

1.9.4 Bite Force Values and Occlusion Category

A number of research studies in the literature took into account malocclusion as a possible influential factor on bite force level in young children, adolescents and adults (Rentes *et al*., 2002; Kamegai *et al*., 2005; Sonnesen and Bakke, 2005; Lemos *et al*., 2006; Castelo *et al*., 2007; Gaviao *et al*., 2007; Su *et al*., 2009; Mountain *et al*., 2011; Andersen and Sonnesen, 2012).

There has been the postulation that malocclusion presence negatively impacts the amount of occlusal contacts, subsequently causing lower bite force when contrasted alongside bite forces in cases of normal occlusion (Sonnesen *et al*., 2001; Gaviao *et al*., 2007; Castelo *et al*., 2007). Notably, there are not always statistical differences in the bite force of children with malocclusion and those with normal occlusion. Thus, it should be noted that researches considering occlusion in the case of children are limited as the majority have examined the impacts of such in adults and older children.

Importantly, it has been found by Mountain *et al*. (2011) that there were lower mean bite forces in children with primary dentition malocclusion (194.2 N) when compared with those of normal primary occlusion (197.10 N), although this difference was not statistically significant.

Maximum bite force and its link with facial morphology was examined by Castelo *et al*. (2010) by taking a sample of 67 young children aged 3.5–7 years, all of whom had posterior crossbite.

It was stated through the conduction of univariate analyses in the mixed dentition stage that the subjects found to have lower bite forces were markedly more vulnerable to exhibit posterior crossbite, although this could not be recognised as an indicator for the presence of crossbite as multiple logistic levels did not illustrate significant levels. It was further emphasised that bite forces in mixed-dentition children with posterior crossbite were markedly lower when compared against those with normal mixed dentition occlusion.

They further added that such a difference was due to differences in masticatory cycle duration, length of lateral excursions, combined with impaired muscles function. It is recognised that all of these elements may result in neuromuscular adaptation so as to avoid any tooth interferences. On the other hand, Rentes *et al*. (2002) established bite force in 30 primary dentition children, with the sample split amongst three subgroups according to occlusion (normal occlusion, crossbite and open bite), with the authors subsequently highlighting that there were no prominent influences of malocclusion on bite force.

Similarly, Kiliaridis *et al*. (1993) carried out a cross-sectional research with a sample of 136 subjects divided into subgroups, with a total age range of 7–24 years.

Following conduction, the investigators reported no marked impact of malocclusion on bite force magnitude. In this way, Sonnesen and Bakke (2005) stated parallel findings in a group of 7–13 year old children, remarking that occlusion Angle's classification does not impact the levels of bite force, although they do recognise that the lower bite force values were found amongst individuals experiencing class III malocclusion.

This was supported by Lemos *et al*. (2006), who stated that the occlusion variable in their 36 subject sample was not found to impact bite force magnitude.

In contrast, bite force was examined across a large sample of Japanese subjects by Kamegai *et al*. (2005), with occlusion examined, amongst other variables, and participants classified in relation to the presence of normal occlusion, protrusion of the maxilla, crowded arches, crossbite, or open bite. In both genders, bite force was found to reduce with the presence of any category of malocclusion. Furthermore, statistical significance as a result of the negative impact of malocclusion was found in children over 9 years, with the researchers further stating that bite force had a positive correlation with normal occlusion.

In regard to the impact of malocclusion on masticatory performance, Toro *et al*. (2006) took this into account in regard to the ability to break food. It was suggested that malocclusion was known to reduce masticatory performance, although such an effect was recognised as being relatively minor.

With the above discussions taken into consideration, it can be seen that a negative link between malocclusion and bite force is generally acknowledged, although some degree of discrepancy remains in regard to whether or not there is any significance. Furthermore, there is a lack of understanding concerning whether such a link is present in primary dentition or whether this arises during the mixed-dentition phase.

1.9.5 Influences of Facial Morphology and Maxillofacial Growth on Bite Force

In a number of researches, cranio-facial morphology has been reported as a variable directly impacting the maximum bite force exerted (Proffit and Fields, 1983; Kiliaridis *et al*., 1993; Sonnesen *et al*., 2001; Castelo, 2010). For example, Koc *et al*. (2010) stated that cranio-facial morphology description includes the ratio between anterior and posterior facial heights, inclination of the mandible, and gonial angle. The researchers further added that maximum bite force suggests the "mandible's lever system's geometry".

Moreover, Sonnesen *et al*. (2001) examined bite force, TMD and facial morphology across a sample of pre-orthodontic children aged 7–13 years. It was established through their exploratory research studies that there was the presence of an association between muscles tenderness, long face and lower maximum bite forces, although such a link was recognised as being low to moderate.

Additional research showed a link between facial vertical morphology and bite force low magnitude, in addition to weaker mandibular elevator muscles (Proffit *et al*., 1983). Particularly, however, it should be recognised that the link was highlighted in studies with adults.

In contrast, the work of Castelo *et al*. (2010) examined bite force, the presence of posterior crossbite and facial morphology in regard to a sample of 67 children aged 3.5–7years, with this examination establishing no valuable link between maximum bite force and facial morphology.

One possible justification for this may be seen when considering the research took a sample of young children, which therefore means other studies cannot be directly compared which looked at older age groups. Moreover, Kiliaridis *et al*. (1993) studied the link between bite force magnitude and facial morphology in the case of 136 individuals aged 7–24, with subjects' facial morphology determined through assessing different variables from standardised photographs. Markedly, only slight positive links were established between incisor maximum bite force and upper facial height/lower facial height ratio.

Furthermore, no other link between the two variables was found, nor was any link between molar bite force and facial morphology variables. However, the work of Sonnesen and Bakke (2005) highlights the presence of a link between bite force and cranio-facial morphology, but only in the case of males aged 7–13.

As such, the most fundamental of considerations in regard to craniofacial morphology impacting boys' bite force was the vertical jaw relationship. Thus, it can be stated that males with a shorter, lower facial height demonstrated a greater degree of force in bite.

In this same regard, Usui *et al*. (2007) established a strong link between the mandibular plane angle and maximum bite force amongst certain subgroups within their subject sample, namely those aged 8.5–10.5 years. In conclusion, it was stated that a greater bite force was established through a more acute mandibular plane angle, with the opposite similarly true.

Overall, it may be stated that there is the presence of a negative link between long face tendency and maximum bite force; in other words, those subjects found to have shorter lower facial height demonstrated a greater degree of bite force. Notably, such a conclusion has been supported by numerous other studies targeting adult samples.

Furthermore, as well as the impacts of cranio-facial morphology on bite force, there is also an effect demonstrated through maxillo-facial growth. In this regard, it is believed that variation in maximum bite force magnitude is witnessed following changes in the cranio-facial growth, which complements normal growth process in addition to the growth of masticatory muscles (Braun *et al*., 1995a, 1995b; Castelo *et al*., 2007; Usui *et al*., 2007; Barrera *et al*., 2011).

For example, the link between occlusal contacts, masticatory muscles thickness and bite force values were considered by Castelo *et al*. (2007) by taking a sample of 46 child subjects, each of whom was assigned to a group in regard to the dentition stage and their occlusion. The researchers highlighted a strong positive link between thickness of the masseter muscle and maximum bite force amongst children with normal occlusion.

1.9.6 Ethnicity and Bite Force

The potential link between bite force and ethnicity has not obtained much attention from scientific researchers. If we acknowledge a strong link between socio-economic/ethnic background and oral health status, it should then be recognised that the presence of a bite force/ethnicity link is not unlikely. Nevertheless, such a relationship has not been widely researched.

However, one research study examined ethnicity in regard to maximum bite force by taking a sample of 46 participants and dividing them according to ethnicity (Danish (Caucasians), Japanese (Asians)), with age and gender also taken into account. The authors (Shinogaya *et al*., 2001) subsequently found no significant link. It must be mentioned that amongst their inclusion criteria was the absence of dental fillings or disease including malocclusion. Therefore, they were comparing two ethnic groups with comparable dental status.

In regard to children and a link between bite force and ethnicity, there is no published data in this regard, although Mountain (2008), in a PhD thesis, did analyse ethnicity effects, with a statistically negative correlation ($r = -0.17$, $p < 0.01$) for Asian origin and maximum bite force in young children. In contrast, there was a positive statistically significant link between individuals of black origin and maximum bite force ($r = .12$, $p < 0.05$).

1.9.7 Temporo-Mandibular Joint and Disorder Effects on Bite Force

Temporomandibular joint disorders may be described as the symptoms and signs linked with pain and the functional-structural disturbances of the masticatory system, with such symptoms including abnormal sounds, such as clicking or crepitation, pain in the TMJ and/or muscles, and limitations in regard to the opening of the mouth (Sonnesen *et al*., 2001; Kogawa *et al*., 2006).

Notably, numerous research studies have sought to examine whether or not bite force is impacted by the TMD disorder (Kogawa *et al*., 2006; Pereira *et al*., 2007). For example, Pizolato *et al*. (2007) state that there is a negative impact of TMJ disorders and muscles pain on bite force recorded values. Likewise, the same link was acknowledged by Kogawa, although other reports illustrate no significant impact as a result of TMD on bite force (Pereira *et al*., 2007). These differences in reported results could be attributed to variation in recording techniques as well as variation in severity of TMD cases studied in different studies.

1.9.8 Periodontal Tissues Health and Influence on Bite Force

The periodontal ligaments mechanoreceptors control the force load on the dentition induced during the process of mastication. In instances where periodontal support is found to be lower owing to disease impacting the periodontium, it is recognised that there will also be an effect on the mechanoreceptors function (Williams *et al*., 1987; Alkan *et al*., 2006; Takeuchi and Yamamoto, 2008). Alkan *et al*. (2006) drew a comparison between participants with healthy periodontal tissues with those with chronic periodontitis, considering bite force. The authors underlined a remarkable relationship between bite force and periodontium health, with a significantly higher bite force amongst healthy subjects than those with periodontitis. Williams *et al*. (1987) also provided similar findings, noting that those subjects with periodontal disease showed a lower bite force magnitude as a result of lower sensory function.

1.9.9 Dental Status and Caries Effects on Bite Force Level

There has been very little research carried out in regard to the effects of dental caries/fillings on bite force, with other variables receiving greater attention, such as body build, facial morphology and malocclusion, all believed to impact bite force (Linderholm *et al*., 1971; Shinogaya *et al*., 2001; Rentes *et al*., 2002; Kamegai *et al*., 2005; Castelo *et al*., 2007). However, a few studies have taken into account dental status assessments through calculating the number of decayed, missing and filled teeth (Helkimo *et al*., 1976; Kampe *et al*., 1987; Shiau and Wang, 1993; Sonnesen *et al*., 2001; Tsai, 2004; Su *et al*., 2009; Mountain *et al*., 2011).

With this in mind, although the remarkable negative effects associated with dental caries and poor dental status have been publicised in regard to various aspects of a child's wellbeing, in regard to the direct impacts on bite force and thus mastication performance and chewing, findings remain inconclusive and thus require deeper examination.

Bite force magnitude and occlusal perception was examined by Kampe *et al*. (1987) with a sample of 29 young adults aged 16–18, some with and some without dental fillings. The sample was divided into intact dentition group and fillings group. It is acknowledged that the fillings were mainly minor posterior teeth restorations. Accordingly, the mean maximum bite force values for intact dentition group were found to be 532 N, whilst the recorded mean for participants in the dental fillings group was 516 N. Notably, however, such differences were not considered to be statistically significant, although it was recognised as valuable that subjects with intact dentition had a notably greater anterior bite force when contrasted with mean values in the fillings group.

Moreover, the link between the state of dentition and bite force was assessed by Helkimo *et al*. (1976), who took a sample of 125 individuals aged 15–65 years. For the entire sample, the maximal bite forces range was 10–73 Kg, with the authors highlighting that the presence of a decline in bite force values was found to be in line with increasing age, particularly in the case of females, with the further statement that a variation in bite force value could be linked with dental condition differences amongst participants. It was further concluded that bite force magnitude may be as much as five times greater in younger people with natural dentition when contrasted alongside older denture wearers.

With this in mind, one very important point needs to be raised, that the sample taken comprised individuals aged 15–65; thus, owing to the presence of various confounders, the results could have been affected, with gender and age potentially impacting the bite force differences.

Shiau and Wang (1993) examined the impacts of dental status on bite force and hand strength on primary, middle and high school students, with the investigators subsequently establishing that those with extracted and carious teeth were more likely to illustrate a lower bite force value, although bite force was notably unaffected by hand force.

Thus, the conclusion was drawn that there does not seem to be a link between hand strength and bite force; rather, bite force is linked with dental condition (Shiau & Wang, 1993).

Furthermore, the maximum bite force exerted by primary dentition children can be predicted by the number of decayed, missing and filled teeth surfaces, according to Mountain *et al*. (2011).

In this regard, it was noted that a significant negative relationship between dmfs and maximum bite force (dmfs $r = -0.16$, $p<0.05$; dmft $r = -0.15$, $p < 0.05$) suggested that a child with deteriorated dentition was potentially more likely to demonstrate weaker bite forces when contrasted with a child with a healthy, normal dentition.

Su *et al*. (2009) focused on the oral condition and its influence on bite force magnitude in preschool children. There results were interesting in that they could not detect any obvious association between number of carious teeth, number of fillings, occlusion and the bite force value. However, a positive significant relationship between bite force and number of posterior teeth in contact was reported. They further added that regression analysis failed to demonstrate significant association of bite force with any of the factors except age of the child, maximum mouth opening and number of teeth in contact.

It is essential to note that in this study, investigators used the dmft index (number of decayed, missing, filled, teeth) and not dmfs (number of decayed, missing, filled surfaces) which could be the reason why its value (that is normally smaller than dmfs) showed no effect on the recorded bite force.

On the other hand, Su *et al*. (2009) reported that although the total dmft was not correlated with the bite force, there was however a negative relationship between the number of missing teeth and the recorded bite force. This finding was interpreted as suggestive that teeth were crucial for proper mastication in this stage of dentition. The authors suggested that as their results failed to demonstrate bite force-caries association, then this correlation was possibly more important when we describe the severity of tooth decay rather than number of carious teeth.

Using the dmfs index (decayed, missing, filled surfaces) greater accuracy in describing the caries severity will be obtained. Subsequently Su and colleagues suggested that dmfs should be considered in future research studies.

In addition, an investigation was carried out by Tsai (2004), who took a sample of 676 Taiwanese children aged 3–5 years with the objective to establish maximum bite force. In this study, a custom bite force gauge was utilised in order to assess bite force, which was recorded in kilograms. Markedly, the study established that maximum bite force ranged between 15 and 18Kg, which was equivalent to between 147 and 176 N. As predicted, a clear link between the number of carious teeth and plaque index was found. Furthermore—and potentially more importantly—Tsai (2004) found a negative link between the number of decayed teeth and maximum bite force.

As well as the periodontal feedback reflex, central states, e.g., the fear of pain as a result of dental decay may also be an important factor in muscle force reduction (Tsai, 2004), with the research of Tsai providing support for the belief that the presence of decayed teeth negatively impacts health and the overall efficiency of mastication system.

One factor potentially responsible for low bite force is pain owing to the fact that carious teeth can cause high levels of pain, particularly when the disease is advanced. This then weakens bite strength (Linderholm and Wennstrom, 1970). In this regard, it is also noted that a greater value of dmfs/dmft goes hand-in-hand with a lower level of bite force, which provides a statistically significant negative link.

As Mountain *et al*. (2011) emphasised that bite force at the primary stage of dentition development may ultimately depend on caries prevalence (Mountain *et al*., 2011).

In summary, it can be seen that research studies carried out previously have not directed much attention to the level of caries and their severity when examining bite force and its corresponding factors. Moreover, very few researchers have considered the potentially negative link, with only one study utilising DMFS/dmfs when explaining the caries level. Thus, additional studies are needed in order to draw a sound conclusion.

1.10 Technical Variables that could Influence Bite Force Measurement

The extent to which the mouth can open, as well as the head posture during measurement, the positioning of the bite force device whilst recording bite force and the number of recordings are all aspects needing consideration as they all notably impact the measurements obtained (Paphangkorakit and Osborn., 1997).

It has been stated that an increase in the vertical dimension can result in variations in the orofacial morphology. Subsequently, masticatory system and bite force values are also affected (Olthoff *et al*., 2007). Several studies reported that the degree of jaw separation influenced the bite force and the mean jaw separation for populations at which bite forces are recorded ranged from 14–20 mm (Koc *et al*., 2010).

When considering factors affecting bite force it is recognised that the position at which the recording device is placed within the oral cavity differs, as highlighted by Tortopidis *et al*. (1998). Commonly, stronger bite forces are normally recognised in the dental arch's posterior region, as has been acknowledged through two different theories. First and foremost, the mechanical lever system of the jaw; and secondly, posterior teeth (premolars and molars) are able to withstand greater forces than anteriors (Braun *et al*., 1996; Tortopidis *et al*., 1998; Ferrario *et al*., 2004).

