Factors influencing the duration of orthodontic treatment for patients with a Class II malocclusion treated with a functional/fixed appliance approach

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STRUCTURED ABSTRACT

Background: Information regarding the various factors that can influence the duration of orthodontic treatment has been investigated before; however, despite the increasing amount of evidence becoming available, controversy still exists. Therefore, this investigation was considered to be useful as additional information to the orthodontic literature.

Aim: To determine factors associated with the duration of orthodontic treatment for patients with a Class II malocclusion treated with a functional/fixed appliance approach to treatment.

Design: Retrospective, observational study.

Setting: Orthodontic Department, Liverpool University Dental Hospital, UK.

Method: Data were collected from the records of eligible patients**.**

Inclusion criteria:

Patients were included if they had:

1) Undergone a course of orthodontic treatment involving a first phase of treatment with the Twin-Block appliance between the 1st of January 2005 and 31st of December 2008;
2) A Class II dental malocclusion;
3) Required a functional/fixed orthodontic approach to orthodontic treatment;
4) Completed two phases of orthodontic treatment;
5) Records available in a satisfactory condition.

Outcome measures:

- Duration of the functional appliance phase of orthodontic treatment
- Total duration of orthodontic treatment

Results:

The pre-treatment overjet was the only factor that had a statistically significant influence on the duration of the functional phase of the treatment ($p= 0.016$).

The factors that were statistically significant predictors for the duration of the full course of orthodontic treatment were: the number of treating clinicians (p=0.001), the number of failed appointments (p=0.001), the chronological age of the patient (p=0.002) and whether the patient had extractions or not (p=0.021).

Conclusions:

1. The only factor that had a statistically significantly influence on the duration of the functional phase of treatment was the overjet at the start of treatment (positive association).
2. The factors that had a statistically significantly influence on the total treatment duration were the:
    a) Number of the treating clinicians (positive association);
    b) Number of appointments the patients failed to attend (positive association);
    c) Chronological age of the patient (negative association);
    d) Presence or absence of dental extractions (positive association).

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CHAPTER 1

1.0 INTRODUCTION

"*Orthodontics is the branch of dentistry concerned with growth of the face, development of the occlusion and the prevention and correction of occlusal anomalies"* (Houston et al., 1992).

A malocclusion is said to exist when an occlusal trait e.g. overjet or overbite, lies out with normal limits. Orthodontic treatment aims to correct malocclusions by using a variety of appliances to move teeth and influence the growth of the jaws.

The need for orthodontic treatment has been assessed using a variety of occlusal indices (Shaw et al., 1991, Tang and Wei, 1993). Recently, epidemiological data suggest that between a quarter and a third of children, worldwide, have a defined need for orthodontic treatment as determined by the Index of Orthodontic Treatment Need (IOTN) (Josefsson et al., 2007). However, this does vary depending on the age at which the assessment is made and the country of origin, with Eastern Europe recording the highest prevalence of 40% in the year 2007. In UK, there are regional variations; however, the lowest prevalence can be detected among older subjects in the year 2003. See Tables 1.1, 1.2 and 1.3.

There are four main classes of malocclusion i.e. Class I, Class II division 1, Class II division 2 and Class III (Mitchell, 2013). The prevalence of the different malocclusions varies world-wide with Class II malocclusion being relative common in many countries and ranging from 6.3% in Nigeria (Aikins and Onyeaso, 2014) to 38% in Brazil (Almeida et al., 2011). See Table 1. 4.

Table 1. 1: Racial Origin studies (Josefsson et al., 2007)

Racial Origin	N	IOTN 4/5 (%)
Swedish	253	39.5
Eastern European	60	40.0
Asian	116	32.7
Other	47	29.8
All	**476**	**37.0**

Table 1. 2: International studies demonstrating prevalence of IOTN 4/5

Study	Country	Age	%
Alhaija et al. (2004)	Jordan	12-14	34
Tausche et al. (2004)	Germany	Mix dentition	26
Gherunpong et al. (2006)	Thailand	11-12	35
Christopherson et al. (2008)	USA (MI)	8-11	17

Table 1. 3: UK studies demonstrating prevalence of IOTN 4/5

UK Study	Site	Age	IOTN 4/5 (%)
Burden and Holmes (1994)	Manchester	11-12	21
	Sheffield	11-12	24
Breistein and Burden (1998)	Northern Ireland	15-16	23
Children's Dental Health in England (2003)	UK (Office for National Statistics)	12	26
Children's Dental Health in England (2003)	UK (Office for National Statistics)	15	16

Table 1. 4: International studies demonstrating prevalence of Class II malocclusion

Study	Age	Class II malocclusion %	Population
Dimberg et al. (2013)	7 years	28%	Sweden
Almeida et al. (2011)	7-12 years	38%	Brazil
Lagana et al. (2013)	7-15 years	29.2 %	Albania
Aikins and Onyeaso (2014)	13-20 years	6.3 %	Nigeria
Kaygisiz et al. (2015)	4.6-23 years	11.4 %	Turkey
AlQarni et al. (2014)	27.07 $\pm$ 9.76 years	13.6 %	Saudi Arabia
Prabhakar et al. (2014)	7-13 years	36.2 %	India

To treat Class II malocclusion at an early stage, there is a wide variety of appliances that are used in different regions of the world, however, the Twin-Block appliance is the most frequently used functional appliance in UK (Chadwick et al., 1998) and Australia (Miles, 2013) when compared to the United States; where it is not used routinely (Keim et al., 2014). For patients treated with a Twin-Block appliance, the course of treatment usually consists of two phases; a first phase of treatment with a Twin-Block appliance followed by a second phase with fixed appliances. Another survey revealed that among orthodontic departments in the UK; 12% of dental hospital patients were treated with functional appliances, 53% with upper and lower fixed appliances and 3% with removable appliances only. This survey had a response rate of 75% (Russell et al., 1999).

As the orthodontist aims to maximise the benefits and minimise the risks of the orthodontic treatment; within the shortest possible duration, it is important to realise the factors that could influence the treatment duration. From the literature, many factors that can influence the duration of treatment can be identified (Mavreas and Athanasiou, 2008).They can be divided into four main categories, which are: patient related factors; treatment related factors;

clinician related factors and setting related factors. This categorisation was derived from several studies with some modifications (Beckwith et al., 1999, Fink and Smith, 1992 and Mavreas and Athanasiou, 2008). The patient related factors include age, stage of dental development, cervical vertebrae maturation stage at the start of the treatment (Baccetti et al., 2000), classification of the malocclusion, buccal segment relationship, pre-treatment Peer Assessment Rating (PAR) score, dental health component (DHC) grade of the Index of Orthodontic Treatment Need (IOTN), the number of the failed or cancelled appointments and the number of repairs or damages to the appliance. The treatment related factors include the number of stages of treatment, the type of the appliances or auxiliaries required during the treatment and the need for extractions during the treatment. The clinician related factors include the number of the clinicians undertaking the treatment and the orthodontic qualification of the clinician. The setting related factors include the type of setting (e.g. public health care system, private practitioner or graduate orthodontic programme at a dental hospital) or the frequency of the visits (determined from the average time interval between appointments) (Mavreas and Athanasiou, 2008). As uncertainty remains evident in this field, further investigations would clarify the factors influencing the duration of functional/fixed orthodontic treatment of patients with a Class II malocclusion treated with a Twin-Block appliance during the functional phase and during total treatment duration.

CHAPTER 2

2.0 BACKGROUND AND LITERATURE REVIEW

2.1 ORTHODONTICS AND ORTHODONTIC TREATMENT

"*Orthodontics is the branch of dentistry concerned with growth of the face, development of the occlusion and the prevention and correction of occlusal anomalies"* (Houston et al., 1992). A malocclusion is the presence of an occlusal trait outside normal limits e.g. increased overjet and has been shown to have a significant negative impact on quality of life (Johal et al., 2007, Al-Bitar, 2013). Orthodontic treatment aims to correct a malocclusion to produce a functional occlusion, aligned dental arches, improved facial and dental aesthetics and achieve higher levels of oral function and aesthetics. However, there is no conclusive evidence to support whether orthodontic treatment can improve oral health and/or prevent oral diseases significantly (Davies et al., 1991, Kiyak, 2008, Ghijselings et al., 2014, Campbell et al., 2008).

So, what is a normal occlusion and what is an abnormal occlusion? What does orthodontic treatment aim for? In 1899, Edward Angle described normal occlusion as: "*The key to occlusion is the relative position of the first molars. In normal occlusion the mesio-buccal cusp of the upper first molar is received in the sulcus between the mesial and distal buccal cusps of the lower*". The rest of the teeth will follow in harmony as a result. However, in 1972, Lawrence Andrews suggested six key points for an ideal static occlusion and they were:

Key 1 - Molar relationship: the distal surface of the distal marginal ridge of the upper first permanent molar occludes with the mesial surface of the mesial marginal ridge of the lower second molar. The mesio-buccal cusp of the upper first permanent molar falls within the groove between the mesial and middle cusps of the lower first permanent molar.

Key 2 - Crown angulation or mesio-distal tip: the gingival portion of the long axis of each tooth crown is distal to the occlusal portion of that axis. The degree of tip varies with each tooth type.

Key 3 - Crown inclination or labio-lingual/bucco-lingual torque: for the upper incisors the occlusal portion of the crowns labial surface is labial to the gingival portion. In all other crowns, the occlusal portion of the labial or buccal surface is lingual to the gingival portion.

Key 4 - Rotations: there should be an absence of any tooth rotations within the dental arches.

Key 5 - Spacing: there should be an absence of any spacing within the dental arches.

Key 6 - Occlusal plane: the occlusal plane should be flat.

These keys formed an idea of the occlusion to be aimed for, at the end of the orthodontic treatment, whenever possible. Another key point was added by Bennett and McLaughlin (2001) and that was that there should be:

Key 7 - Correct tooth size.

As it is crucial to have static aims of where the teeth will finish at the orthodontic treatment, there should be some functional aims as well. Several points were established to guide the clinician in achieving an ideal functional occlusion; nevertheless, it is considered a controversial and debatable concept to prolong orthodontic treatment just to achieve them (Clark and Evans, 2001).

The following functional occlusal guidelines are considered to be acceptable and reasonable aims to accomplish whenever it is possible:

1. Achieve occlusal contacts on both sides of the dentition in the retruded contact position (RCP).
2. Achieve coincidence between the RCP and the Inter-cuspal position (ICP) or maintain a discrepancy of less than 1 mm between those two positions.
3. On lateral excursions, the working side achieves contacts on canines only (canine guidance) or contacts on canines with one or more posterior teeth (group function).
4. On lateral excursions, no contact should take place on the non-working side.

The aetiology of a malocclusion is often multi-factorial. The malocclusion can be caused by evolutionary trends, genetic influences and environmental factors (Cobourne and DiBiase, 2010). These environmental factors can be further classified into physiological factors (e.g. soft tissue balance, mouth breathing and muscular activity), sucking habits and pathology (e.g. un-diagnosed jaw fractures during childhood, juvenile rheumatoid arthritis, hormonal imbalance such as excessive release of growth hormone, periodontal diseases, dento-alveolar trauma during dental development and after dental eruption, in addition to the premature loss of primary dentition due to carious lesions). It is therefore, often difficult to determine whether a malocclusion is caused by a skeletal discrepancy, dental factors, soft tissue related

factors or environmental factors. Malocclusions, resulting from different aetiologies may require a different approach to treatment and the aim of the treatment is to create a functional occlusion, that is aesthetically pleasing, within a stable soft tissue environment, that resists relapse.

The preferred way to treat a malocclusion may be to identify the underlying cause and treat or modify it before thinking about how to align the teeth. If the aetiological factor was related to a skeletal discrepancy, such as a prognathic or hypoplastic jaw, then, in order to create an ideal occlusion, surgical correction (combined orthognathic/orthodontic treatment) may be the treatment modality of choice. Otherwise, orthodontic treatment would need to camouflage the presence of the skeletal discrepancy. Combined orthodontic / surgical or orthodontic camouflage are the treatment options available for adults who have a skeletal discrepancy, as no further growth is anticipated that may cause changes in the skeletal bases. On the other hand, the two main treatment approaches for growing patients are either orthodontic treatment, aiming to achieve dento-alveolar camouflage of the underlying skeletal discrepancy or a growth modification / functional appliance approach to treatment. This is an approach that utilises the growth capacity present in growing patients and directs it to reduce the antero-posterior (AP) discrepancy that contributes to the malocclusion. These methods can be applied via the functional appliances in isolation or in combination with the fixed orthodontic appliances (McDonald and Ireland, 1998, Cobourne and DiBiase, 2010).

2.2 CLASS II MALOCCLUSION AND TREATMENT OPTIONS

The classification of a Class II malocclusion can be based on the skeletal component or the dental component of the malocclusion. A skeletal Class 2 malocclusion is present when the lower dental base is retruded relative to the upper (Houston et al., 1992). However, a dental Class II malocclusion is defined differently and it is composed of two main divisions. The first one is Class II division 1 malocclusion in which the lower incisor edges lie posterior to the cingulum plateau of the upper central incisors. The overjet is increased and the central incisors are proclined or at normal inclination. The second one is Class II division 2 malocclusion in which the lower incisor edges lie posterior to the cingulum plateau of the upper central incisors and the upper central incisors are retroclined (BSI, 1983).

The potential methods to treat Class II malocclusion may depend on the aetiology and the sub-division of the malocclusion. In a case of Class II division 1 malocclusion; the determinant factor would be the presence or the absence of a skeletal discrepancy as pure soft

tissue factors are rare in such a malocclusion, most dento-alveolar factors can be treated within orthodontics limits and if the malocclusion was caused by habits, discouraging the habit and re-assessment will take place before treatment can be commenced. In a case of Class II division 1 malocclusion, where no skeletal discrepancy is present in the antero-posterior (AP) plane or the vertical plane, the treatment will be similar to treatment of a Class I malocclusion. The treatment could include fixed appliances with or without extractions; depending on the space requirements, aiming to create a Class I molars, canines and incisors in a stable soft tissue environment. On the other hand, if a skeletal discrepancy is present then the direction and the severity will indicate the preferred treatment method. Mild AP or vertical discrepancies can be accepted or camouflaged using orthodontic treatment, however, as severity increases, an aesthetic and a stable result cannot be achieved by orthodontics only and as a result, surgical intervention may be deemed necessary in adult patients. In growing patients, functional appliances, which can be used to achieve antero-posterior correction of the malocclusion, can be considered as a treatment option (McDonald and Ireland, 1998).

2.3 HISTORY OF FUNCTIONAL APPLIANCES

In 1879, Norman W. Kingsley; from the United States of America, was the first to utilize the forward positioning of the mandible using a removable orthodontic appliance. However, the majority of functional appliances were developed in Europe with orthodontists from other regions of the world also participating in their development (Wahl, 2006, DiBiase et al., 2015).

In 1902, Pierre Robin designed an appliance for children with glossoptosis syndrome (known as Pierre Robin syndrome nowadays), aiming to influence the muscular activity of the face and normalize the occlusion. This appliance was named the monobloc and it was a modification of the maxillary plate developed by Kingsley (Wahl, 2006, DiBiase et al., 2015).

In 1905, Emil Herbst introduced a fixed functional appliance that postured the mandible forward; the herbst appliance. However, it was Hans Pancherz who reintroduced and popularised the use of this appliance in the late 1970s (Wahl, 2006, DiBiase et al., 2015).

The monobloc was followed by Andresen activator in 1909. Viggo Andresen was a Danish dentist who realized that placing upper and lower removable appliances, that guided the mandible forward by 3-4 mm during night-time, in a child mouth, with a Class II malocclusion, could eliminate the Class II malocclusion. His discovery was a result of an

accident whilst he was treating his daughter. He removed her fixed appliances, before she left for her summer holiday and placed the removable appliances as retainers. He was then surprised with the changes when his daughter returned from the holiday. Andresen activator was a modification of Robin monobloc (Wahl, 2006, DiBiase et al., 2015).

The successor of the Andresen activator, as a removable functional appliance, was the Bimler appliance which was invented by Hans Peter Bimler, a surgeon during World War II (1939-1945). The Bimler appliance was designed as a maxillary splint for patients who lost a gonial angle from injury but he noticed some widening in the maxillary arch as a result. The Bimler appliance design was finalized in 1949 (Wahl, 2006, DiBiase et al., 2015).

In 1950, Wilhelm Balters invented the bionator appliance by modifying Andresen activator. It acted by forcing the mandible into a forward position. There are three designs of the bionator for the treatment of different malocclusions

In 1956, Martin Schwarz joined the activator and the active plate into an appliance that consists of maxillary and mandibular acrylic plates that guide the mandible into a protrusive position. His appliance was called the double plate as it was a modification of a monobloc or an activator; however, the double plate was made of two separate parts (Wahl, 2006, DiBiase et al., 2015).

In 1957, Rolf Fränkel invented the functional regulator (FR) appliance and that appliances had three different versions; FR-1, FR-2 and FR-3 to treat Class I, Class II and Class III malocclusions. The mode of action in FR was based on the oral vestibule with minimal if any contact with the teeth. Despite the complex fabrication, the FR gained rapid popularity and that was not limited to Europe as it was also accepted in the United States (Wahl, 2006, DiBiase et al., 2015).

2.4 FUNCTIONAL APPLIANCES AND ORTHODONTICS

Functional appliances are defined as "*appliances that utilize, eliminate, or guide the forces of muscle function, tooth eruption and growth to correct a malocclusion*" (Mitchell, 2013). The majority of functional appliances are used in patients with a Class II malocclusion; however they can also be used to treat patients with a Class III malocclusion or anterior openbites (Thiruvenkatachari et al., 2013, Watkinson et al., 2013, Lentini-Oliveira et al., 2014). Functional appliances alter the oro-facial environment (including soft tissues, muscles of

mastication, teeth and jaws) leading to the adaptation of the dentition to the new position and enhancing the remaining growth in a favourable direction (Cobourne and DiBiase, 2010).

Their efficiency and mode of action is still a controversial issue which, in part, can be attributed to the fact that a significant amount of evidence related to their action has been derived from animal studies (Aelbers and Dermaut, 1996, Dermaut and Aelbers, 1996). Although animal studies can provide useful information, they have many limitations which include; variations in morphology and physiology between the different species, rapid growth and short life cycle of animals compared to humans and intolerable appliance regime forced on animals. For these reasons, results gathered from animal studies lack generalisability to humans.

Functional appliances can be classified in several ways:

1. Working method: active fit or passive fit when inserted.
2. Supporting tissue: tooth-borne, tissue-borne or combination.
3. Number of components: mono-block or several blocks constituting the appliance.
4. Method of fixation: fixed or removable

There are several types of functional appliance: Activators (e.g. Andresen activator, Woodside/ Harvold, Bionator and medium opening activator), the Frankel appliance, the Twin-Block appliance and the Herbst appliance.

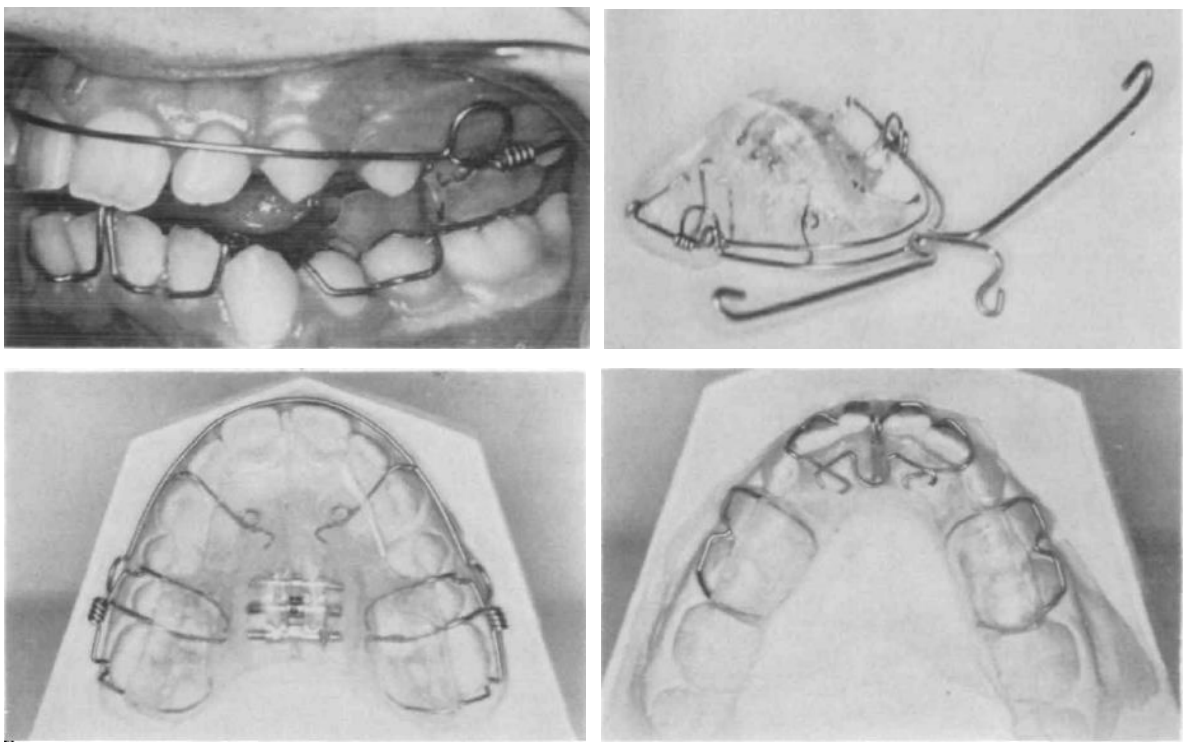
This study has investigated Twin-Block appliances that are active tooth-borne appliances that consist of two blocks and are removable from the mouth.

2.5 ORIGINAL DESIGN OF TWIN-BLOCK APPLIANCE BY CLARK

The original Twin–Block appliance was introduced by W.J. Clark in 1982, who concluded from his studies and those of other researchers that "*occlusal forces transmitted through the dentition provide a constant proprioceptive stimulus to influence the rate of growth and the trabecular structure of the supporting bone. Fixed occlusal inclined planes have been used to alter the distribution of occlusal forces in animal experiments investigating the effects of functional mandibular displacement on mandibular growth and on adaptive changes in the temporomandibular joint*". These concepts lead Clark to develop the original Twin-Block design, which was a combination of Robin monobloc and Schwarz double plate. It included maxillary and mandibular bite blocks that interlocked at an inclination of 45 degrees. The maxillary unit included modified double arrow-head clasps on the maxillary first molars and

second premolars with a coiled tube to allow the insertion of a face-bow when extra-oral traction was required; a midline expansion screw; a labial bow placed between the mesial surfaces of the maxillary first molars; a lingual bow (in some cases); C-clasps on the permanent lateral incisors or Adams clasps incorporated on the permanent first molars where increased retention was essential and a bite-block that extended along the lingual cusps of posterior teeth and stops to include the mesial ridge of the maxillary second premolar. The lower Twin-Block was designed with peripheral clasps; interdental clasps including two teeth from the incisors and two teeth from the premolar region, the front part could be divided to accommodate a lingual U-loop (if extra-oral traction was required), a screw or a helical spring (if expansion was needed) and a bite-block that maintained a complete coverage of the occlusal plane of the mandibular first and second premolars.

Figure 2. 1: Original design of Twin-Block appliance (Clark, W. J. (1982) 'The Twin-Block traction technique'. *European Journal of Orthodontics.* 4 (2), 129-138). Used with permission of Oxford University Press/ on behalf of the European Orthodontic Society



In patients with a severe skeletal discrepancy, the technique could be modified using a face-bow with intermaxillary and extra-oral traction, in combination with the Twin-Block appliance, known as Orthopedic Traction. The intermaxillary traction was applied through the use of intermaxillary elastics passing from a hook attached to the upper labial bow to the mandibular Twin-Block, lingual to the central incisors. The extra-oral traction was applied

through high-pull headgear. For the bite registration for Clark original Twin-block, it registered the position of the mandible while assuring 5-7 mm of mandibular protrusion and maintaining 4-5 mm of inter-occlusal distance in the premolar region. Also, it was advised that during the bite registration, centreline discrepancies should be eliminated if they were caused by a premature contact and mandibular displacement (Clark, 1988). This was the original design of a Twin-Block functional appliance in Orthodontics.

2.6 THE EVIDENCE ON THE EFFECTIVNESS OF THE TWIN-BLOCK APPLIANCE

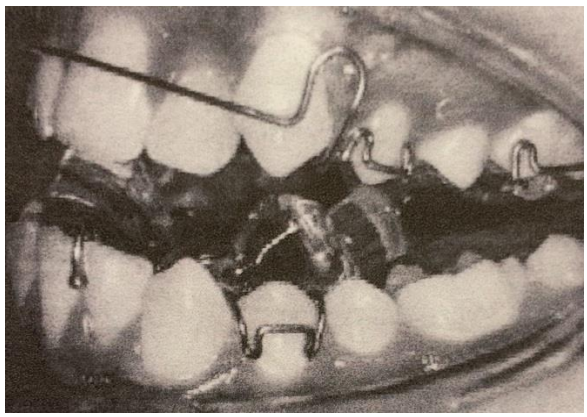
Over the years, many different practitioners have modified the original Twin-Block design but the traditional philosophy has remained the same i.e. to advance the mandible and open the bite to correct the Class II incisor relationship. During this, many studies have been undertaken to assess the efficacy of these and other functional appliances and an interesting debate has developed regarding how to test the effect of growth modification treatment on Class II Division 1 malocclusion.

At the time the current study planned, the most comprehensive evidence available was from a Cochrane systematic review (Harrison et al., 2008). This review included all randomised and controlled clinical trials of orthodontic treatments to correct prominent upper front teeth in children or adolescents of 16 years of age or younger. Only eight trials met the inclusion criteria, five of them had unclear risk of bias and the authors concluded that providing early orthodontic treatment, for children with Class II division 1 malocclusion, was no more advantageous than providing one course of orthodontic treatment in early adolescence. However, this review has since been updated (Thiruvenkatachari et al. 2013). The objectives were to assess the effects of orthodontic treatment for Class II division 1 malocclusions when treatment was initiated when the child was 7 to 11 years old compared with when they were in early adolescence, or when treatment uses different types of orthodontic appliances. The studies included were all randomised controlled trials of orthodontic treatment to correct Class II division 1 malocclusions. The evidence from this updated review suggested that providing orthodontic treatment, for children with a Class II division 1 malocclusion, in two phases appeared to reduce the incidence of trauma to the upper incisor teeth significantly compared to treatment that was provided in one phase when the children were in early adolescence. No advantages of providing a two-phase treatment i.e. early from age seven to 11 years and again in adolescence compared to one phase in adolescence were identified. When functional appliance treatment was provided in early adolescence it appeared that there

were minor beneficial changes in skeletal pattern, however, these were probably not clinically significant. Similarly, the choice of functional appliance did not influence the outcome. Their results were based on data from 17 studies and included the results from 9 additional studies compared with their earlier review. They also had eliminated the weaker evidence from non-randomised clinical trials. Despite this, the overall quality of the trial was low. Of the 9 newly added studies, only two had a low risk of bias in all domains, 3 a high or unclear risk of bias in a single domain and the remaining 4 studies a high risk of bias. The rest of the studies were those included in both the 2008 and the 2013 reviews with 7 out of the 8 studies having a high risk of bias in at least one domain.

