Effects of QScan on Plaque Accumulation and Demineralisation in Orthodontic Patients.

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctorate of Dental Science.

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Acknowledgments

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Abstract

Objective: To test the efficacy of the QScan oral hygiene device used by patients with fixed orthodontics appliances and its effect on plaque accumulation and demineralisation.

Design and Setting: A prospective randomised control trial was undertaken at Liverpool University Dental Hospital.

Materials and methods: Sixty patients with upper and lower fixed orthodontic appliances were recruited and randomly divided into two groups. The intervention group was provided with the QScan device to use as an at home oral hygiene adjunct. The control group were asked to continue with thier oral hygiene care at home without the use of QScan. Both groups were assessed over a period of three orthodontic appointments. At each visit Quantitative Light Fluorescence Induced - Digital (QLF-D) photographs were taken of the dentition in an aim to quantify the amount of plaque and demineralisation.

Results: Fifty-six (93.3%) participants completed the study. There was a total reduction in plaque accumulation in the QScan group, which was statistically significant ($p<0.001$) when compared to the control group (t-test analysis). Though there was an evident reduction in plaque accumulation, this did not reflect on the levels of demineralisation. Data analysis revealed that the changes in demineralisation between the QScan and control group were insignificant ($p>0.05$).

Conclusions: The Qscan device has shown to be an effective adjunct for plaque control in orthodontic patients following a longitudinal assessment. However, this reduction did not translate to a significant reduction in demineralisation following an average 15 week assessment.

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1.0 Introduction

In Orthodontics, the use of fixed appliance components such as bands, brackets and archwires makes the daily maintenance of oral hygiene more of a challenge. This is due to the increase in the number of stagnation sites (Van der Veen et al. 2007) and as plaque matures the number and volume of bacteria increases (Rosenbloom & Tinanoff 1991). Plaque is a well-documented aetiological factor in the demineralisation of tooth substance (Atack et al. 1996), and in severe cases this may lead to unsightly marks on tooth surfaces. This can even progress to cavitation requiring restoration (Benson et al. 2003). In addition to this, periodontal inflammation often occurs as a consequence of increased plaque accumulation, which increases the risk of periodontal disease (Zotti et al. 2016).

A high proportion of patients who undergo Orthodontic treatment are at the transitional period between puberty and adulthood. Their “manual ability and overall motivation regarding oral hygiene maintenance are often suboptimal”. This is thought to be related to a number of complex factors, including concerns in relation to the appearance of their fixed appliances, feelings of discomfort and sometimes bullying as a result of their malocclusion, or as a result of the orthodontic intervention itself. Young individuals are proficient in using smart phones and devices in order to communicate, learn and share information (Zotti et al. 2016). For this reason, it may be thought that the use of a device which assists with oral hygiene may motivate and educate people to improve plaque control. Thus potentially reducing the occurrence of demineralisation during fixed appliance therapy.

There have been numerous dental advancements that aid patients in their at home oral care. Some have been investigated continuously with various methods of

research (Yaacob et al. 2014). Others lack high quality evidence supporting their efficiency. A recent technological advancement in plaque detection has been the development of the QScan device (Inspektor Research Systems, Amsterdam). This device utilises light emitting diodes (LED) in an aim to detect plaque accumulation. The areas of plaque that patients are missing when brushing becomes very evident using this ‘at home’ device. The concept of having a plaque detecting device to use at home is very thought-provoking, however the efficacy of this device remains uncertain. A great concept may not necessarily be one of benefit.

The randomised controlled trial reported in this thesis investigated the influence of the QScan device as part of an “at home” oral hygiene routine. This study compared the levels of plaque accumulation (primary outcome) and demineralisation (secondary outcome) in patients using the QScan device when compared to a control group. All the participants were recruited in the Orthodontic Department at the Liverpool University Dental Hospital. Participants in both groups received all of the regular oral hygiene advice for orthodontic patients. Therefore, they were not disadvantaged when compared to orthodontic patients at the department. Data was gathered in the form of Quantitative Light Induced Fluorescence – Digital (QLF-D) photographs which were analysed following assessment of intra and inter reliability with an experienced QLF researcher (GK). Levels of plaque and demineralisation were quantified using the QLF-D system. Statistical analysis was completed using SPSS software (version 24.0, IBM Corporation, Armonk, NY, USA) with the assistance of an experienced statistician (GB).

This thesis consists of 10 chapters starting with a detailed literature review, which will discuss the main aetiological factors related to demineralisation and dental caries. This will be followed by methods of assessing oral health related to

demineralisation, including the evidence based methods proposed to ensuring satisfactory oral care. The aims and objectives related to testing the efficacy of the QScan device will be described in chapter 3, followed by the methods to test the null hypothesis. The results chapter will be followed by a discussion interpreting the findings and a final conclusion for the study. The final chapters will outline documents related to the study and all the references used in this thesis.

2.0 Literature review

In this literature review the evidence available in relation to the aetiology of demineralisation will be outlined. Important preventive approaches including patient information and oral health promotion methods will also be discussed, followed by a summary of various methods to identify both plaque and demineralisation.