In this way, during the process of bite force recording, head position impacts the end result. Furthermore, it is noted that different approaches and the number of measurements impact on the bite force values. Evidently, although one single measurement is not as reliable as more than one, Usui *et al*. (2007) highlighted that repetitive recording can results in a reduced bite force as a direct consequence of muscle fatigue.

In bite force investigations, the number of recordings necessary should be determined whilst considering the reliability factor and importantly avoiding fatigue that will result in reducing bite force magnitude.

1.11 Devices used Previously to Record Bite Force

Establishing bite force in the context of clinical practice is carried out in order to assess dental prosthesis and to accordingly determine the overall success of rehabilitation in the case of adults. Furthermore, such calculations are also geared towards obtaining bite force reference ranges in an attempt to guide prosthetic device and implant design (Koc *et al*., 2010).

In the literature, various bite force measurement devices have been highlighted (Koc *et al*., 2010). One such example is that of the spring device, which utilises compression forces in order to document bite force; there is also the more advanced foil transducer, which relies on the piezo-electric principle. Markedly, the majority of modern designs utilise electrical resistance strain gages (Fernandes *et al*., 2003).

Overall, the majority of recording tools concerned with bite force have the potential to record forces between 0 and 800 N at a rate of 80% precision and accuracy amounting to 10 N (Bakke *et al*., 1992; Fernandes *et al*., 2003).

As early as 1681 Borelli was one of the first to consider instruments able to assess intra-oral forces, with the subsequent design of the grantodynamometer, this was concerned with measuring bite force in this way. Furthermore, in 1893, the redesign and modification of the tool was carried out by Black (Ortug, 2002).

As a result of such primary examinations, academics and investigators continue to improve upon and introduce new sensitive high-technology instruments able to measure human bite force for a number of different reasons. As any tool, each bite force described in the literature has certain advantages and positive features. Additionally it also carries limitations when it comes to its applicability and design.

One example of a bite force device is a pressurised rubber tube that must be connected to a sensor element (Pressure sensor MPX 5700 Motorola) (Rentes *et al*., 2002; Lemos *et al*., 2006; Castelo *et al*., 2010). There is the need to connect the system to the computer and software so as to enable pressure reading and thus establishing the values in Psi. However, there is the disadvantage that the Psi must then be converted to N, taking into consideration the tube area due to the fact that force equals pressure multiplied by area, which will markedly impact the easiness such utilisation and thus make it less practical. In addition, there is also the need to connect to a computer, and so it may be recognised that the device is not portable.

Another recording system utilised in the context of bite force is ‘dental prescale system’, which comprises a horse-shoe shaped bite foil made from a pressure-sensitive film, and further includes a computerised scanning system, which is able to analyse the applied forces. Upon the application of force to the occlusal surfaces, a graded colour will result from a chemical reaction. Koc *et al*. (2010) stated that ‘the exposed pressure-sensitive foils are analysed in the occlusal scanner which reads the area and colour intensity of the red dots to assess occlusal contact area and pressure’, with occlusal load automatically analysed (Koc *et al*., 2010).

With this in mind, Shinogaya *et al*. (2000) assessed bite force with the use of dental prescale system, stating that it has the benefit of measuring bite forces at inter-cuspal position, and accordingly delivering prediction of bite forces under natural conditions. Moreover, the force distribution can also be assessed simultaneously, although there is a technical limitation in terms of the computerised scanning apparatus, as highlighted previously.

In addition, this dental prescale system is also recognised as being time-consuming, as Shinogaya *et al*. (2000) acknowledge.

Another commercially available and highly sophisticated tool is the 'Tekscan' (http://www.tekscan.com/occlusal-analysis-system#applications), which has been utilised in research centred on occlusal analysis studies, as occlusal indicators, in implantology, aesthetic dentistry, as well as temporomandibular disorders (Kerstein, 1999; Kerstein, 2001; Mahoney, 2004; Garg, 2007). However, the costs of utilising the tool need to be taken into account as they are known to be very costly.

Throughout the course of this research, the device that will be implemented has been proven reliable and accurate in the study of Mountain *et al*. (2011).

The instrument is recognised as a single-tooth bite force gauge, which includes various critical concept design factors in an attempt to confirm effectiveness and accuracy, and the overall capability to function in all areas of a child's mouth, safely and unobtrusively. A single use parallel bite sensor prong is accommodated through the bite force measurement tool's main body, facilitating natural occlusion and required minimal jaw opening during the process of measurement (Mountain *et al*., 2011). The tool comprises a hinged stainless steel body, containing a model 13 sub-miniature precision load cell (1112 N). Markedly, the main body, with pivoting arms, accommodates removable (single-use only) and parallel upper and lower HSS tool steel bite prongs.

The bite prongs were constructed from hard steel in order to ensure undue bending is not experienced upon compression. Moreover, the main body had an overall length of 112 mm, with the bite prongs measuring 55 mm. Bite force data is recorded through the use of a “hand-held battery operated TR150 microprocessor-based portable strain display load cell/force transducer sensor with an output sensitivity of up to 5m v/v” (Mountain, 2008; Mountain *et al*., 2011).

Chapter Two

Research objectives, questions and hypothesis

2.0. Rational for Carrying out the Present Study

After conducting a critical review of the available relevant literature it became apparent that there was an obvious lack of studies evaluating bite force in children. A lack of research on all factors influencing bite force in children has also been noted. Caries and dental health have not had adequate attention from research studies. Very few contemporary studies that evaluate bite force values in young children and analyse possible influencing variables exist. Out of the very restricted number of studies available that evaluated the bite force in children only one is UK-based (Mountain *et a.l*, 2011). Currently no previous studies have specifically evaluated what the impact of full mouth rehabilitation (complete dental treatment) can have upon the bite force in young children. Therefore the purpose of this study was to evaluate the effect of full mouth dental rehabilitation by measuring and comparing pre- and post-treatment bite forces in the primary and mixed dentition of children.

2.1. Objective I

The first objective of the current study was to analyse the potential effects of full mouth rehabilitation on maximum voluntary and comfortable bite force of young children in the primary and mixed dentitions stages. Although there are many published research studies reporting the positive impacts of full dental treatment in children on quality of life measures as well as general health status, no studies were found to determine the possible influence of improving dental status by comprehensive dental treatment on children's bite force.

2.2. Objective II

To analyse and critically assess different influencing factors on the magnitude of children's bite forces in order to advance knowledge in relation to bite forces and their interplay in young children.

2.3. Research Question

This study has one defined question that should be answered on completion. The question is: "What effect does full mouth rehabilitation, including both restorative treatment and/or extraction of carious teeth, have on the maximum voluntary bite force in children who are in the primary or mixed dentition stage".

2.4. Research Hypothesis- Null hypothesis

Full mouth rehabilitation that involves restorative treatment as well as extraction of carious teeth does not affect the maximum voluntary bite forces in young children with primary or mixed dentitions.

Chapter Three

Materials and Methods

3.0. Obtaining Ethical Approval

Carrying out a study that is considered ethically informed needs to be assigned significant emphasis (Blaxter, 2001). Documentation and guidelines relating to the elements, factors and requirements to be considered in regard to ethical studies are available from multiple sources (Gogging, 2005).

In adherence to the values underpinning good practice and the standards of the Department of Health (DH, 2005), a copy of the study protocol was presented to the local research ethics committee for independent review. Before the research was initiated, ethical approval was obtained from the National Health Services (NHS) through Integrated Research Application System (IRAS) (Appendix 3.1), and the investigator's HE institution through the Dental Research Ethics Committee (DREC). In addition an approval from the Research and Development Forum (R&D) was also obtained (Appendix 3.2). Prior to designing the study's methodology, expert's methodological opinion from the study's supervisors was similarly obtained. The supervisors of the research and the researcher first ensured that the research fulfilled all governance and pre-requisite regulatory requirements, as highlighted by fundamental institutions, such as the World Medical Association Declaration of Helsinki (2000 and 2008), and the good clinical practice documentation provided by the MRC/ICH. As a key aspect of the study approval process, there was the inclusion of an intrinsic agreement relating to the suitable arrangements for reporting and monitoring.

3.1. Ethics and the Involvement of Children in Research Projects

Ethics in the context of a research study can be described as the moral principles underpinning the activity, with such principles outlined and detailed in individual countries' codes of conduct. Without question, childhood may be problematic to define, although there has been growing recognition of the rights of children in studies as informants to scientific study approaches (Mountain *et al.*, 2000/2001; Knox and Burkhart, 2007).

Studies directly impacting children that are carried out in an ethical, reliable and timely fashion are becoming more and more important in terms of modern-day studies. The inclusion of the views and insights of children is a critical factor to be taken into account when designing or preparing any child-related research, and is advantageous when encompassed at all study phases.

Nevertheless, there are numerous research studies relating to children that are commonly guided by a particular theme—usually adult-oriented—that does not necessarily reveal or take into account the perspectives of the child (Sargeant, 2010). With this in mind, the value of the child's voice and the perspectives of the children must be given enhanced attention in the context of child-related professions, and should further be acknowledged as being fundamental at a grass roots level. However, the potential of children to handle and manage, and accordingly process the data, associated with their everyday lives is less keenly recognised in a broader societal context, as highlighted by Sargeant (2010). The comparatively new nature of studies comprising child participants has caused both academics and researchers to experience novel, significant challenges.

As investigators, if we have the objective to give power to children and accordingly gather accurate and usable child-led data as well as ensuring the rights of children remain integral, it is then fundamental that age-appropriate child-centred strategies are selected (Mountain *et al*., 2000/2001). Studies must implement new approaches that are probably imaginative in order to ensure the recruitment and retention of children are improved in the context of clinical studies (Knox and Bukhart, 2007). Whilst patient or public information sheets are a key part of the ethical approval process in this case it is imperative that we meticulously craft approaches that ensure that the child is able to give informed consent and/or assent.

The conventional approach of utilising research describing sheets is considered not suitable for the language abilities and cognition levels of young children, such as the sample applicable to this research. Importantly, it is recognised that very young children are commonly unable to deal with theoretical descriptions that are written on papers, thus necessitating that the investigator to make all efforts to enter a world familiar to the child (Bretherton and Ridgeway, 1999). Investigators or researchers need to have discussions with the children, ensuring the use of terms familiar to them, and designing the research in an attempt to reflect the experiences of the child and their own special world (Cullingford, 1997; Mountain *et al*., 2000/2001).

3.2. Securing Parental Consent and Assent from the Child

When considering informed consent, the participants of a study or the representative of such participants need to "provide authorisation for involvement following the communication of what is involved in the research study, i.e. what is being proposed, what approaches will be implemented, and why such choices have been made". Informed consent, as a concept, requires that the target sample has the necessary decision-making capacities, and is able to act without pressure or control from others, and are also legally and morally able to refuse involvement (Department of Health, 2005).

Importantly, when establishing whether an individual has the ability to make decisions, this can be considered in terms of whether he/she is able to comprehend the request, as well as the advantages and risks associated with such, and can also communicate their decision. In the right situation, young children may be able to partake in well-reasoned, informed conversations and express views on issues. Essentially, the main considerations to be taken into account are respect and esteem, safety, rights, and well-being of all participants. Suitable arrangements are necessary for gathering consent, i.e. from the parent or guardian of the child, but the child must also be asked for assent (Johnston, 2006).

The assent process should comprise assisting the child in developing awareness of the research, in a developmentally fitting mean, examining the child's overall understanding of the research and the individual elements impacting her/his response to the request to be involved, and at last requesting the willingness or denial of the child to participate (Darbyshire, 2000; 2005).

In this research, as well as securing the consent of the child's parent/guardian, attempts were made to secure the assent of the child. This strategy was implemented so as to ensure the ingrained adultist orientation to quantitative paediatric study was avoided, thus circumventing any nature of 'research on children' as opposed to 'research with children' (Darbyshire, 2000).

Notably, the assent of the child participants was achieved through the use of developmentally suitable approaches, taking the form of a specially designed story board, which takes the child through the study process, phase by phase, and describes all that is involved and this was approved by the local research ethics committee. The story board was adapted from storytelling approaches that was subsequently verified through a prior study, incidentally approved by Local Research Ethics Committee (Mountain G, 2008, PhD thesis).

In order to ensure that both parental information sheet and story board are clear, appropriate and acceptable to research participants, they were assessed by approaching families (not involved in the research) and asking them to evaluate the material and suggest if any further clarifications or amendments were required (see Figure 3.1).

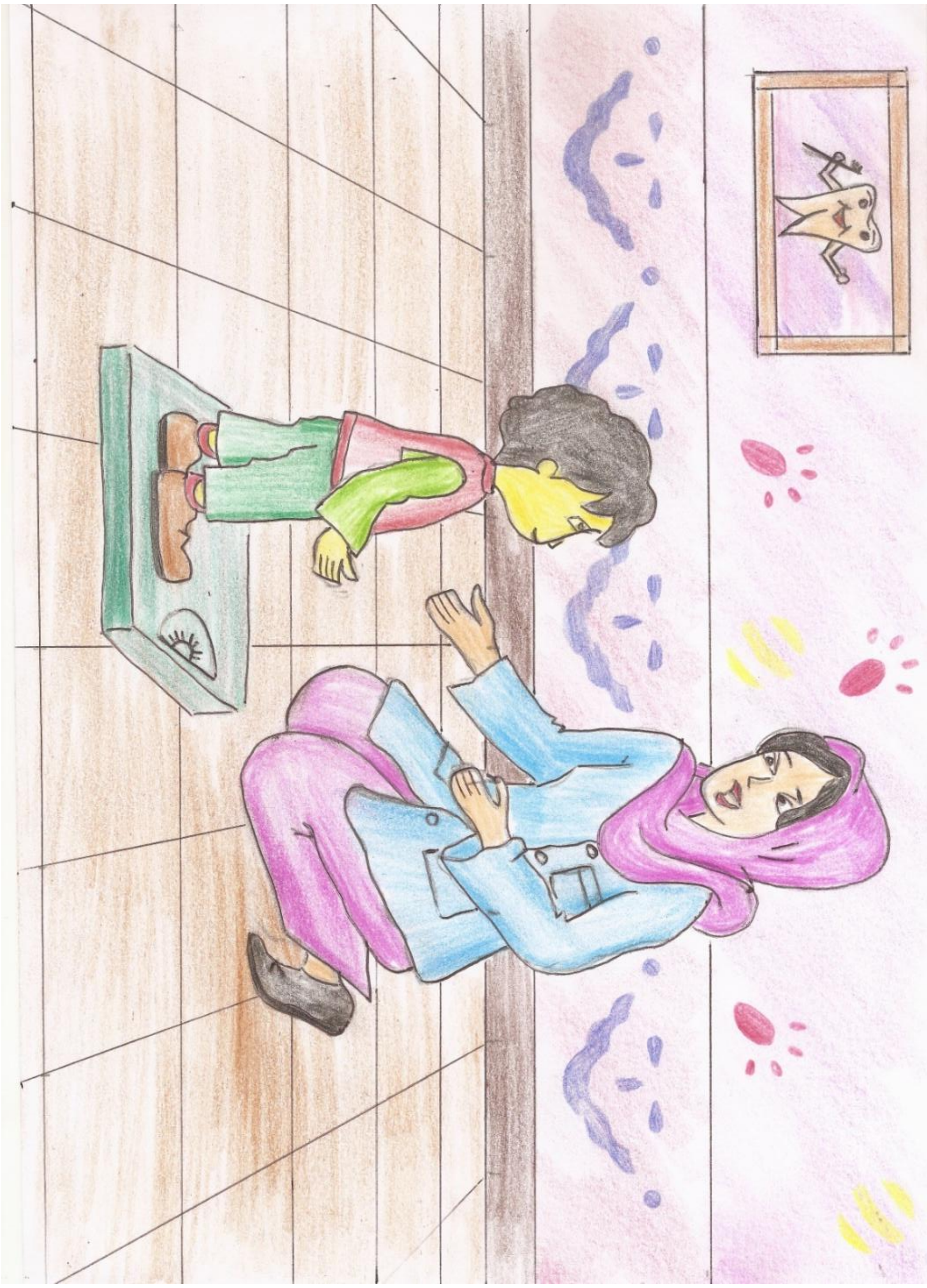
Figure 3.1. Story board

An A2 printed version of the story board was used. The child was shown the pictures and a simple explanation given in 'childrenese terms 'of the research process.

A picture that was used to demonstrate to the child participant what we are going to do next and shows dental clinic atmosphere.

A picture shows a young child sitting in the dental chair and going to have a dental examination by a dentist.

Simple drawing shows how we are going to check the teeth. The use of this picture helped in explaining the process specifically for young children.



Weight measurement explained in a drawing to simplify the procedure for young children.

A picture that explains how we are going to check the height

A photo shows the measurement of anterior bite force of a child. Picture was taken, following permission, from Mountain (2008).