One of the studies included in the Cochrane review was a multi-centred randomised control trial (RCT) using a modified Twin-Block appliance (O'Brien et al., 2003a, 2003b). The maxillary unit consisted of a passive labial bow with Adams clasps on the first permanent molars and a midline expansion screw, when needed. The mandibular unit contained Adams clasps on the permanent first molars and ball ended clasps located in the incisors interproximal region. The bite blocks were made to a position that would give 7-8 mm protrusion of the mandible, with a thickness of 7 mm in the premolar region and inclined at 70 degrees to the occlusal plane.

Figure 2. 2: Modified Twin-Block appliance (Parkin, N. A., McKeown, H. F. and Sandler, P. J. (2001) 'Comparison of 2 modifications of the Twin-block appliance in matched Class II samples'. *American Journal of Orthodontics and Dentofacial Orthopedics.* 119 (6), 572-577). Used with permission from RightsLink Copyright Clearance Centre and Elsevier.



In this RCT, cephalometric radiographs and study models were used to measure antero-posterior skeletal discrepancy, overjet and Peer Assessment Rating (PAR) score (OBrien et al. 2003b). Although the correction of the class 2 skeletal discrepancy was evident, it was not

clinically significant. The authors concluded that the changes achieved, using a modified Twin-Block appliance, are mainly dento-alveolar rather than skeletal.

In a non-randomised study, that was not included in the Cochrane Review (Thiruvenkatachari et al. 2013), Lund and Sandler, (1998) found that treatment with a modified Twin-Block resulted in anterior repositioning of the mandible: an increase in SNB angle; increase in the anterior lower facial height; proclination of the lower incisors; retroclination of the upper incisors; distal movement of the maxillary molars and anterior superior eruption of the mandibular molars, all of which contributed to the correction of the increased overjet and the buccal segment relationship. In general, lower incisor proclination is associated with alveolar bone remodelling and a reduction in SNB angle. However, this small, potential reduction in SNB angle did not mask the increase of SNB angle that occurred as a result of the treatment and contributed to the reduction of ANB angle. In addition, retroclination of the maxillary incisors was detected, together with distalisation of the maxillary molars and mesialisation of the mandibular molars. All these effects played a role in reducing the severity of Class II malocclusion**.** This was a prospective, longitudinal controlled study but these results should be interpreted with caution due to the lack of randomisation, blinding and an a priori sample size calculation that make it prone to a high level of allocation and detection bias.

In another study (Parkin et al., 2001), two more modifications were added to the modified Twin-Block appliance, namely a high-pull headgear and torqueing spurs on the upper central incisors. The main effects detected when comparing treatment utilising a combined high-pull headgear with a Twin-Block appliance to the treatment using the modified Twin-Block appliance on its own were: increase in maxillary restraint; increase reduction in ANB angle (indicating higher efficiency in correcting the antero-posterior discrepancy in class II skeletal malocclusion) and maintenance of the ratio of the lower facial height relative to the total anterior facial height which is usually increased when using a modified Twin-Block alone. All these effects are combined with those seen previously with the modified Twin-Block appliance. These results also have to be interpreted with caution for the same reasons as Lund and Sandler (1998).

A RCT compared Twin-Block and Herbst appliances (a fixed functional appliance) concluded that both appliances had the same overall treatment duration and both achieved similar dento-alveolar and skeletal changes. The Twin-Block appliances had a lower rate of breakages and a lower number of appointments needed for repair. The only drawback with

the Twin-Block appliance was that the compliance was significantly less than for the Herbst appliance. This was likely to be due to the Twin-Block appliance being a removable appliance and depends completely on patient compliance so if the patient does not wear the appliance, no favourable changes will be achieved (O'Brien et al., 2003c).

From the previously mentioned (O'Brien et al., 2003a, 2003b, 2003c, Lund and Sandler, 1998, Parkin et al., 2001 and Thiruvenkatachari et al. 2013), the following can be related to the treatment using a Twin-Block appliance: routine practice would use Twin-Blocks in growing patients, aiming to achieve some skeletal changes through restraining the maxilla and forward movement of the mandible. The dento-alveolar changes achieved would include proclination of lower labial segment, retroclination of upper labial segment, distal tipping of upper molars and mesial eruption of lower molars. All of these effects would correct a class II buccal segment into a class I relationship, or ideally into an overcorrected class III buccal segment. This, in turn, would provide anchorage and a reduction in the complexity and anchorage requirements of the case. For the planning of the second phase of treatment, each case would need to be assessed individually. The aim would be to consolidate the corrections achieved during the functional appliance phase, to assess the degree of crowding, the degree of incisors proclination post Twin-Block treatment and the stability of their new position and whether the patients profile would improve by extractions or not (Cobourne and DiBiase, 2010).

2.7 FACTORS INFLUENCING THE DURATION OF ORTHODONTIC TREATMENT

2.7.1 The Chronological Age

Chronological age is one of the variables that are continuously being researched in an attempt to determine at what age it is best to commence orthodontic treatment in order to achieve the best occlusal result in the shortest treatment duration. The ability to predict the length of the treatment from the patient's chronological age at the start of the treatment could be useful when planning and discussing treatment with a patient.

Some researchers have also observed a possible association between chronological age and compliance. However, that association is debatable as each patient is unique in his or her behaviour, attitude and compliance with the treatment modality (Sergel and Zentner, 2000; Meikle, 2005).

A study conducted by Banks et al. (2004), investigated the Twin-Block appliance and concluded that patients who were age 12.3 years old or younger, were 3 times more likely to complete their treatment compared with older patients. In this study the factors that influenced the completion of the treatment were the chronological age and the clinicians. In addition, the initial overjet was found to be a factor that influenced treatment duration. This suggested that Twin-Block treatment was clinician-sensitive and different clinicians vary in their clinical success when using the same appliance. In other words, the same appliance can work differently in different hands. This study was a randomised control trial and was included in the Cochrane systematic review (Thiruvenkatachari et al., 2013). With the exception of attrition bias, it had a low risk of bias. The percentage of the patients who were lost from those who were randomised was 20% in the experimental group and around 36% in the control group. The completion of treatment could be interpreted as an indicator of compliance with the treatment modality and as a result, can influence the treatment duration. However, age, compliance and treatment duration are highly inter-related and separating them for analysis can be very difficult. This would need either sophisticated statistical analysis or several studies to achieve this.

It is not known why these different age groups behave differently. Based on the available evidence, the chronological age should be included in the analysis whenever variables influencing orthodontic treatment duration, are being investigated.

2.7.2 Stage of Dental Development

Starting times for treatment with functional appliances, from a dental development point of view, can be divided into those starting before the eruption of the first premolars and those after. Commencing the treatment after the eruption of the first premolars is considered normal or late. The advantage of this approach is that the permanent dentition develops over the 9 months treatment duration with the functional appliance, thus allowing a smooth transition into the second phase of treatment with fixed appliances. The disadvantages of this approach are that by delaying treatment, the patients may be under psychological stress from their peers (teasing and bullying at school) and may be at an increased risk of trauma to the prominent incisors. On the other hand, some clinicians may start the course of treatment before the eruption of the first premolars and this is considered to be an early treatment. Despite the obvious disadvantages, which include; increasing the overall length of the treatment, increasing number of visits and losing the patients compliance; the main advantages gained by undertaking early treatment are the potential psychological benefits that

result from early treatment and a reduction of the risk of trauma to the upper incisors (Thiruvenkatachari et al. 2013, O'Brien et al., 2003a). Also, knowing that the patients are happier and more satisfied because they are no longer teased at school is an advantage that makes early treatment sound appealing. This is supported by the second part of a study undertaken by O'Brien and colleagues that assessed the psychological effects of Twin-Block treatment in patients with a Class II Division 1 malocclusion (O'Brien et al., 2003a). The results suggested that participants confidence and self-esteem improved in the early treatment group. The participants in the early treatment group also felt that their dental health, periodontal health and occlusal function improved, when compared with their status before the treatment. In addition, participants in the early treatment group claimed that, on a social level, they had a reduced number of incidents of teasing and bullying after the completion of the treatment. This study showed that early treatment with the Twin-Block appliance had two main advantages, one to correct the antero-posterior aspect of the malocclusion and the second to improve the patients feelings and emotions toward themselves (O'Brien et al., 2003a and b). However, despite the advantages gained by early treatment, the additional costs and time may not be justified in term of outcome because the final results in term of PAR were no better and treatment time increased significantly (O'Brien et al., 2009b).

In analysing the influence that the stage of dental development has on the outcome of treatment, Von Bremen and Pancherz (2002) concluded that treatment of Class II division 1 malocclusion was more efficient in the permanent dentition (late treatment) than the mixed dentition (early treatment). Their sample was divided into 3 categories based on the stage of dental development; they were, early mixed dentition, late mixed dentition and permanent dentition. This was a retrospective, observational study involving the use of a variety of appliances so was prone to a high risk of bias. The results, therefore, should be interpreted with caution.

Tulloch et al., (2004) also explored the impact of starting treatment at different stages of dental development using headgear or a modified bionator compared with an observation only group. The study was a randomised controlled trial and compared starting treatment in the mixed dentition (early) with that starting treatment in the permanent dentition (late). The authors concluded that early treatment might be considered to be less efficient because there was no reduction in the duration of the fixed appliances phase or reduction in complexity of the remaining orthodontic treatment. This study was included in the Cochrane review (Thiruvenkatachari et al. 2013), however it was considered to be at a high risk of bias due to

detection bias (blind assessment of the outcome was not performed); selection bias (information about the allocation concealment was not reported) and attrition bias (information on the rates and reasons for excluding participants from the analysis were incomplete). Therefore, the authors' conclusion should be interpreted with caution.

The current study was planned and designed in 2010 so the best current evidence at that time was the Cochrane Review (Harrison et al., 2008). The conclusion of this version was that early treatment had no advantages compared with late treatment and the minor beneficial changes gained were not clinically significant. However, when this Cochrane review was updated (Thiruvenkatachari et al. 2013) the conclusion was slightly different and concluded that early treatment was more effective in reducing the incidence of incisal trauma when compared with late treatment. This update included data from 9 new studies and excluded previously included data from controlled clinical trials and quasi-randomised trials. In the 2008 Review, the North Carolina study was the only study that provided data about the incidence of incisal trauma. However, in the 2013 update, three studies i.e. Florida (Chen et al., 2011), North Carolina (Koroluk et al., 2003) and UK (O'Brien et al., 2009b), provided additional data in relation to the incidence of incisal trauma. As a result, the updated review concluded that data from the studies that explored incisal trauma, suggested that to prevent dental trauma, treatment should be considered at the time the incisors erupt into the oral cavity because by the time they started treatment as part of the trials, many of the participants had already suffered trauma. However, it was difficult to justify this very early start because it appeared that the majority of the dental trauma incidents were minor and could be treated at relatively low cost when compared to the increased cost (in terms of time and money) of earlier orthodontic treatment (Chen et al., 2011, Koroluk et al., 2003). It may be possible to answer this question by undertaking an economic analysis of the competing strategies.

However, the evidence suggested that the earlier the treatment was started, the longer the treatment duration would be. As chronological age, dental development and skeletal maturity are inter-related but unpredictable; each one of them would need to be investigated and assessed separately in order to assess the relative impact of each variable on the duration of treatment. However, using regression techniques, the current study may help to identify which, if any of the factor(s) has the most influence on the duration of treatment.

As the controversy of the timing of treatment remains, the stage of the dental development was considered an important variable when considering influences on the treatment duration so it is important for it to be included in the regression analysis.

2.7.3 Overjet at the Start of Treatment

The overjet at the start of the treatment was one of the variables that were found to influence the duration of the functional phase of orthodontic treatment by Banks et al., (2004).

It would be reasonable to suggest that the larger the overjet, the longer the time needed to reduce the value to zero mm. This can be achieved clinically using a functional appliance because the end point of the active treatment, using the Twin-Block appliance, is often the reduction of the overjet and overbite to an edge-to-edge relationship. So, the further the incisors are away from zero, the longer time needed (Gill et al., 2005).

Banks et al., (2004) found that the initial overjet can be an influencing factor on treatment duration. This was a well conducted randomised controlled trial that compared two different methods for the advancement of the blocks in Twin-Block orthodontic treatment. In addition, the completion of treatment and the duration of the treatment were investigated. The authors found that the number of clinicians and the initial overjet were the two factors that influenced treatment duration

A study by Grewe and Hermanson, (1973) investigated the correlation between the complexity of the malocclusion and the treatment duration. It utilised three different indices (Handicapping Malocclusion Assessment Record, Occlusal Index and Treatment Priority Index) to provide an objective judgment of the malocclusion, in addition to subjective ranking of the malocclusion carried out by the orthodontist. They concluded that there was no significant correlation between malocclusion severity and treatment length. However, this was a retrospective observational study, considered to be of a low quality of evidence due to the high risk of selection bias, detection bias, reporting bias as well as other possible biases that could have been introduced at every stage. As a result, the authors' conclusion should be interpreted with caution. Also, it has to be noted that although the overjet at the start of the treatment could be considered as an indicator of the severity of the malocclusion, Grewe and Hermanson (1973) did not investigate the severity of the malocclusion on its own, they looked at the complexity of the malocclusion which cannot be determined from the pre-treatment overjet alone.

Vig et al., (1998) found a difference in treatment duration attributed to the severity of malocclusion. Class I and Class II malocclusions were compared and categorised according to the overjet. If the overjet was 5mm or more, it was classified as a Class II and if the overjet lay between 0-5 mm, it was classified as a Class I malocclusion. The Peer Assessment Rating

index (PAR Index) was used as an objective measure of the severity of the malocclusion. The pre-treatment and post-treatment PAR scores were determined from study models and the reduction between the two scores was determined. Also, clinicians were asked to assess the severity of the malocclusion, treatment difficulty and duration of treatment subjectively. The study found that the treatment duration of patients who had Class II malocclusion was about 5 months longer than those with a Class I malocclusion. However, the authors' conclusion should be interpreted with caution as the results were derived from retrospective and cross-sectional studies into which various types of bias could have been introduced. For example, selection bias (no randomisation or allocation concealment), detection bias (no blinding of assessors) and reporting bias (selective reporting).

Due to these conflicting results, the overjet was included in this study as a reflection of the complexity of the malocclusion, which may influence treatment duration.

2.7.4 Extraction or Non-Extraction Treatment

This study aimed to investigate the factors influencing the length of treatment with functional appliances and the duration of the total (2-phase) orthodontic treatment, therefore the impact of extractions, as a possible influencing factor, was considered.

The need for the dental extractions, as part of functional/fixed orthodontic treatment, is usually decided at the end of the functional phase of the treatment, however, in a few cases, the need for extractions may be decided earlier due to the presence of crowding, a history of trauma or the presence of dental pathology. In the majority of cases, premolars are the teeth of choice for extractions for the relief of crowding; however, this is not always the case for example, when a patient possesses teeth with a poor long-term prognosis or morphology then extraction of these teeth is considered. If a patient has compromised teeth and dental extractions are required, then extraction of the teeth with a poor prognosis is often undertaken.

The overall conclusion from the literature suggests that extractions increase the time required for space closure which in turn increases treatment length (Vig et al., 1990; Fink and Smith, 1992; Mavreas and Athanasiou, 2008). Also, the greater the number of teeth extracted, the longer the duration of treatment (Vig et al., 1990; Fink and Smith, 1992; Mavreas and Athanasiou, 2008).

As the association between dental extraction and treatment duration has been established, extractions were included as an independent variable in this study.

2.7.5 Number of Clinicians Treating the Patient

Another variable that could influence the duration of orthodontic treatment is the number of clinicians involved in a patients treatment. It is unlikely that the number of clinicians who treat a patient is the primary indicator of treatment duration; however, it can affect the duration of the treatment and may be a reflection of the patients compliance. University dental hospitals, that deliver orthodontic postgraduate training programmes, are likely to have a large proportion of their patients treated by the trainees under the supervision of consultants or senior academics. The majority of the training programmes in the UK last for 3 years, which is sufficient to complete treatment for most of the cases. However, if the patient is not compliant and/or has poor attendance, treatment will be prolonged and possibly not completed within one trainees training programme. In such cases, the patient will be transferred to have his or her treatment completed by another clinician. This does not mean that only non-compliant patients are transferred, some patients are transferred for many other reasons for example; patients requiring multi-disciplinary treatment often have treatment lasting longer than 2½ - 3 years. Several studies have shown that if a patient is transferred between clinicians, then the duration of his/her treatment will be longer (Beckwith et al., 1999, Fink and Smith, 1992 and Mavreas and Athanasiou, 2008).

McGuinness and McDonald (1998) compared two groups of patients treated by postgraduate students who had treatment with upper and lower fixed appliances. One group was bonded, treated and debonded by a single student, whilst the other group started treatment with one student and were debonded by another student. They compared the PAR index at the start and at the end of the treatment and the treatment duration between bond-up and debond of the appliances for both groups. They concluded that the standards of the treatment (measured by PAR index) were not significantly influenced by the change of the postgraduate student during the course of treatment. However, the treatment duration increased significantly for patients treated by two students compared with those for whom treatment was completed by a single student. Nevertheless, the authors' conclusion, in relation to the number of clinicians, cannot be considered as the absolute predictor. This study was a retrospective observational study and despite the attempts to reduce bias, selection bias, detection bias and reporting bias could have been introduced so the results should be interpreted with caution.

Other factors that could influence the number of the clinicians treating a patient include the clinicians workload, the complexity of the cases treated and the interval between the visits. These variables can be extremely difficult to assess or define precisely and as a result, the number of the clinicians can be used as a reasonable indicator of the variation related to the clinicians in this study and as an indirect indicator of the patients compliance.

2.7.6 Other Clinician Related Factors

In addition, other clinician related factors, can lead to variability in treatment duration for example, the level of experience of the clinician (more or less experienced), their work load (high or low number of patients) or their preferred approach to treatment (e.g. preference of extraction over non-extraction; use of a transition phase following the active functional phase of treatment or not and use of elastomeric material or nickel-titanium coils in space closure) could have an influence on treatment duration (Mavreas and Athanasiou, 2008).

When examining the level of a clinicians experience, as an influencing factor on treatment duration, the results of previous studies were inconclusive. Turbill et al. (2001) concluded that practitioners with an orthodontic qualification (higher qualification and experience) had longer average treatment duration and that this was possibly due to higher level of complexity of the malocclusions undergoing treatment.

Despite the wide range of factors that could be investigated in this field (other clinician related factors), it was decided not to explore this topic in the current investigation. A prospective approach of research could address these factors more appropriately.

2.7.7 Number of Visits that Patients Failed to Attend (FTAs)

The number of FTA appointments was introduced as an indicator variable for the level of compliance of the patient during the treatment. However, there are many other appointment related factors that are highly inter-related that can influence each other as well as the treatment duration. These include the number of visits the patient was unable to attend (UTAs), the number of emergency visit (broken brace appointments / BBs) and the reasons behind attending these clinics.

Beckwith et al., (1999) established an association between six variables and treatment duration and found that about half of the variation in the regression model was explained by these variables. These variables were divided into those related to patient compliance (the number of missed appointments; re-cemented bands; re-bonded brackets and negative chart

entries regarding oral hygiene) and those related to treatment modality (e.g. number of treatment phases and whether headgear was prescribed for the patient or not).

Fink and Smith (1992) also detected an association between the number of broken appointments (missed appointments) and the treatment duration. They concluded that half of the variation in treatment duration could be explained by the following variables: number of extracted premolars, number of broken appointments, pre-treatment mandibular plane angle, pre-treatment ANB angle and pre-treatment Salzmann index (Salzmann, 1967). However, no indication was given as to whether the broken appointments were FTAs or UTAs.

Järvinen et al., (2004) also concluded that a high number of missed appointments could prolong the duration of the treatment. Melo et al., (2013) concluded that patients compliance; expressed in terms of the number of missed appointments (no show) and number of appliance breakages or issues related to the appliance, influenced the treatment duration. These two variables predicted about 40% of the overall variability in treatment duration.

Using information from these studies highlighted the importance of including the number of FTAs as an indicator of patient compliance in this research, aiming to reduce the confounders and the level of bias to the minimum.

Table 2. 1: Summary of the Studies investigating the influencing factors of orthodontic treatment duration.

Study ID	Intervention	Participants (sample size)	Outcomes Measured and Factor Investigated	Conclusion	Comments
Tulloch et al., 2004	2-phased RCT: early vs. late, randomized to headgear, functional appliance (modified bioantor) or observation. Followed by comprehensive treatment (after 15 months).	University of North Carolina Class II malocclusion	Skeletal and dental changes, treatment outcome (PAR score), time and complexity of treatment.	2-phase treatment (early) no more clinically effective than 1-phase treatment (late). Early treatment less efficient as no reduction in the time in fixed appliances during 2nd phase of treatment, no decrease in complexity.	Lost to follow-up 17.5%
Grewe and Hermanson (1973)	Retrospective observational. Pre-treatment casts assessed to determine correlation between severity of malocclusion (quantitatively and subjectively) and length of treatment time.	Patients ranging from 11-15 years old, completed treatment at the University IOWA (n=66). Casts and records.	Quantitative measures: handicapping malocclusion assessment records, the occlusal index and treatment priority index. Subjective measures: for malocclusion severity.	No significant correlation was detected.	
Fink and Smith, 1992	Retrospective observational investigation of pre-treatment and post-treatment to evaluate causes for variation in treatment durations.	Six private offices (n=118) had a single phase with fixed appliances.	Lateral cephalograms, dental casts and photographs: severity of malocclusion (Salzmann index) and office charts.	50% of variation in treatment duration was explained by: number of extracted premolars, number of broken appointments, pre-treatment mandibular plane angle, pre-treatment ANB angle and pre-treatment Salzmann index. Finishing was a source of variation in duration.	

Study ID	Intervention	Participants (sample size)	Outcomes Measured and Factor Investigated	Conclusion	Comments
Vig et al. 1990	Telephone survey to determine whether a systematic relationship existed between the relative frequency of extraction treatment and the duration of active appliance therapy.	238 Michigan orthodontists, 5 practices, records of 438 patients.	Telephone survey: to determine the estimated extraction rate and difference in treatment duration between extraction and non-extraction approaches.	Differences in duration of treatment were apparent when extraction and non-extraction patients within each individual practice were compared. Treatment who had extractions was more likely to be longer. The sampling method to identify high and low extraction practices obscure differences by confounding .	90% response rate
McGuinness and McDonald (1998)	Retrospective, records of patients treated by a single postgraduate vs. patients treated by 2 postgraduate students.	Clinical records of patients treated with fixed appliances in a district general hospital orthodontic department	Pre-treatment and post-treatment PAR score of study models. Length of treatment time.	Change in operator contributes significantly to a lengthening in treatment times in fixed orthodontic appliance therapy	
Beckwith et al. (1999)	Retrospective, to identify factors that influence orthodontic treatment duration	Records collected from 5 offices in Kansas City and Denver (n=140)	31 variables related to patient characteristics, diagnostic factor, modality of treatment and patient cooperation	About 50% of variation explained by: number of missed appointment, number of replaced brackets and band, number of treatment phases, number of negative chart entries oral hygiene and headgear.	

Study ID	Intervention	Participants (sample size)	Outcomes Measured and Factor Investigated	Conclusion	Comments
Turbill et al. (2001)	Retrospective, to clarify factors associated with treatment duration	Systematic 2% sample of cares completed in National Health Service practices in England 1506 cares from 723 practices in England and Wales.	Characteristics of practitioners, patients, malocclusion, treatment variables and outcomes.	Factors that increased treatment duration were fixed appliances, multiple phases in treatment, premolar extraction and correction of AP buccal occlusion. Age, buccal segment , malocclusion, DHC-IOTN grade 5 and orthodontically qualified clinician .	
Järvinen et al. (2004)	Retrospective , to investigate factors that affected the duration of orthodontic treatment in children	Records of 93 patients, age 7-13 years old at the start of treatment	Duration of treatment and 15 variable describing patient, age at the start of treatment, gender, progress of treatment, occlusal status, skeletal deviation, gender, malocclusion classes (Angle), type and number of appliances used, number of missed appointments and main additional diagnosis. Explained about 40% of variation in treatment time.	Treatment of class I and class II patients with a combination of fixed and removable appliances, early start, high number of appliances used and missed appointments prolong duration of treatment.	
Melo et al. (2013)	Retrospective, observational of records to investigate how different variables influence treatment time in adult patients	Treated by 3 experienced orthodontics (n=70)	Treatment time, age, gender, facial pattern, severity of malocclusion (PAR index) sagittal relationship of canines, type of brackets, tooth extraction, missed appointments, orthodontic appliances issues/breakages	Missed appointments and number of appliance breakages predicted about 40% of overall variability in treatment time. Treatment duration in adults is mainly influenced by patient compliance.	