2.1 Aetiology of Dental Caries

Miller (1988) described dental caries as a dynamic process that occurs due to the association between four main factors. The tooth surface, the substrate in the presence of plaque over a time period. This has been diagrammatically presented as follows (Figure 1):

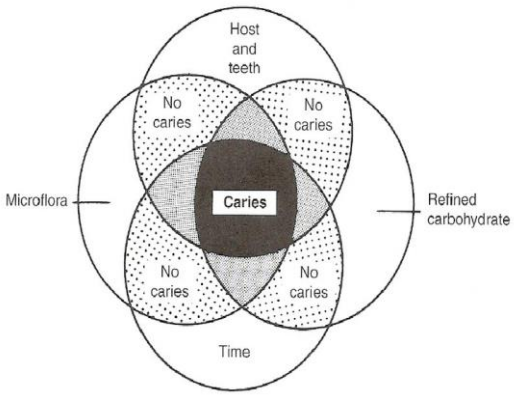


Figure 1: Basic diagrammatic process of caries (Miller 1988)

This basic diagram displays the main process in relation to dental caries. The process of dental caries extends beyond these basic elements. Risk factors are known to play a direct role in the final result of caries. Fejerskov and Manji (2010) combined this basic process with the risk factors associated with dental caries (Figure 2):

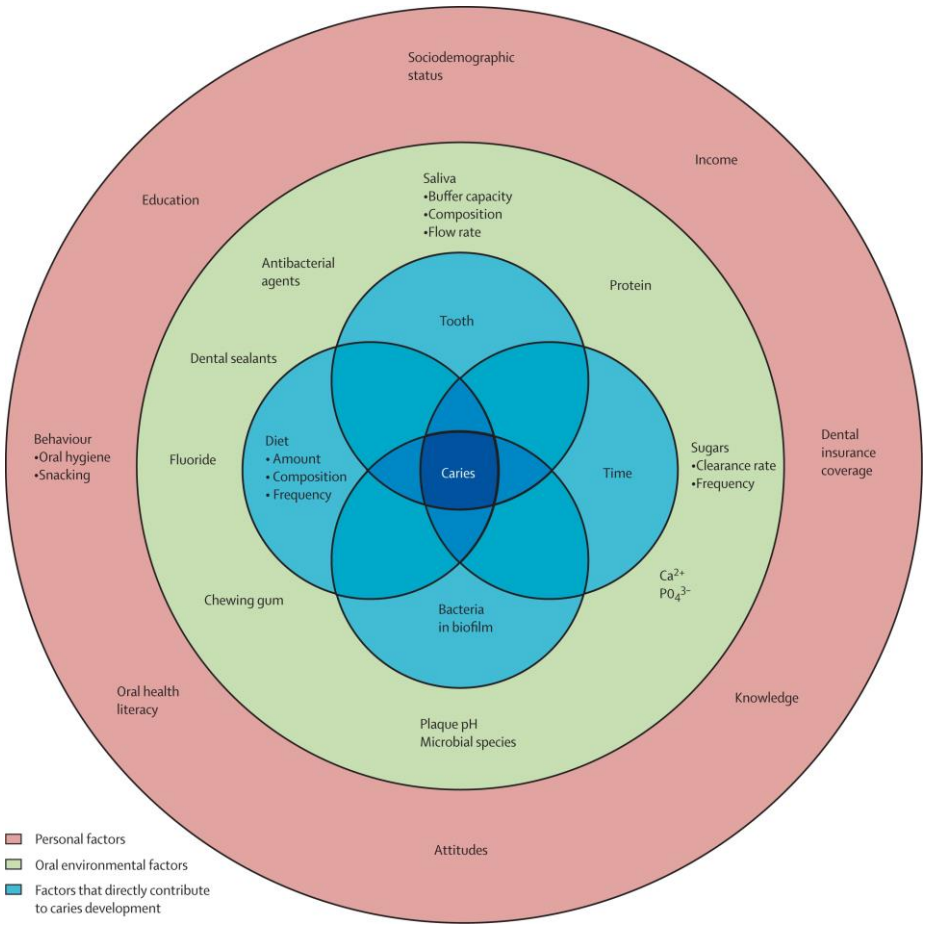


Figure 2: Illustration of the basic process with the risk factors associated (Fejerskov & Manji 2010)

The cause of dental caries as evident in Figure 2 is a complex process. It stems beyond the basic physiological process of plaque formation in the presence of a substrate, and the acidic effects on teeth over time. The factors that directly contribute to dental caries are effected by the oral environment and personal factors as well. The understanding of dental caries and its aetiology is key in limiting the risks for dental caries. The aim would be to either directly tackle the basic process of dental caries (Figure 1) or to tackle the more general factors which may be related to

dental caries (Figure 2). This is dependent on the complications a patient may present with. As an example, a patient that doesn't have dental insurance and access to dental treatment in some areas of the world may have an increased risk of dental caries which needs to be addressed. Luckily, this is not the case in the UK with National Health Service dental treatment being available. This particular point would be considered as a personal factor (Figure 2) which is a complication that extends beyond the basic physiological process in figure 1.

2.2 Plaque/Bacterial biofilm

Dental plaque has been defined as *"the diverse community of microorganisms found on the tooth surface as a biofilm, embedded in an extracellular matrix of polymers of host and microbial origin"* (Marsh 2004). The process of caries can occur on any tooth surface with the presence of dental plaque for a substantial amount of time (Fejerskov 2004). Plaque is a key factor in the development and pathogenesis of caries and periodontal disease (Axelsson *et al.* 2004). There are 5 distinct phases of plaque development as described by Marsh (Marsh 2004):

a) Adsorption of host and bacterial molecules to the tooth surface.
b) Passive transport of oral bacteria to the tooth surface.
c) Co-adhesion of later colonisers to early colonisers which are already attached.
d) Multiplication of attached microorganisms.
e) Active detachment enabling colonisation elsewhere in the mouth.