3.3. Participant Recruitment

The invitation to participate in this study and a parental information sheet (Appendices 3.3 and 3.4) were sent to parents of children deemed suitable to participate, according to pre-specified inclusion criteria, together with their appointment letters to attend the Leeds Dental Institute. The information sheet was designed in such a way so as to outline the purpose and details of the research study, using simple language, avoiding complex medical terms, and was approved by the research ethics committee (REC).

Patients scheduled to have appointments at the Children's Department in Leeds Dental Institute were identified, and those who, from their records, were seen to meet the inclusion criteria, were identified. The departmental secretary was given copies of information sheets in order to attach them with the patients' appointment letters.

On the day when the patients attended the department, either to commence the treatment or for consultation and preventive treatment, they were met by the researcher, at which time opportunities were provided to ascertain that they had received, read and understood the information provided concerning the study. Opportunity was also given for parents to seek any further clarification on any matters relating to the study.

3.3.1. Research Participants' Inclusion Criteria

Young children, aged 3-10 years, currently in the primary or mixed dentition stage who had been referred to the Paediatric Department for dental treatment, were recruited.

Participants or those deemed suitable for inclusion in the study met the following criteria:

- Children were medically fit or not affected by any compromising medical condition at the time of treatment.
- Had the presence of at least two opposing molars.
  - Were scheduled to receive full comprehensive dental treatment that includes restorations and extractions.

This study had both primary and secondary outcome measures. The primary outcome measures were defined to be the maximum bite force both before and after completing dental treatment as well as the changes in the values of bite force following treatment. The secondary outcomes were the interplay of different variables on the maximum bite force including: age, gender, body variables, caries, dental pain and/or abscess.

3.3.2. Research Participants' Exclusion Criteria

Participants who were not included in the study were those children who:

- Had the absence of at least two opposing molars, thus preventing bite force measurements to be taken in the molar region.
- Exhibited uncooperative behaviours that could affect measurement procedures and/or compromise their safety.

- Any other dental conditions, such as severe swelling, that might prevent them from participating in the bite force measurement.

Informed consent had been obtained from the parent or guardian for every participant using a standard consent form (Appendix 3.5). Immediately prior to data collection, careful checks were carried out by the researcher in order to ascertain whether the child assented or dissented to study participation.

The child's assent to participate was secured using developmentally appropriate methods, which took the form of a specifically designed story board, as discussed previously (Figure 3.1).

3.4. Anthropometric Measurements and Intra-oral Examination

For all of the participants involved in the study, height and weight anthropometric measurements were recorded with the use of portable weight and height scales. The measurements were taken in an attempt to assess the body build and body variables' influence and to be analysed alongside each participant's bite force value. The standing height of the child was measured to the nearest 1.00 mm with the use of a portable Seca 217 Stadiometer, which did not necessitate recalibration upon movement. Each child was asked to stand against the measuring rod, their back straight and feet aligned with the foot positioner, and their head in the 'Frankfurt plane' (Figure 3.2). With the use of Seca 877 calibrated electronic scale for mobile use, each child's weight was also determined (Figure 3.3). Body Mass Index (BMI) was then calculated in consideration of the weight and height measurements by a known formula which is: (BMI= Weight/Height^2).

Figure 3.2. Height measurement using a portable Seca scale

Figure 3.3. Weight measurement using portable Seca scale

Baseline data were gathered regarding the children's gender and age. In addition, questions regarding the presence of dental pain as well as abscesses or recent facial swelling were queried, with the data subsequently recorded. The side of pain or swelling, if present, was also recorded. Dental examination (standard dental charting) was carried out using disposable dental examination kits (mouth mirror and probe) by the investigator, noting missing, present teeth, as well as any signs of dental abscess.

Additionally, caries experience at both tooth and surface levels were determined in accordance with the WHO criteria (WHO, 1997). In order to quantify the level of caries in each child, the dmft/dmfs for primary teeth and DMFT/DMFS for permanent teeth indices (decayed, missing and filled teeth- decayed, missing and filled surfaces respectively) were calculated. Present restorations, overjet and overbite were also noted. The presence and category of any malocclusion was recorded.

At this stage, children were excluded from the study if they were found to have missing teeth in areas where the bite force was to be recorded. All data collected were recorded in a specifically designed data collection proforma (Appendix 3.6).

Two series of bite force measurements were taken for all participants. The first one was immediately prior to the start of dental treatment, whether the treatment was performed under local anaesthetic or under general anaesthesia. Each series of bite force recording involved the measurement of the maximum comfortable bite force at three different positions along the dental arch, namely anterior and right and left posterior (D/E/6).

The same bite force measurements were repeated 4 weeks ±7 days post-treatment, as well as the dental charting and anthropometric measurements of height and weight using the same form used for the pre-treatment measurements. Additionally, all patients who attended for the post-treatment measurements were given appropriate prevention advice and treatment as necessary, including topical fluoride application where indicated.

3.5. Bite Force Measurement Protocol (in accordance with the procedure adopted by Mountain, 2008)

Bite force magnitude was measured in Newtons (N) with the adoption of a formerly tested and verified prototype bite force measurement instrument. Each of the children was seated in a chair. Their body and head were kept in a natural, upright position, ensuring the Frankfort plane was positioned parallel to the floor. Subsequently, each of the children was asked to carry out a maximum voluntary comfortable bite force (MVCBF), lasting 2–3 seconds, at three different locations (anterior, right posterior and left posterior) within the dental arch, with each recording accompanied by a 5-seconds interval.

The bite prongs' nylon protective ends were positioned correspondingly with the occlusal/incisal central incisors' surfaces, right first primary molar and second primary molar; if not present, on the other hand, the right second primary molar and right first permanent molar, with the same applying to the left posterior side.

For each of the three positions, the peak bite force was measured and accordingly recorded, with each participant's highest of the three taken as the maximum voluntary comfortable bite force.

3.6. Apparatus/Instruments Used to Record Bite Force

Through the use of a bite force instrument created by Mountain (2008) as part of his PhD. research, bite force was measured, ensuring adherence to best guiding principles, as highlighted in Figure 3.4. The instrument comprised a “main body of hinged stainless steel, housing a Model 13 sub-miniature precision load cell”.

The main body’s lower and upper arms were made from HSS tool steel, and are single-used and easily removed, such as for sterilisation purposes. The main body of the tool was 112mm in length, whilst the length of the bite prong was 51mm, as depicted in Figures 3.3, 3.4 and 3.6. The bite prongs’ ends were covered with a tough, hard-wearing nylon, able to decrease the potential of tooth penetration as a result of its thickness, and also reducing any subsequent contact with the prong’s metal part, which may impact the accuracy of the bite force measurement and can cause unnecessary discomfort.

For the aforementioned purpose, the bite force tool had undergone verification, with the Medicines and Healthcare products Regulatory Agency (MHRA) consulted via telephone concerning the utilisation of the bite force instrument. They stated that the proposed research device does not fall within the essential requirements of the Medical Devices Regulations 2002; thus, it became clear that there was no need for an application to be made to the UK competent Authority. An email from MHRA sent to the study’s supervisor was obtained to confirm the above (Appendix 3.7).

To record bite force values for participants an attached “hand held battery operated TR 150 microprocessor based portable strain display load cell/force transducer sensor with an output sensitivity of up to 5m v/v” (Figure 3.5) was used.

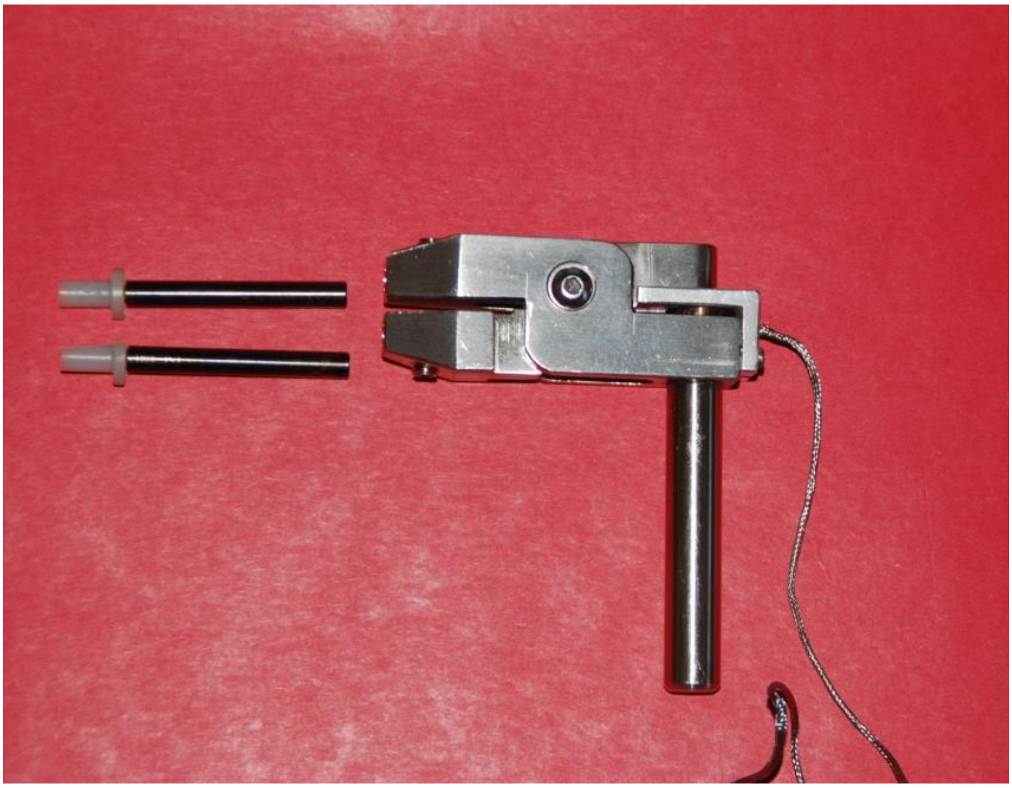


Figure 3.4. **Bite Force device before attaching bite prongs.**

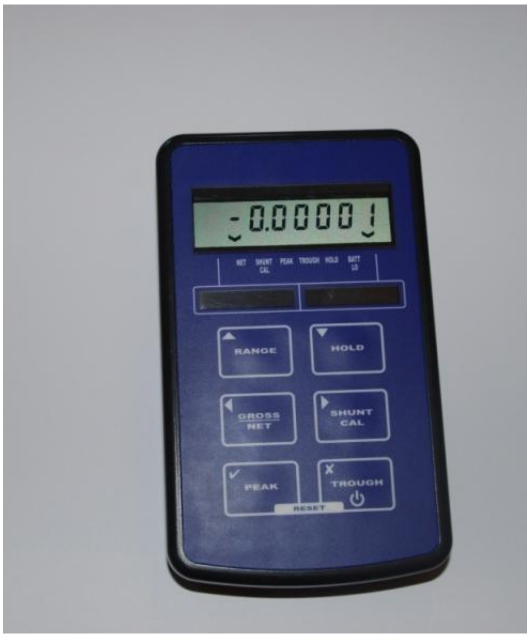


Figure 3.5. **Portable strain display.**

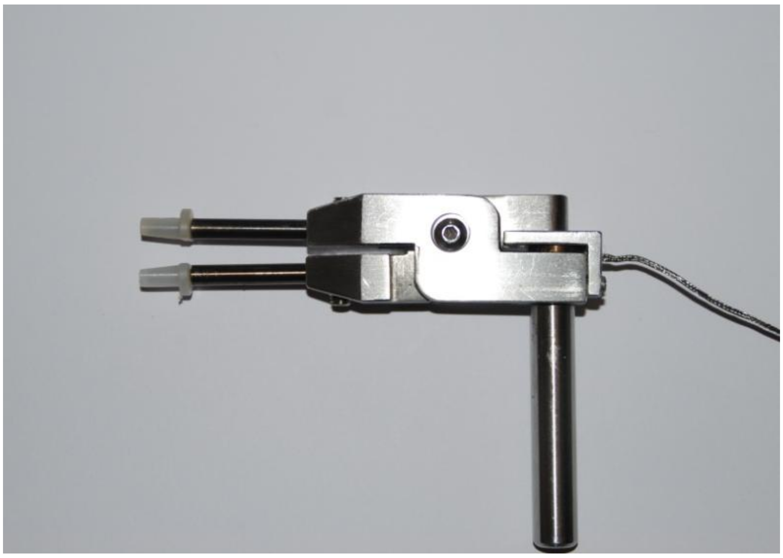


Figure 3.6. Bite Force device with bite prongs attached.

Figure 3.7. Sterilised and individually packaged bite prongs.

3.7. Calibration of the Bite Force Measurement Device

The bite force sensor underwent *in vitro* calibration prior to the data being gathered. This process was implemented at room temperature against a universal dynamic mechanical tester (E 3000, INSTRON).

The load cell calibration was to a maximum of 700 N, and to ensure the device could be calibrated precisely, it was clamped firmly in a horizontal plane. Following this, in order to approximate the bite prongs to each other and to the testing machine, a metallic gauge block was utilised. The upper and lower bite prongs' parallelism was ensured before the application of the high calibration stimulus.

The testing machine knife edges were then brought in to contact with the ends of the bite prongs, at which point calibration was initiated. There was an application of increasing compressive forces, starting at 0 N and proceeding up to 700 N. At 7 points, i.e. every 100 N, calibration recordings were taken.

Markedly, the greatest discrepancy (uncertainty factor) was 4 N (range was 0.8-3 N), at which point the maximum of 700 N load was recorded (Figures 3.8-3.10).

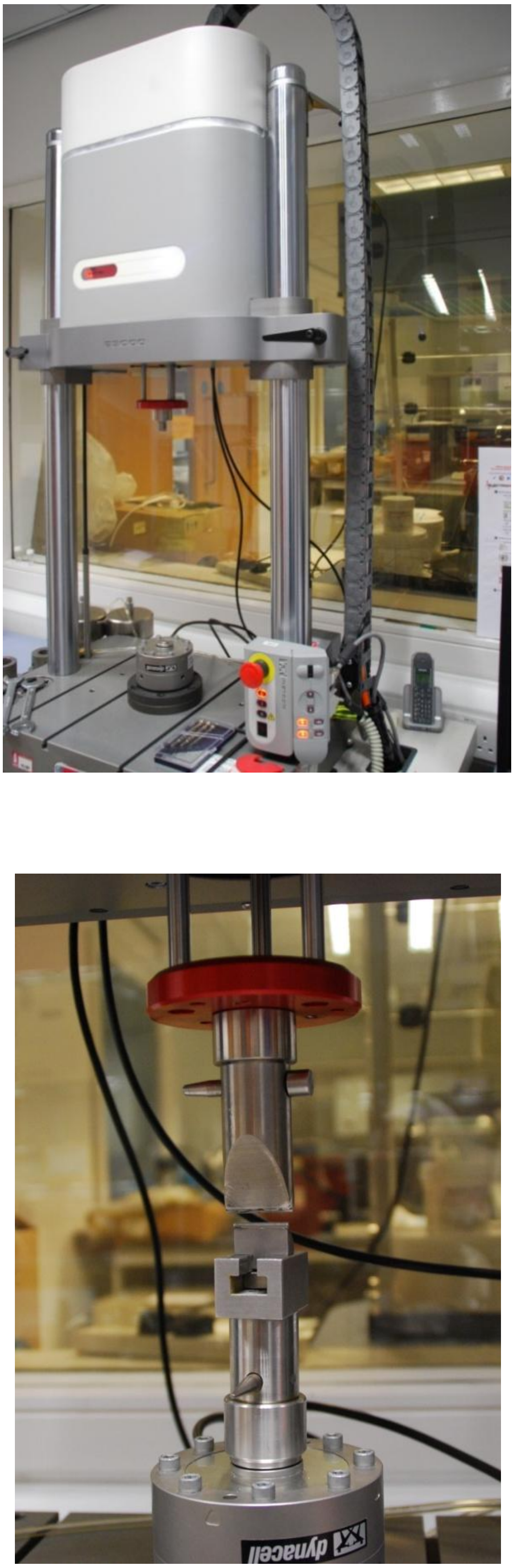


Figure 3.8. E3000 INSTRON Mechanical tester machine.

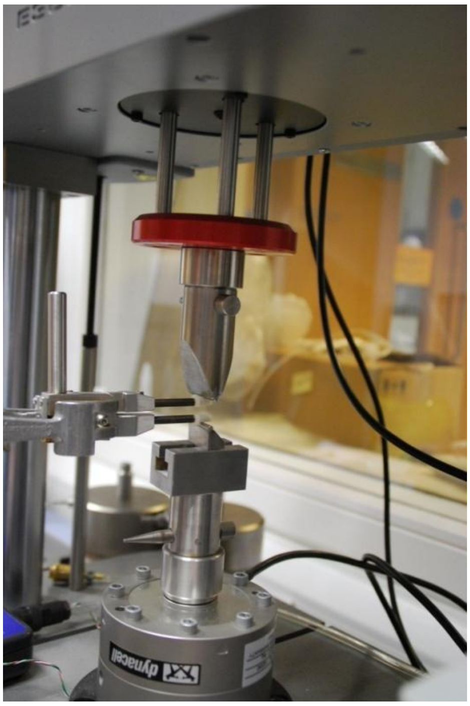


Figure 3.9. Clamped Bite Force device with approximated edges of testing machine.