2.7.8 Cervical Vertebrae Maturation (CVM) Stage

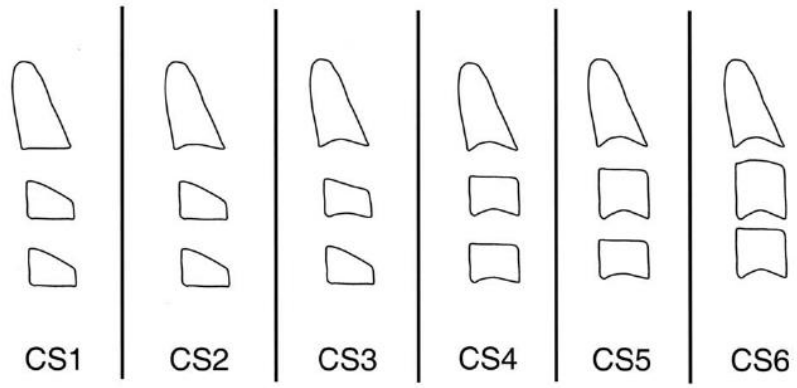
Baccetti et al., (2000) attempted to determine the best timing for treatment, with functional appliances such as Twin-Blocks, in a way that maximises the dento-alveolar and the skeletal changes induced by the treatment. This concept relies on the fact that the growth rate of the mandible varies between individuals and that it is influenced by the pubertal peak spurt (Mitani and Sato, 1992). Several attempts have been made to establish the best indicator for mandibular growth rate, pubertal spurt and as a measure for the skeletal maturity. Currently, some of the available indicators are body height, hand and wrist bone development, development and eruption of the dentition, menarche, changes associated with voice, breast development and cervical vertebrae maturation (Sullivan, 1983, Fishman, 1982, Hagg and Taranger, 1982, Lamparski, 1972)

The characteristics of an ideal indicator are that it should: be accurate, be easy to apply, form a part of routine treatment, have little risks or side effects, not be based on retrospective data and be possible to apply with minimal intervention (Baccetti et al., 2005). Among the previously mentioned indicators; body height can be easily applied, however, it requires close monitoring, involving several measurements, over a prolonged period of time and there is a great possibility that the identification of the growth spurt will be missed (Moore et al., 1990). As an indicator, hand and wrist ossification is a very complicated index to apply, requires specialist knowledge and additional exposures to radiation (Isaacson et al., 2008). Dental development and eruption is versatile but its variability makes it unsuitable to be used as a reliable indicator (Hagg and Taranger, 1982). Although menarche, voice changes and breast development can be identified, it can be considered a sensitive topic to be discussed in the orthodontic setting. The cervical vertebrae maturation (CVM) stage was proposed as a quick, reliable, easily applied index of skeletal maturity and does not require an extra exposure to radiation (Franchi et al., 2000; Rainey, 2013).

Baccetti et al., (2000) found a strong correlation between cervical vertebrae maturation and mandibular growth rate. They looked at the best timing of treatment by recruiting two groups of patients undergoing orthodontic treatment with the Twin-Block appliance. The two groups had different levels of skeletal maturity based on their cervical vertebrae maturation. They evaluated the amount of change achieved during the treatment and determined the best time for treatment. They used the method developed by Lamparski (1972), modified by O'Reilly and Yanniello (1988), and based on dividing the pubertal period into six stages, which were

correlated to the six stages of the cervical vertebrae maturation. Each phase has characteristic changes to the shape and the dimensions of the 2nd, 3rd, 4th, 5th and 6th cervical vertebra.

Figure 2. 3: Stages of Cervical Vertebrae Maturation (Baccetti, T., Franchi, L. and McNamara Jr.A. (2005) 'The cervical vertebral maturation (CVM) method for the assessment of optimal treatment timing in dentofacial orthopaedics'. Seminars in Orthodontics. 11 (3), 119-129). Used with permission of RightsLink Copyright Clearance Centre and Elsevier.



The stages can be categorised under three main groups, before peak (Stages 1-3, accelerative growth), pubertal growth peak (between Stage 3 and 4) and after peak (Stages 4-6, decelerative growth). The skeletal maturation measure was used in this study to categorise the recruited patients into being treated before the pubertal growth spurt or being treated during or immediately after the pubertal growth spurt. From the results of this study, it was observed that more desired skeletal changes took place in the group that started Twin-Block treatment during or after the mandibular growth pubertal spurt, when compared with the early treatment group. All these skeletal changes contribute to the correction of the Class II skeletal antero-posterior discrepancy. These observations should be interpreted with caution as they were derived from a retrospective study, during which several methodological flaws were detected (e.g. no sample size calculation was presented, no randomisation or blinding of assessors was performed, intra-observer and inter-observer reliability were not presented clearly).

In conclusion, starting Twin-Block treatment a little later is thought to be a more favourable choice because although starting the treatment early would help in reducing the incidence of trauma to maxillary incisors and improve self-esteem (O'Brien et al. 2003a; 2003b, O'Brien et al. 2009b), it can have many disadvantages. These disadvantages include the skeletal changes taking place over a longer period of time as the treatment has started early and the post-functional treatment or retention period would include the pubertal growth spurt during

which the growth pattern may re-establish itself into a skeletal class II discrepancy causing most of the corrections to relapse.

Franchi et al., (2000) carried out an investigation to test the association between cervical vertebral maturation, body height and mandibular growth. They concluded that the peak of maxillary and mandibular growth takes place in very close association with the peak in body height, either at the same time or immediately after it. However, these results should be interpreted with caution as the sample was derived from a historical sample (University of Michigan Growth Study), sample size calculation was not performed, blinding and randomisation were not performed, intra-observer reliability was measured only for a single examiner and not for both of them. Based on the work by Nanda (1987), body height is a very reliable measure for the assessment of skeletal maturity. This is supported by Sullivan (1983) who suggested that measuring the standing height would enable the pubertal growth spurt to be predicted. This could then be used to identify the optimum time for orthodontic treatment to coincide with the increased rate of growth during the pubertal growth peak (Sullivan, 1983). Sullivan's measurements were based on height velocity charts (Tanner et al., 1966a; 1966b). The drawback of using height as an indicator is that it requires the height to be measured over a number of visits, arranged over regular time interval and have sufficient data points to be able to draw a curve of growth velocity for a patient. Also, the peak velocity may only be identified once it has passed and the curve starts to drop.

To avoid this disadvantage, the idea was to use a single radiographic exposure to evaluate the skeletal age, but for that radiographic exposure to be ideal, it has to include some specific properties. These were that it should be valid and show sensible results when compared with other biological indicators such as body height; it should be clear and effective at identifying the peak of mandibular growth and it should not need any extra radiographs other than those taken for routine orthodontic assessment eg. lateral cephalogram or orthopantomogram (Baccetti et al., 2005, Isaacson et al., 2008). All these criteria were met when cervical vertebrae maturation was used to assess the skeletal maturity on a lateral cephalometric radiograph. Another observation from this study was that the peak in skeletal growth, the peak in mandibular growth and body height, all took place during the same time interval, which was coincident with the change between cervical vertebrae maturation (CVM) Stage 3 and Stage 4.

In conclusion, the cervical vertebral maturation is an attractive measure for orthodontists to assess skeletal maturity and to detect the pubertal growth peak in craniofacial growth rate, in general and specifically in mandibular growth rate (Franchi et al., 2000). Therefore, for Twin-Block treatment, it has been suggested that the best timing for peak growth would be to commence the treatment during or immediately after the pubertal growth spurt, which coincides with time between Stage 3 and Stage 4 of cervical vertebrae maturation. This timing would aim to maximise the small favourable skeletal changes, including an increase in mandibular length, ramus height and condylar growth (Baccetti et al., 2000).

However, there is some controversy regarding the staging of cervical vertebrae maturation and in particular its reliability, reproducibility and validity (Gabriel et al., 2009, Hassel and Farman, 1995).

Hassel and Farman (1995) assessed the radiographs of 220 patients (equally divided between males and females), taken from Bolton-Brush growth study at Case Western Reserve University. They assessed the left hand-wrist radiograph and the lateral cephalogram to investigate the correlation between skeletal maturation indicators (SMIs) determined from hand-wrist radiograph (following the Fishman's method that was developed in 1982) and the cervical vertebrae maturations indices (CVMIs) determined from the lateral cephalogram. Inter-operator and intra-operator reliability of staging the radiographs were measured. The results revealed a significant agreement for intra- and inter-operator reliability. Also, a high level of correlation was detected between SMIs and CVMIs (Hassel and Farman, 1995).

Another study followed a similar methodology with a different sample (Garcia-Fernandez et al., 1998). Their sample was taken from patients' files from the Orthodontic Graduate Program, Mexico and had both the hand-wrist and lateral cephalometric radiograph taken on the same day. Fishman's method (Fishman, 1982) was used to assess the SMIs and Hassel and Farman (Hassel and Farman, 1995) modification of the Lamparski's criteria (Lamparski, 1972) was utilised in the assessment of the CVMIs. The investigation concluded that there was no significant difference between those two methods as a high level of agreement was shown. The CVMI was therefore shown to be a valid and race-neutral method of assessing skeletal maturity.

Franchi et al., (2000) investigated the validity and reliability of the CVM method as an indicator for skeletal maturity. Their sample was selected from files from the University of Michigan Elementary and Secondary School growth study. The lateral cephalograms were

used to determine the skeletal age, regardless of the chronological age, using a modified Lamparski's method. Their longitudinal data provided the corresponding statural heights of the used cephalograms. The results showed a high level of intra- and inter-operator agreement. The study concluded that the CVM method was a reliable and a valid method for the evaluation of skeletal maturity and the identification of the pubertal peak in craniofacial growth rate in individuals.

Meanwhile, Pancherz and Szyska, (2000) published a study that investigated the reliability and validity of the cervical vertebrae analysis (Hassel and Farman, 1995) and the hand-wrist bone analysis (Hagg and Taranger, 1980a; 1980b) in evaluation of skeletal maturity. To assess the reliability, the inter-observer and intra-observer variance were measured. The validity of both methods was assessed by relating the skeletal maturity stages to three growth periods on the growth curve (pre-peak, peak and post-peak). The results showed a high level of reliability and validity of the cervical vertebrae analysis that was comparable to the hand-wrist bone analysis

Two other studies, (Gandini et al., 2006; Uysal et al., 2006) investigated the correlation between skeletal maturity and the CVM. The method used to assess the skeletal maturation, from hand-wrist radiograph, was the one developed by Björk (1972) and Grave and Brown (1976) and those were used in both studies. However, for assessing the CVM stage, one of the studies used Hassel and Farman method (Hassel and Farman, 1995), while the other used the improved version of Baccetti's method (Baccetti et al., 2002). Both studies demonstrated a moderate to high level of reliability and validity.

Gabriel et al. (2009) also investigated the reliability and reproducibility of the CVM method but showed only moderate levels of intra-observer and inter-observer agreement, unlike the results obtained from previous literature. They used the CVM method developed by Baccetti et al., (2005) and aimed to reduce the bias in previous studies. Gabriel and co-workers observed that several studies used tracings of the cervical vertebrae rather than the unmodified lateral radiographs, which they thought was a potential source of bias. Also, they noted that in some studies, the observers assessing the CVM stages were the authors themselves and as such, would possess a research-level of understanding compared to another orthodontist. This may, in turn, have led to an over estimation of the reliability of the CVM staging method in those studies. In addition, the sample size of images in those studies was small and appeared to be selected from a bigger pool, which might have introduced selection

bias and lack generalisability when applied to a larger sample. In addition, statistical flaws were detected as inappropriate statistical analyses were used to address the research question; i.e. correlation was used instead of agreement (Hassel and Farman, 1995; Franchi et al., 2000; Uysal et al., 2006).

Nestman et al., (2011) investigated the reliability of the CVM method as they considered that bias was evident in the previous literature and as a result the conclusions were questionable. Bias could have been introduced in the previous literature as several studies have used small sample that seems to be chosen from a larger sample and random selection was questionable, in such cases ascertainment bias and selection bias could have taken place in those studies. Other studies have used tracings of the lateral cephalograms rather than the lateral cephalogram itself to assess the CVM stage and this could allowed information bias and measurement bias to occur. Also, in some of those studies the authors were the investigators or the observers and as they may have a researcher level in the investigated topic, this could have introduced observer bias and reporting bias. In addition, some studies have used inaccurate statistical analyses which may lead to invalidate the obtained results. Nestman and his group recruited the same observers and used the same sample as Gabriel et al., (2009), which was derived from the Iowa growth study. They investigated the inter-observer reliability for determination of the CVM stage based on Baccetti et al., (2005). For the intra-observer reliability, they included the results from Gabriel et al. (2009) in the statistical analysis. Their results showed a moderate level of agreement but concluded that overall there was poor reproducibility due to difficulty of determining the shape of the cervical vertebra (trapezoidal, rectangular horizontal, square or rectangular vertical).

However, Rainey (2013) assessed the reliability and the reproducibility of the CVM method and attempted to avoid the drawbacks noticed in previous studies. She looked at the inter-observer and intra-observer agreement of the CVM Index using a sample of 72 full cephalograms and 20 observers. She found that both agreements were substantial, suggesting that this method can be considered as reliable and reproducible.

As discussed earlier (Franchi et al. 2000), the CVM staging method possesses several advantages i.e. its reliability, validity and ease of application. The CVM staging can therefore be utilised as a diagnostic tool to augment and improve the treatment delivered by the orthodontist; however, it should not be used as the only and absolute diagnostic tool on which to base decisions.

Table 2. 2: Summary of the Studies investigating the CVM

Study ID	Intervention	Participants (sample size)	Outcomes Measured and Factors Investigated	Conclusion	Comments
Baccetti et al. (2000)	To evaluate skeletal and dental changes induced by Twin-Block appliance	36 patients records. Two groups early (n=21) vs. late (n=15) based on CVM. Control sample (untreated class II from University of Michigan growth study, selected on basis of CVM stage, (n=30),	Cephalometric measurements	Optimal timing for Twin-Block therapy of class II is during or slightly after the onset of the pubertal peak in growth velocity. Late Twin-Block treatment produces more favourable effects when compared to early treatment	
Franchi et al. (2000)	Retrospective, to analyse the validity of 6 stages of CVM as a biologic indicator for skeletal maturity.	24 subjects selected from University of Michigan Growth study.	Peak in statural height and mandibular length (Cvs3 to Cvs4) from records.	CVM appears to be an appropriate method for appraisal of mandibular skeletal maturity in individual patients on the basis of a single cephalometric observation.	
OReilly and Yannietto (1998)	Retrospective cephalometric study to assess the relationship of CVM and mandibular growth changes in annual lateral cephalometric radiographs.	13 Caucasian subjects from Bolton-Broadbent growth study	Measured mandibular length, corpus length and ramus height	CVM stages are related to mandibular growth changes during puberty. Stages 1-3 occurred prior to peak velocity, with 2 and 3 in the year immediately preceding peak growth velocity.	
Rainey (2013)	Two phased investigation to assess reliability and reproducibility of CVM assessment.	A sample lateral cephalograms taken at Liverpool University Dental Hospital, UK. And a sample of ideal images (n=72).	Agreement among orthodontists in training and specialist orthodontists. (intra-observer and inter observer reliability)	Intra-observer and inter-observer agreement were substantial. This method suggests that method of CVM clarification is reproducible and reliable.	
Hassel and Farman (1995)	Retrospective study to develop a CVM index	Lateral cephalometric and left hand wrist radiographs from the Bolton-Brush Growth Centre (n=220)	Skeletal maturation from hand-wrist radiograph. CVM stage from tracings of lateral cephalograms.	By using the lateral profiles at the 2nd, 3rd and 4th cervical vertebrae, it was possible to develop a reliable ranking of patients, according to the potential for future adolescent growth potential.	Using tracing of lateral cephalogram

Study ID	Intervention	Participants (sample size)	Outcomes Measured and Factors Investigated	Conclusion	Comments
Pancherz and Szyska (2000)	To compare reliability and validity of CVM and hand-wrist analysis in evaluating skeletal maturity.	N=48 subjects.	From lateral head radiographs, hand-wrist radiograph. Individual velocity growth curves of standing height including the pubertal peak of growth	CVM has a comparable high reliability and validity as the hand-wrist bone analysis and could replace it.	
Gandini et al. (2006)	A radiographic analysis to compare skeletal maturation as measured by hand-wrist bone analysis and by cervical vertebral analysis	(n=30) patients undergoing orthodontic treatment	Concordance and correlation between hand-wrist bone analysis and CVM	Vertebral analysis on a lateral cephalogram is as valid as the hand-wrist bone analysis with the advantage of reducing the radiation exposure.	
Uysal et al. (2006)	Investigate relationship between chronological age and CVM: Identify relationship between chronological age and maturation from hand-wrist radiographs. Determine correlations between CVM and maturation from hand-wrist radiographs in Turkish population	(n=503) Turkish lateral cephalogram hand-wrist radiographs from Orthodontics Department, Faculty of Dentistry, Turkey.	CVM and skeletal maturation from hand-wrist radiograph and correlation among them	CVM stages are clinically useful maturity indicators of pubertal growth period in Turkish subjects.	
Garcia-Fernandez et al. (1998)	To assesss skeletal maturity, determine if the CMV would correlate with maturation indicated by hand-wrist radiograph in a Mexicans.	(n=113) Orthodontic graduate programme, Mexican.	Lateral cephalometric and hand-wrist radiograph ,CVM and SMI for agreement	No significant difference between the 2 techniques.	

Study ID	Intervention	Participants (sample size)	Outcomes Measured and Factors Investigated	Conclusion	Comments
Gabriel et al. (2009)	To evaluate reproducibility of CVM stage determination	Randomly selected 30 individual and 30 pairs of cephalometric radiographs of white subjects from longitudinal growth records of untreated subjects. 10 orthodontists	Inter-observer and intra-observer reliability of radiographs	All degrees of inter-observer and intra-observer agreement were moderate. CVM cannot be recommended as a strict clinical guideline for timing orthodontic treatment	
Nestman et al. (2011)	To further investigate reproducibility of individual vertebral pattern. To determine which of the individual CVM vertebral patterns could be clarified reliable or not.	30 cephalometric radiographs of white subjects. 10 orthodontists	Inter-observer and intra-observer reliability of radiographs	Weakness in CVM result from difficulty in clarifying for vertebral bodies, C3andC4 shape. This lead to poor overall reproducibility and not recommended as strict clinical guideline for timing orthodontic treatment.	

As a result, it has been suggested that treatment duration may be influenced by the CVM stage of the patient at the start of the orthodontic treatment. It was therefore thought that this variable should be considered and be included in the statistical analysis as an independent variable, if possible. However, if the availability or the quality of the lateral cephalograms were questionable, the CVM staging would be excluded from the statistical analysis.

2.8 RESEARCH PROBLEM

Recently, the modified Clark's Twin-Block appliance has become one of the most widely used functional orthodontic appliances in the UK (Chadwick et al., 1998) and is usually followed by a second phase of treatment. As the modified Clark's Twin-Block is used in growing patients, it can achieve small skeletal changes in addition to the dento-alveolar changes that are produced by using the Twin-Block and the fixed appliances combined (Thiruvenkatachari et al. 2013, Lund and Sandler, 1998, Gill et al., 2005). The benefits gained from undertaking functional treatment in an early adolescent population could reduce the complexity of treatment for severe malocclusions and potentially avoid a surgical approach to treatment, with all its associated complications, if treatment were left until late adolescence or adulthood (Thiruvenkatachari et al. 2013).

Functional appliance treatment can therefore widen the envelope of tooth movement achieved by orthodontic treatment alone. In addition, functional appliance treatment can be commenced earlier than fixed appliance treatment, i.e. in the mixed dentition while waiting for the remaining permanent teeth to erupt. Using this appliance gives the possibility of finishing treatment at a younger age; especially if a second phase of treatment is not required and a satisfactory result has been achieved at the end of the functional phase, when compared with a single course of fixed orthodontic treatment (Gill et al., 2005). On the other hand, functional/fixed treatment is comprised of two courses of treatment with a possible transition phase in between. The potential need for a transition phase for patients starting treatment earlier, can make clinicians reluctant to start treatment earlier because it may prolong the total treatment duration which can, in turn, increases the risk of developing side-effects related to the orthodontic treatment and the burden on the patients' compliance (Fleming et al., 2007). However, the advantage gained and wider scope of movements enabled by the functional/fixed combination makes it a tempting approach for clinicians.

When the clinician decides to use a functional appliance, such as the modified Clark's Twin-Block, the dilemma arises regarding when is the best time to start the treatment with view to

aiming for the best outcome and the shortest possible treatment duration. This then leave the clinician with the question: Is it better to start earlier based on the evidence that a better compliance can be accomplished with younger patients, despite the possibility that the treatment might be prolonged for those patients? Or is it better to delay the functional/fixed orthodontic treatment on the basis that the treatment will be shorter since it will be continuous without the need to wait for the permanent dentition to erupt before the start of the second phase of the treatment? Choosing the early approach suggests that, in most of the cases, the clinician will be under the pressure by parents and children to start the treatment as early as possible aiming to protect the child from potential trauma and being bullied or teased by peers for their dental appearance.

The other question that would arise is; what is the best cut-off point that can be used to differentiate between early starters and late starters? Is it the chronological age? Is it the level of dental development? Or is it the skeletal growth and development? Which of these will be the most influencing factor on treatment duration? In addition, what else could have a significant influence on the duration of the treatment in the functional phase on its own and on the total treatment duration? Which one will have the greater influence? Is it age, stage of dental development, level of compliance, the complexity of the original malocclusion or the level of skeletal maturity?

This research will attempt to contribute to the evidence of how to advise patients regarding the best time to start the functional/ fixed treatment. What are the factors that could be associated with a longer or a shorter treatment?

An aim of clinicians is to provide their patients with the best orthodontic treatment in the shortest possible time, while maintaining the patient's right to make their own decision based on the knowledge of the advantages and the disadvantages related to all the available approaches. However, despite the availability of high quality research in this field, published in recent years, the evidence was not conclusive when the current research project was conceived in 2010. The aim of this study was therefore, to investigate and determine the factors that had the greatest influence on treatment duration, specifically when the treatment was composed of two phases; a functional phase, using Twin-Block appliances, followed by a second phase of fixed appliances.

CHAPTER 3

3.0 AIMS AND OBJECTIVES

The aim of this investigation was:

- To investigate the factors that influence the duration of treatment in patients, with a Class II malocclusion, who had undergone orthodontic treatment with a modified Twin-Block appliance followed by a fixed appliance.

In order to achieve the aim of this investigation, the main primary objectives were to:

- Investigate the factors that could influence the duration of the functional phase of orthodontic treatment i.e. length from fitting the functional appliance until the end of the active functional phase. The factors, at the start of treatment, include the:
    - Chronological age - whether younger or older patients have a shorter functional phase;
    - Stage of dental development - whether those at an earlier or later stage of dental development have shorter functional phase;
    - overjet - whether those with a larger or smaller overjet have shorter functional phase;
    - CVM stage (as an indicator for skeletal maturity level) – whether those at an earlier or later CVM stage have shorter functional phase.
- Investigate the factors that could influence the total duration of orthodontic treatment: ie duration from fitting the functional appliance until the date of debonding (removal of the fixed appliance);
    - Chronological age - whether younger or older patients have a shorter total duration of orthodontic treatment;
    - Stage of dental development - whether those at an earlier or later stage of dental development have shorter total duration of orthodontic treatment;
    - Overjet - whether those with a larger or smaller overjet have shorter total duration of orthodontic treatment;
    - CVM stage (as an indicator for skeletal maturity level) – whether those at an earlier or later CVM stage have shorter total duration of orthodontic treatment;

- Dental extractions - whether those who have or do not have extractions, as part of the orthodontic treatment, have shorter total duration of orthodontic treatment
- Number of the treating clinicians (as an indicator of compliance) - whether those who have more or fewer treating clinicians have shorter total duration of orthodontic treatment
- Number of appointment**s** the patient failed to attend (FTAs) (as an indicator of compliance) - whether those who have more or fewer FTAs have shorter total duration of orthodontic treatment.

CHAPTER 4

4.0 METHODS

4.1 ETHICAL APPROVAL AND CONSENT

The study protocol was approved by the West of Scotland Research Ethics Committee, Greater Glasgow and Clyde NHS on the 11th of March, 2013 (REC reference number 13/WS/0060). This is shown in appendix 10.11.

4.2 DESIGN

The study was a retrospective, observational study based on the analysis of data collected from the patients records.

4.3 SETTING

Orthodontic Department at Liverpool University Dental Hospital, UK.

4.4 THE SAMPLE

The study included patients who had received a Twin-Block appliance as a first phase of their orthodontic treatment at Liverpool University Dental Hospital (LUDH) between 1st of January 2005 and 31st of December 2008 inclusive.

4.4.1 Sample Size Calculation

In an attempt to detect a medium effect size (f^2=0.15) in the duration of the functional phase of treatment with 80% power, an alpha of 0.05 and 3 predictor variables, a sample size of 76 subjects would be required.

In an attempt to detect a medium effect size (f^2=0.15) in the duration of the total orthodontic treatment with 80% power, an alpha of 0.05 and 6 predictor variables, a sample size of 97 subjects would be required (Cohen, 1988).

4.4.2 Inclusion Criteria

In this study, patients were included if they had:

1) Undergone a course of orthodontic treatment involving a first phase of treatment with a Twin-Block appliance between the 1st of January 2005 and 31st of December 2008;
2) A Class II dental malocclusion;
3) Required a functional/fixed orthodontic approach to orthodontic treatment;
4) Completed two phases of orthodontic treatment;
5) Records available in a satisfactory condition.

4.4.3 Exclusion Criteria

In this study, patients were excluded if they:

1) Had a congenital cleft of the lip and/or palate or any craniofacial-syndromes.
2) Had Twin-Block appliance treatment as part of their orthodontic treatment, but did not proceed into a second phase of fixed appliances for any reason e.g. a low level of compliance, inadequate level of oral hygiene, or low level of complexity and limited need for fixed orthodontic treatment.
3) Did not complete the two phases of orthodontic treatment.
4) Had incomplete records that would result in missing data.

4.5 PROVISION OF ORTHODONTIC TREATMENT

The orthodontic treatment was carried out in the orthodontic department at LUDH and performed by consultants, specialist trainees (Senior Registrars – FTTAs, Specialty Registrars - StRs) and postgraduate students under consultant supervision.

4.6 DATA SOURCE

Data to identify patients who had received treatment with the Twin-Block appliance were extracted from the laboratory records (diary / log-book) of Liverpool University Dental Hospital, manually.

4.7 PATIENT IDENTIFICATION

One hundred and twenty-eight patients, who received a Twin-Block appliance at some stage of their orthodontic treatment at Liverpool University Dental Hospital between 1st of January 2005 and 31st of December 2008 inclusive, were identified.

4.8 RECORD RETRIEVAL

4.8.1 Case Notes

The case notes of the patients were requested in batches from the Medical Records Department of Liverpool University Dental Hospital. Those records not initially made available to the investigator (AM) were requested a second time. If notes were still missing the second time, the investigator carried out a hand search for the case notes, following initial familiarisation with the archiving system.

A second hand search was carried out by the investigator (AM) for the remaining missing case notes. If still not retrieved, the case notes in question were labeled as being unavailable. From those case records made available, all relevant data were extracted and entered onto a data collection sheet

4.8.2 Study Models

Study models were obtained from the model storage room at the Orthodontic Department at Liverpool University Dental Hospital to confirm the teeth present at the start of the treatment, the overjet (mm) at different key stages of treatment and the extraction pattern identified from the case records.

4.9 DATA COLLECTION SHEET

A specifically developed data collection sheet was designed and used to record all the relevant information obtained from the case notes and study models. The data collection sheet is shown in Appendix 10.1.

From the available patients' notes, the following data were extracted and entered onto the data collection sheet.