The process of plaque formation begins immediately after brushing and is initiated by the attachment of planktonic bacteria to the enamel (Kim et al. 2014). As plaque matures it is held within a matrix of polymers of salivary and bacterial origin (Pretty et al. 2005; Marsh 2004). This results in a complex community which accumulates

preferentially at stagnant sites which include proximal areas, gingival margins, margins of restorations, deep fissures and around orthodontic appliances (Pretty et al. 2005; Van der Veen et al. 2007). The biofilm has high levels of acidogenic (produce acid through fermenting carbohydrates) and aciduric bacteria (have the ability to resist the acid produced) which become more dominant with time (Kim et al. 2014). As they accumulate and the plaque layer becomes thicker, the protective buffering and antimicrobial properties of saliva have less of an effect (Donlan & Costerton 2002).

There are a number of different hypotheses which have aimed to identify the role of bacteria in caries. These include:

1) Specific plaque theory: This theory proposes that only specific bacteria are the cause of dental caries in their production of acid. Therefore with this theory the aim is to tackle the specific bacteria in the biofilm (Miller 1980).

2) Non – specific plaque theory: This theory proposes that the overall and total plaque biofilm is the cause of dental caries. Therefore with this theory the aim is to fully remove all the bacteria rather than focus on a specific one. This can be resolved by means of tooth brushing and mechanical plaque control (Loesche 1976).

3) Ecological plaque hypothesis: This theory proposes that bacteria causing caries are on all the host sites. The cause of acid production and caries is due to change in the oral environment. If the sugar intake increases, this changes the oral environment leading the cariogenic bacteria to ferment the substrate, and release acid, demineralising enamel. Therefore in this theory the aim is to

not only tackle the bacteria in plaque, but create an environment which would reduce the risk of caries by controlling the environment (Marsh 1994).

2.3 Carbohydrates/Diet

The evidence available strongly suggests that carbohydrates and sugar consumption play a major role in the formation of caries. The evidence can be divided into intervention clinical trials, non-intervention and epidemiological studies. An example of the intervention clinical trials is the Vipeholm dental caries study (Gustafsson et al. 1954). A total of 436 'mentally deficient patients' were divided into groups to assess the effect of sugar in a number of different forms. The sugars were given at different time periods to assess how the rate of dental caries is affected by a) the amount of sugar, b) frequency of intake and c) the form of sugar. The groups included ones that were on a normal diet, high level of non-sticky sugars (that wouldn't be retained on teeth), low level of sticky sugars and a high level of sticky sugars at different periods. The study concluded that:

1) The increase in the number of sugars increases the risk of dental caries

2) The sticky form of sugar that retained on teeth increased the risk

3) The risk increases if the sugars are consumed between meals rather than during

Although this study (conducted in the 1950s) is considered unethical, it has provided strong evidence to suggest the effects of carbohydrate intake, retention and frequency on dental caries (Gustafsson et al. 1954).

In the non-intervention clinical studies participants were mainly observed to assess the rate of caries in a population and its relation to their daily sugar intake. A study conducted in the UK looked at 405 English school adolescents' daily sugar intake and assessed it in relation to the rate of caries. An annual dental examination was conducted with the use of radiographs to assess the rate of caries. The results showed a clear correlation between the total daily consumption of sugar and the rate of caries. Adolescents with the highest sugar intake developed a DMFS (decayed missing filled surfaces) score as high as 5.0 in compared with the ones that had half the amount of sugar intake with a DMFS of 0.9 (Rugg-Gunn et al. 1984). This non–intervention clinical study gave further evidence to the amount of sugar intake and diet on the rate of dental caries.

The epidemiological evidence in relation to the relationship between caries and sugar intake has been observed during times where the level of sugar availability was low. Severe dietary restrictions were evident in World War II, one of which was the availability of sugar. A reduction in the availability of sugar was accompanied by a decrease in the rate of dental caries in permanent teeth. The same concept of sugar availability was evident in Tristan da Cunha, where the locals had low caries rates which reflected the islands dietary habits; mainly low in sugar with the consumption of natural unprocessed foods. After the 1940s there was a clear increase in dental caries which reflected a shift in the rate of sugar intake following its importation (Holloway 1962). Another form of epidemiological evidence is with patients suffering from fructose intolerance disease. This rare hereditary disease forced patients to refrain from eating foods containing sucrose and fructose. These patients present with low caries rates which is a reflection of their low sugar intake.

With the evidence currently available looking at the amount of sugar consumption and the frequency of intake on caries levels, it is recommended that sugar intake is limited. This can be done by advising patients to reduce the amount of sugar intake or more practically reducing the frequency. Reduction in the frequency of intake would evidently reduce the amount of intake and the risk of caries in the long term (Prevention and Management of Dental Caries in Children SDCEP 2010). The maximum daily, safe limit for the amount of sugar intake has been set at 50g/60g (Sheiham 2001). In terms of the frequency of intake, it has been clearly demonstrated that an intake of sugar more than four times daily can have an increased risk of caries activity. This is particularly evident if patients intake sugar three times per day between meals (Holbrook 1995).