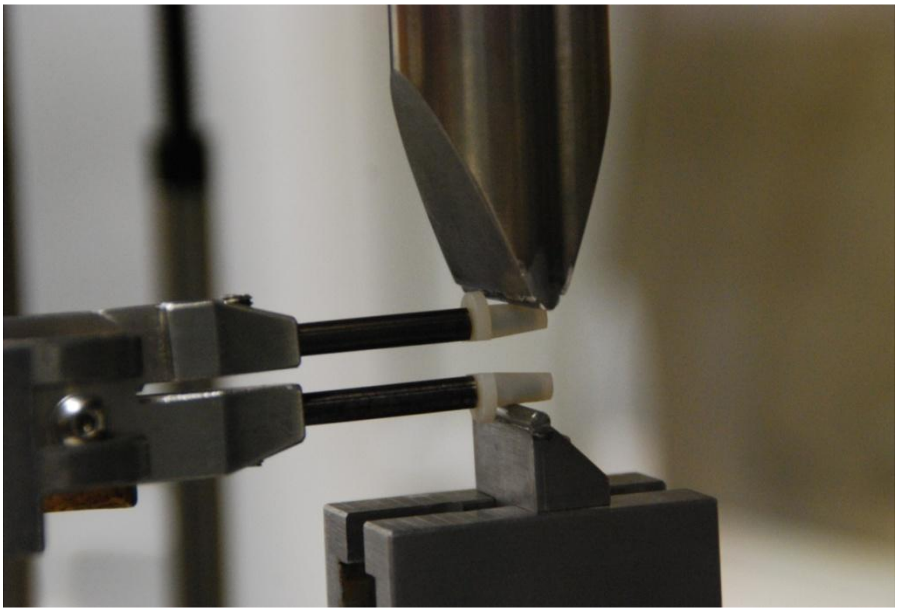


Figure 3.10. Close-up of the bite prongs during calibration

3.8. Intra-Examiner Reproducibility

The examination procedure and bite force measurements were carried out by the same investigator (L.A.), who was trained on how to use the bite force device to measure the bite force by Dr. Gary Mountain. The results were subjected to tests for intra-examiner reproducibility. A random re-examination and re-measurement of 10% of the studied population were carried out for bite force, height and weight measurements using the Bland and Altman plots method.

3.9. Data Handling and Analysis

All collected data were immediately entered into password-protected documents in the computer. SPSS Version 19 (SPSS Inc. Chicago, IL) program was employed. The data was statistically analysed in order to determine differences pre-treatment and post-treatment, and to accordingly test the research question and experimental hypothesis generated.

3.10. Sample Size Calculation

As there were no similar studies available in the literature, there were no estimates that could be used for sample size determination. Therefore it was agreed following consultation and opinion from a statistician that this study can be considered as exploratory and can help to determine suitable sample sizes for similar future studies. In addition, an alpha level of less than 0.05 was determined to be statistically significant in the current study. Initially, it was planned to conduct a pilot study from which power and sample size calculation can be estimated however; due to time limitations this plan was not possible.

Notably, Cohen (1992) suggested simple guidelines to enable estimating the required sample sizes in such cases. For instance, if we require the power at 0.8, as normally recommended, and we consider an alpha level of 0.05 then to detect a small effect (i.e. $r = 0.1$) a sample size of 783 is required, while for a medium effect perception (i.e. $r = 0.3$) a sample size of 85 subjects is needed. In addition, to detect what is considered a large effect size (i.e. $r = 0.5$) a sample consisting of 28 subjects is considered sufficient (Cohen 1992; Field, 2009).

3.11. Statistical Tests Used in the Study to Analyse Data

Statistical advice was obtained with regard to the statistical tools and tests required to analyse data and answer the research question. The following is a summary of the statistical tests that were used, and will be further described in the next chapter:

- Bite force measurements before and after dental treatment will be compared with the use of paired t-tests since the data is paired.
- Quantitative variables will be summarised via means and standard deviations if normally distributed, otherwise, medians and inter-quartile ranges will be used for skewed data.
- Graphical summaries, such as box plots and tables, will be used to display data.
- Categorical variables will be summarised with the use of proportions.

Chapter Four

Results

4.0. Statistical Tests

All collected data were entered into SPSS (Statistical Package for Social Sciences, Version 19) for Windows (SPSS Inc. Chicago, IL), software to analyse data.

The first step was to test data for missing values and checking for any errors prior to starting data analysis. Data were tested for normality of distribution using Kolmogorov-Smirnov (K-S) and Shapiro-Wilk (S-W) tests. Following this step, data were analysed by descriptive, conventional statistical tests including, mean, standard deviation (SD) as well as standard error of mean (SE). For all numeric variables, minimum and maximum values were determined. In addition, correlation coefficients between different variables and maximum voluntary bite force in the pre-treatment stage were calculated.

To assess repeatability of the methods employed, Bland Altman's plots were used on repeated measurements of bite force in all three positions and height, and weight. Dahlberg's formula (1940) was also used to confirm results from the Bland Altman's Plots.

Additionally, paired sample t-tests were used to determine the effect of dental treatment on maximum bite force values. The following section will detail all the statistical methods employed and the results obtained.

4.1. Tests of normality of data distribution

Normality of distribution was checked utilising Kolmogorov-Smirnov (K-S) test as well as Shapiro-Wilk (S-W) test. The results obtained from the test shows that values from the present study sample were close to normal as illustrated in Table 4.1.

Tests of Normality

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	Df	Sig.	Statistic	Df	Sig.
MBF	.071	32	.200*	.981	32	.818
DMFS/dmfs	.198	32	.003	.951	32	.156
DMFT/dmft	.197	32	.003	.953	32	.176
Weight	.073	32	.200*	.981	32	.820
Height	.078	32	.200*	.982	32	.845
BMI	.113	32	.200*	.951	32	.152
DS-Decayed surfaces	.207	32	.001	.921	32	.023
ABF-Anterior BF	.140	32	.113	.921	32	.022
RBF-Right BF	.142	32	.098	.943	32	.094
LBF-LBF	.101	32	.200*	.974	32	.621
Age	.146	32	.079	.951	32	.152

*. This is a lower bound of the true significance (this value must be above 0.05 for data to be normally distributed).

Table 4.1. Results of K-S and S-W for all variables studied.

Most values of K-S and S-W tests had p values > 0.05 for the studied variables. This means that the data were almost normally distributed. However, as demonstrated in Table 4.1, the K-S and S-W results of DMFS/dmfs, DMFT/dmft, and the number of decayed surfaces revealed p values smaller than 0.05 and thus those variables were non- normally distributed. When testing for correlation, non-parametric tests (i.e. Spearman's Rank correlation coefficient, r_s and/or Kendall's tau) will be employed for those variables that were not normally distributed.

4.2. Descriptive Statistics

A total of 32 patients agreed to participate in the present study and were subsequently recruited. A total of 26 children (81.25%) attended the post-treatment appointment and had completed measurements, with six children therefore lost to follow up. Girls constituted 56.25% of the total sample while boys constituted the remaining 43.75%. The mean age of the boys subgroup was 6.59 years and the mean age for the girls in the total pre-treatment sample was 6.34 years. The following table shows the sample's pre and post treatment distribution according to gender.

Total number of participants recruited = 32		
Gender	Boys n = 14	Girls n = 18
Percentage	43.75 %	56.25 %
Mean age	6.59	6.34
Total number of participants returned following treatment = 26		
Gender	Boys n = 11	Girls n = 15
Percentage	42.31 %	57.69 %
Mean age	6.52	6.57

Table 4.2. Sample distribution according to gender and sample number in both pre and post treatment stage.

4.2.1. Bite Force Measurements (Pre Treatment Phase)

The bite force values measured at three different positions for all children recruited prior to dental treatment, bite force in the anterior position, right posterior bite force, and left posterior bite force are shown in Table 4.3. The mean maximum bite force recorded in the anterior centric position was 31.23 N (SD= 18.97, SE= 3.35). In the right posterior area a mean of 149.55 N was obtained (SD= 76.06, SE= 13.44). The mean left bite force magnitude was 154.41 N (SD= 66.44, SE= 11.74). In addition, Table 4.4 displays the maximum bite force obtained for all participants recruited together with mean values of age, weight, height and BMI prior to dental treatment. Importantly, the mean maximum bite force for this sample was 169.32 N before the start of comprehensive dental treatment.

Bite force according to position	Maximum (Newtons)	Minimum (Newtons)	Mean	SD	SE
Anterior Bite Force	94.50	1.60	31.23	18.97	3.35
Right posterior Bite Force	310.00	36.50	149.55	76.06	13.44
Left Posterior Bite Force	312.60	40.80	154.41	66.44	11.74

Table 4.3. Maximum, minimum, mean, standard deviation (SD), and standard error of means for bite force measurements in all three different positions recorded before treatment.

All participants	Maximum bite force obtained	Age	Weight	Height	BMI
Maximum	312.60	9.80	33.80	137.50	21.80
Minimum	48.90	3.80	15.10	97.00	13.80
Mean	169.32	6.45	23.59	118.97	16.55
SD	66.20	1.66	4.86	10.22	1.77
SE	11.70	0.29	0.85	1.80	0.31

Table 4.4. Maximum, minimum mean, standard deviation (SD), standard error (SE) of maximum bite force, age, weight, height, and BMI before treatment.

The following box plot shows the median maximum bite force in the total sample (i.e. the 50th percentile) that is represented by the dark black line within the box. The top and bottom borders of the box represent the upper and lower quartiles respectively. The minimum and maximum values of bite force in the total sample are demonstrated by the upper and lower ends of the whiskers.

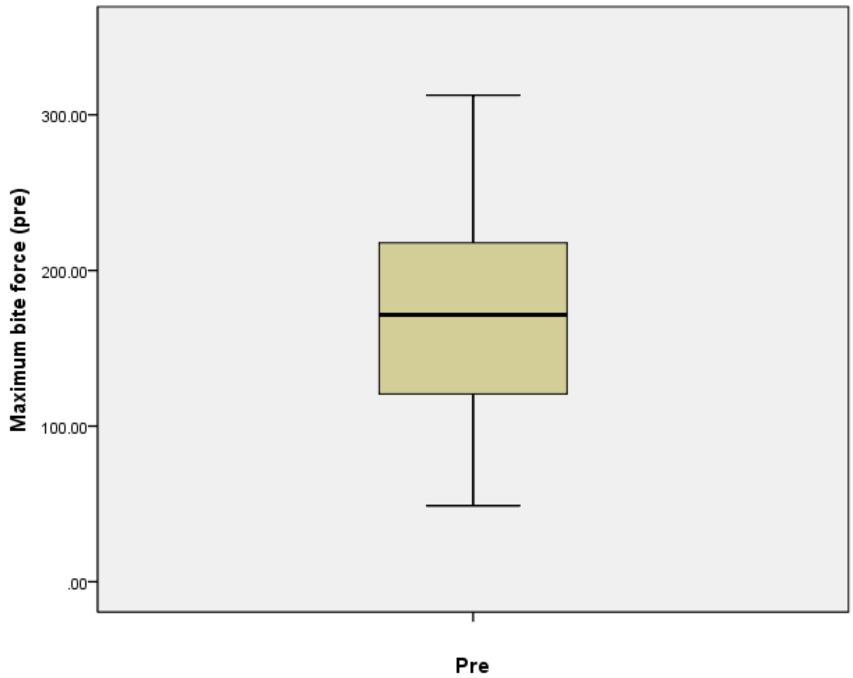


Figure 4.1. Box plot demonstrating bite force distribution obtained from all participants prior to treatment.

4.2.2. Maximum Bite Force in Boys Versus Girls

A total of 18 girls and 14 boys were recruited and had the pre-treatment set of measurements completed. The mean age of participants comprising this sample was 6.45 years (SD= 1.66). The mean maximum bite force values were determined for both genders and compared to each other. Mean maximum bite force prior to dental treatment in boys was 174.49 N (SD=64.69), while the corresponding bite force value for girls was 165.29 N (SD=68.93). Although the bite force level was higher in boys this difference was not statistically significant at the $p < 0.05$ level when subjected to independent sample t-test ($p > 0.05$).

	Gender	N	Mean	SD	SE
Maximum bite force (pre- Treatment)	Boys	14	174.49	64.69	17.29
	Girls	18	165.29	68.93	16.24

Table 4.5. The mean maximum bite force before treatment distributed according to gender.

		t-test for Equality of Means		
		t	df	Sig. (2-tailed)
Maximum bite force (pre)	Equal variances assumed	.384	30	.703
	Equal variances not assumed	.388	28.877	.701

Table 4.6. Independent sample t test to show difference in maximum bite force recorded in boys and girls.

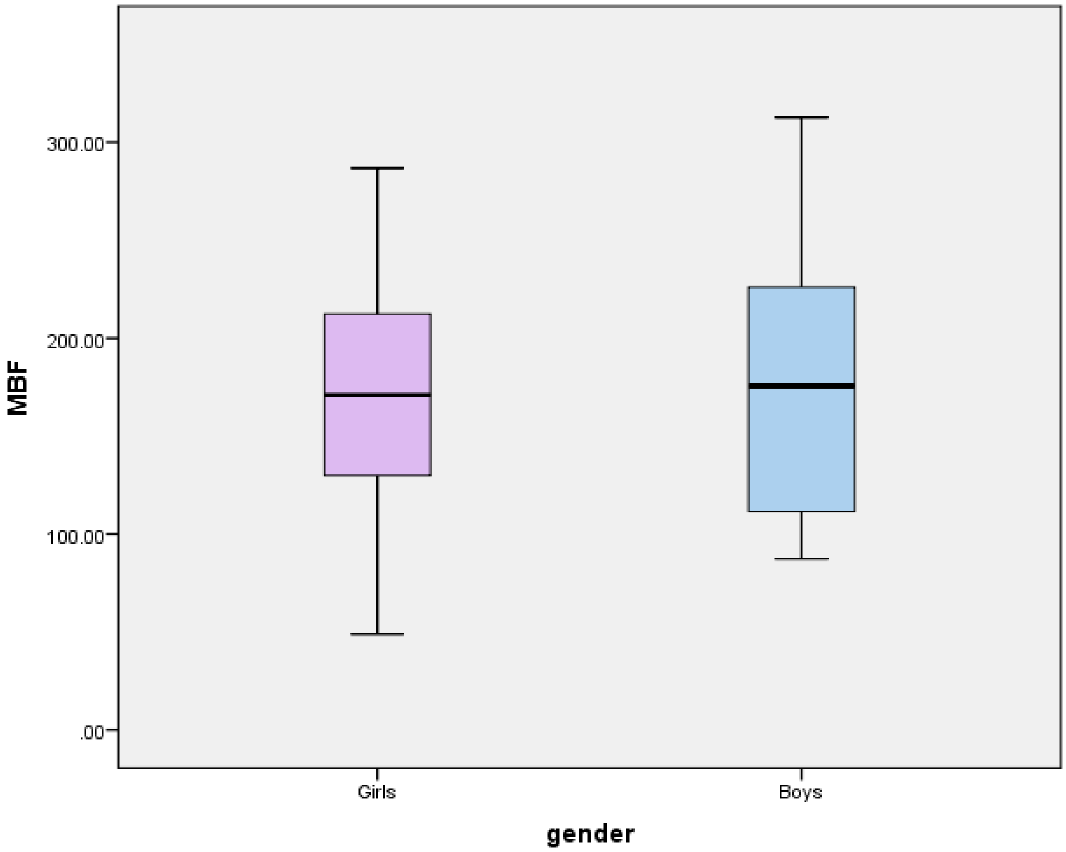


Figure 4.2. Box plots for bite force measurements before treatment in boys and girls.

4.2.3. Caries indices

Both dmfs/DMFS and dmft/DMFT were calculated for each participant child and recorded to enable analysis of any correlation with bite force magnitude measured.

In addition the number of decayed surfaces was calculated separately prior to treatment (DS) in order to describe the severity of caries in each child more accurately than DMFS alone since DMFS also includes the number of filled surfaces. All participants were examined clinically and the caries prevalence in our sample was 100% as those children were patients presenting to paediatric dentistry department for dental caries treatment.

The number of decayed, missing and filled teeth (dmft/DMFT) for this sample before treatment ranged between 2 to 14 while the corresponding value for dmfs/DMFS ranged between 2 to 31. The mean dmfs/DMFS score for the whole sample was 15.09 (SD= 6.91, SE= 1.22) while the median was 14. For dmft/DMFT the mean value was 7.62 (SD= 2.79, SE= 0.49) while the median was 8 (Table 4.7.).