4.9.1 Patient Identification Number:

A reference number, unique for each patient's records, was allocated to allow easy case note identification on separate occasions. This also anonymised the data collection sheets in case they were lost or misplaced.

4.9.2 Demographic Data Extracted:

Demographic data extracted were:

a. The date of birth - This was used to determine the patients age at the start of the orthodontic treatment and at key stages of the orthodontic treatment.
b. The gender - male or female.

4.9.3 Number of Clinicians/ Consultants:

a. The number of the clinicians treating the patient.
b. The number of the consultants supervising or treating the patient.

4.9.4 Dates and Durations of Key Stages of the Orthodontic Treatment:

a. The date of the start of the functional treatment: The date on which the Twin-Block appliance was fitted.
b. The date of the end of active functional treatment: The date on which the Twin-Block appliance was stopped, the transition phase was started or the teeth were bonded up.
c. The date of bond-up: The date on which the fixed appliance was placed and the teeth were bonded/ banded.

d. The date of the end of orthodontic treatment: The date on which the fixed orthodontic appliance was removed and a retainer, when required, was placed.
e. The duration of the functional appliance therapy (months): Calculated as the duration between the date of the start of the functional treatment until the date of the end of active functional treatment.
f. The duration of the fixed appliance treatment (months): Calculated as the duration between the date of the bond-up appointment until the date of the end of orthodontic treatment.
g. The total duration of orthodontic treatment (months): Calculated as the duration between the date of the start of the functional treatment until the date of the end of orthodontic treatment. This measurement also included the time spent in transition from the Twin-Block appliance to fixed appliances.

4.9.5 Number of the Visits:

a. The number of scheduled visits: The number of the visits that were arranged between the clinician, the patient and the reception desk and attended by the patient.
b. The number of un-scheduled visits: The number of broken brace appointments attended by the patient, also called emergency clinics.
c. The number of UTA visits: The number of the appointments that the patient was unable to attend due to an acceptable reason, of which Liverpool University Dental Hospital was informed.
d. The number of FTA visits: The number of the appointments that the patient failed to attend without an explained reason.

4.9.6 Overjet Progress (mm)

a. The starting overjet: The overjet measured at the start of the treatment.
b. The end of functional treatment overjet: The overjet measured at the end of active functional treatment.
c. The bond-up overjet: The overjet measured at the bond-up appointment.
d. The end of treatment overjet: The overjet measured at the end of the orthodontic treatment indicated by the debond visit.

4.9.7 Type of Transition:

Type of transition is classified into the following options:

1-When the patient did not have a transition phase; this was called no transition.

2-When a steep and deep appliance (upper removable appliance) was fitted for full-time or part-time wear; this was called steep and deep appliance.

3-When the patient wore the Twin-Block without any alteration at night-time only; this was called night-time only.

4-When the Twin-Block appliance underwent trimming and removal of the posterior blocks, while maintained wearing the Twin-Block full-time; this was called reduction of blocks.

5-When the Twin-Block appliance underwent trimming and removal of the posterior blocks, while wearing the twin-block night-time only; this was called reduction of blocks and night-time only.

6-When the patient wore an extra-oral appliance (the headgear) at night-time only; this was called Headgear.

7- When the patient wore a steep and deep appliance, had the of blocks in the Twin-Block appliance reduced, in addition to wearing the Twin-Block at night-time only during the treatment period; this was called 2+5.

4.9.8 The Extractions Carried out for Orthodontic Purposes (with the Exception of Third Molars)

The teeth, that were extracted, were recorded in terms of premolars, molars and other teeth, together with the site (jaw) involved in the extraction procedure.

The exact number of teeth extracted was recorded.

Teeth were charted using The Palmers Notation i.e. grid ---|--- as shown (Appendix 10.8) on the data collection sheet.

4.9.9 Stage of Dental Development

The date the teeth were charted was recorded.

Tooth chart - the teeth were charted using The Palmers Notation as shown (Appendix 10.8) in the data collection sheet.

Categorisation into early and late dental development was based on:

1) Early dental development: if none of the first premolars had erupted into the oral cavity and if less than the four first premolars had erupted into the oral cavity.
2) Late dental development: when all the four first premolars had erupted into the oral cavity.

4.9.10 Cervical Vertebrae Maturation Stage (explained in Appendix 10.2)

The CVM stage was determined by assessing the shape of the cervical vertebrae 2, 3 and 4 (Baccetti et al., 2005) when viewed on the lateral cephalogram radiographs.

a. Pre-treatment lateral cephalogram: this radiograph was used to analyse the CVM stage before starting the orthodontic treatment. This radiograph was taken before the start of the functional phase of the treatment.
b. Post-functional lateral cephalogram: this radiograph was used to analyse the CVM stage before the start of the fixed appliance phase of the orthodontic treatment. This radiograph was taken at the end of the functional phase of the orthodontic treatment.
c. Pre-finish lateral cephalogram: this radiograph was used to analyse the CVM stage before the end of the fixed appliance phase of the orthodontic treatment. This radiograph was taken near the end of the fixed phase of the orthodontic treatment.

4.9.11 Meeting Inclusion Criteria or not

A question was placed to check whether the patient has met the inclusion criteria or not.

If not, why not?

4.10 DATA TRANSFER

4.10.1 Computerised Method

In order to analyse the data collected on each data collection sheet, the data were entered into the software Statistical Package for the Social Science (SPSS version 20, Chicago, USA) for Windows.

4.11 RELIABILITY OF THE METHOD

4.11.1 Errors in Data Transcription

In order to ensure that the data entered manually onto the computer programme, from the data collection sheet, were accurate, two manual checks were carried out, on separate occasions and any necessary corrections were made. A printout of the entered data was also obtained and manually checked against the data collection sheet for each patient, to ensure that the transcription from the data collection sheet to the computer database was accurate.

4.11.2 Error Calculation

To confirm the computers calculation of the total treatment duration and other calculated durations, an error calculation was made. This involved checking by hand and comparing it with the data entered on the computer for 10% of the sample (n=8). The 8 case notes were selected randomly by a supervisor (NF), using sealed envelopes.

4.11.3 Intra-Examiner Reliability

A percentage agreement assessment was carried out to check the consistency of data collection for 10% of the patients case notes (same as in section 4.11.2) who met the inclusion criteria and completed the treatment. The case notes were re-examined blindly and data re-entered on to the data collection sheet 2 months after the initial data extraction.

The reliability of identifying the CVM stages was undertaken as part of a study undertaken at Liverpool University Dental Hospital, UK (Rainey 2003). The participants were consultants, FTTAs, StRs and postgraduate students who received training in the used of the improved version of the CVM staging method (Baccetti et al., 2005). Following the training the participants assessed 72 lateral cephalograms to the CVM stage from the radiograph displayed. This was repeated 3 months later, using the same radiographs in a different random order. The weighted kappa statistic was then used to assess inter- and intra-examiner agreement (Rainey, 2013).

4.12 STATISTICAL ANALYSIS

4.12.1 Descriptive Statistics

Statistical Package for Social Sciences software (SPSS version 20.0, Chicago, Illinois, USA) was used to analyse the data. Frequency and percentages were calculated for the categorical data.

Descriptive statistics including mean, median, standard deviation (SD), interquartile range, confidence intervals (CI), minimum and maximum values were calculated for continuous data related to the total sample of patients.

4.12.2 Statistical Methods

Descriptive statistics for the sample were calculated. Exploratory uni-variate analyses were undertaken, including the independent two-tailed t-test and correlation coefficients to assess associations between a single factor and the effect on the duration of the functional phase of treatment and on the total treatment duration. These factors were: chronological age, stage of dental development (early or late), the overjet, the stage of skeletal maturity (CVM stage) for both the functional and total duration, while presence or absence of extractions, number of

clinicians and the level of compliance (FTAs) were analysed for the total duration only. No adjustment for multiple testing was made in these exploratory analyses.

4.12.2.1 Statistical Methods for the Duration of the Functional Phase of Treatment

A multiple stepwise linear regression analysis was used to identify which of the following variables, i.e. chronological age, stage of dental development (early or late), the overjet and the stage of skeletal maturity (CVM stage), were significantly related to the duration of the functional phase of the treatment (months). Significance (α level) of all statistical tests was set at $p < 0.05$.

4.12.2.2 Statistical Methods for the Total Treatment Duration

A multiple stepwise linear regression analysis was used to identify which of the following variables, i.e. chronological age, stage of dental development (early or late), the overjet, the stage of skeletal maturity (CVM stage), presence or absence of extractions, number of clinicians and the level of compliance (FTAs), were significantly related to the total treatment duration (months). Significance (α level) of all statistical tests was set at $p < 0.05$.

As this was a retrospective study, it was recognised that missing data could be a problem and the level of missing data for each variable was considered prior to inclusion in the statistical analysis.

4.13 SUMMARY

This study aimed to assess the factors that influenced the duration of treatment in patients with Class II malocclusion who had undergone a course of orthodontic treatment including a functional appliance phase with a Twin-Block appliance followed by a fixed appliance phase. This study was based on a sample of patients who had attended and received their orthodontic treatment between the years 2005 and 2008 inclusive, in the Orthodontic Department at Liverpool University Dental Hospital.

CHAPTER 5

5.0 RESULTS

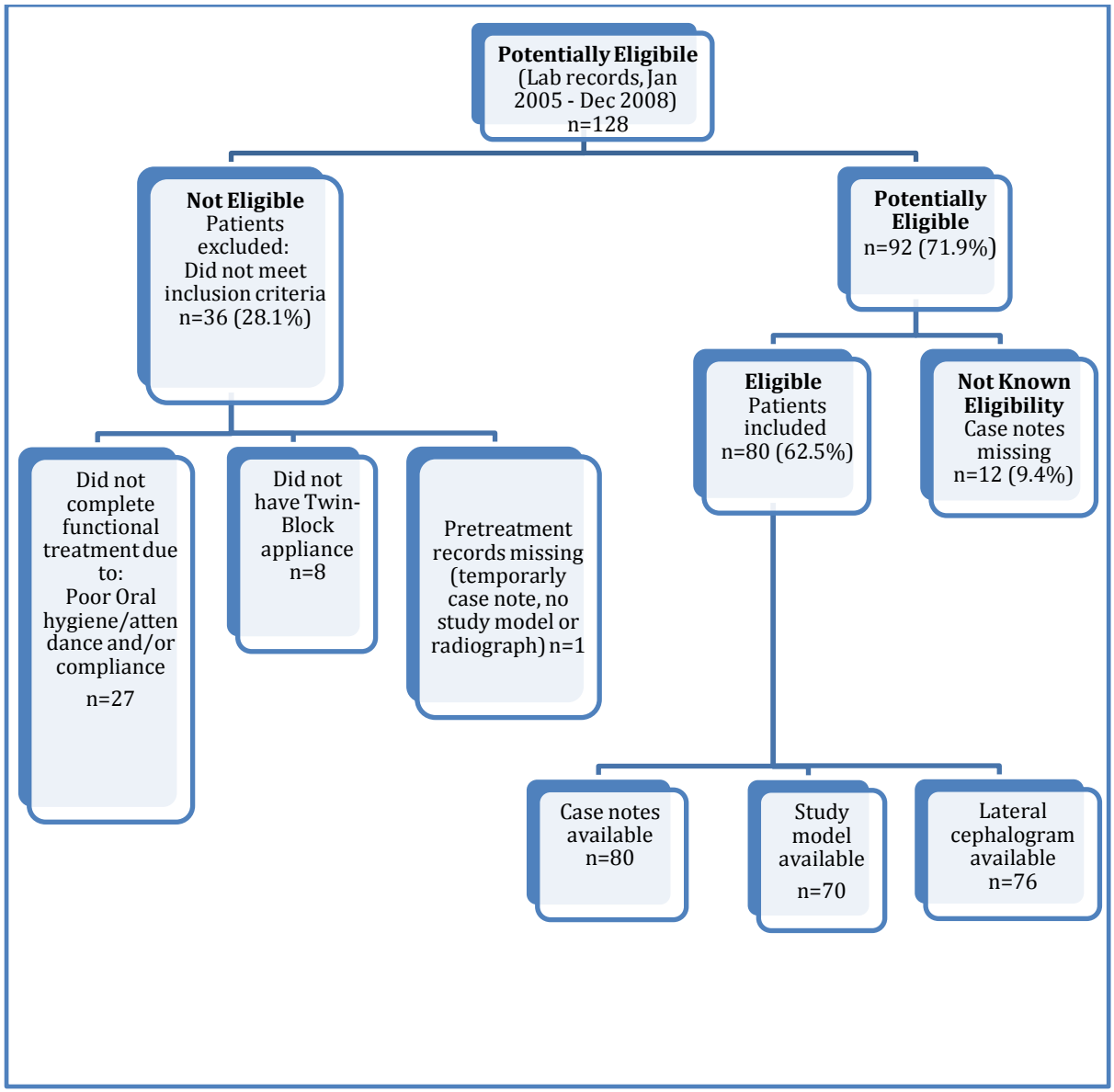
5.1 STUDY SAMPLE

A total of 128 patients were identified as having undergone a course of orthodontic treatment involving a first phase with a modified Clarks Twin-Block appliance at Liverpool University Dental Hospital between the 1st of January 2005 and 31st of December 2008 inclusive, from the Laboratory and Administration records. The case notes of the 128 patients were reviewed to assess whether the patients fulfilled the study's inclusion criteria or not.

Thirty-six patients (28.1%) were unsuitable for the current study, as they did not fulfill the inclusion criteria and 92 (71.9%) patients were potentially eligible however, the case notes of 12 (9.4%) patients were missing. These 48 patients were, therefore, excluded from this study. This left 80 (62.5%) patients fulfilling the inclusion criteria for the current study.

Of the thirty-six excluded patients (28.1%), the pre-treatment records were missing for 1 patient and 8 patients were wrongly identified as having had treatment with a Twin-Block. The reasons why the remaining 27 patients were excluded included: not completing the two-stages of treatment for reasons ranging between poor level of oral hygiene, poor attendance of the orthodontic appointments and poor compliance with the treatment modality. These reasons led to an early end to the treatment as the risks of further treatment outweighed the potential benefits that were to be gained. In addition, a few of those patients had a low level of treatment need which meant that they did not proceed to a second phase of treatment at the end of a successful first phase of treatment using the Twin-Block appliance. These numbers are demonstrated in Figure 5. 1.

Figure 5. 1: Flow Chart: Number and percentages of patients screened and included or excluded from the study.



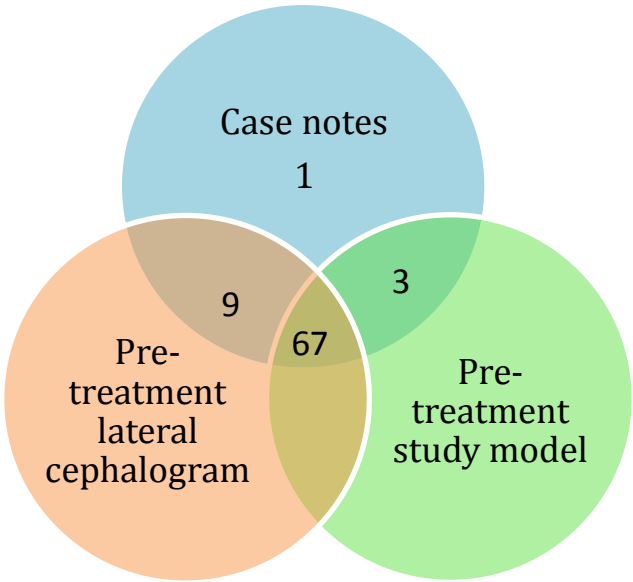
5.2 AVAILABILITY OF RECORDS

As this was a retrospective study, the availability of the records was a concern. Among the 92 potentially eligible subjects, only 80 subjects who met the inclusion criteria had case notes available. The remaining 12 subjects had to be excluded as their case notes were not available to confirm their eligibility for the study. In addition to the missing case notes, some of the study models and lateral cephalograms were missing. From the 80 included subjects, 10 had missing study models and 4 had missing lateral cephalograms. This can be demonstrated in Figure 5. 1 and Figure 5. 2.

Table 5. 1: Availability of records

Type of pre-treatment records	Available	%	Not Available	%
Case notes	80/92	87%	12/92	13%
Pre-treatment study model	70/80	88%	10/80	12%
Pre-treatment lateral cephalogram	76/80	95%	4/80	5%

Figure 5. 2: Venn diagram showing availability of records



5.3 DEMOGRAPHIC CHARACTERISTICS OF PATIENTS WHO COMPLETED FUNCTIONAL/ORTHODONTIC TREATMENT

The histograms of the distribution of the dependent variables revealed that the dependent variables (e.g. duration of the functional phase and the total orthodontic treatment duration) were slightly skewed. However, it was considered to be not sufficient to either invalidate the use of parametric descriptive analysis methods, such as the mean and the standard deviation, or necessitate replacing them by the non-parametric median and interquartile range. This decision was based on an expert advice from a professional statistician.

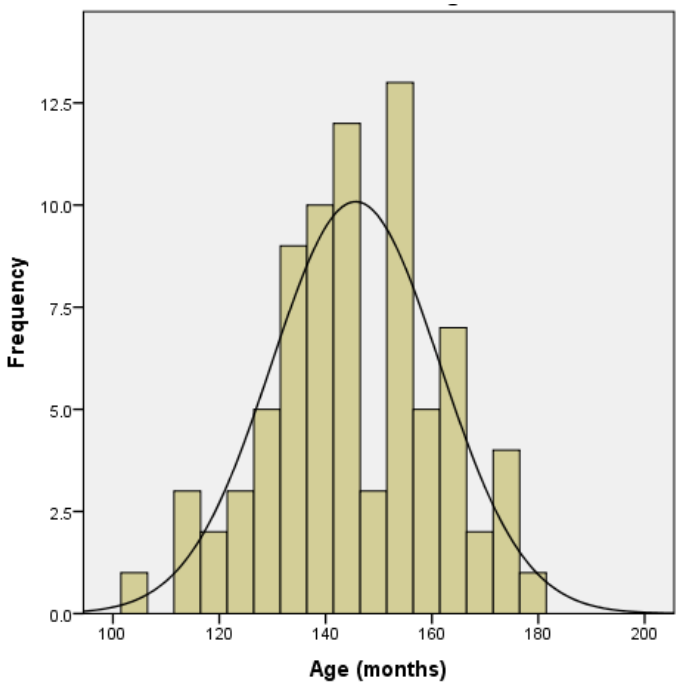
5.3.1 Gender

Of the patients who completed their functional/fixed orthodontic treatment, 34 were male (42.5 %) and 46 were female (57.5 %).

5.3.2 Age at the Start of the Treatment

The mean age of the patients at the start of the orthodontic treatment was 145.65 months (12.1 years) (SD=15.83 months). Further details are displayed in Figure 5. 3.

Figure 5. 3: A histogram showing the distribution of the age of the sample at the start of the treatment (months).

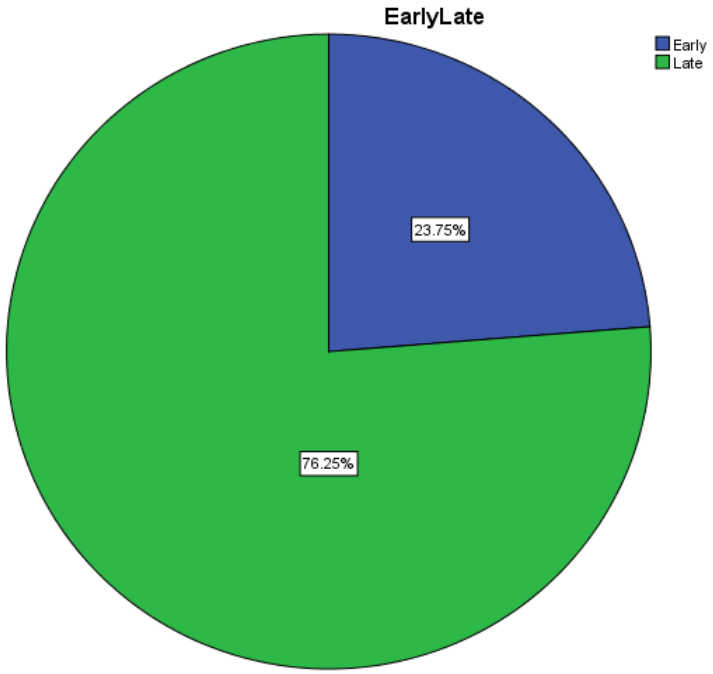


The mean age for males was 148 months (12.3 years) (SD= 14.7 months), whilst for females it was 143.9 months (12 years) (SD=16.4 months) at the start of the treatment. The youngest male and female were 115 months (9.6 years) and 104 months (8.7 years) respectively whilst the eldest male and female were 174 months (14.5 years) and 179 months (14.9 years), respectively, at the start of the orthodontic treatment.

5.3.3 Stage of Dental Development

When looking at the stage of dental development, 19 were considered to be in the early group (none of the first premolars had erupted into the oral cavity) at the start of the treatment (23.8%) while the remaining 61 were in the late group with the four first premolars present in the oral cavity (76.2%). This can be viewed in Figure 5. 4.

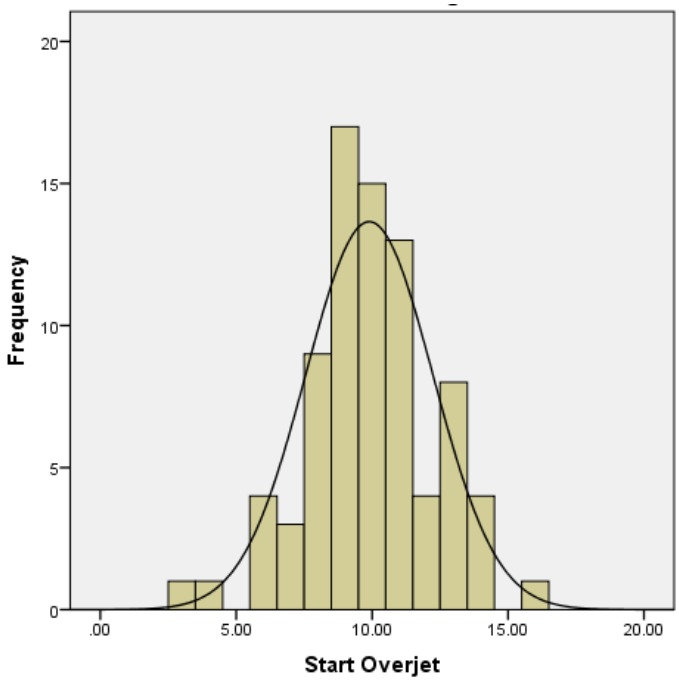
Figure 5. 4: The distribution of patients based on stage of dental development.



5.3.4 Overjet at the Start of the Treatment

From all the 80 patients, the mean overjet at the start of the treatment was 9.9 mm (SD=2.34 mm). The largest overjet was 16 mm and the smallest overjet was 3 mm. Further details can be seen in the Figure 5. 5 below.

Figure 5. 5: The distribution of the overjet at the start of the treatment (mm).



5.3.5 Cervical Vertebrae Maturation Stage at the Start of the Treatment

Of the 80 lateral cephalograms that were analysed, 4 (5%) radiographs were missing and 31 (38.8%) were adequate for identifying and determining the cervical vertebrae maturation stage. The remaining 45 radiographs (56.3%) had suffered cone-cut and did not include cervical vertebra numbers two, three and four to enable an accurate identification of the CVM stage. Further details can be viewed at Table 5. 2.

Table 5. 2: State of lateral cephalograms in relation to CVM staging

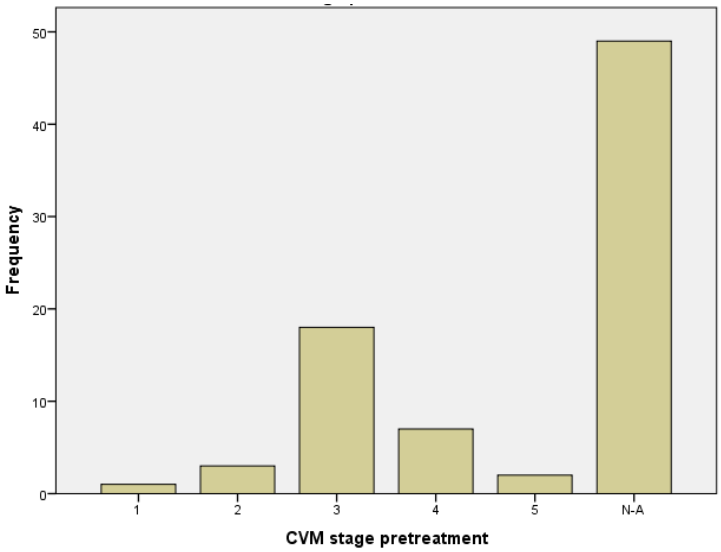
Status	Number	%
Adequate	31/80	38.8%
Inadequate (cone-cut)	45/80	56.3%
Missing from notes	4/80	5%

The CVM stages identified on the radiographs ranged between Stage 1 and Stage 5, with one patient in Stage 1, three patients in Stage 2, eighteen patients in Stage 3, seven patients in Stage 4 and two patients in Stage 5. This suggested that among the 31 patients with lateral cephalograms that were adequate to allow staging, four patients started too early (Stages 1 and 2), twenty-five patients started the treatment in the optimum time (Stages 3 and 4) and two patients started too late (Stage 5) (Baccetti et al., 2002, Baccetti et al., 2005). This is displayed in

Figure 5. **6**.

When repeated CVM staging was undertaken, the reliability was 100%, suggesting that despite the difficulties, the CVM assessment was accurate and reliable.

Figure 5. 6 The distribution of the CVM Stages from the lateral cephalograms taken at the start of the treatment.



When the 80 subjects were classified according to the stage of dental development and the CVM stage, the results were summarized and combined in Table 5. 3.