As mentioned above there is a lot of evidence to support the reduction of sugar intake and the care needed in relation to the frequency of intake as well. The effects of sugar intake has been shown to have a positive linear correlation with caries. The effects on the type of sugar intake has also been demonstrated through the low pH oral environment that is created following sugar intake. The significant reduction of pH is thought to have a more important role in the development of caries than the intake of sugar (Marsh 1998). Though there may be a high sugar intake the effects on the dentition are very much dependent upon the oral environment created and the pH level. Therefore any aspects of the oral environment which may affect the pH can affect the caries risk. Behaviours such as tooth brushing, use of mouthwash or even water intake at a pH of 7 may alter the balance which can also reduce the effects on the enamel. The intake of foods such as cheese have been recommended by the SDCEP guidelines after sugar intake and meals (Prevention and Management of Dental Caries in Children SDCEP 2010). This is to ensure that a gradual increase in pH occurs away from the critical level. Though caution has been advocated to the

excessive consumption of foods which may also be high in calories and fat, such as cheese for general health purposes.

The consumption of sugars such as sucrose is known to result in a pH reduction and a negative cariogenic environment is created if the pH falls below the critical level. This was demonstrated by Stephan (1944) showing a rapid reduction in the pH following sugar consumption (Figure 3). Within 2-3 minutes the pH can fall below the critical pH level. Time is needed for the pH to rise gradually in an oral environment with salivary buffering characteristics. The increased frequency of dietary sugars may maintain the pH at the critical pH level. This will prolong the cariogenic environment and prolong the effects on enamel which may lead to significant demineralisation.

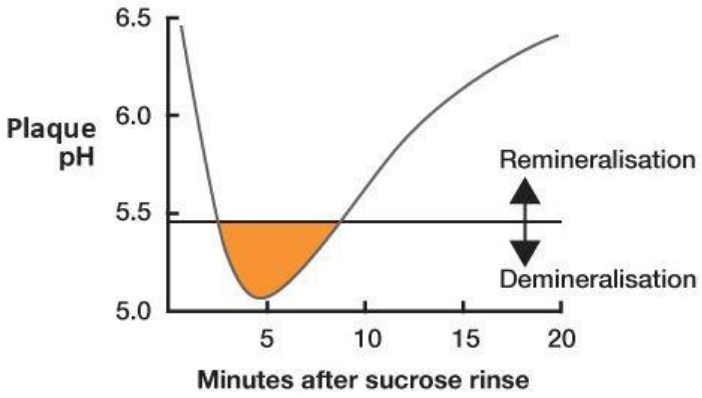


Figure 3 - Stephan curve outlining the effects of sucrose intake on pH levels (Stephan 1944)

2.4 Enamel/Host

Dental enamel is largely inorganic, with 86-95% of its volume comprising of hydroxyapatite crystal of Calcium Phosphate (Ca10(PO4)6(OH)2) which is arranged in prisms. Pores are present due to inter-crystalline spacing and this allows for the movement of ions between the enamel and the surrounding oral environment. The space can act as a pathway for diffusion which is an important factor in the development of dental caries (Robinson et al. 2000).

The organic component is mainly composed of proteinaceous material (1-2% of the total volume), with water making up the remainder (Weatherell 1975). This proteinaceous material is formed of small peptides and amino acids distributed throughout the tissue. These are thought to be the remnants of the original developmental matrix which formed the tooth structure (Robinson et al. 2000).

2.5 Demineralisation of dental enamel

The demineralisation of tooth substance associated with plaque accumulation is a common unwanted occurrence during fixed appliance treatment (Atack et al. 1996). Fermentation of dietary sugars produces inorganic acids and results in demineralisation. The bacteria present in plaque lower the oral pH by producing acids which act to change the pH of the oral environment to below that of the critical level. This results in the dissolution of mineral content of the tooth (Chang et al. 1997). The idea of a critical pH at which tooth demineralisation occurs, was represented in a curve produced by Stephan using data from a landmark *in vivo* study (Stephan 1944 – see Figure 3).

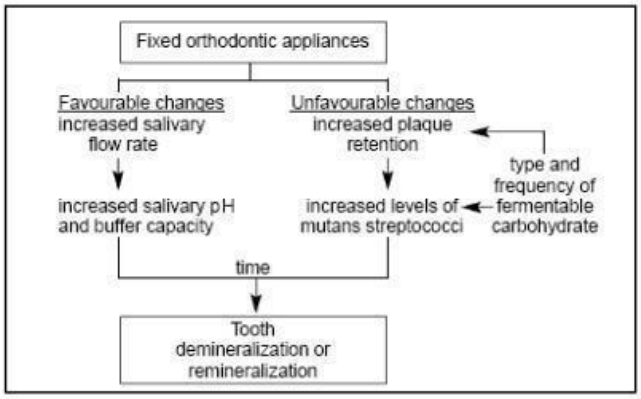


Figure 4 - Demineralisation and remineralisation during orthodontic treatment (Chang et al. 1997)

Most importantly, demineralisation is the first stage of dental caries and in the early stages this is reversible. When the pH is lowered below the critical level; calcium, phosphate and hydroxyl ions diffuse from the tooth into the surroundings. Reversal and remineralisation of tooth substance is aided mainly by the protective components of saliva, and fluoride found in toothpastes, mouthwashes, or drinking water. In the UK about 10% (6.1 million people) have drinking water with fluoride content sufficient enough to benefit oral health (1ppm fluoride). Of these, 5.8 million people receive artificially fluoridated water (British Fluoridation Society 2016).

The carious process is episodic and an individual with an increased frequency of carbohydrate intake will have longer periods of low pH and thus more demineralisation may occur. If the rate of ion loss from enamel occurs at a greater rate than remineralisation, caries occurs. Caries then has the potential to advance through enamel and into dentine, destroying the tooth structure.

The tooth demineralisation and remineralisation cycle which can occur during Orthodontic treatment is represented in Figure 4 above (Chang et al. 1997). This

outlines the sequence of events and influencing factors which are often involved in the process.