Because these variables proved to be not normally distributed (see Table 4.1.) medians and inter-quartile ranges were also considered to describe central tendencies and dispersion (Table 4.8.).

All participants (n=32)	DMFT/dmft	DMFS/dmfs	DS (Decayed surfaces)
Minimum	2	2	2
Maximum	14	31	31
Mean	7.62	15.09	13.81
SD	2.79	6.91	6.34
SE	0.49	1.22	1.12

Table 4.7. Minimum, maximum, mean, standard deviation (SD), and standard error (SE) for all caries indices and number of decayed surfaces (DS) for all participants.

Total sample (n=32)	DMFS/dmfs	DMFT/dmft	DS
Median	14.00	8.00	12.50
Percentiles 25 50 75 90 95	11.25 14.00 17.50 26.10 29.05	6.00 8.00 9.50 12.00 12.70	10.25 12.50 16.00 24.00 28.40

Table 4.8. Medians and percentile for DMFS/dmfs, DMFT/dmft, and DS (number of decayed surfaces) values for all participants before dental treatment.

In addition to caries indices, the presence of malocclusion and its category if present in both primary and mixed dentitions was determined. 75% of participants had normal occlusion while the remaining 25% had one category of malocclusion. Only 4 children (12.5%) were diagnosed with anterior crossbite, 3 children (9.4%) had posterior crossbite and only 1 child (3.1%) had an anterior open bite.

4.3. Differences in bite force before and after treatment

For participants that attended for a review appointment (n=26), post-treatment bite force measurements were taken following the same techniques and procedures. All measurements were recorded, analysed and subsequently compared with measurements taken immediately before treatment.

Bite force according to position	Maximum (Newtons)	Minimum (Newtons)	Mean	SD	SE
Anterior Bite Force (n= 21)	96.50	9.30	41.14	21.40	4.67
Right posterior Bite Force (n= 25)	315.00	60.30	167.90	69.44	13.88
Left Posterior Bite Force (n= 25)	323.30	57.37	168.15	63.52	12.70
Maximum bite force (n=26)	323.30	63.80	180.60	65.85	12.91

Table 4.9. Maximum, minimum, mean, standard deviation (SD), and standard error of means (SE) for bite force measurements in all three different positions recorded after treatment.

The maximum bite force post-treatment ranged between a minimum of 63.80 N to 323.30 N and the mean was 180.60 N (SD= 65.85, SE= 12.91). The mean maximum bite force recorded following completion of dental treatment was higher than the mean maximum bite force obtained from participants before treatment (mean before treatment = 169.32).

4.3.1 The Paired Sample t-test for Differences in Bite Force

The paired sample t test was employed to examine whether the difference detected in maximum bite force magnitude was significant statistically or not.

Paired Samples Statistics

	Mean	N	SD	SE
MBF (Pre)	167.65	26	71.20	13.96
MBF (Post)	180.60	26	65.85	12.91

Table 4.10. Shows the mean, SD, SE for the sample before and after dental treatment.

Paired Samples Test

		Paired Differences		
		Mean	Std. Deviation	Std. Error Mean
Pair 1	Maximum bite force (pre) - Maximum bite force (post)	-12.95	17.74	3.48

Table 4.11. Shows the mean, SD, and SE for the difference in bite force before and after dental treatment.

Paired Samples Test

		Paired Differences		
		95% Confidence Interval of the Difference		
		Lower	Upper	t
Pair 1	Maximum bite force (pre) - Maximum bite force (post)	-20.11	-5.78	-3.72

Table 4.12. Shows the 95% Confidence Interval of the difference in bite force before and after dental treatment.

Paired Samples Test

		df	Sig. (2-tailed)
Pair 1	Maximum bite force (pre) - Maximum bite force (post)	25	.001

Table 4.13. Shows the p value of the difference in bite force before and after dental treatment.

The mean difference was – 12.950 (SD= 17.73, SE= 3.47). The increase in maximum bite force post treatment proved to be statistically significant ($p = 0.001$).

4.3.2. Height and Weight Differences

The mean weight for all participants prior to treatment was 23.59 Kg (SD= 4.86, SE= 0.85). Height in centimetres showed a mean of 118.97 for all 32 participants recruited (SD= 10.22, SE= 1.80). following treatment and in the 3-5 weeks post treatment review, the recorded weight for 26 children had a mean of 24.24 Kg (SD= 5.26, SE= 1.03) and height mean for those attended the post treatment review was 119.76 (SD= 11.14, SE= 2.18). The increase in both height and weight was statistically significant ($p < 0.05$). Height and weight gain with reference to child's normal growth will be addressed later in the discussion chapter.

	Mean	N	SD	SE
Height (Pre)	119.37	26	11.11	2.18
Height (Post)	119.76	26	11.15	2.19
Weight (Pre)	23.86	26	5.25	1.03
Weight (Post)	24.24	26	5.27	1.03

Table 4.14. Shows the Paired Sample descriptive statistics for height and weight.

Paired Sample t test

	Paired Differences					t	df	Sig. (2-tailed)
	Mean	SD	SE	95% Confidence Interval of the Difference				
				Lower	Upper			
HeightB – HeightA	-.38462	.19533	.03831	-.46351	-.30572	-10.040	25	.000
WeightB - WeightA	-.38077	.90555	.17759	-.74653	-.01501	-2.144	25	.042

Table 4.15. Shows the Mean, SD, SE and p values of the difference in height and weight before and after dental treatment.

4.4. Correlation Coefficients

To detect any potential relationship between maximum bite force before dental treatment and different predictor variables studied correlation coefficients were analysed (Table 4.16). Correlation coefficient can be defined as a statistical measure of the direction as well as the power of a linear relationship between two different defined variables.

	Maximum bite force before treatment	
Predictor variable	**Correlation coefficients Spearman's rho/Pearson's correlation**	**P Value**
Age	**.590**	**.000****
Gender	**-.075**	**.682**
Weight	**.514**	**.003****
Height	**.535**	**.002****
BMI	**.147**	**.422**
DS	***-.560*** ***(Kendall's tau -.411, p = .001)*****	**.001****
DMFT/dmft	***-.375*** ***(Kendall's tau -.279, p = .034)****	**.035***
DMFS/dmfs	***-.437*** ***(Kendall's tau -.313, p = .014)****	**.012***
Pain	**-.429**	**.014***
Abscess	**-.570**	**.001****

Table 4.16. Correlation coefficients of maximum bite force before dental treatment and predictor variables.

** Correlation is significant at the 0.01 level (2-tailed)

* Correlation is significant at the 0.05 level (2-tailed)

In Italic text, Spearman's rho and in regular text, Pearson's coefficients

As shown in the above table, analysis of correlations revealed significant associations amongst a considerable number of the key variables and maximum voluntary bite force in the studied group of children. The values analysed are those from the pre-treatment stage.

The strongest relationship found was that between maximum bite force and age of the child with a Pearson's correlation coefficient almost equal to 0.6. This correlation showed a statistical significance ($r = .59$, $p < 0.01$). The correlation between bite force and age was positive indicating that bite force magnitude increases in older children in our sample.

Gender differences did not demonstrate significant correlation with maximum bite force, however the Pearson's coefficient indicated that whilst the mean bite force was higher in boys this proved to be non-statistically significant ($r = -0.075$, $p > 0.05$). Body build variables were similarly tested for possible correlation with maximum bite force and this included weight, height and body mass index. Both stature and weight showed a significant positive correlations with maximum bite force as indicated by Pearson's correlation coefficient and respective p values ($r = 0.514$, $p < 0.01$) for weight and ($r = .535$, $p < 0.01$) for height.

On the other hand, the same was not applicable for BMI and bite force correlation, as it proved to be statistically non-significant ($r = .147$, $p > 0.05$). Similarly, all recorded caries indices were analysed. Non-parametric tests (Spearman's correlation and Kendall's tau correlation tests) were utilised as data of caries indices was not normally distributed as discussed previously.

Both DMFT/dmft and DFMS/dmfs illustrated a significant (at the 0.05 level) negative correlation with recorded maximum bite force before treatment (r_s = - 0.375, $p < 0.05$ for DMFT/dmft and r_s = - 0.437, $p < 0.05$ for DMFS/dmfs). The strongest negative correlation was found between the number of decayed surfaces and maximum bite force ($r_s = -0.560$, $p< 0.01$).

Additionally, data regarding presence of pain and/or dental abscess was analysed and showed a significant negative correlation with maximum bite force exerted by participants prior to treatment ($r = -.429$, $p < 0.05$ for pain and $r = -.570$, $p < 0.01$ for the presence of an abscess).

Ideally, multiple regression analysis would be the best to reveal which of the above discussed predictor variables would maximally correlate and influence bite force however; in this situation, the conduction of multiple regression is recognised as unfeasible due to the limited sample size. Statisticians suggest that a substantial sample size (i.e. 30 participants) is required for each variable to accurately run multiple regression analysis (Field, 2009).

4.5. Method's Repeatability

Bland Altman plots, which are also named plots of differences, are statistical methods used to analyse the agreement between two different measurements. The investigator employed Bland Altman plots to detect the degree of agreement of two measurements taken by the same examiner of all quantitative variables (i.e. weight, height, anterior bite force, posterior right side bite force, and posterior left side bite force) performed twice on the same day on 5 randomly chosen participants.

4.5.1. Bland and Altman Plot for Anterior Bite Force

To construct a Bland and Altman plot the average of the two repeated measurements and the difference between measurements were calculated. The average of the difference between the two repeated measurements was equal to 0.96 (SD = 4.64) Therefore the bias was equal to the mean which was - 0.96 with 95% limits of agreement around bias equal to -0.96+/-(1.96 x 4.644) = (8.142, -10.062).

Figure 4.3 shows the Bland and Altman plot for repeated measurements of anterior bite force which showed that there were no outliers and all measurements (points) fell within the 95% limits of agreement.

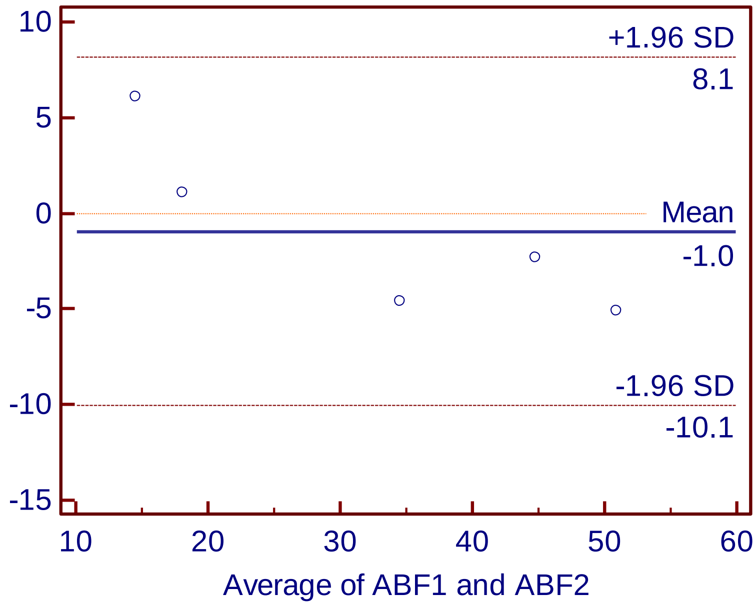


Figure 4.3. Bland and Altman plot for anterior bite force measurements.

4.5.2. Bland and Altman Plot for Right Posterior Bite Force

The mean of the difference between the two measurements (RBF1-RBF2) was found to be – 3.63 with a standard deviation of differences between the repeated measurements to be SD= 5.605. The 95% limits of agreement around bias equal to -3.63+/-(1.96 x 5.605) = (6.185, -12.437). Bland and Altman plot confirmed that there were no outliers and all points fell within the 95% limits of agreement.

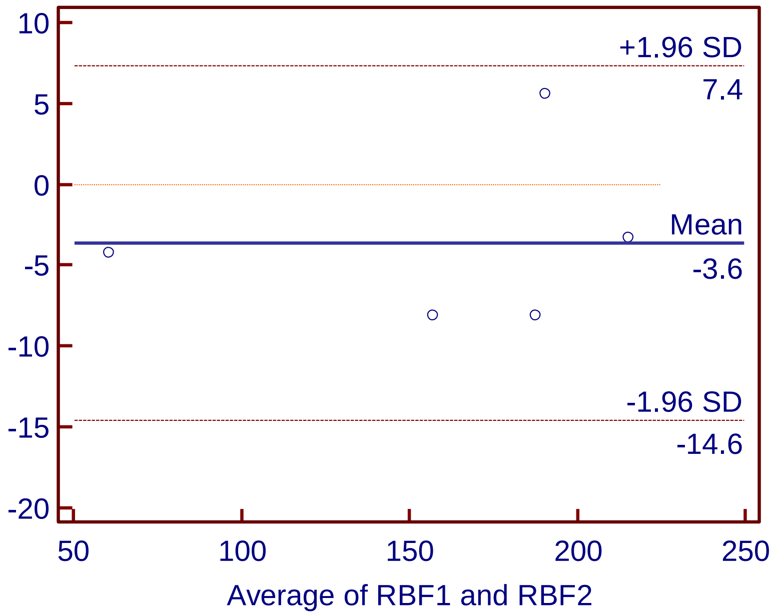


Figure 4.4. Bland and Altman plot for right posterior bite force measurements.

4.5.3. Bland and Altman Plot for Left Posterior Bite Force

The mean of the difference between the two measurements (LBF1-LBF2) was found to be – 2.62 while the standard deviation of differences between the repeated measurements SD= 4.327. The 95% limits of agreement around bias equal to -2.62+/-(1.96 x 4.327) = (5.862, -11.101). Bland and Altman plot (Figure 4.5) showed that all points are located within the 95% limits of agreement.

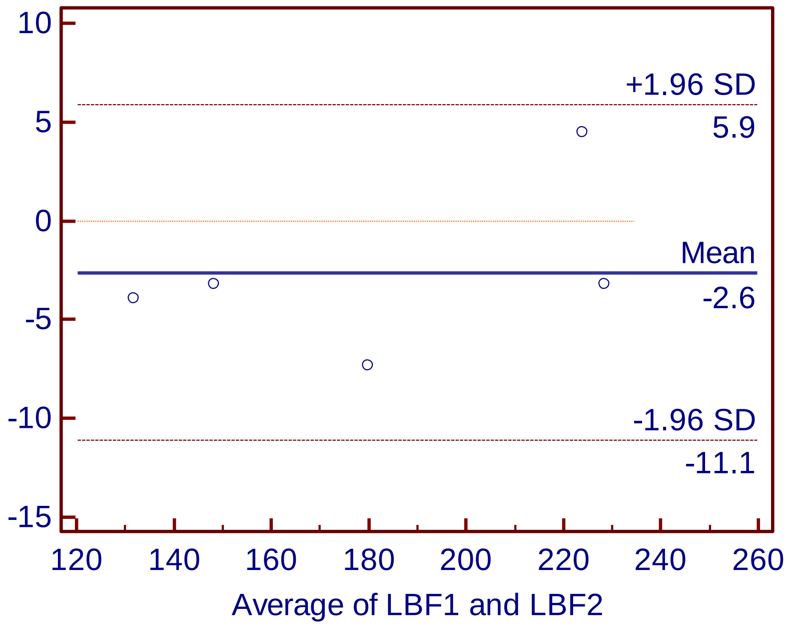


Figure 4.5. Bland and Altman plot for left posterior bite force measurements.

4.5.4. Bland and Altman Plot for Weight Measurements

The mean of the difference between the two repeated weights was equal – 0.180 with a standard deviation of differences between the repeated values to be 0.130. Therefore the bias was equal to the mean i.e. - 0.180 with 95% limits of agreement around bias equal to -0.180+/-(1.96 x 0.130) = (0.075, -0.436). Bland and Altman plot (Figure 4.6) proved that there were no outliers and all points were within the 95% limits of agreement.

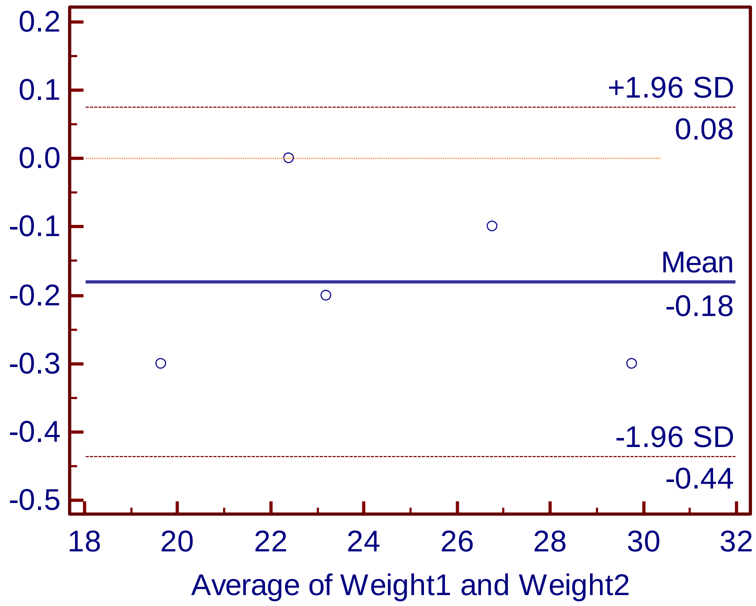


Figure 4.6. Bland and Altman plot for weight measurements.