Table 5. 3: Comparison of CVM stage and the stage of Dental Development

	CVM 1	CVM 2	CVM 3	CVM 4	CVM 5	CVM not possible
Early Dental Development	1	1	4	0	1	11
Late Dental Development	0	2	14	7	1	36

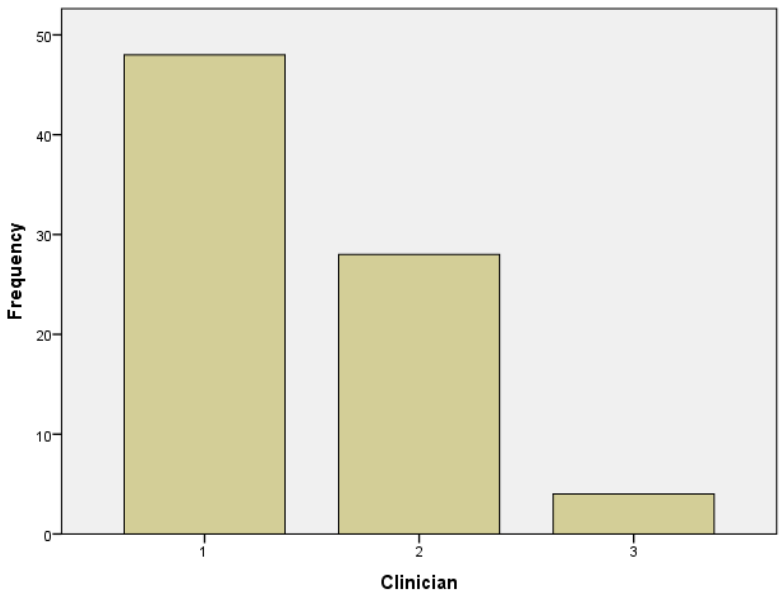
Although the stage of skeletal maturity (indicated by the CVM stage) was to be analysed as an independent variable in relation to the two dependent variables, the small number of subjects for whom it was possible to stage there CVM, prevented the investigator from including CVM stage as an independent variable in any of the statistical analyses.

5.4 DESCRIPTIVE CHARACTERISTICS RELATED TO THE ORTHODONTIC TREATMENT

5.4.1 Number of Clinicians

Of the 80 patients, only four patients had 3 clinicians treating each of them. The remainder ranged between either having a one clinician or two clinicians. Therefore, a more generalised classification was done to analyse whether these patient were transferred between clinicians or not. This was done by dichotomising this variable into having one clinician during treatment or having more than one clinician during the treatment. The resulting numbers were 48 patients (60%) and 32 patients (40%) respectively. This is demonstrated in Figure 5. 7.

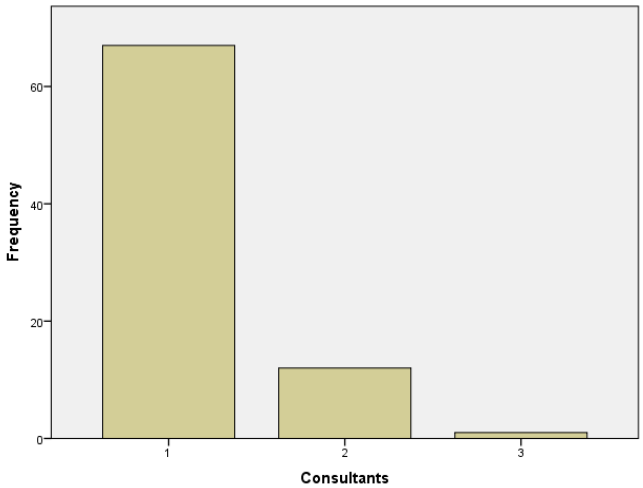
Figure 5. 7: The range of the number of clinicians



5.4.2 Number of Consultants

Of the 80 patients in this sample, one patient (1.2%) had 3 consultants supervising their case, eighteen patients (22.5%) had 2 consultants and the remaining sixty-one patients (76.3%) had 1 consultant supervising their treatment. This variable was not dichotomised nor included in the statistical analysis. See Figure 5. 8.

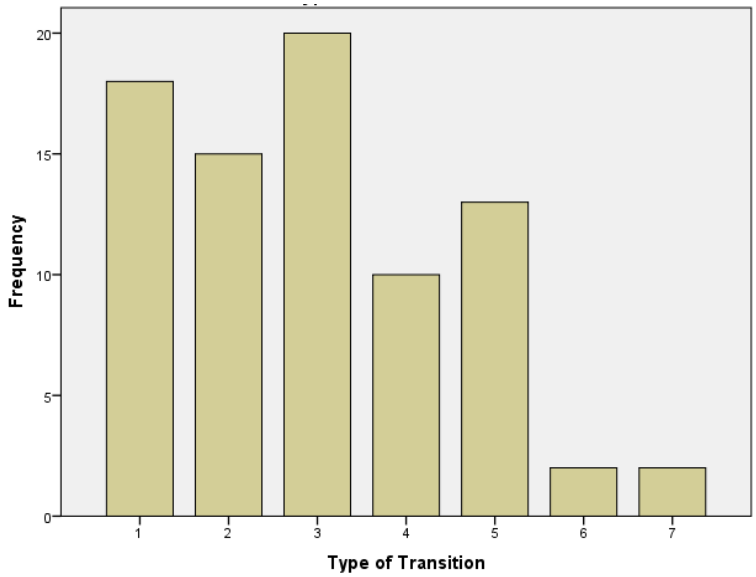
Figure 5. 8: The range of the number of consultants supervising treatment



5.4.3 The Transition Phase

As the patient moved from the first phase of treatment, using the Twin-Block appliance, to the second phase of treatment with fixed appliances, a transition phase could exist. The transition phase varies and highly dependent on the clinicans and the consultants preferences. Of the 80 patients, 18 patients (22.5%) did not have any kind of transition, while 62 patients (77.5%) underwent one kind of transition or another. See Figure 5. 9.

Figure 5. 9: The distribution between different transition regimes



Key to Type of Transition

1: None
2: Steep and Deep
3: Night-time only
4: Reduction of blocks
5: Night-time only + reduction of blocks
6: Headgear
7: Steep and Deep + Night-time only + reduction of blocks

5.4.4 Presence or Absence of Extractions During Treatment

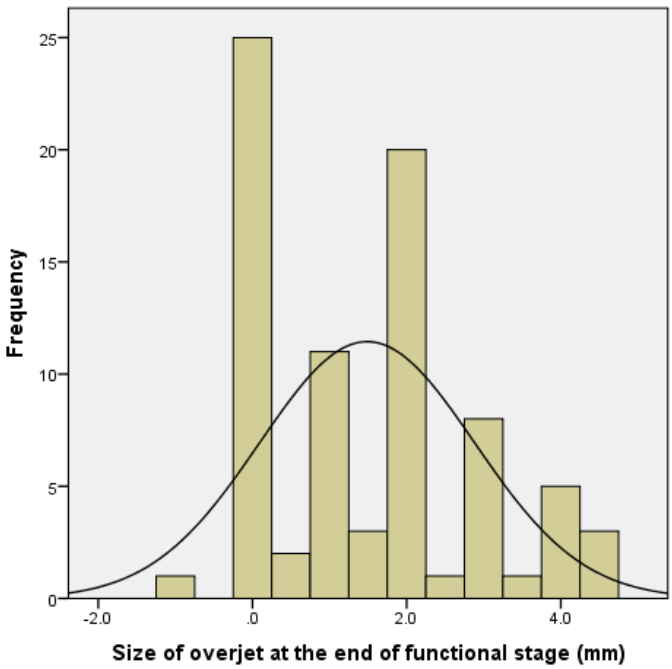
Equal numbers of patients had either an extraction approach (40 patients, 50%) or a non-extraction approach (40 patients, 50%) for the second phase of their treatment. Details of the extracted teeth are available in Appendix 10.4.

5.5 DESCRIPTIVE DATA RELATED TO THE OVERJET AT THE END OF EACH KEY STAGE OF THE ORTHODONTIC TREATMENT

5.5.1 Overjet at the end of the Functional Phase of the Treatment

The mean overjet at the end of the functional phase of the treatment was 1.5 mm (SD= 1.4 mm) with a maximum value of 4.5 mm and a minimum value of -1 mm. A graphical representation of the results is shown in the Figure 5. 10 below.

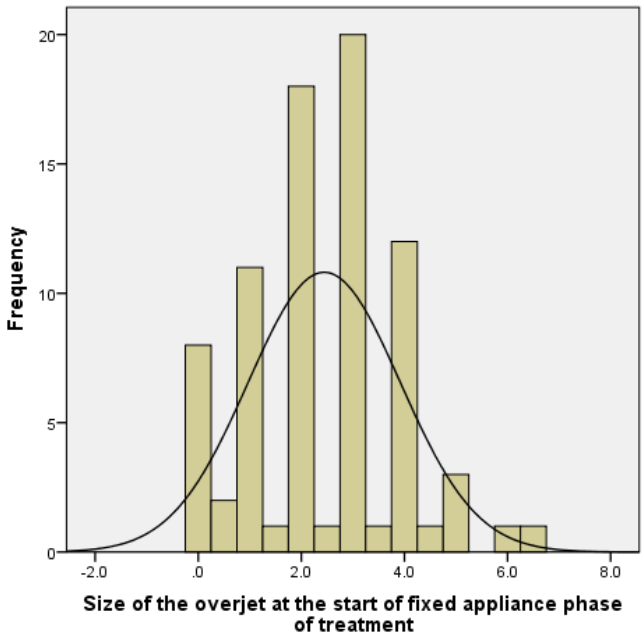
Figure 5. 10: Histogram showing the distribution of the overjet at the end of the functional phase of treatment.



5.5.2 Overjet at the Start of the Fixed Appliance Phase of the Treatment

The mean overjet at the start of the second phase of the treatment (fixed appliance phase of the treatment/ bond-up overjet) was 2.4 mm (SD= 1.5 mm). The overjet ranged between a maximum value of 6.5 mm and a minimum value of 0.0 mm. The values are demonstrated in Figure 5. 11 in more details.

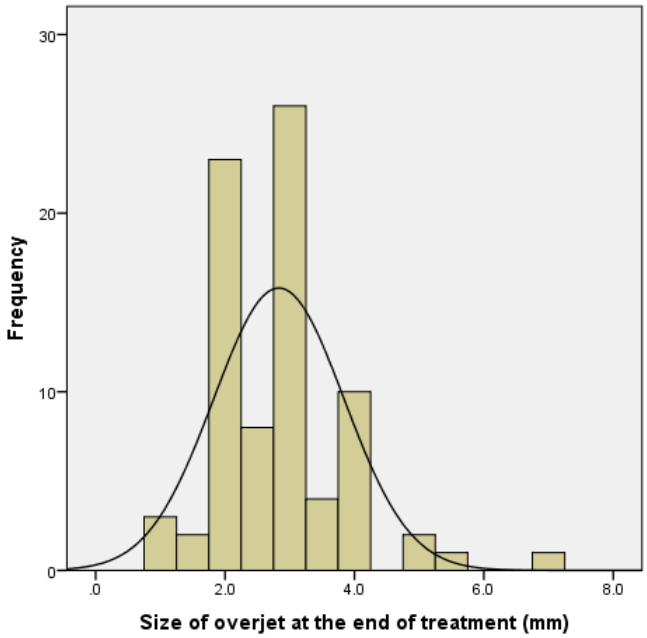
Figure 5. 11: The distribution of the overjet at the start of the fixed appliance phase of treatment



5.5.3 Overjet at the end of the Orthodontic Treatment

The overjet at the end of the complete course of orthodontic treatment had a mean value of 2.8mm (SD=1.0) with a maximum value of 7 mm and a minimum value of 1 mm. A graphical representation of the distribution of the overjet at the end of the orthodontic treatment is shown in Figure 5. 12.

Figure 5. 12: The distribution of the overjet at the end of the orthodontic treatment.

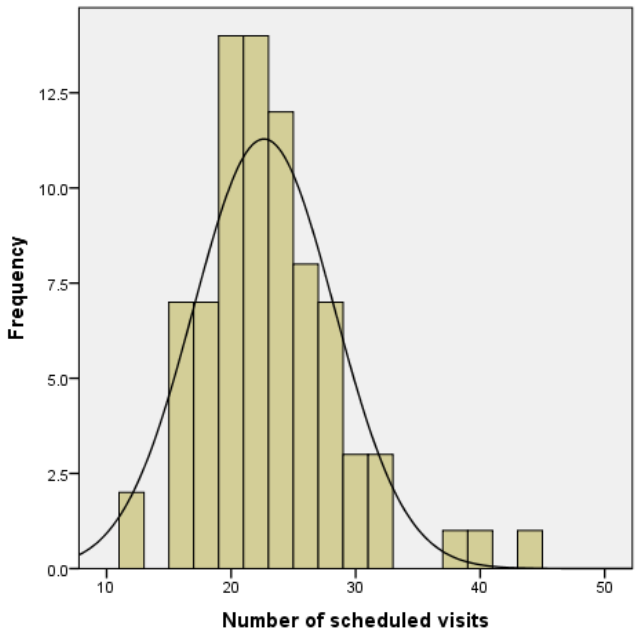


5.6 DESCRIPTIVE DATA RELATED TO THE LEVEL OF COMPLIANCE

5.6.1 The Number of the Scheduled Visits

The mean number of the scheduled visits required to complete the orthodontic treatment was 22.6 visits (SD=5.66 visits), with a maximum number of 44 visits and a minimum number of 12 visits. The following histogram demonstrates in further detail the distribution of the number of scheduled visits.

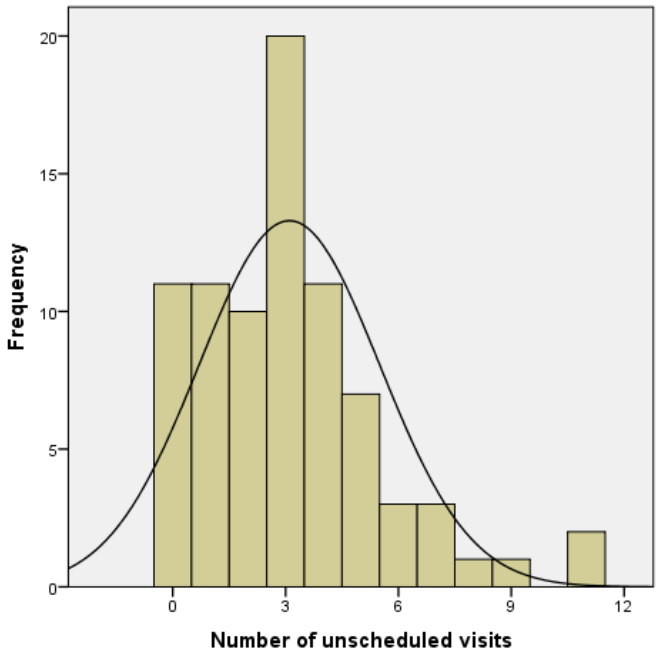
Figure 5. 13: The distribution of the number of scheduled visits.



5.6.2 The Number of Emergency Visits

The mean number of the emergency visits was 3.1 visits (SD=2.4) with a maximum number of 11 visits and a minimum number of 0 visits. The following figure shows the distribution of the number of emergency visits.

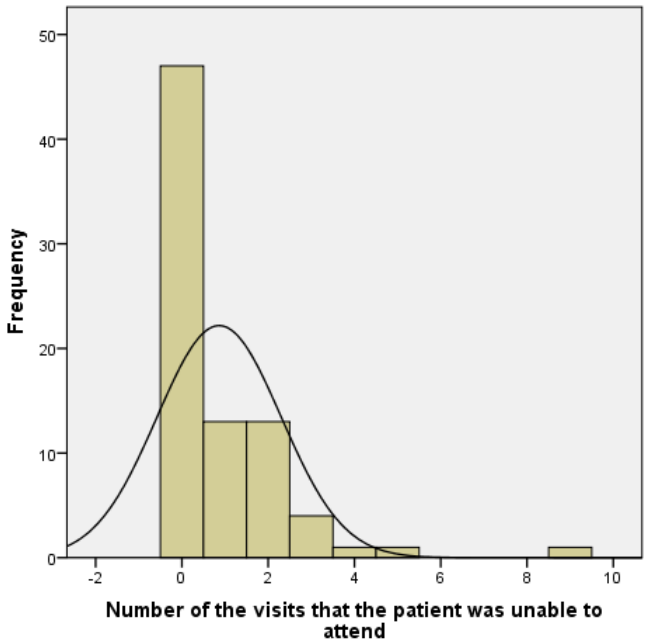
Figure 5. 14: The distribution of the number of emergency visits



5.6.3 The Number of Visits that the Patient was Unable to Attend the Appointment

These are the appointments that the patient missed during the treatment; however he or she called or left a message explaining the reasons behind missing those appointments. The mean number of these visits was 0.9 visits (S.D. =1.4 visits) with a maximum number of 9 visits and a minimum number of 0.0 visits. Figure 5. 15 below demonstrates the distribution of the data in more details.

Figure 5. 15: The number of visits that the patient was unable to attend the appointment



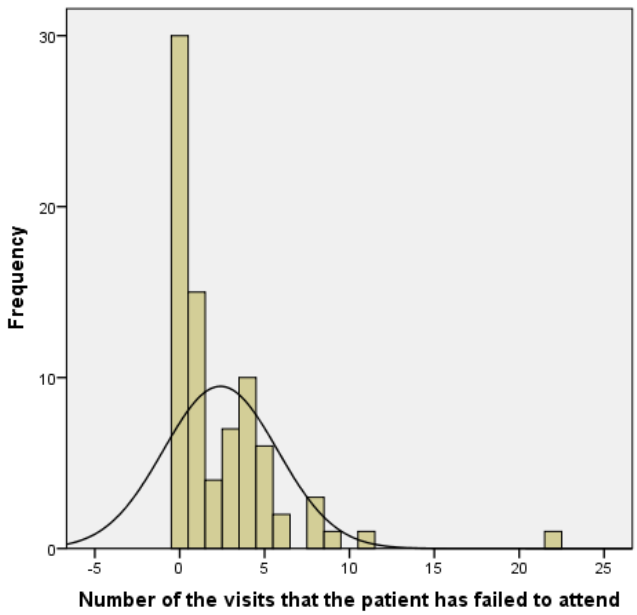
5.6.4 The Number of the Visits that the Patient Failed to Attend the Appointment (FTAs)

These are the appointments that the patient had missed during the orthodontic treatment without providing an acceptable excuse or reason for missing these appointments.

The histogram shows a skewed distribution, so the data should be described using median and an interquartile range; however, the data were dichotomised to eliminate the influence of the skewed distribution. The variable of failed to attend appointments was categorised into two groups for the statistical analysis, these groups were low FTAs (n = 45); which included patients who never failed to attend the appointments or failed to attend a single appointment only (the range of 0-1 visits inclusive) and high FTAs (n = 35); which included patients who failed to attend 2 or more of their appointments.

The median number of FTA appointments was 1 visit (25^{th} percentile = 0 visit and 75^{th} percentile = 4 visits), with a maximum number of 22 visits and a minimum number of 0 visits. Figure 5. 16 shows a histogram demonstrating the distribution of the number of visits failed by the patients.

Figure 5. 16: The number of the visits that the patient failed to attend the appointment (FTAs)



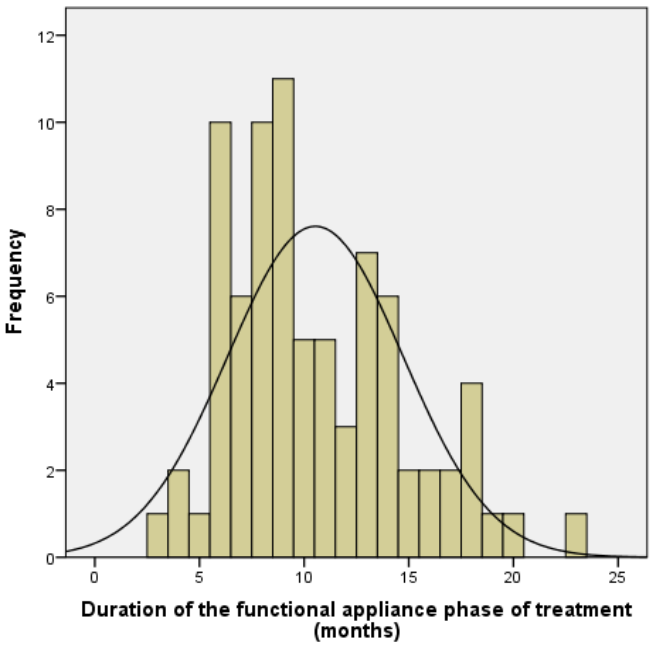
5.7 DESCRIPTIVE DATA RELATED TO THE DURATION OF FUNCTIONAL PHASE/ TOTAL ORTHODONTIC TREATMENT

5.7.1 Duration of the Functional Phase of Treatment

The duration of the functional appliance phase was calculated as the duration between the date of the start of the functional treatment until the date of the end of the active functional treatment.

The mean duration of the functional appliance phase was 10.5 months (0.9 years) (SD=4.2 months), with a maximum length of 23 months (1.9 years) and a minimum length of 3 months (0.3 years). A graphical representation of this information is shown in Figure 5. 17.

Figure 5. 17: Duration of the functional appliance phase of treatment.

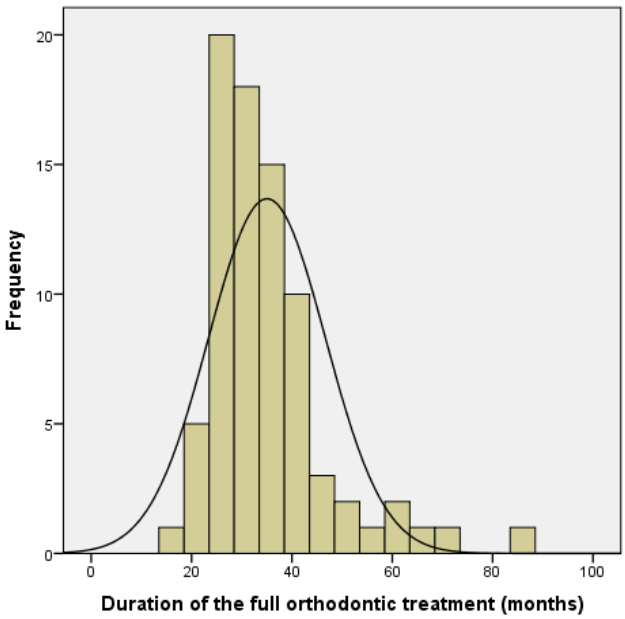


5.7.2 Total Duration of Orthodontic Treatment

The total duration of orthodontic treatment was calculated as the duration between the date of the start of the functional treatment (the date the Twin-Block was fitted) until the date of the end of the orthodontic treatment (the date of debond). This measurement also included the time spent in transition from the Twin-Block appliance to fixed appliances. The mean total duration of orthodontic treatment was 35.0 months (2.9 years) (SD=11.7 months), with a maximum value of 85 months (7.1 years) and a minimum value of 16 months (1.3 years). A graphical representation of the results is shown in the

Figure 5. **18**.

Figure 5. 18: Total duration of orthodontic treatment.



The descriptive values of the continuous variables are displayed in the following table.

Table 5. 4: Descriptive analysis for the continuous variables

#	Variable	Mean	Standard Deviation
1	Age at the start of treatment	145.7 months (12.1 years)	15.8 months (1.3 years)
2	Overjet at the start of treatment	9.9 mm	2.3 mm
3	Overjet at the end of functional appliance phase	1.5 mm	1.9 mm
4	Overjet at the start of the fixed appliance	2.4 mm	1.5 mm
5	Overjet at the end of treatment	2.8 mm	1.0 mm
6	Number of scheduled visits	22.6 visits	5.7 visits
7	Number of emergency visits	3.1 visits	2.4 visits
8	Number of visits patient was unable to attend (UTA)	0.9 visits	1.4 visits
9	Number of visits patient failed to attend (FTA)	Median 1 visit	IQ Range 0-4 visits
10	Duration of functional appliance phase of treatment	10.5 months (0.9 years)	4.2 months (0.4 years)
11	Total duration of orthodontic treatment	35.0 months (2.9 years)	11.7 months (1.0 years)

5.8 STATISTICAL SIGNIFICANCE

From the previous data, it can be observed that some of the dependent and independent variables were slightly skewed (e.g. age, number of FTAs, duration of the functional and the

total treatment). Despite this, it was not sufficient to invalidate the use parametric statistical analyses methods such as the t-test and the multiple regression analyses. This decision was based on expert advice from a medical statistician.

In this study, there were two dependent variables. These were the duration of the functional phase of treatment and the total duration of orthodontic treatment.

For the first dependent variable; the duration of the functional phase of orthodontic treatment; three independent variables were analysed in an attempt to detect the presence of an association. These were: chronological age, stage of dental development and the overjet at the start of the treatment.

For the second dependent variable; the total duration of orthodontic treatment; six independent variables were analysed in an attempt to detect the presence of an association. These were: chronological age, stage of dental development, the overjet at the start of the treatment, the presence or absence of dental extractions during the treatment, the number of clinicians treating the patients and the number of visits that the patient failed to attend (FTAs).

Although there was an intention to use the stage of skeletal maturity (indicated by the CVM stage) in the analysis as an independent variable; in relation to the two dependent variables, there were too few patients for whom these data were available from their cephalograms. This, therefore, prevented the investigator from including the CVM stage as an independent variable in any of the statistical analyses.

5.8.1 T-tests:

5.8.1.1 Early Versus Late Stage of Dental Development

When assessing the duration of the functional phase of the treatment between the early group and the late group, the mean was 11.5 months (SD= 4.2 months) for the early group and 10.2 months (SD= 4.2 months) for the late group. When equal variances were assumed, the mean difference between the two groups was 1.3 months (95% CI of the difference -0.9- 3.5), which was not statistically or clinically significantly different.

On the other hand, the duration for the full orthodontic treatment had a mean of 39.0 months (SD=13.3 months) for the early group, while the mean for the late group was 33.8 months (SD= 10.9 months). When equal variances were assumed, the mean difference between the two groups was 5.2 months (95% CI of the difference -0.8- 11.2), which was not statistically significantly different but may have been clinically. These differences were not statistically significant. The results can be seen in Table 5. 5 and Table 5. 6.

Table 5. 5: Uni-variate comparison of the duration of functional phase of treatment

Variables	Mean (S.D.) Months	Mean difference (95% CI) months	p-value
Stage of Dental Development			
Early (n=19)	11.5 (4.2)	1.3 (-0.9 to 3.5)	0.242
Late (n=61)	10.2 (4.2)		

Table 5. 6: Uni-variate comparison for the total duration of treatment

Variables	Mean (S.D.) months	Mean difference (95% CI) months	p-value
Stage of Dental Development			
Early (n=19)	39.0 (13.3)	5.2 (-0.8 to 11.2)	0.089
Late (n=61)	33.8 (10.9)		
Number of clinicians			
0 or 1 (n=48)	31.1 (9.2)	-9.8 (-14.6 to -4.9)	0.000*
2 or more (n=32)	40.9 (12.7)		
Extractions			
No (n=40)	32.0 (8.4)	-6.0 (-11 to -0.95)	0.020*
Yes (n=40)	38.0 (13.7)		
FTAs			
0 or 1 (n=45)	31.4 (9.0)	- 8.2 (-13.1 to -3.3)	0.001*
2 or more (n=35)	39.6 (13.1)		

* = Statistically significant at the p > 0.05 level

5.8.1.2 Appointments that were Failed to Attend by the Patients (FTAs)

Failure to attend appointments was dichotomised for the statistical analysis, these groups were Low FTAs; which included patients who failed to attend 1 or fewer, appointment inclusive and High FTAs; which included patients who failed to attend 2 or more appointments. The mean duration of the total course of orthodontic treatment was 31.4 months for the Low FTAs group and 39.6 months for the High FTAs group. The details are shown in Table 5. 6.