Microscopically dental caries has been divided into 4 zones in the literature depending on the degree of change in mineral content which can be seen when examined under polarised light. The original work of Darling (1963) was a new approach to analysing structural changes seen in caries by utilising polarised light and imbibition media to show changes in porosity as lesions progressed. These 4 porosity related zones are defined as (Robinson et al. 2000; Darling 1963):

1. Translucent zone: This is the deepest part of the carious lesion where the main ions affected are magnesium and calcium which are lost form the peripheral rod structures. There is a loss of about 1-2% mineral content and thus a small number of relatively large pores are present.

2. Dark zone: This zone has both larger and smaller pores with an increased porosity of between 5-10%. In this portion more rods are involved than in the deepest zone. The mineral dissolution seen is mainly calcium and phosphate ions.

3. Body of the lesion: The majority of the rods have been destroyed and porosity is high at between 25-50%. This is a destructive process in which the pores continue to increase in size until cavitation ultimately occurs. It is located just below the surface of the tooth. Rods have been replaced by bacteria surrounded by water. This area of lost mineral content may be seen clinically as a white spot on the tooth (hence the term '*white spot lesion'* is often used).

With dietary or smoking related staining however this lesion may appear darkened or brown with time.

4. Surface zone: This is the outermost layer which is dynamic with the mineral content fluctuating continuously depending on the oral pH. Despite this, changes beneath the surface zone may remain demineralised and an almost porous yet mineral rich layer can act to disguise a larger lesion below (Arends & Christoffersen 1986).

2.6 Demineralisation classification

There have been many indices designed with the aim of standardising the assessment of demineralisation and caries. Common examples of indices used to assess demineralisation of enamel include:

a. International Caries Detection and Assessment System II (ICDAS II) which differentiates between cavitated and non cavitated lesions (Pitts 2004). It was also designed to allow for a better and more consistent assessment for cariological studies.

Code	Description
0	Sound
1	First visual change in enamel (seen after prolonged air drying)
2	Distinct visual change in enamel
3	Localised enamel breakdown (without clinical visual signs of dentinal involvement)
4	Underlying dark shadow for dentine
5	Distinct cavity with visible dentine
6	Extensive distinct cavity with visible dentine

Table 1 - ICDASII classification

b. This was then modified by the International Caries Classification and Management System (ICCMS™) in which the basic ICDAS was merged to result in the following (ICCMS™ guide for practitioners and educators 2014):

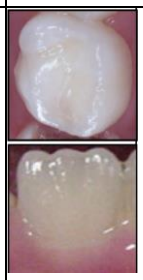
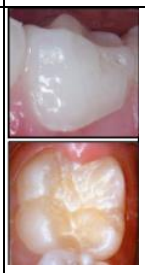
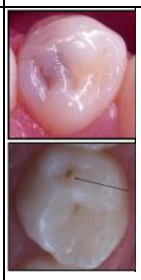
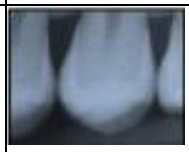
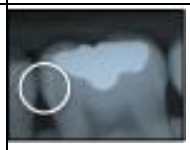
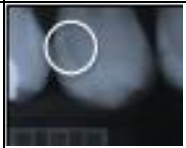
Code	Description	
Sound Surfaces (ICDAS 0)	**Sound tooth surface** – show no evidence of visible caries when viewed clean and after prolonged air drying	
Initial stage caries (ICDAS 1+2)	**First or distinct visual changes in enamel** – seen as a carious opacity or visible discolouration not consistent with the clinical appearance of sound enamel and which show no evidence of surface breakdown or underlying dentine shadowing.	
Moderate stage caries (ICDAS 3+4)	A white or brown spot lesion with **localised enamel breakdown**, without visible dentine exposure or **an underlying dentine show.**	
Extensive stage caries (ICDAS 5+6)	A **distinct cavity** in opaque or discoloured enamel **with visible dentine.**	

Table 2 - ICCMS™ classification

c. When categorising caries progression radiographs can be a very useful source of information. They can not only aid in assessing the presence or absence of caries but also the depth of caries. This becomes very useful in many situations such as areas that may not necessarily be clinically visible such as below the contact points. In many clinical cases where there is no evident cavitation, a radiograph may provide further evidence in relation to the presence and depth of caries. This will not only aid in caries diagnosis but also caries management. Therefore, a radiographic system was devised by ICDAS in which to stage caries radiologically. This staging system allowed for the assessment of the carious lesions to not only cover the basic levels of enamel, dentine and pulp but also divide these three layers. Furthermore, it combined the pulpal layer with clinical changes. This is evident in the table below (ICCMS^{TM} guide for practitioners and educators 2014):

Scoring	Description	
No radiolucency	No radiolucency	
RA1	Radiolucency in the outer half of enamel	
RA2	Radiolucency in the inner ½ of enamel +/- enamel dentine junction	
RA3	Radiolucency limited to the outer third of dentine	

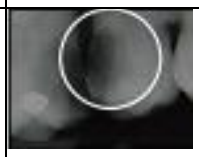
RB4	Radiolucency reaching the middle third of dentine	
RC5	Radiolucency reaching the inner 1/3 of dentine, clinically cavitated	
RC6	Radiolucency into the pulp, clinically cavitated	

Table 3 - Radiographic ICDAS classification

d. As with the visual caries staging in ICDAS the ICCMS merged the ICDAS radiographic stages in a system that has been shown to be reproducible and accurate (Pitts & Ekstrand 2013). See below:

Scoring	Description
R0	No radiolucency
RA – Initial stages	Combining RA1 – outer 1/3 enamel RA2 – inner 1/3 of enamel +/- EDJ RA3 – limited to the outer 1/3 of dentine
RB – Moderate stage	RB4 – inner 1/3 of dentine
RC – Extensive stages	Combining RC5 – inner 1/3 of dentine, clinically cavitated RC6 – into the pulp, clinically cavitated

Table 4 - Combined ICDAS, ICCMS and ICDAS radiographic classifications

e. Finally both the radiographic and clinical assessments were combined classifying the lesions into initial, moderate and extensive caries risk. The combination between the clinical and radiographic examination would aid a treating clinician to come up with a treatment plan which includes a preventative and definitive action (table 5) (ICCMS^{TM} guide for practitioners and educators 2014):

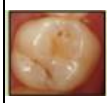
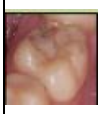
	R0 	RA1/2 	RA3 	RB 	RC 
Sound 	Sound	Initial	Initial	Moderate	Extensive
Initial 	Initial	Initial	Initial/ Moderate	Moderate	Extensive
Moderate 	Moderate	Moderate	Moderate	Moderate	Extensive
Extensive 	Extensive	Extensive	Extensive	Extensive	Extensive

Table 5 - Combined ICDAS radiographic and clinical examination

f. Demineralisation can be categorised on a scale depending on the severity (Gorelick et al. 1982) in which tooth drying can allow for detection of white spot lesions. The general scale used by Gorelick was as follows:

Score	Description
I	No white spot formation
II	Slight white spot formation
III	Severe white spot formation (thicker band)
IV	White spot formation and cavitation

Table 6 - Demineralisation according to severity by (Gorelik et al. 1982)

g. Boyd and Rose (1994) assessed white spot lesions in combination with the clinical representation and a clinicians clinical judgement:

Score	Description
0	No visible white spots or surface disruption
1	Visible white spot without surface disruption
2	Visible white spot lesion having a roughened surface
3	Visible white spot lesion requiring a restoration

Table 7 - Assessment of white spot lesions and its clinical representation (Boyd & Rose 1994)

h. Mizrahi (1982) devised a scoring system that divided the tooth surface into three distinct sections and assessed the extent of demineralisation accordingly:

Score	Description
0	No enamel opacity, an opacity of less than 1mm in length or diameter (which was considered absent)
1	An opacity covering upto one third of the surface area
2	An opacity covering up one third to two thirds of the surface area
3	An opacity covering up two thirds of the surface area

Table 8 - Extent of demineralisation in segments in accordance with Mizrahi 1982

In the scoring systems above there is a clear emphasis on the clinician's clinical examination in an aim to screen for caries lesions. This has a number of advantages and disadvantages. Its advantages is that it is a very simple and inexpensive method with minimum tools needed. Though the main disadvantages is that using simple clinical examination methods means that the assessment is subjective. The scoring systems above are mainly descriptive as well and rarely is there an accurate quantification. The layer of enamel is very thin and to assess a radiolucency by dividing that thin layer in half may be considered unreliable. Reliability and reproducibility is key when using scoring measures for research. The inability to reproduce a measure poses questionable outcomes to any research.

2.7 Plaque stagnation and Orthodontic treatment

In Orthodontics, the use of fixed appliance components such as bands, brackets and archwires lead to an increase in plaque accumulation mainly at the gingival margins (Van der Veen et al. 2007). In addition, the teeth are also more challenging to clean, which together with the reduced natural clearance of plaque by saliva, acts to compound plaque retention (Mattousch et al. 2007). The greater the complexity of appliance components, the more difficult it is for a patient to clean adequately (Zachrisson & Zachrisson 1971). When compared with traditional caries formation, the rate of caries progression is reported to be faster around fixed appliances. Early caries (white spot demineralisation) can present within 4 weeks of appliance placement (Ogaard & Ten Bosch 1994).

The cited prevalence of demineralisation during Orthodontic treatment varies greatly in the literature with data reported between 2-96% (Gorelick et al. 1982; Mizrahi 1982; Ogaard 1989). This variation of prevalence in studies was mainly due to the different methods of assessing white spot lesions, and the lack of standardisation between studies. For example, enamel abnormalities such as fluorosis or hypoplasia may be documented as a white spot lesion leading to a false positive finding. Also, a thorough pre-treatment examination must be completed so pre-existing areas of demineralisation are not mistaken for areas which have developed during orthodontic treatment.

In 1982, Mizrahi completed a cross sectional study of patients undergoing multibanded fixed appliance orthodontic treatment (Mizrahi 1982). In this study, demineralisation was assessed using the opacity index, and it showed a 12% increase in the number of white spot lesions in the patients undergoing orthodontic

treatment. The relevance of this in today's clinical practice however is questionable, as multibanded fixed appliances are no longer commonly prescribed. In 1989, Ogaard compared a group of patients whom had received fixed Orthodontic treatment (on average they were debonded 5.7 years prior to data collection), with a group of untreated controls. The median of white spot lesions was significantly higher in the orthodontically treated group compared with the untreated group ($p=<0.01$). There was no significant difference in white spot occurrence between males and females, upper and lower arches, or between left and right sides (Ogaard 1989).