4.5.5. Bland and Altman Plot for Height Measurements

The mean of the difference between measurement 1 and measurement 2 was found to be – 0.040 with a standard deviation of the differences between the repeated heights to be 0.207. The 95% limits of agreement around bias equal to -0.040 +/- (1.96 x 0.207) = (0.366, -0.446).

Bland and Altman plot (Figure 4.7) showed that there were no outliers and all measurements are within the 95% limits of agreement.

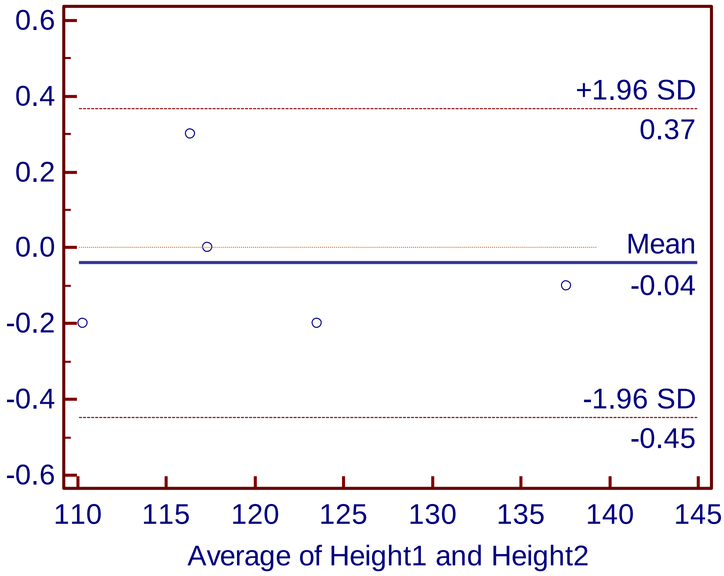


Figure 4.7. Bland and Altman plot for height measurements.

4.6. Assessing Method Errors with Dahlberg's Equation

Dahlberg's formula was applied to determine method error in bite force measurements recorded for all three different positions. The error of measurements for the anterior bite force, right posterior bite force, and left posterior bite force were found to be 3.015 N, 4.37 N and 3.304 N respectively.

Chapter Five

Discussion of findings

5.0. Study Aims

The overall purpose for carrying out this research was to explore the possible impacts that comprehensive dental treatment had on the maximum voluntary bite force of children in the primary and mixed dentitions. Additionally, the research further sought to analyse the link between maximum bite force amongst children and a number of other factors, namely age, gender, body build, presence of dental abscess and/or dental pain, and caries severity. Although, one previous UK study had explored the correlation between maximum bite force and key factors, that study involved young children only in the primary dentition and with generally healthy teeth (Mountain *et al*, 2011) in contrast to the sample studied here who are children in both primary and mixed dentition who are awaiting comprehensive dental treatment and with diseased dentitions.

Following an in-depth literature search and review, it was found that there have been no other studies published with the same objective as that of the current study in relation to children's bite force. The majority of those studies carried out previously have examined bite force magnitude in regard to its link with other factors, including masticatory efficiency (Lemos *et al.*, 2006; Toro *et al*., 2006). Furthermore, various other researchers have investigated bite force and its relationship with the status of occlusion, such as Sonnesen *et al*. (2001) and Rentes *et al*. (2002).

Very few contemporary studies have focused on the impacts of the presence of caries on bite force, with only a handful of studies doing so (Tsai, 2004; Su *et al*., 2009; Mountain *et al*., 2011). Notably, only the study of Mountain *et al*. is a UK-based research; thus, not all studies may be viewed as comparative. Accordingly, when considering that no studies have reported the impacts of dental treatment on the bite force of children, it is recognised as important that the level of bite force amongst those children with diseased dentitions be examined with the aim of establishing the impacts of dental treatment on bite force. The results may provide value to this area of dentistry through detailing bite force reference range values amongst children with caries-affected dentitions, and the expected outcome in terms of the bite force once comprehensive dental treatment has been completed. It can additionally support the evidence that comprehensive dental treatment in children has the capability to improve the oral health related quality of life.

5.1. Study design

This study is a clinical exploratory research, with a convenient sample comprising children who have attended the Leeds Dental Hospital in order to receive dental treatment, either with the use of local or general anaesthesia. The methodology, measurement protocol and instrument used were adopted from a previous study by Mountain, 2008. The device proved to be reliable and acceptable for clinical use in children. Section 5.6 will further discuss the reliability of the bite force device as found in the current study.

5.2. Summary of the Main Findings

Fundamentally, this research study's outcomes revealed a number of key findings, such as that, following the provision of comprehensive dental treatment, children showed a significant increase in maximum bite force. Unfortunately, however, although such a finding is remarkable and clinically valuable, as no prior study has been conducted in this regard, no comparisons with other previous studies can be drawn in terms of this specific aspect of the results.

Nevertheless, the results have shown valuable correlations of bite force with those variables studied that agree with other published studies.

For instance, age, height and weight all showed a strong, positive correlation with the magnitude of bite force, as has been emphasised by other studies (Braun *et al*., 1996; Kamegai *et al*., 2005; Mountain *et al*., 2011; Owais *et al*., 2012). One fundamental correlation that was seen in this sample is a significant negative link between the presence and severity of caries and bite force magnitude. Only three research studies carried out in the past—namely Tsai (2004), Su *et al*. (2009) and Mountain *et al*. (2011), —have documented the link between caries and bite force, with two of them (Tsai, 2004; Mountain *et al*., 2011) supporting the findings of this study.

The section below provides a discussion of this study's results while simultaneously integrating evidence-based literature, and further demonstrating as well as identifying original novel data, viewpoints, and understanding achieved. This chapter concludes by recognising and detailing the research limitations, and further considering any recommendations for subsequent studies.

5.3. Mean Maximum Bite Force Differences - Before and After Dental Treatment

This study's main aim was the investigation of possible or potential impacts on the magnitude of bite force following the provision of comprehensive treatment of dental caries. The paired sample *t* test (page. 92) suggests that there is a statistically significant increase in the values of mean maximum bite force after the child participant has received comprehensive dental treatment ($p < 0.001$).

Despite the fact that there are some earlier studies that have examined the impact of orthodontic problems and different types of malocclusion on the magnitude of bite force in children (Rentes *et al*., 2002; Sonnesen and Bakke, 2005; Lemos *et al*., 2006), no previous study has specifically analysed the impacts of improving dental status through the restoration and/or extraction of symptomatic non-restorable teeth.

It has been reported that masticatory ability has a direct link with and is influenced by the level of bite force (Kampe *et al*., 1987; Braun *et al*., 1995; Julien *et al*., 1996;; Hatch *et al*., 2001; Koc *et al*., 2010;), with masticatory function similarly affecting food intake in terms of both quantity and quality, and thereby impacting nutritional status. It may be further suggested that there is an interaction between a number of key factors, i.e. bite force, dental status, and mastication, which will ultimately impact the growth and nutritional status of the children. Other studies conducted previously have emphasised that, should children have good masticatory ability, ingested food will then be more easily digested, thus resulting in the proper absorption of such foods (Julien *et al*., 1996).

It has also been reported that nutrition is a key factor impacting children’s growth and development and that proper digestion has direct influence on nutritional status (Su *et al*, 2009).

Furthermore, it has been noted by Shatenstein (1986) that 56% of people who are unable to properly chew subsequently develop digestive problems, thus tending to choose to consume softer food, which eventually results in malnutrition as a direct result of the insufficient intake of fibres, minerals, and vitamins. Similarly, it is suggested by the study of N’gom and Woda (2002) that chewing process-related impairments can result in the occurrence of numerous diseases as a direct result of malnutrition.

In this same regard, Yamanaka *et al*. (2009) have examined the impacts on dietary preference amongst Japanese children aged 7–12 years old as a result of the level of bite force. The authors concluded that those children found to have a greater bite force were more likely to opt for harder foods, whilst those with lower bite force had a disinclination to choose such types of foods for consumption. This finding is important as together with our current findings allow us to suggest that improvement in bite force values as a result of dental treatment is expected to have positive effects on children’s health through improved nutritional habits.

Many different previous studies—such as those by Low *et al*. (1999), Acs *et al* (2001), and Versloot *et al*. (2006)—have highlighted the positive and strong impacts associated with the treatment of dental caries amongst children on a number of different aspects oral health related quality of life.

Moreover, bite force is one additional aspect that showed significant improvement in the present sample following comprehensive dental treatment and can be added to the previously proven aspects that can ensure better quality of life a child can get once dental treatment is completed. As it has been shown in earlier studies how bite force impacts the efficiency of chewing and mastication and because it is known that masticatory process has a direct influence on dietary quality and nutritional status (Shatenstein, 1986; N'gom and Woda, 2002; Su *et al*, 2009; Yamanaka *et al*, 2009), it can be said that improvements in bite force of children has a positive effects on their oral health related quality of life.

5.4. The Mean Maximum Bite Force Prior to Dental Treatment as Compared to previously Studied Samples

Maximum bite force may be described as "the ability of the mandibular elevation muscles to exhibit maximum strain of lower teeth against upper teeth, under favourable conditions" (Calderon *et al*., 2006). Wide variation of bite force has been recorded and reported in previous studies.

The fact that different subjects have been studied and different instruments have been employed could have contributed to this variation.

In addition, several physical characteristics have shown to impact bite force values such as age, gender, and dental condition (Sasaki *et al*, 1989; Tortopidis *et al*, 1998; Varga *et al*, 2011). Linderholm and Wenstrom (1970) have acknowledged the difficulty of comparing findings from different reports on bite force.

The reason behind this is the fact that various devices and measurement protocols have been used and those have an influence on the bite force values obtained.

The mean maximum bite forces recorded in the sample studied before dental treatment was provided was 169.32 N, which is considered lower than those results previously reported by other international studies, such as that of Rentes *et al*. (2002), who recorded a maximum bite force value ranging 213–241 N in children with primary dentition.

Moreover, a range of 203.4—374.4N was found by Kamegai *et al*., who took a sample of children from preschool to primary school age. Additionally, the study of Mountain *et al*. was concerned with examining bite force amongst healthy children aged 3–6 years; a mean of 196.60 N was subsequently reported.

A crucial factor that could have led to recording low bite force magnitudes here is that in this study's sample all participants were children who were due to have comprehensive dental treatment either under local anaesthesia or general anaesthesia. Of those children 69.7% were suffering from dental pain related to at least one quadrant of the mouth in addition to 37.5 % who had had at least one dental abscess related to a specific primary tooth. Thus, such children could not exhibit high bite force without experiencing pain, and were therefore inclined to bite more gently. However, a significantly lower bite forces than those recorded in the current study were recorded in 6–8 year olds in the study of Braun *et al*. (1996), who found mean bite force levels to be approximately 78 N. Tsai (2004) reported bite force values lower than the values found in our study but were much more comparable to ours than other studies, and found a range of 147-176 N in children with primary dentitions.

To further highlight the suggested explanation of low bite forces recorded in the present study's group of children, the previous studies' samples where school children who were mainly dental disease free or with minor and asymptomatic disease in contrast to a group of children awaiting comprehensive dental treatment and recruited from a dental hospital with approximately 70% suffering from dental pain as in the studied group here. It is difficult to compare mean bite forces of children in this sample with those from other studies, the reason is that the dental status, level and severity of tooth decay were not analysed or documented in most previous studies.

Very few contemporary studies took caries experience of participants into consideration. For instance, Mountain *et al*. (2011) reported a caries prevalence of 30.4% in a sample of 205 young children while Tsai (2004) reported a prevalence of around 67%. The corresponding mean bite forces in these two samples were 196.6 and a range of 147-176 N respectively. However, in the present study all children were suffering from dental caries with median DMFT/dmft and DMFS/dmfs of 8 and 14 respectively while the prevalence of tooth decay was 100%. It is not surprising to see these high levels as the children were patients attending the children's department for treatment. In contrast to school students derived samples as in other studies (Tsai, 2004; Mountain *et al*., 2011).

In future studies, it would be a very good practice to report caries prevalence and severity in studies documenting bite force in children in order to enable comparison of findings with other studies.

5.5. Improvements in Weight and Height following Dental Treatment

In the current study the participant's weight and height were recorded before and after treatment in an attempt to detect statistically the presence of any possible correlation between the child's maximum bite force and body build. In addition, one more finding was detected following conducting a paired sample t test and that was a statistically significant increase in body build variables, defined by weight and height, within 3 to 5 weeks following completion of comprehensive dental treatment. This result is an agreement with several earlier studies that investigated children's oral-related quality of life and positive impacts of comprehensive management of childhood caries (George *et al.*, 1999; Jankauskiene and Narbutaite, 2010). A possible explanation would be that once dental treatment has been completed and sources of pain and infection have been eradicated, oral cavity's function is improved and thus the child eats better.

A fact that must be mentioned about normal children's growth in terms of weight and height gain is that an average child in the age between 5 to 10 years gain on average 2.3 – 3.2 kg per year and add 5 to 7.5 cm to their height (Hull and Johnston, 2000).

Furthermore, we found that a normal child gain on average 0.2 kg per month and 0.52 cm is added to their height monthly (Hull and Johnston, 2000). In the present study the mean increase in height was 0.4 cm and also 0.4 kg in an average period of four weeks.

This simple analysis shows that the significant increase in height can solely be explained by normal growth process however; the increase in weight can be partly (around 50%) contributed by other factors including dental intervention and thus it can be suggested that comprehensive dental treatment and bite force improvement have had a positive effect on children's weight.

5.6. The Effects and Correlation of Different Studied Variables with Bite Force

There are a number of inter-related variables believed to impact the bite force of not only children but also adults (Braun *et al*., 1996; Rentes *et al*., 2002; Kamegai *et al*., 2005; Koc *et al*., 2010; Mountain *et al*., 2011). It is not always possible to compare or generalise the influence of certain variables on bite force on all populations or age groups as there are other confounding factors such as study design, measurement techniques and characteristics of the sample studied as well as sample size that could have effects on findings and prohibits generalisation on other populations.

In this specific study, a number of factors were considered for analysis to detect any significant correlation with the bite force magnitude in children. These factors are the child's age, height, weight, body mass index, gender, caries experience that is described as DMFT/dmft, DMFS/dmfs indices, and the number of decayed surfaces. With these in consideration, the following section will focus attention to analysing each of these factors with interpretations compared to the results obtained from other related prior studies.

5.6.1. Bite Force in Boys and Girls- the Influence of Gender

The mean of bite force in boys (174.49 N) was found to be greater than that of girls (165.29 N) in this study sample, although the results were shown not to be statistically significant ($p > 0.05$). Importantly, this finding supports the findings of other studies (Serra *et al*., 2007; Su *et al*., 2009; Sonnesen *et al*., 2001; Mountain *et al.*, 2011). The study of Mountain *et al*. reported a greater bite force amongst males aged 3–6 years than females, however these differences were also not considered statistically significant, as in the current study.

Moreover, and in line with our findings, the work of Sathyanaryana and Permkumar (2012) emphasises a strong difference between genders in bite force, but only amongst adults; in the case of children, this difference was not statistically significant.

In contrast, Owais *et al.* (2012) emphasised a strong link between gender and bite force amongst three sub-groups of the sample, i.e. those subjects in late primary, early mixed, and late mixed dentition stages children, with bite force found to be higher in males. Owais *et al.* (2012) took a sample of 1,011 children, with the sample divided in regard to the developmental phase of dentition. Such factors (i.e. sample size and characteristics) could be reasons as to why gender impacted bite force in their sample. The present study's sample included children in the age range of 3 to 10 years and no attempt was made to divide the sample according to age and/or dentition stage.

Koc *et al*. (2011) recently reported a gender significant influence on bite force value in a sample of 19-20 year olds. Again, it should be noted that this gender influence might not be applicable in children.

It has been postulated that the gender differences in bite forces are the result of anatomical variation as well as higher muscular mass in males as compared to females. These physiological variations are not normally apparent until puberty and therefore in a sample of children (3-10 years) it is not unusual to detect no significant differences in bite force between boys and girls. From previous studies and current results, it can be said that boys have higher bite forces than girls but this does not normally show statistical significance in young children or in other words, in pre-pubertal stage individuals.