This difference was considered as statistically significant (p-value < 0.05) when analysing the total duration of treatment. So, for those patients who failed to attend two or more appointments, the total duration of their treatment was significantly longer than for those who FTAs fewer appointments.

5.8.1.3 Clinicians

The number of clinicians carrying out treatment for the patients was another factor that was considered. For analysis purposes, this variable was dichotomised and the patients were

classified into a group who had one clinician throughout their treatment and those patients who had two or more clinicians throughout their treatment. For the total duration of orthodontic treatment, the mean for the one clinician group was 31.1 months and 40.9 months for the two or more group respectively. Details can be seen in Table 5. 6.
These differences were considered to be statistically significant when analysed in relation to the total duration of orthodontic treatment.

5.8.1.4 Extractions

An equal number of patients were treated using an extraction and a non-extraction approach. When looking at the total duration of orthodontic treatment, the mean treatment duration of for the non-extraction group was 32.0 months while the extraction group had a mean treatment duration of 38.0 months. This is demonstrated in Table 5. 6.
The difference was statistically significant, suggesting that the total duration of orthodontic treatment was associated with the extractions status. This can be seen in Table 5. 6.

5.8.2 Pearson's Correlation Analysis:

This analysis was used to assess the correlation between the continuous variables (overjet at the start of the orthodontic treatment and the chronological age of the patient) and the duration of both the functional phase and the total duration of orthodontic treatment.

5.8.2.1 The Overjet at the Start of the Treatment

When Pearsons correlation analysis was done for the overjet at the start of the treatment, it was found that it had an extremely weak correlation (0.193) that was not statistically significant (p=0.087) in relation to the total duration of orthodontic treatment. On the other hand, the overjet at the start of the treatment was significantly related to the duration of the functional appliance phase (p=0.016). Although this correlation was statistically significant, it had a weak correlation (0.268). See Table 5. 7 for further details.

5.8.2.2 The Chronological Age of the Patient

The same analysis was used to test for the correlation between the duration of the functional phase and the total duration of orthodontic treatment with regard to the chronological age of the patient. It was found that there was no statistically significant association between the age and the duration of the functional phase of the treatment.

On the other hand, the correlation was statistically significant between the total duration of orthodontic treatment and the chronological age (p= 0.01), however, it was a weak negative correlation (-0.28). For further details, see Table 5. 7.

Table 5. 7: Correlation of the continuous variables with the duration of treatment

Test / Variables	Duration of functional phase (months)		Total duration of treatment (months)	
	Pearsons correlation coefficient	p-value	Pearsons correlation coefficient	p-value
Starting overjet (mm)	0.268	0.016*	0.193	0.087
Age	-0.164	0.146	-0.278	0.013*

* = Statistically significant at the p > 0.05 level

5.8.3 Multiple Regression Analysis (Stepwise Regression Analysis)

This analysis was applied for the duration of the functional phase and for the total duration of orthodontic treatment separately.

5.8.3.1 Duration of the Functional Appliance Phase of the Orthodontic Treatment

A regression analysis was performed and it showed that from all the included independent variables (i.e. the chronological age of the patient at the start of the treatment, the stage of dental development at the start of the treatment and the overjet at the start of the treatment), the overjet was the only factor that had a statistically significant influence on the duration of the functional phase of the treatment. This is demonstrated in Table 5. 8.

Table 5. 8: Step wise multiple regression analysis for the duration of the functional phase of treatment

Variable	β (standard error)	p-value
Starting overjet (mm)	0.481 (0.196)	0.016*

* = Statistically significant at the p > 0.05 level; $R^2 = 0.072$

5.8.3.2 Duration of the Total Orthodontic Treatment

A regression analysis was performed to assess the impact of the independent variables (i.e. chronological age of the patient, stage of dental development and overjet at the start of the treatment; presence of dental extractions or not; number of clinicians treating the patient and number of the FTAs) on the total duration of orthodontic treatment. It suggested that the only factors that were statistically significant predictors for the total duration of orthodontic

treatment were: the number of clinicians, number of FTAs, chronological age of the patient and whether the patient had extractions or not. Table 5. 9.

Table 5. 9: Step wise multiple regression analysis for the total duration of orthodontic treatment

Variable	β (standard error)	p-value
Number of clinicians	7.871 (2.181)	0.001*
FTAs	7.420 (2.149)	0.001*
Age	0.216 (0.067)	0.002*
Extractions	4.984 (2.110)	0.021*

* = Statistically significant at the $p > 0.05$ level; $R^2 = 0.385$

5.8.4 Reliability of the Data Extraction

The reliability of the data extraction showed 100% agreement.

5.9 SUMMARY OF THE MAIN FINDINGS

The study sample included 80 patients who met the inclusion criteria and completed their orthodontic treatment successfully. From those patients, the results were as follows:

- 42.5% were males and 57.5% were females.
- Mean (S.D.) age of the patients at the start of the orthodontic treatment was 145.7 months / 12.1 years (S.D. 15.8 months / 1.3 years).
- 23.8% were considered to be early starters while 76.2% were considered to be late starters, when considering the stage of dental development.
- The mean (S.D.) overjet at the start of the orthodontic treatment was 9.9 mm (2.3 mm).
- Although it was not possible to determine the CVM stage from 61.2% of the radiographs, from those that were usable, the majority (80.6%) of the patients were in Stages 3 and 4 at the start of their orthodontic treatment.
- A single clinician had treated 60% of the patients whilst more than one clinician treated 40%.
- A single consultant supervised 76.3% of the patients, whilst more than one consultant supervised the remaining patients.

- The majority of the patients (77.5%) underwent a transition phase while the remaining patients (22.5%) did not.
- Half of the patients had extractions, while the other half of the patients did not.
- Mean (S.D.) overjet at the end of the functional phase of the treatment was 1.5 mm (1.4 mm).
- Mean (S.D.) overjet at the start of the fixed appliance phase of the treatment was 2.4 mm (1.5 mm).
- Mean (S.D.) overjet at the end of the orthodontic treatment was 2.8 mm (1.0 mm).
- Mean (S.D.) number of the scheduled visits required to complete the treatment was 22.6 visits (5.7 visits).
- Mean (S.D.) number of the emergency visits/ emergency visits was 3.1 visits (2.4 visits).
- Mean (S.D.) number of the visits that the patients were unable to attend was 0.9 visits (1.4 visits).
- Median (Interquartile range) number of the visits the patients failed to attend was 1 visit (0, 4 visits).
- Mean (S.D.) duration of the functional appliance phase of the treatment was 10.5 months/0.9 years (4.2 months).
- Mean (S.D.) total duration of orthodontic treatment was 35.0 months/2.9 years (11.7 months).
- No statistically significant association was found between the duration of the functional phase of the orthodontic treatment and:
    - Stage of dental development (p= 0.242).
    - Chronological age of the patient (p= 0.146).
- However, a statistically significant association was found between the duration of the functional phase of the orthodontic treatment and:
    - The overjet at the start of the orthodontic treatment (p= 0.016).

These results suggested that patients who had a larger overjet had a longer total duration of treatment.

- No statistically significant association was found between the total duration of orthodontic treatment and the:
    - Stage of dental development (p= 0.089).

    - Overjet at the start of the orthodontic treatment (p= 0.087).
- However, a statistically significant association was found between the total duration of orthodontic treatment and the:
    - Number of the clinicians treating the patient (p= 0.001).
    - Number of the visits patients failed to attend (p= 0.001).
    - Chronological age of the patient (p= 0.002).
    - Number of extractions (p= 0.021).

These results suggested that patients who were treated by more than one clinician, who failed to attend more than one appointment, were younger and had extractions as part of their treatment, had a longer total duration of treatment.

CHAPTER 6

6.0 DISCUSSION

6.1 INTRODUCTION

This study was a retrospective, observational investigation to assess the factors that influenced both the duration of the functional appliance phase of the orthodontic treatment and the total duration of orthodontic treatment, for patients with a Class II malocclusion who were treated with a functional (Twin-block) / fixed approach, at LUDH.

This study aimed to identify whether any of the following factors:

- chronological age of the patient;
- stage of dental development at the start of the treatment;
- overjet;
- presence or absence of extractions;
- number of the clinicians carrying out the treatment and
- number of appointments the patient failed to attended

influenced the duration of the functional phase and the total duration of orthodontic treatment.

The only factor that had a statistically significantly influence on the duration of the functional phase of treatment was the overjet at the start of treatment in that patients who had a larger overjet had a longer functional phase of treatment.

The factors that had a statistically significant influence on the total treatment duration were the number of treating clinicians; the number of appointments the patients failed to attend; the chronological age of the patient and the presence or absence of dental extractions; meaning that patients who were treated by more than one clinician, who failed to attend more than one appointment, were younger and had extractions as part of their treatment, had a longer total duration of treatment.

6.2 LIMITATIONS OF THE STUDY

As this study was a retrospective observational study, there were a number of limitations. The majority of these can be considered as general limitations associated with any retrospective study and they are bias, confounding and error.

It is important, in every study, to aim to minimise all types of bias that could have been introduced at various stages of the study. However, it is not always possible to achieve this, especially in retrospective studies, as only limited types of bias can be minimised.

6.2.1 Bias

Bias is a systematic error in the design and/or conduct of a study that can lead to the wrong interpretation of the resultant data. Bias needs to be distinguished from random error which is related to the variability in the sampled population and can be reduced by increasing the sample size (Pandis, 2014). Bias can influence the resulting association by over-estimating or under-estimating the influence of a factor (Petrie and Sabin, 2009).

The introduction of bias, at any stage of a study, is one of the main concerns a researcher might face and it has to be addressed during study design. Some study designs can minimise the risk of bias by, for example, randomising the allocation of treatment to participants in randomised control trials. However, in a retrospective study several types of bias can be introduced (Pandis, 2014, Petrie and Sabin, 2009).

6.2.1.1 Selection Bias

Selection bias occurs in a study when the participants who are in a study are systematically different from the patients who were not selected to participate, despite being eligible for the study. As a result, the selected sample will not be representative of the population of interest.

6.2.1.1.1 Allocation Bias

Allocation bias is a bias in allocating treatment to the groups of patients. This type of bias occurs as a result of lack of randomisation. Despite the fact that all comers were included in the current study, the sample was not selected randomly, as a result there is a chance that the sample was different from the population in question. This can be minimised by random allocation and concealment of the allocation (e.g. by using sequentially numbered, sealed, opaque envelopes).

6.2.1.1.2 Attrition Bias

This applies to those subjects who were lost to follow up in samples of longitudinal studies. As a result, they might be systematically different from the included subjects. In the current study, those subjects who did not complete two phases of treatment or had incomplete records and excluded from the study as a consequence were lost to follow up. This could be another source of bias in the current sample. If this is the case then the implication would have been for the effectiveness of treatment (e.g. OJ at the end of the functional phase) to be overestimated however, the impact on the duration of treatment may have resulted in an over- or under-estimation.

6.2.1.1.3 Sample

To minimise selection bias, all the patients who had functional/fixed orthodontic treatment between 1st of January 2005 until 31st of December 2008 were eligible for inclusion in the study. Unfortunately, there was no electronic data for the information required and as a result the closest accurate source of information was the laboratory record. Those years were chosen because prior to 2005, the Twin-Block appliance was not used as frequently as nowadays due to the familiarity of the clinicians with other growth modification devices. So, if earlier years had been included in the search, this would have resulted in additional work without achieving a sufficient increase in the number of patients included. On the other hand, the end point aimed to maximise the number of patients available for inclusion whilst maintaining the power of the study. The year 2008 was chosen as an endpoint because functional/fixed orthodontic treatment takes about 2-3 years to complete (O'Brien et al., 2009b), so patients who started their treatment later than this would not have had completed their treatment by the time the data for this study were collected.

The sample frame used in this study was the list of patients recorded in the laboratory book who had a removable (including functional) appliance made, repaired or adjusted between 2005-2008. Selection bias could have been introduced if some patients' laboratory work had not been recorded in the Lab Book during this period. On the other hand, some patients' names were repeated as they had attended multiple times to have their appliances repaired/replaced. This was considered as an advantage because it reduced the chance of missing some patients. However, the repeated names of patients who had their appliances repaired and for whom a removable appliance but not necessarily a Twin-Block appliance, was made/repaired significantly reduced the potential pool of patients from which the sample

for this study was selected. This meant that sample size was reduced which had an impact on the power of the study. The resultant sample size meant that the study was adequately powered to determine a difference with the three factors that influenced the duration of the functional phase of treatment. However, more factors influenced the total duration of treatment so this part of the study was slightly underpowered due to the sample size being 80 rather than the 97 that was required with six predicting factors.

6.2.1.1.4 Missing case notes/ missing clinical data

Despite all the efforts by the principal investigator to locate and find notes, electronically and via a hand-search of the records department, on two separate occasions, 12 (9.4%) case notes were not located. This is less than the 20% that is considered a high risk of bias (Higgins and Green, 2011) so the impact on the results of this study may not have been significant. The missing case notes and their data did, however, reduce the potential sample size which could have affected the validity and precision of the results of this study and in turn, the inferences that could be drawn from them. It is difficult to determine how this selection bias has affected how representative the resultant sample was relative to all those patients receiving Twin-Block treatment at LUDH especially if all the patients, whose case notes were missing, met the inclusion criteria. In addition to the impact on this study with respect to the missing data, serious medico-legal issues could arise from case-notes being missing. However, no explanation could be found for these case notes being missing.

6.2.1.2 Information bias

This type of bias occurs when a misclassification of outcome or exposure takes place or when a systematic error in measurement is introduced. It includes several types of bias including measurement/ascertainment, observer/assessment and accuracy/recall bias.

6.2.1.2.1 Measurement bias/ Ascertainment Bias

This type of bias occurs when an inaccurate measurement tool introduces a systematic error (e.g. poorly calibrated scales, digit preference or rounding error). To minimise this bias assessors were calibrated and undertook an assessment of their reliability which were substantial / perfect respectively. Ascertainment bias is another name for measurement bias, i.e. when two groups are measured differently because of inherent prejudices. It can be limited by blinding the assessors to which group the patients are allocated. Also, it can be limited by calibration of assessors and reliability testing.

6.2.1.2.2 Observer/ Assessment Bias

This occurs when the observer or the investigator under-reports or over-reports one or more of the variables, resulting in a systematic error.

In this study, attempts were made to reduce assessment and measurement bias by staging the CVM from the cephalograms blind to the data extracted from the case notes and vice versa. The reliability of data extraction and CVM staging was assessed but no further precautions could have been taken to reduce the aforementioned sources of bias.

6.2.1.2.3 Accuracy of Information in Patients' Case Notes

All the case notes were hand written. As a result, the data extraction was time consuming and a thorough reading was necessary to avoid missing any information. This was especially evident where the case notes had many abbreviations or when the treatment plan, particularly the extraction pattern, was changed as the treatment progressed. However, when repeat data extraction from 10% of the case notes was undertaken, the reliability was 100% suggesting that, despite the difficulty in data extraction, it was accurate and reliable. Nevertheless, AM was dependant on what information was recorded by the various treating clinicians and this may not have been completely accurate and some data may have been missing. This is analogous to recall bias in the survey.

6.2.2 Confounding

Confounding occurs when a false association is detected or when a real association is missed between exposure and outcome. This can result from the failure to adjust for confounding variables. A confounding variable is one that is related to both exposure and outcome. Unlike other types of bias, confounding can be controlled at the design stage and at the analysis stage. At the design stage, randomisation allows equal distribution of known and unknown baseline characteristics including confounding factors. However, randomisation is not possible in observational studies. Matching is another option to reduce confounding, however; due to the presence of many confounders in our study, it was not possible and it was avoided so as not to reduce the power of the study further.

As in any retrospective study, confounding variables can be a major cause of bias, especially when the study is dependent on historic records from which important information, for one or more reasons, was missing. In this study, the aim was to minimise any possible confounding bias by including and analysing all the possible factors that could influence the duration of the functional and the total orthodontic treatment in order to answer the primary objective:

What are the factors that influence the duration of the functional phase and the total duration of treatment? From all the possible predictive factors, the independent variables chosen for this investigation were: age, stage of dental development, overjet at the start of the treatment, extractions for orthodontic reasons, the number of the clinicians treating the patient and the number of failed appointments. These variables were entered into the statistical analysis. Another factor that could have influenced the duration of the treatment was the compliance of the patient. This study aimed to measure this through two other variables. The first was by analysing the attendance record of the patient and the number of visits that the patient failed to attend. The second was the compliance with treatment modality measured in terms of the number of the emergency visits that the patient needed. As a result of the non-compliance, the patient may have had a prolonged course of treatment, resulting in them being treated by several clinicians. So, the number of clinicians treating the patient and the number of consultants supervising the treatment were also considered to be indicators of compliance. A confounding factors with these predictive factors was the number of treating clinicians because if any of the other factors increased the length of treatment beyond 2½ - 3 years then the number of treating clinicians would increase as the trainee completed their training programme.

6.2.3 Error and Sample Size

A power calculation was performed before the initiation of this study. To detect a medium effect size (f^2= 0.15) in the treatment duration of the functional phase of orthodontic treatment with 80% power, an alpha of 0.05 and 3 predictor variables would require a sample size of 76 subjects. In addition, to detect a medium effect size (f^2= 0.15) in the total treatment duration with 80% power, an alpha of 0.05 and 6 predictor variables would require a sample size of 97 subjects (Cohen, 1988).

Initial screening of the Lab Book identified 128 patients who were potentially eligible for inclusion into the study. Upon further assessment, only 80 patients met the inclusion criteria and were included in the study. So, although a priori sample size calculation was undertaken, the sample size of the total treatment duration for this study was 17 (17.5%) less than the desired sample size of 97 and as a result, the total treatment duration of this study was underpowered. This would have influenced the potential of this study to identify a difference in treatment but not to a significant level as it did not exceed the recommended percentage of 20% (Higgins and Green, 2011). As a possible result, the statistical difference in some outcomes might not have been significant even if a difference really existed.

A larger sample size, that met the calculated sample size, could have overcome this. This could have been achieved by including patients treated in other hospitals in the region. A multi-centre approach should be considered as an important step in any future research related to this topic.

6.3 RELIABILITY OF THE METHOD

6.3.1 Error in Data Tabulation

The data collection involved extracting information from the patients case notes and manually entering it into the data collection sheets. It was then transferred manually into a computerised electronic database and computational errors could have occurred. To reduce these errors, data collection was limited to 10 records per session. This meant that errors related to fatigue were minimised. To increase the accuracy of transferring data from the data collection sheet into the computer spread-sheet, a print out of the computerised data was obtained and checked against the data collection sheet. This allowed the data to be cleansed and inaccurate data to be corrected.

To assess the intra-examiner reliability of data collection, data were extracted from 8 case notes on two separate occasions. Following this, every pair of data collection sheets was compared and the results showed 100% agreement.

The reliability of staging CVM from lateral cephalogram radiographs was undertaken as part of another DDSc project at Liverpool University Dental Hospital (Rainey, 2013). The intra-examiner agreement for the principal investigator (AM) was found to be substantial (weighted kappa = 0.65; S.E. = 0.02).

6.3.2 Data Collection Sheet

A pilot study to assess the adequacy of the data collection sheet would have been useful; however, this was not undertaken. Instead, alterations were carried out to the data collection sheet as the data were collected. Although, this could be considered time and effort consuming as the data needed to be collected again once the sheet design was finalised. This repeated data collection process increased the reliability of the information gathered.

6.4 THE INDEPENDENT VARIABLES AND OTHER CONFOUNDING FACTORS

6.4.1 Gender

This sample was comprised of 42.5% males and 57.5% females. This shows that female: male ratio for the orthodontic treatment was 4:3, which is similar to orthodontic literature. The explanation could be that more females seek and receive orthodontic treatment when compared to males (O'Brien el al., 1996, Harris and Glassell, 2011 and Badran and Al-Khateeb, 2013). A study performed by O'Brien et al. (2003c) compared the Twin-Block appliance with the Herbst appliance. In that study, the results showed that females responded better to the Twin-Block appliance but it did not confirm whether this effect was due to higher level of compliance or due to biological differences and recommended further investigation in this field. As a result of this inconclusive evidence, gender was excluded from the regression analyse in the current study.

6.4.2 Age at the Start of the Treatment

Functional appliances are generally used in growing patients (adolescents), as it coincides with the pubertal growth spurt, in an attempt to maximise any beneficial skeletal changes (Baccetti et al., 2000). An early start to functional appliance treatment would allow the patients original growth pattern to resume and thus dilute the small skeletal changes previously gained by treatment with the functional appliance (Tulloch et al., 1997 and 1998, Dolce et al., 2007).

Although the chronological age data were slightly skewed, it was thought that the mean and standard deviation were more appropriate measures than the median and interquartile range for describing the data. In addition, the level of skewness was not considered to be sufficient to invalidate the use of parametric measures in the statistical analysis. The mean age of the patients in this study was 145.7 months (12.1 years) with a standard deviation of 15.8 months. When comparing this with earlier studies using the Twin-Block appliance, (O'Brien et al., 2003b, Banks et al., 2004) the mean ages in these two studies were 12.4 years and 12.6 years respectively with ranges of 11-14 and 10-14 years. These ages are similar to that found in this study and suggests that the patients at LUDH receiving treatment with a Twin-Block appliance were similar to those treated in different hospitals of the United Kingdom.

A previous association between compliance and age was identified in Banks et al., (2004), where they concluded that patients who were 12.3 years or less were 3 times more likely to

complete their treatment when compared with older patients. From this finding, an increase in the total treatment duration could be anticipated in older patients as a result of reduced level of compliance with the treatment modality. It was with this assumption in mind that the chronological age was included in the statistical analysis in this study as an independent variable. However, the results obtained from this study suggested an inverse relationship with chronological age and the total treatment duration with the older patients having shorter total treatment duration. This does not concur with previous studies when compliance is considered, however it agrees with the findings of O'Brien et al. (2009b) who found that early treatment increases the number of visits and treatment duration when compared with a single phased treatment commencing in adolescence. An essential point to be considered here is that their findings were derived from two groups, early starters; who had two phases of treatment (including an early functional phase) and late starters; who had a single phase of treatment (including either fixed or functional appliances). This is slightly different from the current study, as both early and late participants underwent two phases of treatment; the first including a functional appliance phase and the second a fixed appliance phase. This may cause the differences between the two groups in the current study to be smaller when compared with O'Brien et al. (2009b).

This could be explained by the fact that older patients are likely to have been at a later stage of dental development, with their permanent teeth erupted at the end of the first phase of the treatment, thus leading to a smooth transition between the first and the second phases of the treatment. This, in turn, could outweigh any effect that the anticipated reduced level of compliance would have had to prolong the treatment duration in older patients. For younger patients, a waiting period may be needed for further dental development to occur before the second phase can be commenced, which would overturn any benefit from their increased compliance. The association between chronological age and the level of compliance, as assessed from the number of clinicians and FTAs visits, was not investigated in this study and these assumptions are based on the results of Banks et al. (2004). Although these considerations could justify the findings of the current study, they have to be interpreted with caution because chronological age has not been shown to be an absolute predictor for the stage of dental development (Demirjian et al., 1985, Kurita et al., 2007, Feijóo et al., 2012).

6.4.3 Stage of Dental Development

There is also debate as to whether the functional phase of treatment should start early or late in relation to the stage of dental development.

Most clinicians aim to start the orthodontic treatment when all the permanent teeth, anterior to the first permanent molars, have erupted or about to erupt, which roughly coincides with the chronological age of 12 years. The presence of the permanent dentition allows better retention of the Twin-Block components and allows a smooth transfer between the functional phase and the fixed appliance phase of the treatment with the assumption that it would reduce the overall treatment duration in most of the cases (DiBiase et al., 2015). This relationship was seen in a study that stratified participants based on their stage of dental development which found that as the stage of dental development increased, the duration of the orthodontic treatment decreased and the reduction in PAR score increased (Von Bremen and Pancherz, 2002).

Alternatively, treatment may be started early if there are indications to do so. Prominent maxillary incisors are perceived as an unpleasant feature and the profile of treated patients has been evaluated to be a more attractive and pleasing in comparison to the untreated patients (O'Brien et al., 2009a). This perception may mean that postponing treatment could expose the child to experience a higher level of bullying and teasing from peers and friends at school leading to an increase in the negative experiences, especially at school (Al-Bitar, 2013, Johal et al., 2007). In addition, an increased overjet and lack of an adequate lip seal increased the risk of trauma to prominent maxillary incisors, which may be an indication to start the treatment earlier (Thiruvenkatachari et al., 2013). However, in order to reduce the risk of trauma it may mean starting functional appliance treatment at the time the permanent incisors erupt i.e. 8-9 years of age which may prolong the overall treatment duration excessively. When considering this option from a cost effectiveness point of view, it may not seem as worthwhile because most traumas was reported to be minor, with the teeth having a good prognosis and treatment having low cost. This has to be compared to the costs of a long maintenance phase, waiting until the permanent dentition to erupt, before the second phase of orthodontic treatment, with fixed appliances, could be started (Koroluk et al., 2003, Ferguson, 2006, Chen et al., 2011). Currently, a full economic analysis of these two options has not been carried out so it is difficult to make a clinical decision from a cost-effectiveness point of view.

In the current study, the cut off between the early and late treatment groups was that all first premolars had to be erupted for patients to be classified as a late starter. So, any patient who did not have even one first premolar unerupted was classified as an early starter. In hindsight, it may have been better to divide the sample based on the presence of all the deciduous

canines and molars (Cs, Ds and Es) in the oral cavity for the early group. Patients with any of the permanent canine or premolars (3s, 4s and 5s) erupted would have been in the late group. This may provide a better separation point between the early and the late starters because the eruption times of the permanent canines, 1st and 2nd premolars are close together. In addition, in some cases the canines (3s) and second premolars (5s) erupt before the first premolars (4s) and categorising these patients as early starters would not be representative of their stage of dental development. This point should be considered when interpreting the results of this study and for future research.

6.4.4 Overjet at the Start of the Treatment

The mean overjet for this sample was 9.9 mm (SD= 2.3 mm) at the start of the functional treatment. When looking at the overjet distribution in more detail, the outliers were one patient who had an overjet of 16 mm and three patients, who had an overjet 3 mm, 4 mm and 5.5 mm respectively.