The use of Quantitative Light Induced Fluorescence (QLF) in a study by Al-Maaitah (2011) found the prevalence of demineralisation to be 71.7%. This was higher when compared with a 29.7% ($p < 0.001$) prevalence at debond, reported in the placebo group (in a randomised control trial) of Orthodontic patients using digital images (Stecksttén-Blicks et al. 2007). It is difficult to compare the results of studies that use different means of recording and quantifying the amount of plaque and/or white spot lesions. The fact that demineralisation is a well-recognised potential complication of treatment means that patients must be made aware of the risks of white spot lesions. During the consent process before treatment this must be made very clear. Different strategies need to be discussed as well to avoid demineralisation if they are to be satisfied with the post orthodontic results. Teeth may be straight with an adequate occlusion, though the aesthetic and dental health outcomes may be compromised with the presence of demineralisation. This is particularly concerning to patients when in the anterior smile zone.

Demineralisation can affect any tooth surface, but some areas appear to be more prone than others. The maxillary lateral incisors are most frequently reported to

demonstrate white spot lesions following Orthodontic treatment, followed by the maxillary canines, premolars and central incisors respectively (Chapman et al. 2010). Gorelick et al. (1982) reported the incidence of white spot lesions in lateral incisors are as high as 23%. This was concluded following an assessment of 121 Orthodontic patients. This increase may be due to several factors including (Ogaard 1989):

- Bracket positioning being closer to gingival margin.
- Morphology of the lateral incisor itself.
- Tendency of the lateral incisor to be displaced palatally making it more challenging to remove plaque in the early stages of fixed appliance treatment.

Fixed appliance treatment has been documented to negatively impact tooth cleaning and may result in the formation of chronic hyperplastic gingivitis in some cases. Plaque is the main causative factor of chronic hyperplastic gingivitis, but this condition is also greatly influenced by environmental and genetic factors (Atack et al. 1996). An important aspect to question is whether Orthodontic appliances, by increasing plaque stagnation, may influence the progression from gingivitis to periodontitis (Anhoury et al. 2009).

Changes due to plaque retention can be permanent. It is essential that Orthodontic patients demonstrate their ability to maintain excellent oral hygiene both before and during treatment. Methods of detecting early signs of demineralisation are likely to be a very useful tool for both clinicians and patients alike. This helps to limit progression of the demineralisation and potentially reduces the risk of further lesions occurring. Therefore, patients need to be informed of the consequences related to poor oral

hygiene and the methods in which the incidence of white spot lesions can be reduced.

2.8 Patient information

It is thought that no single method of instruction will suit all learners equally (Yoder 1994). Previous literature in medicine and dentistry has commonly provided patients with information in verbal (chair-side), written or videotape form (Lees & Rock 2000). Of these, written instructions alone is thought to be the least effective (Self et al. 1983). Lees and Rock (2000) conducted a clinical trial comparing the effect of verbal, written or videotape oral hygiene information using knowledge, plaque and gingival indices as outcomes. Although the results did not reach a level of significance, there was greater improvement in the oral hygiene of patients in both the verbal and videotape groups. Those who received only written instructions demonstrated no improvement in their plaque index. This study was prone to multiple biases including the use of a single examiner, and outcomes were only tested on two occasions (once before information being given, and the second time 8 weeks later). At both of these appointments plaque, gingival indices and knowledge were all examined.

2.9 Oral health promotion

In a systematic literature review of randomised and quasi-randomised controlled clinical trials, Grey and McIntyre (2008) assessed the effects of oral health promotion programs on plaque and gingival health. They concluded that oral health promotion programmes for Orthodontic patients were beneficial in reducing plaque and improving gingival health. This was over a short term period of 5 months. They also reported that based on the available evidence, no method of oral health promotion appeared to be superior to the others. Verbal advice from a health care professionals

along with a plaque disclosing programme has been reported in the literature to reduce plaque levels when compared to verbal instruction alone (Gray & McIntyre 2008).

Health education has been recommended to be part of a continuous process rather than part of a single episode to gain optimal outcomes (Talvi et al. 1999). Marinho et al. (2003) in a Cochrane Review outlined the benefits of fluoride toothpastes demonstrated in numerous trials as part of health education programs. Clinical studies support the use of a 0.05% sodium fluoride mouthwash on a daily basis during Orthodontic treatment as part of an oral health program (Boyd & Rose 1994).

2.10 Plaque and demineralisation identification

In this section the various methods of assessing oral hygiene status and in particular methods of plaque and demineralisation identification will be demonstrated. This will include direct visual assessment, plaque disclosure and photography. More recent diagnostic tools have also been developed including Quantitative Light Induced Fluoresce (QLF), Quantitative Light Induced Fluorescence - Digital (QLF-D), DIAGNOdent, Toothcare and Q-Scan which are available for use in a chair-side setting. These will also be discussed in detail in an aim to summarise the latest advancements in the field of plaque and demineralisation identification.

2.10.1 Direct visual assessment

In order for individuals to clean their mouth effectively they need to be able to identify plaque, and in particular, to note the problematic areas which are inherently more prone to its collection (Pretty et al. 2005). Large amounts of plaque are quite easily visible to the naked eye, but smaller amounts in shadowed areas and around appliances can be more difficult to visualise directly.