5.6.2. The Impact of Age on Bite Force Value

The findings of this study reaffirm that an increase in bite force is recognised alongside an increase in age (Pearson correlation coefficient of $r = 0.590$, $p < 0.01$), which also correlates to progression from early primary dentition through early mixed dentition to late mixed dentition. This finding is in agreement with several previously conducted studies that have shown a positive correlation of age with bite force (Kiliardis *et al*, 1993; Braun *et al*, 1996; Kamegai *et al*, 2005; Usui *et al*, 2007; Owais *et al*, 2012).

On the other hand, the work of Braun *et al*. (1995), who examined bite force amongst adults aged 26–41 years, noted a lack of significant link between bite force and that of age. In this case, it is essential to acknowledge the fact that the sample cannot be compared with the sample of this study due to the fact that the former targets adults whilst the latter targets children.

An increase in bite force with age in children can be explained by two theories. First, as children grow with increasing age they will have higher muscle masses and thus will have stronger bite forces as muscles are one of the essential components of bite force. Second, as Sonneson and colleagues (2001) suggested that bite force increases in children when growing from 7 to 12 years due to dental eruption through the different dentition stages which subsequently allows for greater number of occlusal units and higher bite forces.

5.6.3. Body Build and its Impact on Bite Force Magnitude

With the aim of examining the possible link between bite force and body build, it was necessary to analyse body mass index, height, and weight, with the statistical analysis of correlation coefficients.

5.6.3.1. Child's Weight Influences on Bite Force

It was found that there was a strong, positive link between weight and bite force magnitude, as revealed by Pearson's correlation coefficient ($r = 0.514$, $p = 0.003$). Such a finding is in agreement with this of Owais *et al*. (2012), who stated a positive link between bite force and body weight amongst their sample (1,011 subjects), comprising both children and adolescents. Interestingly, the correlation coefficients were found to be at their highest levels in the cases of those at permanent and mixed phases of dentition stages ($r = .0219$ and $r = 0.186$ respectively).Similarly, a weak, positive correlation was found between weight and bite force ($r = 0.24$) through the study of Rentes *et al*. (2002).

Moreover, the investigators further emphasised that weight is believed to have contributed to 6% of bite force variation amongst their sample of young children.

Similarly, Mountain (2008) in a PhD study reported that child's weight was found to be a predictor variable that continued to show, following hierarchical regression modelling, significant effects on recorded bite force and further stated that around 7% of bite force variation was contributed by the weight of the child.

Furthermore, the study of Linderholm *et al*. (1971) confirmed a small but positive impact of weight on bite force amongst their sample comprising 79 children. Braun and colleagues (1995) agreed with the results of the present study and reported that correlation coefficient of bite force and weight equals to 0.401 and it was the highest among all other studied predictors. They further stated that 16% of variation in bite force can be predicted by body weight.

On the other hand, Su *et al*. (2009) suggested that body build—as defined by height and weight—showed no positive or significant impact on the bite force values reported when considering their sample of children aged 4–6 years. Racial differences, variation in bite force recoding systems and techniques as well as sample characteristics could partly be the rational of this discrepancy between their findings and the present findings.

Overall, comparisons with results obtained through prior research are not without problems and/or debates. For instance, various studies take a sample of individuals of different genders and age groups, which can subsequently increase variation and ultimately inhibit the interpretation and generalisability of the results gathered. Therefore, it is not surprising to consider that experimental results are somewhat inconsistent in terms of the impact of growth variables on maximum bite force, especially amongst children.

5.6.3.2. Child's Body height and Impacts on Bite Force Magnitude

Bite force and height illustrated a strong positive correlation ($r = 0.535$, $p = 0.002$), which is a finding found to be in agreement with the study of Owais *et al*. (2012), who note a significant positive link between bite force and height ($r = 0.144$, $p = 0.021$). In this same regard, the study of Rentes *et al*. (2002) proved the presence of a positive but weak correlation in terms of bite force and height, with the suggestion that there is a 5% variance contribution of height on bite force values in their sample, which comprised children aged 3–5.5 years.

In the current research, the age range of those in the sample is 3–10 years, which is a factor that may potentially clarify the stronger correlation detected here, as well as the effect of the sample size. Moreover, the work of Mountain *et al*. (2011) has highlighted a positive and significant link between bite force and height through the conduct of a UK-based research with a sample of 205 children with primary dentitions.

In contrast, however, the study of Abu Alhaija *et al*. (2010) investigated bite force amongst adults, subsequently highlighted a positive but not statistically significant link between bite force and height. In a sample of growing individuals (3-10 years) there is normally a direct relationship between age and height and therefore a correlation between height and bite force is not unexpected as found here.

5.6.3.3. Body Mass Index and Bite Force

The body mass index has been investigated in few previous studies to detect influence of body build on bite force and it can be calculated by weight/height^2 (Mountain. 2008; Abu Alhaija *et al*, 2010; and Koc *et a*l, 2011).

The correlation between body mass index and maximum bite force in the current study was found to be 0.147 but this was not statistically significant at the 0.05 level. This finding is in agreement with the findings of Koc *et al*. (2011) who reported that body mass index variable failed to show statistically significant association with the bite force in a sample of 34 adults. Similarly, Mountain (2008) reported a similar correlation in a sample of children that proved to be non-significant.

In contrast, Abu Alhaija and colleagues (2010), stated that in their adult sample of 60 individuals, a significant increase in bite force values were associated with higher body mass index values ($r = 0.265$, $p = 0.032$). Similarly, Lemos *et al*. (2006) reported a similar positive correlation between bite force and BMI.

5.6.4 Caries Level in the Study Sample

One of the objectives of the study was to ascertain the impact of different variables on the maximum bite force of children; thus, decayed, filled or missing teeth and surfaces were taken into account so as to allow for the analysis of the potential impacts of the experience and severity of caries on the magnitude of bite force. Both DMFS/dmfs and DMFT/dmft were found to be at high levels (DMFS/dmfs = 14, DMFT/dmft = 8).

Due to the fact that this sample comprised children who were to receive dental caries treatment, it is then to be expected that high scores of caries indices would be found. Therefore, this sample's characteristics and caries levels are not comparative with those from child health national studies as those are looking at random samples of children in contrast to a convenient sample of children previously diagnosed with tooth decay as in this present study.

It should be acknowledged that there is a clear demand for increased awareness and belief in prevention to reduce the occurrence as well as the severity of dental caries in children. A large range of negative consequences of caries in children have been reported as discussed in chapter one. In addition, as found in the current study, dental caries and more specifically the number of decayed surfaces has a strong and statistically significant negative correlation with bite force.

In other words, the larger the number of decayed surfaces the lower the bite force a child can exhibit. Lower biting ability can also lead to lower chewing efficiency as bite force is one crucial component of the mastication process. Subsequently, nutrition intake in such a critical stage of individual's life (i.e. childhood) might be negatively affected (Julien *et al*, 1996; Su *et la*, 2009; Yamanaka *et al*, 2009). Efforts should therefore be directed towards enhancing caries prevention as well as treating carious teeth if present in children (EAPD, 2008).

A current dilemma amongst paediatric dentists is "how important is treatment of dental decay in the primary dentition?" (Levine *et al*., 2002; Tickle *et al*., 2008). A number of researchers have questioned the significance of operative intervention and treating dental caries in children and suggested that most unrestored carious deciduous teeth continue to be symptomless until exfoliated, and that regular prevention is all what is needed for those children (Levine *et al*., 2002; Tickle *et al*., 2008). On the other hand van Gemert-Schriks *et al*. (2008) assessed and compared through a randomised controlled trial the impacts of different approaches in managing dental caries in children.

Importantly, the presence of odontogenic infections (abscess/fistula) between the baseline assessment and at the two years recall was compared through statistical analysis. An essential finding was that the children who were assigned to the no treatment group had significantly higher episodes of dental infection when compared to children received either comprehensive dental treatment or extraction only. This study clearly indicated the importance of eradicating dental disease in children with primary dentition.

In addition the findings of the present study add that comprehensive dental treatment in children improves the bite force and subsequently function in this critical stage of human's growth. Our finding can be considered an additional supportive evidence of the positive effects of dental treatment in both primary and mixed dentitions as well as an evidence of serious negative impacts of dental caries on function as expressed by low bite forces strong and significant correlation with caries experience.

5.6.5. Dental Status and its Impact on Bite Force

Various important correlations between mean maximum bite force and numerous variables have been revealed through the statistical analysis. Poor dental status measured by caries indices showed a significant negative impact on bite force in this group of children. When considering children, this finding has only been stated in a few previous research studies (Shiau and Wang, 1993; Tsai, 2004 and Mountain *et al.*, 2011).

As highlighted earlier, dental condition and caries experience are among the fundamental factors of those influencing bite force that has not attracted researcher's attention despite its importance particularly in children.

5.6.5.1. DMFT/dmft, DMFS/dmfs, Decayed Surfaces, and Bite Force

It was found that there was a moderately strong, negative and statistically significant link between scores of DFMT/dmft, DMFS/dmfs, and the number of decayed surfaces (r_s = - 0.375, - 0.437, - 0.560, $p < 0.05$, respectively) and that of bite force. Very limited studies have been found to have considered caries and their impacts on bite force magnitude amongst children (Tsai, 2004; Su *et al*., 2009; Mountain *et al*., 2011).

Research carried out by Kampe *et al*. (1987), which took into account the impacts of the presence of dental fillings on bite force levels, targeted a sample of both adults and adolescents. The results of the study found that the mean bite forces amongst those subjects with intact teeth were greater when compared with those with dental fillings; however, the disparity was not considered statistically significant. Nevertheless, it should be recognised that only the impacts of dental restorations were explored, which are minimal fillings and not dental caries. Markedly, in the sample of the current research, all of the participants were children in the pre-treatment phase and were found to have high DMFT/dmft, DMFS/dmfs values, with mainly high scores in the D/d component of the index, i.e. decayed surfaces and/or teeth. Thus, it can be stated that there was a negative effect experienced on bite force as a direct result of decayed surfaces and/or teeth.

The published results of a study by Mountain *et al*. (2011) agrees with the results obtained through this study, reporting that the experience of caries (dmft and dmfs) in a group of 3–6 year old children showed significant negative links with a child's maximum voluntary bite force (for dmfs r_s = - 0.16, for dmft r_s = - 0.15, $p < 0.05$).

Additionally, Tsai (2004) who took into consideration the number of decayed teeth as an indicator of caries level showed that the maximum bite force in children with primary dentition was negatively correlated with the number of carious teeth. In contrast, Su and colleagues (2009) reported that bite force had no statistically significant correlation with caries experience in a group of 201 preschool children. A possible explanation of disagreement between our findings and Su *et al*. findings is that Su *et al*. relied on dmft only to describe caries experience whereas in the present study DMFT/dmft, DMFS/dmfs and number of carious surfaces were used to describe caries presence and severity. In addition, the study sample in Su and colleagues study comprised 201 preschool children (i.e. primary dentition), and were selected from kindergartens whereas this study's sample comprised a group of children who attended for dental treatment with the majority diagnosed with advanced caries.

Therefore, it can be postulated that the negative effect of caries on bite force becomes evident when the caries is in advanced stages and affecting a substantial number of teeth.

5.6.5.2. Dental Pain and/or Dental Abscess Effects on Bite Force

Thus far, no other study has examined the impacts of dental abscess presence and/or dental pain on bite force. In the current investigation, almost 70% of the sample suffered from dental pain as they stated when were asked about their complain on the day of treatment associated with at least one quadrant, with 37.5% exhibiting at least one dental abscess related to primary molars on the day of start of the planned dental treatment. A significant negative correlation was found between both dental pain and/or presence of an abscess and magnitude of maximum bite force ($r = -0.429$, $r = -0.570$, $p < 0.05$) respectively, thus those children with symptomatic dental disease showed lower bite forces.

Miyaura and colleagues (1999) conducted a case-control study which sought to investigate and contrast bite force amongst adults with mobile and non-mobile teeth. The mean age of the participants was 42.6 years and all of the subjects with tooth mobility were identified as having specific periodontal conditions, subsequently resulting in tooth mobility. The researchers drew the conclusion that bite force was only marginally negatively impacted by tooth mobility.

Furthermore, it is worth mentioning that an abscessed primary tooth illustrates some degree of abnormal or pathological mobility, and so it may be suggested that mobile primary teeth as a result of abscess or infection, for example, may impact a child's bite force. In the current study, all abscessed symptomatic primary teeth were extracted either under general or local anaesthesia.

This treatment was found to illustrate a significant positive effect on maximum bite force, as has been established through the study findings.

This section can be concluded by the suggestion that decayed primary teeth exert lower bite force due to pain and abscess that can result in pathological mobility making the child unable to bite stronger in order to avoid pain and discomfort.

5.7. Reliability of the Bite Force Instrument

In the present research, an intra-oral bite force instrument has been utilised, which was tested and validated for use in children by Mountain (2008), with the tool subsequently found capable of recording bite force with high degrees of precision and accuracy in all positions of a child's mouth. This bite force instrument is characterised by three main advantages in addition to its accuracy. These include its ease of application and use intra-orally, small and portable, removable bite prongs that are easily autoclaved, and cost-effectiveness. The device has shown good acceptability by young children.

An essential characteristic of a bite force device is to be able to produce valid and reliable measurements. In order to check measurement error and the device's reliability as applied in this study, bite force recordings in all three positions (i.e. anterior, right and left posterior) were repeated in more than 10% of randomly chosen subjects. The statistical analysis showed that method error was very small being 3.015 for the anterior position, 4.37 for the right posterior, and 3.304 for the left posterior. In addition, Mountain's PhD study (2008) reported a high precision level of 99.5% of the device used in this study.

5.8. Study Limitations and Challenges Encountered

A clinical-based study is not without difficulties and challenges. Particularly, studies involving children require special care to continuously involve them and their parents/guardians throughout the process of the research. This difficulty was overcome by using an appropriate child-oriented approach and methods to obtain child participant assent and subsequently cooperation during bite force measurement. Another issue is that the purposive sample of this study consisted of children with childhood caries and most of them were affected with high levels of tooth decay at advanced stages of dental disease.

The parents were required to comply in terms of attending a post-treatment review appointment, the compliance of such a group of parents to attend a post-treatment review visit was not ideal despite the efforts made to ensure their attendance that took the form of reminders and letters of appointment.

Furthermore, of those parents who were approached and invited to participate in the study but who declined participation, their reasons for doing so was their disinclination to attend a post-treatment review appointment, although it was explained to them that the appointment would include further preventive advice. Accordingly, it may be stated that the number of subjects is one of the study's limitations, which is an area to be improved upon in the future studies.

5.9. Future Research

The current study is an exploratory and primary study that is considered an original UK based study of its kind. Whilst the current study provided significant findings, further larger studies are still needed to confirm the validity and reliability of the results and broaden the available knowledge regarding bite force in children with carious teeth. It has been found through this study that comprehensive dental treatment and the elimination of carious lesions may improve the overall ability of a child to exhibit stronger bite forces and thus a better quality of life and overall general health.

However, it remains uncertain to what degree or extent the bite force and hence masticatory efficiency deteriorates if carious teeth are left untreated. This question can be answered in a study designed to record bite forces in a sample of children with carious teeth who are awaiting dental treatment on different intervals before the commencement of dental management and then to compare bite forces in a period of time. In addition, a study designed to correlate the maximum bite force in children with the preferred type of food as well as the texture of food they can chew is one area for future research. Moreover, a clinical study designed to compare right and left side's maximum bite force in relation to the side of a carious tooth can further clarify the effects of dental caries on bite force in children.

Furthermore, there is also the need to establish whether bite force is better improved through the extraction approach of carious teeth or the restoration of such teeth (i.e. studies comparing different interventions).

Such a query can be resolved through the conduction of a study with a randomised, controlled design. Information relating to children's bite force remains essential, as this can help to guide and assist in treatment decisions made by paediatric dentists who aim to improve children’s dental health and general wellbeing. Policy and decision makers as well as economists may also be able to use findings from such studies and guide their decisions and policies.

Chapter Six

Conclusion

6.0. Conclusions

Within the limitations of the current study, the following conclusions can be drawn from the reported findings,

1. Comprehensive dental treatment, including the restoration and/or extraction of teeth, can help to improve children's bite force within a period of 3–5 weeks post-operatively. Therefore the null hypothesis was rejected.
2. The maximum voluntary bite force in children prior to dental treatment was influenced by a number of key factors including body variables. A positive correlation existed between both body height and weight and the bite force exerted by the child.
3. Age was an important determinant factor of maximum bite force in the present sample of children.
4. This study confirmed the presence of a significant negative impact of poor dental status (i.e. caries experience) on a child's maximum bite force.

The most noteworthy and the original finding in this study was the fact that there was a positive influence of comprehensive dental treatment on a child's bite force. This finding has never been investigated or reported in the past. It must be highlighted that further research is required in this field in order to broaden knowledge about children's bite force and the various different influencing key factors as well as improving it.