Patients with a large overjet who were included in the study are not a cause of concern because treatment with functional appliances is considered an appropriate approach for the treatment of growing patients who have an increased overjet. However, the patients with the small overjet who have been included in this study may raise some questions in terms of why they received a Twin-Block appliance. They were included because the inclusion criteria included both divisions of Class II malocclusions and did not exclude patients with a Class II division 2 incisor relationship. No stratification for patients with Class II division 1 and division 2 malocclusions was carried out and patients with Class II division 2 incisor relationship were not excluded.

The inclusion of patients with Class II division 2 incisor relationship would have influenced the results of this study because the patients with a Class II division 2 incisor relationship would have started their treatment with a small overjet. This would not have reflected the true extent of the underlying skeletal relationship or dental malocclusion that would have developed during the treatment. In addition, the Twin-Block appliance for these patients may have been designed to decompensate the incisors and thus increase the overjet that would then have been corrected during the functional appliance phase of treatment. Despite this concern, of the 80 patients included in this study, only three had a small overjet at the start of the treatment.

6.4.5 Stage of Cervical Vertebrae Maturation (CVM) at the Start of the Treatment

The results from the current study have demonstrated that the majority of the patients in this sample, who had a course of functional/fixed orthodontic treatment, were growing patients, in their circum-pubertal phase of growth (CVM Stage 3 or 4) with a mean age of 12.1 years and an increased overjet with a mean of 9.9 mm. The majority (76.2%) of these patients had reached the late stage of dental development with all four first premolars erupted.

The stage of cervical vertebrae maturation was recognised by Lamparski (1972) to be associated with the pre-pubertal growth spurt, so it may be able to be used to anticipate the growth potential remaining in the patient; however it could not be related to the chronological age of the patient. O'Reilly and Yanniello (1988) confirmed the observation that the shape of the cervical vertebrae was related to the skeletal changes seen in hand-wrist radiographs. In that longitudinal cephalometric study, the association between the increase in the mandibular skeletal growth and some identified morphological changes was recognised and confirmed. Hassel and Farman (1995) investigated this relationship and confirmed the results. In addition, they clarified that this information was readily available from lateral cephalograms taken as part of routine pre-treatment orthodontic records, whereas the hand-wrist radiograph requires an additional radiographic exposure in order for orthodontists to assess skeletal growth potential.

In the current study, the CVM staging was performed for the pre-treatment lateral cephalograms and it had been intended to include the CVM stage as an independent variable in the statistical analysis. However, it was only possible to assess the CVM stage of 31 (38.8%) of the 80 lateral cephalograms. The remaining radiographs were either missing or did not include the cervical vertebrae 2, 3 and 4 to allow the correct determination of the CVM stage. The omission of C2-4 was mainly due to the vertebrae being excluded from the radiograph as a result of shielding or coning the x-ray beam. When considering the best treatment timing (Baccetti et al., 2000), 4 of the patients were in Stage 1 and Stage 2, 25 patients were in Stages 3 and 4 and 2 patients in Stage 5. This indicated that 80.6% of the 31 patients had started their functional phase of the treatment at the ideal time. From those 31 radiographs, 7 patients were categorised as being early starters with respect to their dental development whilst the remainder were categorised into the late starter group. In addition, it was noticed that some of the patients, who were categorised as in their pre-pubertal growth spurt, belonged to the late starter group and vice versa. This suggests that CVM stage and the stage of dental development may not be reflective of each other.

Unfortunately these results were inconclusive, did not provide sufficient data for further analysis or inclusion in the regression analysis.

It had also been hoped to investigate the CVM stage at the end of the functional phase of the treatment and near the end of the fixed phase of the treatment, in relation to treatment duration. However, due to the high number radiographs in which C2-4 were not included, this was not possible.

Once it was realized that a significant proportion of lateral cephalograms had been cone cut and therefore inadequate for CVM staging, a training course for the radiographers was implemented. This aimed to improve their positing of the patients to ensure that C2, C3 and C4 were included on the radiograph and thus improve the diagnostic quality of the radiographs taken. Rainey (2013) undertook this as part of her DDSc project and associated audit. The training resulted in an improvement in the diagnostic quality of the radiographs taken recently (Rainey, 2013).

Despite the difficulties faced the current study, there may be an opportunity for further investigation using different study designs, such as a prospective longitudinal observational study or a randomised control trial to investigate the association between the stage of skeletal maturity and/or dental development and the duration of treatment with Twin-Block appliances. Young / immature participants could be recruited and then randomised to be treated at an early (i.e. CVM Stage 3 and/or before the first premolars have erupted) or late stage (Stage 4 or later and/or three or more first premolars have erupted). Previous studies investigating early versus late treatment **(**O'Brien et al., 2003a, 2003b, Tulloch et al., 1997, 1998 and 2004) (have selected and/or randomised to treatment at a different chronological age rather than measures of skeletal maturity or dental development.

6.4.6 Number of Clinicians

Patients treated in the current study ranged between having a single clinician to having three clinicians undertaking their treatment. The distribution of the patients was 48 patients (60%) who had a single clinician, 29 patients (36.3%) had two clinicians and 3 patients (3.7%) had 3 clinicians. This variable was dichotomised into two main categories: patients who had one clinician undertaking all the treatment and patients who were treated by more than one clinician.

Multiple clinicians treating patients has been associated with longer treatment duration in previous studies (McGuinness and McDonald, 1998). This is because when changing between clinicians, it takes a few visits for the new clinician to become completely familiar with the case, which in turn prolongs the overall treatment. However, it is important to remember the influence of a non-compliant patient on the number of clinicians variable. Patients who miss their appointment or do not comply with the treatment modality are likely to have a slower progress when compared with an enthusiastic, motivated patient. This means that another explanation for patients who have more treating clinicians have longer treatment times, would be that patients whose treatment duration has been extended, for one or more of a variety of reasons e.g. poor attendance record; awaiting eruption of teeth; breakages; complexity of treatment, have a treatment duration beyond the length of a single trainees training. This inevitably means that they will have more than one clinician undertaking their treatment so a patient having multiple treating clinicians may be due to the increased duration of treatment, for one or more of a variety of reasons, rather than the increased duration being due to the number of clinicians i.e. the increased treatment duration is related to other factors rather than number of clinicians. In addition, clinicians who accept transfer cases may already have a full treatment list so additional patients will increase the interval between the visits, thus leading to a prolonged course of the treatment. In addition, there would have been confounding with those patients with more complex malocclusions i.e. larger overjet; needed extractions, who were likely to have needed longer, more complicated treatment that would have spanned the training period of more than one clinician

6.4.7 Number of Consultants

In this study over three-quarters of the patients treatment (76.3%) was supervised by a single consultant during the full course of their orthodontic treatment. Only one patient (1.2%) was supervised by three consultants and the remaining 18 patients (22.5%) were supervised by two consultants.

In this study, it was thought that this variable could have an influence on the duration of the treatment; however, as all the consultants at LUDH would be expected to have a high level of qualification and experience, it is not thought to have as bigger impact of treatment duration as the number of the clinicians. Also, whenever the consultant supervising the case was on annual leave or not available at the hospital, another consultant is often called for guidance and advice. As the reasons behind seeking supervision from a different consultant are not

clarified, the number of supervising consultants is not likely to be reflective of the level of compliance.

6.4.8 The Transition Phase

The transition phase is the phase between the end of the active treatment with a functional appliance and the start of the fixed appliance phase of the treatment. It aims to maintain and consolidate the skeletal and dento-alveolar changes gained from the functional appliance while proceeding into the fixed appliance with ease and in an efficient manner. The transition phase is highly dependent on the clinicians preferences and the malocclusion present at the end of the functional phase of treatment. There are various methods by which transition can be managed smoothly and these are discussed in detail in a paper by Fleming et al. (2007).

The format of the transition phase varies so in this study, it was categorised into seven different kinds of transition and recorded on the data collection sheet. However, for data analysis, the transition phase was dichotomised into patients who had a transition phase and those who did not i.e. they went straight into the fixed appliance phase. In this study, the majority of the patients 77.5% (62/80 patients) had a transition phase.

Transition was not included as one of the influencing variables despite the possibility that it may have had an impact on the treatment duration, because, regardless of the advantages gained from this phase of treatment, it is likely that by adding an intermediate phase, in addition to a two-phased orthodontic course of treatment, could increase the treatment duration, especially if it involved an additional appliance. On the other hand, there is an argument that supports the transition phase and claims that the transition phase is helpful for settling the occlusion and reducing the detailing and finishing required near the end of the fixed phase of the orthodontic treatment. However, there is no robust evidence to support this claim and as a result it was excluded from the statistical analysis.

6.4.9 Presence or Absence of Extractions During the Treatment

At the end of the functional phase of the treatment, an assessment for the fixed appliance phase is performed to determine the on-going treatment plan and whether extractions will be needed or not. Each patient is different and these decisions are dependent on many factors including the malocclusion present at the end of the functional phase of the treatment.

Extractions have been shown to prolong treatment duration as they create space to be closed along with correction of other occlusal anomalies (Vig et al., 1990, Fink and Smith, 1992, Mavreas and Athanasiou, 2008). A more appropriate analysis could have been performed by

separating the extraction from the non-extraction group during the statistical tests, however, this was not recommended as it would reduce the sample size in each group. Stratification on the need for extractions could be considered in future research.

6.4.10 Overjet at the end of the Functional Phase of the Treatment

The aim for the end of the functional appliance phase is to reduce the overjet to an edge-to-edge incisor relationship. This is considered to be an overcorrection and it is a normal practice to balance the relapse tendency following the functional phase of the orthodontic treatment (Gill et al., 2005). An acceptable range for the overjet at the end of the functional phase would be 0-4 mm.

The mean overjet of the sample in the current study, at the end of the functional phase, was 1.5 mm (S.D. =1.4) with a maximum value of 4.5 mm and a minimum value -1 mm. From the 80 patients, only three patients had the overjet of 4.5 mm, which is considered above the acceptable range. This has shown that patients responded well to the Twin-Block appliance and showed good compliance. However, this may be considered to be subjective because the good compliance is not the only reason for achieving good results; favourable growth can influence the post-functional OJ as well. Also, because of the study design, the attrition bias caused by not including patients who did not complete the treatment would have an important impact on these results. Exclusion of the patients who did not complete the treatment would have over-estimated the reduction in overjet achieved and underestimated the end of functional phase overjet.

6.4.11 Overjet at the Start of the Fixed Appliance Phase of the Treatment

The aim of measuring the overjet at this stage was to examine the amount of relapse that could have happened between the end of functional and the start of fixed phases of treatment. In addition to relapse, as a determining factor of the overjet at the start of the fixed appliance phase, the presence or absence of a transition phase can influence this measurement and the length of the transition can also have an impact on the treatment duration. This measurement may also reflect the compliance of the patient with the appliance used in the transition. So, if the patient had a transition phase and complied with the use of the transition appliance, the overjet reduction should be maintained. On the other hand, lack of appliance wear in the transition phase can lead to an increase in the overjet by the time of the bond-up of the fixed appliance (Fleming et al., 2007).

The range of the acceptable overjet would be similar to the range of the overjet at end of the functional phase i.e. 0-5 mm, with some allowance for biological variation and a reasonable degree of relapse (Gill et al., 2005).

Again, the results suggest that an acceptable level of compliance and relapse were demonstrated in this sample. The mean overjet at the start of the fixed appliance phase was 2.4 mm (S.D. =1.5) with a maximum value of 6.5 mm and a minimum value of 0.0 mm with only two patients falling outside the acceptable range with an overjet of 6.5 mm and 6.0 mm.

Although this measurement can be used to describe the level of compliance and success achieved with the functional appliance in this sample, it is very difficult to analyse it in isolation and thats why it was not included in the statistical analysis.

6.4.12 Overjet at the end of the Orthodontic Treatment

The overjet of this sample at the end of the treatment had a mean value of 2.8 mm (S.D. = 1.0). The values ranged between a maximum of 7 mm and a minimum of 1 mm. An increased overjet was noticed in only three patients who had an overjet of 7 mm, 5.5 mm and 5 mm.

This measurement may be used to indicate the relative success of treatment. An increased overjet may be an indication of the patients lack of compliance, which may result in an early debond or to accepting the results achieved even if they were not ideal. At the end of orthodontic treatment, the aim is to achieve an overjet within the normal range of 2-4 mm (Cobourne and DiBiase, 2010). In addition, compromised treatment planning rather than non-compliance from the patients, may be a reason for patients finishing with an overjet larger than ideal. These cases are rare and may be the result of the patient having an extremely complex malocclusion that was complicated by additional factors e.g. hypodontia or the need for further restorative or surgical treatment. Another explanation for these cases can be the clinicians inexperience however, this should not have happened in the setting of this study where experienced consultants were supervising the treatment of these patients.

Overjet at the end of functional treatment, start of fixed appliance treatment and end of treatment were not included in the statistical analysis because many known and unknown confounders could have influenced the overjet and although many of these possible confounders were investigated in our study it was not possible to account for all of them. In addition, due to sample size related limitations, the variables included in the statistical analysis had to be limited to those most likely to influence the duration of treatment. Future

research, with an appropriately powered sample size, could be undertaken to investigate and determine variable related to compliance.

6.4.13 The Number of the Scheduled Visits

In this sample the mean number of the attended scheduled visits was 22.6 (S.D. = 5.7). Despite the importance of the number of the visits in relation to the duration of the treatment, on its own, it does not in itself reflect the duration of the treatment, as the duration of treatment will impact on the number of scheduled visits. Another important factor to complete the picture is the frequency of the visits. Unfortunately, this was not investigated in this study. However, normal practice would be to aim for the patients to be seen by the clinician every 6-8 weeks; this will result in a treatment duration range extending between 2-3 years on average.

The number of visits is similar to other reported values for the duration of the treatment (O'Brien et al., 2009b) but this variable was not included in the statistical analysis due to the impact of other confounding variables. If used in future research the number of scheduled visits could be supplemented by the interval between appointments and the workload of the clinician which would provide a clearer picture and a better use of this measure.

6.4.14 The Number of the Emergency Visits

The mean number of emergency visits was 3.1 visits (S.D. = 2.4) with a maximum number of 11 and a minimum number of 0.0 visits. From the included 80 patients, only two had 11 emergency visits.

Emergency visits are the visits that were needed between the regular appointments due to a problem or a breakage in the appliance. This measurement, can reflect the level of the compliance of the patient and his/her maintenance of the appliance throughout the treatment duration, however, highly motivated patients may attend for any minor concern. So, although it is a useful measurement, it should be interpreted with caution. For future research, it would be worthwhile recording the reasons behind the emergency visits to provide more accurate information. For example, a patient who attends many emergency visits due to a loss of a module could be considered as a patient with high number of breakages and low compliance when compared to another patient who never had any emergency visits, however, when that patient attended their scheduled visits, the clinician has to spend half the appointment repairing the unreported breakages. Therefore, the number of emergency visits, as a direct predictor of compliance, can be misleading so it was not included in the statistical analysis.

6.4.15 The Number of the Visits the Patient was Unable to Attend (UTAs) or Failed to Attend (FTAs)

The mean number of the UTAs was 0.9 visits (S.D. =1.4) with a maximum of 9 visits for a single patient and a minimum of 0 visits. Although the histogram in Figure 5. 15 shows a skewed distribution, it was decided, following discussion with a statistician, that the mean and S.D. should be representative of the sample distribution because the skew is mainly due to one patient who had 9 visits.

The median number of the FTAs was 1 visit (25^{th} percentile = 0 visit and 75^{th} percentile = 4 visits), with a maximum of 22 visits and a minimum of 0 visits. A similar picture to the UTAs can be seen due to a single patient who had 22 visits and led to skew the results, this can be seen on the histogram in Figure 5. 16.

The number of UTAs and FTAs are highly interrelated and one can influence the other. For both of them, the patient has missed the appointment and the only difference between them is that for the UTAs, the patient was able to call, inform the hospital and request a new appointment. So, although the UTAs reflect a higher sense of responsibility toward the appointments, the patient has still missed the appointment. Within the National Health Service of the United Kingdom, repeated FTAs can justify early withdrawal of the orthodontic treatment due to its association with lack of compliance. As a patient continues to miss appointments, either as a result of FTAs or UTAs, his/her treatment is effectively unsupervised which may result in the risks of treatment outweighing the benefits gained which in turn justifies withdrawal of the orthodontic treatment from the patient. In order to avoid such a situation, the patient or the parent, despite their indifferent behaviour toward the attendance of the appointment, continue to cancel (UTA) rather than fail (FTA) the appointments. In such cases, it would be anticipated that patients with high FTAs would have low UTAs and vice versa. However, it is important to realise that the patient is missing appointments and treatment is unsupervised.

Due to the complex inter-relationship between the FTAs and UTAs and as patients who UTA appointments have contacted the hospital which implies a level of compliance, it was decided to include only the FTAs in the statistical analysis as a reflection of lack of compliance, leaving the UTAs out of the statistical analysis. For the purposes of the statistical analysis, the FTA variable was dichotomised into low FTAs (0 or 1 FTA during the treatment) and those who had frequent FTAs (2 FTAs or more).

There is an opportunity for future research to explore the relationship between missed appointment, treatment outcome and treatment duration.

6.5 DURATION OF FUNCTIONAL AND TOTAL ORTHODONTIC TREATMENT

In this study, the mean duration of the functional phase was 10.54 months (SD= 4.19 months) and the mean for the total duration of treatment was 35.0 months (SD= 11.66 months). Although these results can be considered within normal limits, the study performed by O'Brien et al. (2009b), showed that the mean of the functional phase duration was 527days/17.6 months (SD= 208 days) and the total treatment duration was 968 days/32.3 months (SD= 428 days). In our study there was a shorter functional phase and a longer total treatment duration when compared with O'Brien (2009b).

A possible explanation for this variation could be due to the different level of experience. In this study, the majority of the clinicians carrying out the treatment were StRs who have less experience and were supervised by consultants. However, if the consultants did not see the patients every visit, treatment may not have progressed as efficiently which may lead to prolonged treatment durations. This could be a possible explanation for the different results in comparison with the O'Brien et al. studies (O'Brien et al., 2003a; 2003b), where the majority of clinicians were fully qualified orthodontists with higher level of clinical experience. Anothe possible explanation for the shorter functional phase would be due to the analysis of the patients who completed the treatment, whereas O'Brien et al. studies (O'Brien et al., 2003a; 2003b) were randomised controlled trials and all randomised subjects would have been analysed.

6.5.1 Factors Influenced the Duration of the Functional Phase of the Treatment

Statistical testing, using the t-test, suggested that there was no statistically significant association between the duration of the functional phase of treatment and the stage of dental development ($p = 0.242$).

When the pre-treatment overjet and the chronological age where tested using Pearson's correlation coefficient, the overjet at the start of the treatment was significantly correlated to the duration of the functional phase of the treatment. This correlation was positive and linear, so the larger overjet, the longer the functional phase ($p = 0.016$). However, the correlation was weak and that was assessed from the correlation coefficient value, which was 0.268. On

the other hand, the chronological age at the start of the treatment was not significantly correlated to the duration of the functional phase of the treatment ($p = 0.146$). See Table 5. 7 for further details.

This was confirmed by a statistically significant association, seen in the multiple regression analysis, between the starting overjet and the length of the functional phase ($p = 0.016$). This finding was consistent with previous results, confirming that the pre-treatment overjet has a positive association with the duration of the functional phase of the orthodontic treatment (Banks et al., 2004). However, association was weak as seen by the low adjusted R^2 value of 0.072. This suggests that the model had a poor fit and that only 7.2% of the variability in the duration of the functional phase of treatment can be explained by the association with the pre-treatment overjet.

6.5.2 Factors Influenced the Total Treatment Duration

From all the factors discussed earlier, the t-test revealed statistically significant associations between the total orthodontic treatment duration and the number of clinicians ($p \leq 0.001$), presence or absence of extractions ($p = 0.020$) and the number of FTAs visits ($p= 0.001$). These results were in line with the previous studies (Banks el al., 2004, O'Brien et al., 2009b). The correlation with these factors was further confirmed by the results from the multiple regression analysis where the same variables were statistically significantly related to the total duration of the orthodontic treatment (for the number of clinicians - $p = 0.001$; extractions - $p = 0.021$; number of FTA visits - $p = 0.001$). Another variable was found to be statistically significant and that was the chronological age ($p = 0.013$). There was a weak negative Pearson's correlation coefficient of -0.278. This was confirmed in the multiple regression analysis of which age was statistically significant as well ($p = 0.002$).

However, the sample size of 80, rather than 97, mean that this analysis was underpowered which may have had an influence on the results. To test this conclusion a multiple regression analysis was undertaken and the adjusted R^2 value was found to be 0.385. This suggests that about 38.5% of the variability in the total treatment duration was explained by those variables and the regression model had a reasonably good fit for these four variables.

CHAPTER 7

7.0 CONCLUSIONS

This study answered the primary aim; which was to investigate the factors influencing treatment duration.

From a study sample of 80 patients, the main conclusions drawn about the duration of the functional phase of the orthodontic treatment were that:

1. The only factor that had a statistical significance on the duration of the first phase of the functional/fixed treatment was the overjet at the start of the treatment.
2. The factors that did not have an influence on the duration of the first phase of the functional/fixed treatment were the:
    a. Stage of dental development and
    b. Chronological age.

The main conclusions drawn about the total duration of orthodontic treatment were that:

1. The factors that had a statistical significance on the total duration of the treatment were:
    a. The number of the treating clinicians,
    b. The number of the visits which the patient failed to attend,
    c. The chronological age of the patient and
    d. Whether dental extractions were performed or not.
2. The factors that did not have an influence on the total duration of the orthodontic treatment were the:
    a. Stage of dental development and
    b. Overjet at the start of the treatment.

Although, considerable efforts were made to reduce any possible biases associated with retrospective studies, the potential influence from those factors (e.g. confounding variables, small sample size) could not be eliminated completely.

The conclusions should be interpreted and implemented with caution due to the limitations related to this study design. Future studies could be undertaken to clarify the influence these variables have on treatment duration. This should preferably be designed as a prospective

study with an appropriately sized sample size to allow associations between the known and suggested influencing variables and the outcome of interest (duration of treatment).

CHAPTER 8

8.0 CITED REFERENCE

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CHAPTER 9

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10.0 APPENDICES

10.1 APPENDIX 1

Patient Identification Number

Data Collection Sheet

Patient Name: ID Number:

Hospital Number: Post Code:

Date of Birth: Day Month Year

Age: Gender: F/ M

Models Availability: Y / N Models Box Number:

Clinician:

Consultant:

Number of Clinicians:

Date of Start of Functional Treatment: Day Month Year

Date of End of Active Functional Treatment (Most Achievable Reduction in OJ): Day Month Year

Date of Bond-up: Day Month Year

Date of End of Orthodontic Treatment: Day Month Year

Duration of Functional Appliance Treatment Months

Duration of Fixed Appliance Treatment Months

Duration of Full Orthodontic Treatment Months

Number of Scheduled Visits: ☐☐ Visits

Number of Emergency Visits: ☐☐ Visits

Number of UTA Visits*: ☐☐ Visits

Number of FTA Visits**: ☐☐ Visits

Start overjet: ☐☐ mm

Overjet at end of Functional: ☐☐ mm

Bond-up Overjet: ☐☐ mm

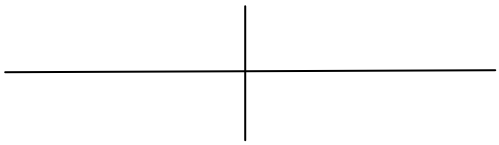
End of Treatment Overjet: ☐☐ mm

Type of Transition: ☐

1- None 2- Steep and Deep 3- Night time only 4- Reduction of blocks 5- Night time only + Reduction of Blocks. 6- Headgear (Hg) 7- 2+5

Extractions: Y / N ☐☐ ☐☐

Teeth Chart: (date: / /)



Dental eruption:

☐ Early ☐ Late

CVM Stage, can be assessed? ☐ Y ☐ N

If yes, which stage at pre-treatment? ☐

If yes, which stage at post-functional? ☐

If yes, which stage at pre-finish? ☐

Did patient meet inclusion criteria? ☐ Y ☐ N

If not, state reason? ……..

* UTA: Unable to Attend (cancelled appointment).

**FTA: Failed to Attend (failed appointment).

10.2 APPENDIX 2

Cervical Vertebrae Maturation Stages

"Cervical Stage 1(CS1), the lower borders of all the three of vertebrae (C2-C4) are flat. The bodies of both C3 and C4 are trapezoid in shape (the superior border of the vertebral body is tapered from posterior to anterior). The peak in mandibular growth will occur on average 2 years after this stage. Cervical Stage 2(CS2), a concavity is present at the lower border of C2 (in four of five cases, with the remaining subjects still showing a cervical Stage 1). The bodies of both C3 and C4 are still trapezoid in shape. The peak in mandibular growth will occur on average 1 year after this stage. Cervical Stage 3 (CS3), concavities at the lower borders of both C2 and C3are present. The bodies of C3 and C4 may be either trapezoid or rectangular horizontal in shape. The peak in mandibular growth will occur during the year after this stage. Cervical Stage 4 (CS4), concavities at the lower borders of C2, C3 and C4 now are present. The bodies of both C3 and C4 are rectangular horizontal in shape. The peak in mandibular growth has occurred within 1 or 2 years before this stage. Cervical Stage 5 (CS5), the concavities at the lower borders of C2, C3 and C4 still are present. At least one of the bodies of C3 and C4 is square in shape. If not squared, the body of the other cervical vertebra still is rectangular horizontal. The peak in mandibular growth has ended at least 1 year before this stage. Cervical Stage 6(CS6), the concavities at the lower borders of C2, C3 and C4 still are evident. At least one of the bodies of C3 and C4 is rectangular vertical in shape. If not rectangular vertical, the body of the other cervical vertebra is squared. The peak in mandibular growth has ended at least 2 years before this stage."

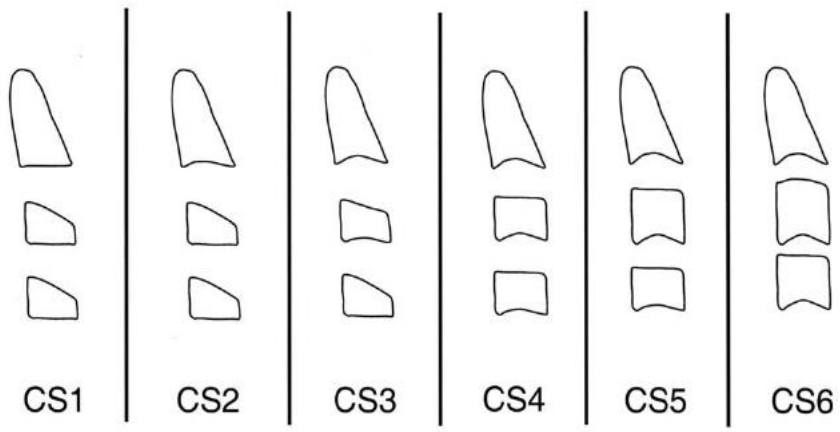


Figure: Stages of Cervical Vertebrae Maturation (Baccetti, T., Franchi, L. and McNamara Jr.A. (2005) 'The cervical vertebral maturation (CVM) method for the assessment of optimal treatment timing in dentofacial orthopaedics'. *Seminars in Orthodontics*. 11 (3), 119-129). Used with permission of RightsLink Copyright Clearance Centre and Elsevier.

10.3 APPENDIX 3

Cervical Vertebrae Maturation Staging and Stage of Dental Development of Patients

Subject Number	CVM Stage	Stage of Dental Development	Subject Number	CVM Stage	Stage of Dental Development
1	Not possible	Late	41	3	Early
2	2	Early	42	4	Late
3	3	Late	43	3	Late
4	3	Late	44	Not possible	Late
5	Not possible	Late	45	Not possible	Late
6	Not possible	Early	46	4	Late
7	3	Late	47	Not possible	Late
8	3	Late	48	3	Late
9	Not possible	Late	49	Not possible	Late
10	Not possible	Late	50	Not possible	Early
11	Not possible	Early	51	5	Late
12	Not possible	Late	52	4	Late
13	2	Late	53	3	Late
14	Not possible	Early	54	Not possible	Early
15	Not possible	Late	55	Not possible	Late
16	Not possible	Late	56	Not possible	Early
17	Not possible	Late	57	3	Late
18	Not possible	Early	58	Not possible	Late
19	Not possible	Late	59	Not possible	Late
20	Not possible	Late	60	4	Late
21	Not possible	Late	61	Not possible	Late
22	Not possible	Late	62	Not possible	Late
23	Not possible	Late	63	3	Early
24	1	Early	64	3	Late
25	Not possible	Late	65	Not possible	Early
26	3	Late	66	Not possible	Late
27	Not possible	Late	67	Not possible	Late
28	Not possible	Early	68	3	Early
29	3	Late	69	2	Late
30	Not possible	Late	70	4	Late
31	Not possible	Late	71	Not possible	Early
32	Not possible	Late	72	Not possible	Late
33	4	Late	73	3	Late
34	Not possible	Early	74	Not possible	Late
35	Not possible	Late	75	3	Late
36	3	Late	76	5	Early
37	Not possible	Late	77	4	Late
38	Not possible	Late	78	Not possible	Late
39	Not possible	Late	79	Not possible	Late
40	3	Early	80	Not possible	Early

10.4 APPENDIX 4

Extraction or Non-Extraction, The Extracted Teeth

No.	Extraction status	No.	Extraction status	No.	Extraction status	No.	Extraction status
1	Non-extraction	21	Non-extraction	41	5|4 5|6	61	-|- -|5
2	4|4 4|4	22	7|7 -|-	42	Non-extraction	62	Non-extraction
3	Non-extraction	23	Non-extraction	43	Non-extraction	63	Non-extraction
4	5|5 4|4	24	4|5 -|-	44	Non-extraction	64	Non-extraction
5	5|5 5|4	25	Non-extraction	45	Non-extraction	65	Non-extraction
6	Non-extraction	26	5|5 4|4	46	Non-extraction	66	Non-extraction
7	Non-extraction	27	5|5 5|5	47	Non-extraction	67	Non-extraction
8	Non-extraction	28	Non-extraction	48	Non-extraction	68	Non-extraction
9	Non-extraction	29	4|4 -|-	49	5|5 5|5	69	5|5 4|4
10	5|5 4|4	30	-|- 5|5	50	5|5 5|5	70	5|6 5|5
11	4|5 4|4	31	Non-extraction	51	Non-extraction	71	Non-extraction
12	5|5 4|4	32	4|4 -|-	52	-|6 6|6	72	Non-extraction
13	-|5 5|5	33	-|- 5|5	53	6|6 5|5	73	Non-extraction
14	Non-extraction	34	5|5 5|5	54	4|4 -|-	74	5|5 5|5
15	-|1 -|1	35	5|5 5|5	55	2|2 4|4	75	5|5 5|5
16	Non-extraction	36	Non-extraction	56	-|4 4|-	76	Non-extraction
17	Non-extraction	37	-|- 1|-	57	5|5 4|4	77	Non-extraction
18	Non-extraction	38	4|4 4|4	58	Non-extraction	78	5|5 5|5
19	5|5 5|5	39	5|5 4|4	59	5|5 5|5	79	5|5 -|-
20	Non-extraction Missing 2|2 1|1	40	Non-extraction	60	Non-extraction	80	-|- 6|6

10.5 APPENDIX 5

Skeletal Classification - Definitions

Class 1

The lower dental base is normally related to the upper. Point B lies a few millimetres behind point A.

Class 2

The lower dental base is retruded relative to the upper.

Class 3

The lower dental base is protruded relative to the upper.

Reproduced by: *Houston WJB, Stephens CD, Tulley WJ, A textbook of Orthodontics. The classifications of occlusion and malocclusion. 2nd ed. pp42-53, 1992, Wright.*

10.6 APPENDIX 6

British Standard Institute Classification of Malocclusion (1983): Incisor Classification

Class I

The lower incisor edges occlude with, or lie immediately below, the cingulum plateau of the upper central incisors.

Class II Division 1

The lower incisor edges lie posterior to the cingulum plateau of the upper central incisors. The overjet is increased and the central incisors are proclined or at normal inclination.

Class II Division 2

The lower incisor edges lie posterior to the cingulum plateau of the upper central incisors. The upper central incisors are retroclined.

Class III

The lower incisor edges lie anterior to the cingulum plateau of the upper central incisors. The overjet is reduced or reversed.

10.7 APPENDIX 7

British Standard Institute (1983): Dental Definitions

Overjet

The extent of the protrusion of the upper teeth ahead of the lower teeth when viewed from the side. Can be termed a "reverse overjet" if the lower teeth are protruding ahead of the upper teeth.

Overbite

The extent of overlap of the upper central incisors over the lower central incisors when viewed from the front.

British Standard Institute (1983): Anatomical terms and points of reference

cephalometric analysis

The analysis of the bony and sometimes the soft tissue, facial pattern from lateral skull radiographs taken with the Frankfort plane horizontal or in the natural head position, or tracings thereof. Sometimes a postero-anterior view orientated in the same horizontal plane is also used.

Soft tissue landmarks nasion (soft tissue)

The deepest point of the concavity between the nose and forehead in the mid-line.

Subnasale

The point where the lower margin of the columella meets the upper lip in the mid-line.

Labrale superius

The uppermost point on the vermilion margin of the upper lip in the mid-line.

Stomion

The most anterior point of the line of contact of upper and lower lips in the mid-line.

Labrale inferius

The lowest point on the vermilion margin of the lower lip in the mid-line

Supramentale (soft tissue)

The lowest point on the vermilion margin of the lower lip inthe mid-line.

supramentale (soft tissue)

The deepest point in the concavity between the lower lip and chin in the mid-line.

pogonion (soft tissue)

The most anterior point on the soft tissue outline of the chin in the profile view.

menton (soft tissue)

The most inferior point on the soft tissue outline of the chin.

Hard tissue landmarks nasion (bony)

The most anterior point of the fronto-nasal suture, as seen in the lateral skull radiograph.

orbitale

The lowest point on the infra-orbital margin.

anterior nasal spine

The tip of the anterior nasal spine, as seen in the lateral ANS skull radiograph.

subspinale

The deepest mid-line point between the anterior nasal point A spine and prosthion.

prosthion

The most anterior point of the alveolar crest in the premaxilla, usually between the upper central incisors.

incision (upper)

Tip of the crown of the most anterior upper central incisor.

incision (lower)

Tip of the crown of the most anterior lower central incisor.

infradentale

The most anterior point of the lower alveolar crest, situated between the central incisors.

supramentale (bony)

The deepest point in the bony outline between the point B infradentale and the pogonion.

pogonion (bony)

The most anterior point of the bony chin.

gnathion

The most anterior and inferior point on the bony outline of the chin, situated equidistant from pogonion and menton.

menton (bony)

The lowest point on the bony outline of the mandibular symphysis.

sella

The centre of the sella turcica, determined by inspection.

basion

The lowermost point on the anterior margin of the foramen magnum or, if this is obscured, the most superior point of the anterior margin of the base of the occipital condyles.

Bolton point

The highest point on the retrocondylar fossa on the occipital bone, posterior to the foramen magnum.

condylion

The highest point on the bony outline of the mandibular condyle.

articulare

The point of intersection of the dorsal contours of the posterior border of the mandible and the temporal bone.

porion

The uppermost point of the bony external auditory meatus, usually regarded as coincidental with the upper most point of the ear-rods of the cephalostat.

pterygo-maxillare

The lowest point of the outline of the pterygo-maxillary PTM fissure.

posterior nasal spine
The tip of the posterior spine of the palatine bone in the hard palate.

gonion

The most lateral external point at the junction of the horizontal and ascending rami of the mandible.

NOTE. On a tracing of a lateral skull radiograph, it is found by bisecting the angle formed by tangents to the posterior and inferior borders of the mandible.

SN plane

A transverse plane through the skull represented on a lateral skull radiograph tracing by the line joining sella and nasion.

de Costers line

The outline, in a cephalometric tracing, of the upper border of the anterior base of skull in the mid-line, used sometimes in the super-imposition of tracings.

Frankfort plane

A transverse plane through the skull represented on a lateral skull radiograph tracing by the line joining porion and orbitale.

maxillary plane

A transverse plane through the skull represented on a lateral skull radiograph tracing by the line joining anterior and posterior nasal spines. If either of these is distored or unclear, an alternative point may be used, produced by bisecting the root of the appropriate spine.

occlusal plane

A transverse plane through the skull represented on a lateral skull radiograph tracing by the line drawn to represent the occlusal line of teeth. There are various definitions.

(a) A transverse plane through skull represented on a lateral skull radiograph tracing by the line which passes mid-way between the incisal edges of maxillary and mandibular central incisors and which also passes mid-way between the tips of upper and lower cusps of the first permanent molar.

(b) A transverse plane through the skull represented on a lateral skull radiograph tracing by the line joining the tips of the cusps of the maxillary first molars to the incisal edge of the maxillary central incisor.

(c) A transverse plane through the skull represented on a lateral skull radiograph tracing by the line joining the tips of the cusps of the lower first permanent molars to the incisal edges of the mandibular central incisors.

(d) A transverse plane through the skull represented on a lateral skull radiograph tracing by the line drawn through the occlusion of the premolars and molars.

This is sometimes called the functional occlusal plane.

mandibular plane

A transverse plane through the skull represented on a lateral skull radiograph tracing by the line representing the lower border of the horizontal ramus of the mandible.

There are several definitions.

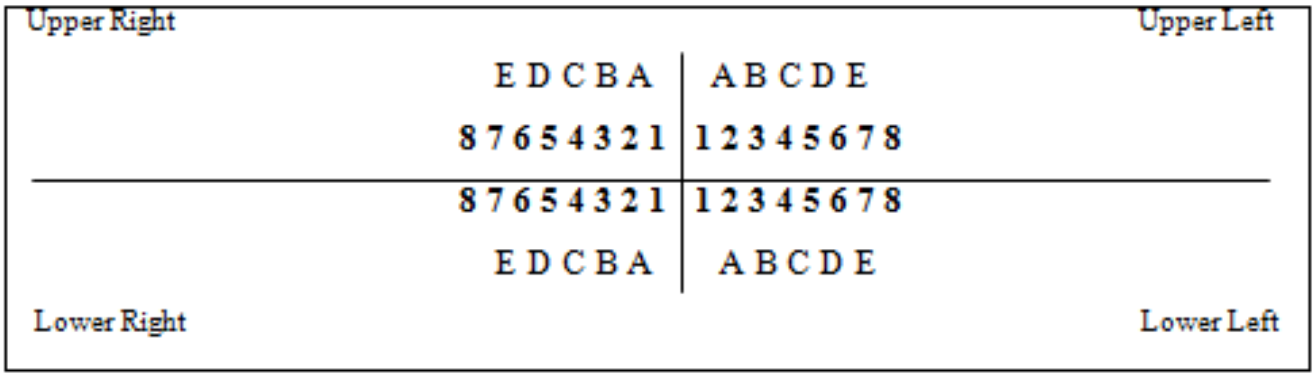
(a) A tangent to the lower border of the mandible.

(b) A transverse plane through the skull represented on a lateral skull radiograph tracing by the line joining gnathion and gonion.

(c) A transverse plane through the skull represented on a lateral skull radiograph tracing by the line joining menton and gonion.

10.8 APPENDIX 8

The Palmer's Notation (1870)



The Palmer's Notation for permanent teeth (numbers in bold, inwards) and deciduous teeth (outwards).

Manjunatha, B.S. (2013) *Textbook of Dental Anatomy and Oral Physiology Including Occlusion and Forensic Odontology*. 1st Ed. New Delhi: Jaypee.

10.9 APPENDIX 9

The University of Liverpool Intention to Co-Sponsor

Dr Norah Flannigan
Orthodontic Department
Liverpool University Dental Hospital
Pembroke Place
Liverpool
L3 5PS

Mrs Lindsay Carter
Clinical Research Governance Manager

University of Liverpool
Research Support Office
2nd Floor Block D Waterhouse Building
3 Brownlow Street
Liverpool
L69 3GL

Tel: 0151 794 8722
Email: lcarter@liverpool.ac.uk

21 November 2012

Sponsor Ref: UoL000899

Re: Intention to Co-Sponsor

"Early versus late treatment using modified twin-block appliance (TB)"

Dear Dr Norah Flannigan

After consideration I can confirm that the University of Liverpool, in principle, will be willing to act as Co-Sponsor with the Royal Liverpool and Broadgreen University Hospitals NHS Trust for the above research project under the Department of Health's Research Governance Framework.

The project is currently being reviewed through the necessary sponsorship approval procedure.

Yours sincerely,

L. Carter

Mrs Lindsay Carter
Clinical Research Governance Manager
Research Support Office

10.10 APPENDIX 10

NHS Trust Co-Sponsor Letter

The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Royal Liverpool University Hospital
Prescot Street
Liverpool
L7 8XP

Tel: 0151 706 2000
Fax: 0151 706 5806

TRUST CO-SPONSORSHIP LETTER

Professor Susan Higham
University of Liverpool
The Edwards Building
Daulby Street
Liverpool
L69 3GN
UK

30/11/2012

Dear Professor Susan Higham

RD&I No: 4439
TB : Early versus late treatment using modified twin-block appliance

I am pleased to confirm that the Trust accepts the responsibilities of co-sponsor in collaboration with The University of Liverpool for the above study. This will only come into effect when confirmation has been received from the co-sponsors.

Please note this does **NOT** constitute final Trust approval to allow your project to proceed. Trust approval will be given when final research ethics, financial and other regulatory requirements have been met.

In accordance with the SOP003 Roles and Responsibilities of the Sponsor and in order to meet the requirements of the Research Governance Framework 2nd Ed 2005, the Trust requires you to agree to the following CI responsibilities: -

- Inform RD&I within 24 hours of awareness of any SUSAR's or SAE's within the Trust as per Trust policy
- Provide copies to RD&I of annual progress and safety reports to Ethics and if appropriate the MHRA
- Complete and return the RD&I annual report form within 28 days of receipt
- Ensure annual review of the IB/SMPC if appropriate

- Comply with the Research Governance Framework 2nd Ed 2005 including but not limited to the Medicines for Human use (Clinical Trials) 2004 act plus it's appendices, the Data Protection Act 1998 and the Human Tissue Act 2004
- Ensure biannual training in GCP of all essential research staff on the study
- Read, disseminate to research team and acknowledge to RD&I, Trust research SOP announcements
- Inform RD&I of any amendments to, or changes of status in the study **prior to** submission to the regulatory authorities or ethics
- Maintain the study site file
- Make available for review any study documentation so requested by the sponsors and regulatory authorities
- Provide the Trust with copies of Data Management Committee reports if appropriate
- Provide the Trust with draft publications 30 days prior to submission to the publisher

Please contact the RD&I Department if you require any advice on the above points.

The RLBUHT sponsorship committee reserves the right to withdraw sponsorship should any significant change be made to the application as per SOP004 available on the Trust intranet.

Yours sincerely

Prof T Walley
Sponsorship Committee Chair

cc Head of Directorate
Co-sponsor
Pharmacy (CTIMP only)

10.11 APPENDIX 11

Favourable Opinion of Research Ethics Service

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

West of Scotland REC 4
Ground Floor – The Tennent Institute
Western Infirmary
38 Church Street
Glasgow G11 6NT
www.nhsggc.org.uk

Professor Susan Higham
Professor of Oral Biology
Department of Health Services Research and
School of Dentistry
University of Liverpool
Research wing
Daulby Street
L69 3GN

Date 11th March 2013
Your Ref
Our Ref
Direct line 0141 211 2123
Fax 0141 211 1847
E-mail Liz.Jamieson@ggc.scot.nhs.uk

Dear Professor Higham

Study title:	**A study to assess the duration of treatment in subjects who started early versus subjects who started late orthodontic treatment using modified Twin-Block appliance.**
REC reference:	**13/WS/0060**
IRAS project ID:	**101950**

The Proportionate Review Sub-committee of the West of Scotland REC 4 reviewed the above application on 05 March 2013.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Liz Jamieson, Liz.Jamieson@ggc.scot.nhs.uk.

Ethical opinion

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

Ethical review of research sites

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

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Investigator CV		
Letter from Sponsor		21 November 2012
Letter from Sponsor		13 November 2012
Letter from Sponsor		30 November 2012
Other: Student CV - Dr Alaa Mohammd		
Protocol	2.5	30 August 2012
REC application		01 February 2013

Membership of the Proportionate Review Sub-Committee

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

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

Feedback

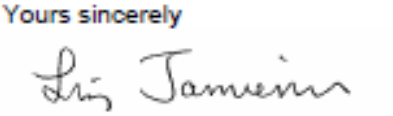
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
information is available at National Research Ethics Service website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

13/WS/0060	**Please quote this number on all correspondence**

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

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

Yours sincerely



Liz Jamieson
Committee Co-ordinator
On behalf of Dr Ken James, Vice Chair

Enclosures: *List of names and professions of members who took part in the review*
"After ethical review – guidance for researchers"

Copy to: *Alex Astor, University of Liverpool Research support office*
Mrs Heather Rodgers, Research Governance Management

West of Scotland REC 4

PRS Sub-Committee of the REC meeting held in correspondence with a deadline of 05 March 2013

Committee Members involved in the Review:

Name	*Profession*	*Present*	*Notes*
Dr Kenneth James	Consultant Anaesthetist	Yes	
Dr Jackie Riley	Statistician	Yes	
Mr Iain Wright	Consultant Engineer (Lay member)	Yes	

10.12 APPENDIX 12

Copyright for Figure 2.1

GRATPERM

Dear Dr Mohammd,

Re: William J. Clark. The twin block traction technique *The European Journal of Orthodontics (1982) 4(2):129-138*, Figure 1A

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Please do not hesitate to contact me if I can be of any further assistance.

Kind regards,

Guffi

Guffi Chohdri (Ms)

Rights Assistant

Academic Rights & Journals

Tel: +44 (0)1865 354454

Email: guffi.chohdri@oup.com

10.13 APPENDIX 13

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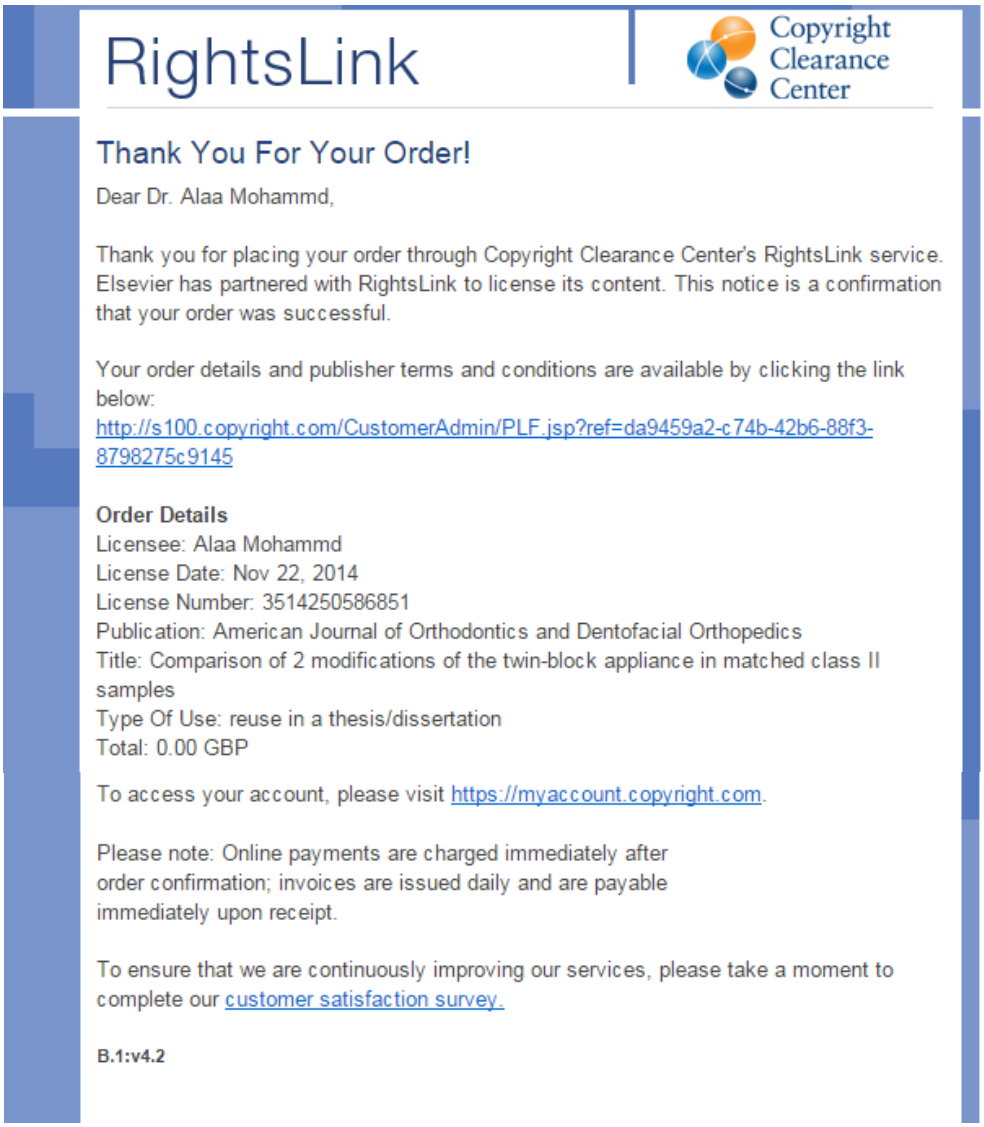

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10.14 APPENDIX 14

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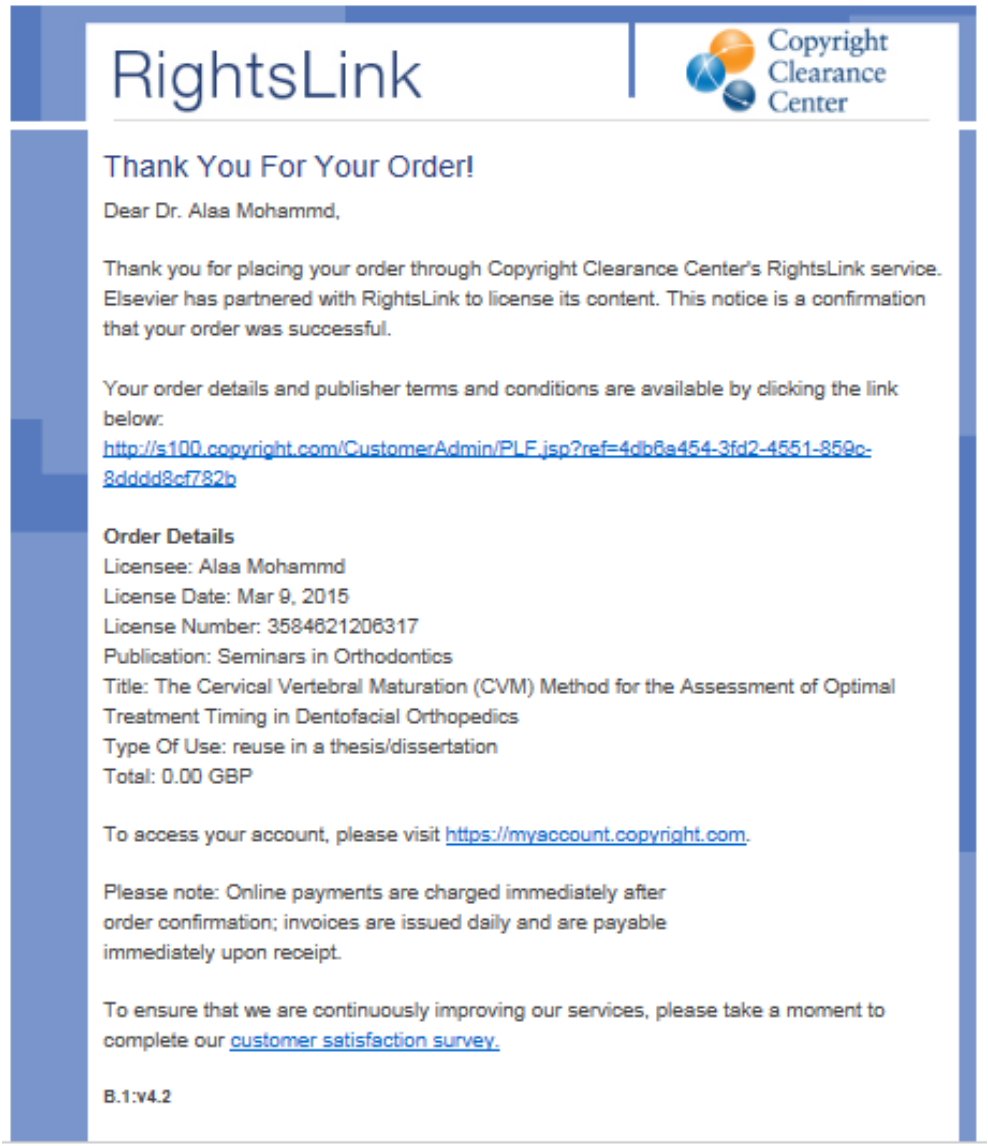

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