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List of Appendices

NHS
National Research Ethics Service
NRES Committee Yorkshire & The Humber - Leeds West
First Floor
Millside
Mill Pond Lane
Leeds
LS6 4RA

Telephone: 0113 3050122
Facsimile:

12 July 2011

Dr Latifa Alhowaish
Postgraduate student
University of Leeds
Leeds Dental Institute
Clarendon way
Leeds
LS2 9LU

Dear Dr Alhowaish

Study title:	**Bite force evaluation in young children following dental treatment. A pilot study.**
REC reference:	**11/YH/0190**
Protocol number:	**-**

Thank you for your letter received 11 July 2011, responding to the Committee's request for further information on the above research.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS 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" below).

Conditions of the favourable opinion

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

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

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).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Evidence of insurance or indemnity		10 September 2010
Investigator CV		10 May 2011
Letter of invitation to participant	1.1	30 June 2011
Other: CV for Professor Toumba		
Other: Storyboard	1	30 April 2011
Other: Email from MHRA		05 December 2003
Other: Email regarding sample size		18 May 2011
Participant Consent Form	1.1	30 June 2011
Participant Information Sheet: Parental	1.1	30 June 2011
Protocol	1	30 April 2011
REC application		12 May 2011
Response to Request for Further Information		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) 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 NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

11/YH/0190	**Please quote this number on all correspondence**

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

Yours sincerely

Dr Rhona Bratt
Chair

Email: Elaine.hazell@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mrs Rachel De Souza*

Ms Anne Gowing, Leeds Teaching Hospitals NHS Trust

The Leeds Teaching Hospitals NHS
NHS Trust

Ref: Amanda Burd

04/10/2011

Latifa Alhowaish

Department of Paediatric Dentistry
Leeds Dental Institute
Clarendon Way
Leeds
LS2 9LU

Research & Development
Leeds Teaching Hospitals NHS Trust
34 Hyde Terrace
Leeds
LS2 9LN

Tel: 0113 392 2878
Fax: 0113 392 6397

r&d@leedsth.nhs.uk
www.leedsth.nhs.uk

Dear Latifa Alhowaish

Re: NHS Permission at LTHT for: Bite force Evaluation in Young Children following Dental treatment
LTHT R&D Number: DT11/9926
REC: 11/YH/0190

I confirm that *NHS Permission for research* has been granted for this project at The Leeds Teaching Hospitals NHS Trust (LTHT). NHS Permission is granted based on the information provided in the documents listed below. All amendments (including changes to the research team) must be submitted in accordance with guidance in IRAS. Any change to the status of the project must be notified to the R&D Department.

Permission is granted on the understanding that the study is conducted in accordance with the *Research Governance Framework for Health and Social Care*, ICH GCP (if applicable) and NHS Trust policies and procedures available at http://www.leedsth.nhs.uk/sites/research_and_development/.

This permission is granted only on the understanding that you comply with the requirements of the *Framework* as listed in the attached sheet "Conditions of Approval".

If you have any queries about this approval please do not hesitate to contact the R&D Department on telephone 0113 392 2878.

Indemnity Arrangements

Chairman Mike Collier CBE Chief Executive Maggie Boyle

The Leeds Teaching Hospitals incorporating:
Chapel Allerton Hospital Leeds Dental Institute Seacroft Hospital
St James's University Hospital The General Infirmary at Leeds Wharfedale Hospital

use the NHS Number

WTA280

Conditions of NHS Permission for Research:

- Permission from your Directorate must be obtained before starting the study.
- Favourable Opinion of the appropriate Research Ethics Committee, where necessary, must be obtained before starting the study.
- Arrangements must be made to ensure that all members of the research team, where applicable, have appropriate employment contracts or letter of agreement to carry out their work in the Trust.
- Agreements must be in place with appropriate support departments regarding the services required to undertake the project and arrangements must be in place to recompense them for the costs of their services.
- Arrangements must be in place for the management of financial and other resources provided for the study, including intellectual property arising from the work.
- Priority should be given at all times to the dignity, rights, safety and well being of participants in the study
- Healthcare staff should be suitably informed about the research their patients are taking part in and information specifically relevant to their care arising from the study should be communicated promptly.
- Each member of the research team must be qualified by education, training and experience to discharge his/her role in the study. Students and new researchers must have adequate supervision, support and training.
- The research must follow the protocol approved by the relevant research ethics committee. Any proposed amendments to or deviations from the protocol must be submitted for review by the Research Ethics Committee, the Research Sponsor, regulatory authority and any other appropriate body. The R&D Department should be informed where the amendment has resource implications within the Directorate and the Directorate research lead/clinical director notified.
- Adverse Events in clinical trials of investigational medicinal products must be reported in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.
- Complete and return Study Status Reports, when requested, to the R&D Department within 28 days of receipt as requested. (NB Failure to comply to such request with the requirement will lead to suspension of NHS Permission.)
- Procedures should be in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage.

- Arrangements must be made for the appropriate archiving of data when the research has finished. Records must normally be kept for 15 years.

- All data and documentation associated with the study must be available for audit at the request of the appropriate auditing authority. Projects are randomly selected for audit by the R&D Department. You will be informed by letter if your study is selected.

- Findings from the study should be disseminated promptly and fed back as agreed to research participants.

- Findings from the study should be exposed to critical review through accepted scientific and professional channels.

- All members of the research team must ensure that the process of informed consent adheres to the standards GCP outlined in the UK Clinical Trials Regulations. Investigators are directed to the R&D website for further information and training availability.

- Where applicable, this NHS Permission includes aspects of the study previously covered by the NRES Site Specific Assessment (SSA) process.

- Appropriate permissions must be in place for studies which are covered by the Human Tissue Act.

- Patient Information Sheet and Consent form must be on The Leeds Teaching Hospitals headed paper and include local contact details.

Commercially Sponsored Trials
If the study is commercially sponsored, NHS Permission is given subject to provision of the following documents.

- Clinical Trials Agreement - agreed and signed off by the R&D Department (on behalf of the Leeds Teaching Hospitals NHS Trust) and the Sponsor. Investigators do not have the authority to sign contract on behalf of the Trust.

- Indemnity agreement, if not included in the Clinical Trials Agreement- (standard ABPI no fault arrangements apply) signed by the R&D Department and the Sponsor

It is essential that all the responsibilities set out in the Research Governance Framework, including those outlined above are fulfilled. The Trust reserves the right to withdraw NHS Permission where the above criteria are not being met. The Trust will not accept liability for any activity where NHS Permission has not been granted.

The Leeds Teaching Hospitals NHS Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority 'Clinical Negligence Scheme for NHS Trusts' for: (i) medical professional and/or medical malpractice liability; and (ii) general liability. NHS Indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust. The Trust only accepts liability for research activity that has been managerially approved by the R&D Department.

The Trust therefore accepts liability for the above research project and extends indemnity for negligent harm to cover you as investigator and the researchers listed on the Site Specific Information form. Should there be any changes to the research team please ensure that you inform the R&D Department and that s/he obtains an appropriate contract, or letter of access, with the Trust if required.

Yours sincerely

Dr D R Norfolk
Associate Director of R&D

Approved documents
The documents reviewed and approved are listed as follows

Document	*Version*	*Date of document*
NHS R&D Form	3.0	12/07/2011
SSI Form	3.0	12/07/2011
Directorate Approval		26/09/2011
E Mail Sample Size		18/05/2011
Poster/Storyboard	V1.0	30/04/2011
Protocol	V1	30/04/2011
REC Letter confirming favourable opinion		12/07/2011
Insurance/ Indemnity		10/09/2011
Letter of Invitiation	V1.1	30/06/2011
Patient information sheet (REC Approved)	V1.1	30/06/2011
Consent form (REC Approved)	V1.1	30/06/2011

Leeds Dental Institute
Department of Paediatric Dentistry
A Centre for Children with Special Needs

Level 6, Worsley Building
Clarendon Way, Leeds LS2 9LU

T (Direct Line) +44 (0)113 343 6177
T (Enquiries) +44 (0)113 343 6138
F +44 (0) 113 343 6140
E m.s.duggal@leeds.ac.uk

Version 1.1
30-6-2011

UNIVERSITY OF LEEDS

Invitation to participate in a research study

Dear parents,

My name is Latifa and I am a dentist based in the Leeds Dental Institute. I am currently involved in undertaking a research study, which is part of my Professional Doctorate degree, looking into how comprehensive dental treatment would affect the strength of the bite in young children. I would like to invite you/your child to take part in my research. Your child's participation in the research will include the usual dental check up along with bite force measurements being taken when your child next attends the Leeds Dental Institute or Leeds General Infirmary for her/his scheduled restorative dental treatment. After the dental treatment your child will be reviewed in the clinic where another dental check up and bite force measurements will be repeated again for comparison. Please find enclosed an information sheet which provides you with full details about the research study. This also contains details on how to contact me should you have any questions or queries regarding the research project.

Thank you in advance for your cooperation

Monty S Duggal
BDS MDSc FDS (Paeds) RCS (Eng) PhD
Professor of Child Dental Health
Head of Department of Paediatric Dentistry

NHS Leeds Dental Institute
The Centre for Oral Health Sciences

Leeds Dental Institute
Department of Paediatric Dentistry
A Centre for Children with Special Needs

Level 6, Worsley Building
Clarendon Way, Leeds LS2 9LU

T (Direct Line) +44 (0)113 343 6177
T (Enquiries) +44 (0)113 343 6138
F +44 (0) 113 343 6140
E m.s.duggal@leeds.ac.uk

Version 1.1
30-6-2011

UNIVERSITY OF LEEDS

Parental Information Sheet

Title of the research project:

Bite force evaluation in young children following dental treatment.

Introduction:

Your child is invited to take part in the above research project. It is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, discuss it with your child, and please feel free to contact me should you require any further clarification or have any questions with regards any element of this research project. Your decision for your child to take part is voluntary and if you wish for your child not to take part in the research, your decision will not affect your child's care or treatment in any way.

What is the purpose of the research?

I am a qualified dentist and the research project is part of my Professional Doctorate degree. The aim of this research is to find out how comprehensive dental treatment will affect the bite force in children.

What will happen to my child if he/she takes part in the research?

If you agree for your child to take part in the study, I will be attending your child's appointment in the Leeds Dental Institute or Leeds General Infirmary. I will examine your child's teeth and will use a small device to measure her/his bite force. I will also check your child's height and weight immediately before the dental treatment. Four to five weeks after your child has completed her/his treatment s/he will be routinely reviewed at the Leeds Dental Institute where another check up and bite force measurements will be undertaken to allow us to make comparisons with the pre treatment measurements obtained.

What do I have to do?

You will need to sign a consent form, answer a few questions regarding your child's general and dental health, and allow me to carry out a dental check up and the bite force measurements with your child. I understand that this may take some of your time but it will not interfere or compromise the purpose of your visit to Leeds Dental Institute or LGI at your appointment. Additionally this procedure will be quick and should not cause any pain or discomfort to your child.

Monty S Duggal
BDS MDSc FDS (Paeds) RCS (Eng) PhD
Professor of Child Dental Health
Head of Department of Paediatric Dentistry

NHS Leeds Dental Institute
The Centre for Oral Health Sciences

What are the possible benefits of taking part?

There are no direct benefits to your child for participating in my research. However, your child's participation will help us to know about the possible effects of dental treatment on the bite force and on general well being. We may be able to indicate how dental treatment has improved your child bite force.

Will taking part in this research be kept confidential?

Yes, your child will not be identified by name in any reports or publications. All information collected about your child during the study will be kept strictly confidential. Our procedures for using, storing and destroying your data comply with the Data Protection Act 1998.

What will happen to the results of the research?

The results will be analysed, studied and maybe published. Any information that we obtain from you and your child we use in the findings will be anonymised. We hope that the result of our study will be well received by the dental community and will go on to improve the dental care for children. You will be given the opportunity to have a simple summary of research results if you wish so.

Who has reviewed this research?

Ethical approval has been sought and obtained for this study from both the Dental Research Ethics and NHS Research Ethics Committees.

Can I withdraw my child from the research?

Yes. Your child's participation is voluntary and so you and your child can withdraw from the research study at any time without giving reason. Withdrawal from the research study will not in any way affect your child's treatment or care. However, any data that has been collected up to the point of withdrawal may still be used in the data analysis stage of this research.

Who is organizing and funding the research?

The study is being organised by myself, Latifa Alhowaish (Specialising Dentist in Paediatric Dentistry), under the supervision of Prof. Jack Toumba (Professor in Paediatric Dentistry) and Dr. Gary Mountain (Senior Child Health Lecturer). The study is sponsored and funded by University of Leeds.

What if I am unhappy or if there is a problem?

If you are unhappy, or if there is a problem, please feel free to let us know by contacting [Latifa Alhowaish] and we will try to help. If you remain unhappy or have a complaint which you feel you cannot come to us with then you should contact the Research Governance Officer by telephoning 01133434897 or via e-mail: governace-ethics@leeds.ac.uk. When contacting the Research Governance Officer, please provide details of the name or description of the study (so that it can be identified), the researchers involved, and the details of the complaint you wish to make.

You may also visit INVOLVE website to provide you with independent advice on taking part in research. http://www.invo.org.uk/About_Us.asp

If you have any questions or concerns, I am happy to answer them prior to or on the day of your appointment or by contacting:

Latifa Alhowaish

E-mail: dnlaa@leeds.ac.uk

Thank you for the time you spent reading these information

Leeds Dental Institute
Department of Paediatric Dentistry
A Centre for Children with Special Needs

Level 6, Worsley Building
Clarendon Way, Leeds LS2 9LU

T (Direct Line) +44 (0)113 343 6177
T (Enquiries) +44 (0)113 343 6138
F +44 (0) 113 343 6140
E m.s.duggal@leeds.ac.uk

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UNIVERSITY OF LEEDS

Parental Consent Form

Bite force evaluation in young children following dental treatment

Please initial the box if you agree with the statement to the left

1. I confirm that I have read and understand the information sheet [date of DREC and REC approval and information sheet version number inserted] for the above study ☐
2. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
3. I understand that my child's participation in this research study is voluntary and that I am free to withdraw my child at any time, without giving any reason, without my child's dental care being affected. ☐
4. I understand that any information I provide, including personal details, will be confidential, stored securely and only accessed by those carrying out the study. ☐
5. I understand that relevant sections of any of my child's dental records and data collected during the Study, may be looked at by responsible individuals from study supervisors, from regular authorities, or from the NHS Trust where it is relevant to my child's participation in the study. I give permission to these individuals to have access to my child's records. ☐
6. I understand that the results of this study may be included in published documents but there will be no reference to me or my child in person made in such documents. ☐

Monty S Duggal
BDS MDSc FDS (Paeds) RCS (Eng) PhD
Professor of Child Dental Health
Head of Department of Paediatric Dentistry

NHS Leeds Dental Institute
The Centre for Oral Health Sciences

I hereby freely give my fully informed consent to my child; NAME IN BLOCK CAPITALS:

Taking part in this research study

Name of child's Parent/Guardian

Signature ____________________

Date ____________________

Name of Researcher (Investigator)

Signature ____________________

Date ____________________

Research Project's data collection sheet

Bite force evaluation in children following dental treatment

Date

No.

DOB

Height	cm
Weight	Kg
BMI	

Bite force (N)

Ant. Bite force			
Right Post			
Left Post			

Sex ☐ M=0 F=1

Dental pain or Complaint/side if present:

Abscess/side if present:

	6	5	4	3	2	1		1	2	3	4	5	6	
B														B
M														M
O														O
D														D
L														L

	6	5	4	3	2	1		1	2	3	4	5	6	
B														B
M														M
O														O
D														D
L														L

0	Sound
1	Arrested Caries
2	Decayed
3	Decayed(extract/Pulp Tx)
4	Filled with recurrent caries
5	Filled
6	Missing
7	Ext Ortho
8	Un-erupted
9	Excluded
T	Trauma
S	Sealant
C	Stainless steel crown

Occlusion:

Right	
Left	
Overjet	
Overbite	

dmfs	
dmft	

Gary Mountain

From:	**Susanne.Ludgate@mhra.gsi.gov.uk**
Subject:	**Proposed research investigation into bite forces in young children**
To:	**g.mountain@leeds.ac.uk**
Date sent:	**Fri, 5 Dec 2003 14:20:49 +0000**

Dear Dr Mountain

Thank you for your letter concerning the above.

Based on the information provided, it appears to the UK Competent Authority that the product is purely for research purposes with no aim for commercialisation.

Under these circumstances we are of the opinion that this does not fall within the scope of the Medical Devices Regulations and as such no application therefore needs to be made to the UK Competent Authority for authorisation of this study.

I hope that this clarifies the situation.

With kind regards

Yours sincerely

Dr Susanne M Ludgate
Medical Director
Medicines and Healthcare products Regulatory Agency
Hannibal House
Elephant & Castle
London SE1 6TQ
Tel: 020 7972 8123
Fax: 020 7972 8111

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