Direct visual assessment is the most common method to assess the presence of dental plaque and there are several indices which enable the clinician to quantify the amount present. Depending on the study, plaque may be quantified by the amount of tooth surface covered, or by the thickness of the plaque in the area measured (Pretty et al. 2005). Some examples of these methods include:

i) The Greene and Vermillion article (1960) was a landmark piece of literature discussing a method for classifying oral hygiene status. This plaque index may be used with plaque disclosing tablets. The tooth is divided into horizontal and vertical thirds leaving the orthodontic bracket in the centre. In a study by Lees and Rock (2000) they used the 5 boxes gingival and directly alongside the bracket to quantify the amount of plaque present.

ii) The Modified Ramfjord Index uses the facial and lingual surfaces of 6 selected teeth and assigns a score between 0-3 depending on the amount of tooth substance covered by plaque (UR6, UL1, UL4, LL6, LR1 and LR4). The total score is divided by the number of surfaces to give a mean (Ramfjord 1967; Shick & Ash 1961).

iii) The Quigley and Hein plaque index (1962), involves disclosing plaque and scoring 0-5 depending on the amount of tooth surface (buccal and lingual) with plaque present. The mean score is established by dividing this by the number of tooth surfaces (Pretty et al. 2005; Quigley & Hein 1962).

iv) The Loe and Silness index (1963) examines the thickness of plaque rather than the extension of plaque on the tooth surface. It can be used with or without plaque disclosing agents. Each of the 4 gingival areas of a tooth are scored 0-3 (Loe & Silness 1963):

0- No plaque.

1- A film of plaque adhering to gingival margin and adjacent area of the tooth. Plaque may be seen in---situ only after application of disclosing solution or by using a probe on the tooth surface.

2- Moderate accumulation of soft deposits within the gingival pocket, or on the tooth and gingival margin which can be seen with the naked eye.

3- Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin.

v) In addition to these methods, the Bonded Bracket Plaque Index (Kiliçoğlu et al. 1997) is specifically designed to assess plaque accumulation during fixed Orthodontic treatment. This index classifies plaque based on location and extent of coverage on the bracket and tooth:

1. No plaque on bracket or tooth surface.
2. Plaque on bracket.
3. Plaque on bracket, tooth, no extension to gingiva.
4. Plaque on bracket, tooth, extension to papilla.
5. Plaque on bracket, tooth, partial coverage to gingivae.
6. Plaque on bracket, tooth, full coverage to gingivae.

Interestingly, although this index is specifically designed for use in Orthodontic patients, the Loe, Silness and Turesky indices (Turesky et al. 1970) are more frequently used. They are reported to be a reliable means of quantifying plaque coverage. In general, the method of plaque detection selected for research is dependent on several factors including (Pretty et al. 2005):

- Type of research
- Population included
- Facilities available
- Duration of the project
- Research question
- Specific changes which are to be measured

In a clinical scenario, the most common method for plaque identification is a simple visual assessment. Issues with reported low sensitivity and specificity of plaque scoring systems have been addressed to a certain extent by calibrating examiners in the assessment process. This calibration however, increases the cost of the research and does not necessarily address the validity of the findings. More precision and better sensitivity is seen with QLF which has the ability to detect even very small amounts of plaque (Cugini et al. 2006).

2.10.2 Plaque disclosure

Plaque is generally colourless. In clinical fields, disclosure is a simple way for the clinician and patient to see the plaque present chair-side. This can then be used as a guide to improve brushing technique (Figure 5) (Faller 2000; Pretty et al. 2005). Disclosing tablets often contain erythrosine dye which stains the areas of concern red demonstrating the plaque distribution. This method is useful for educational purposes and patients can use the disclosing tablets themselves at-home. Issues include potential patient discomfort during disclosure, staining, time implications clinically inconveniencing the operator and the patient if done in the clinic, and reported occurrences of allergies. It is also important to note that this using disclosing tablets doesn't allow for the assessment of the pathogenic status of plaque (Kim et al. 2014).

Fluorescein disclosing can be completed using a UV fluorescent dye that is colourless when applied but adheres to plaque. A digital image is obtained, and using the fluorescence a digital plaque analysis can be completed. This is thought to be a good means of quantifying the amount of plaque present, however it is relatively costly (Pretty et al. 2005).

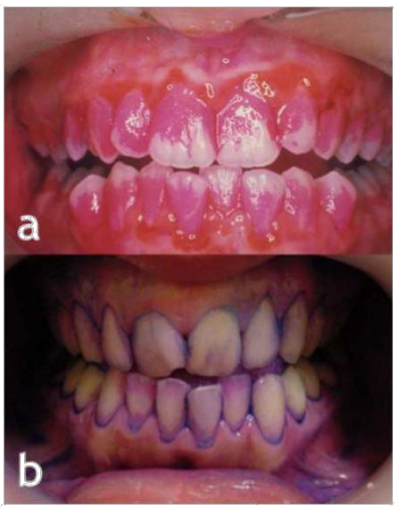


Figure 5 - Plaque discosure using diaclosing dye (Pretty et al. 2005)

2.10.3 Photography

Digital photography is now an integral part of Orthodontic assessment, diagnosis, for monitoring treatment progress, and documenting treatment from start to a final result. It is a reproducible and valid means of measuring the quantity of dental plaque on tooth surfaces (Rosa & Elizondo 2015). Sandler and Murray (2002) following a survey of Orthodontists in Europe recommended the minimum number of photographs for an Orthodontic patient to be 9 pre and 9 post-treatment. This can be divided in to 4 extra-oral (frontal at rest, frontal smiling, profile and three-quarters) and 5 intra-oral (frontal, buccal right and left, occlusal upper and lower). However, 36 photographs are thought to be required to ensure the course of treatment is documented comprehensively.

Photographs act as an efficient, cost effective and permanent means of recording patient information (Benson et al. 1998). The information can be easily stored and analysed at a later date, which is useful in research when observer recall bias can be reduced by completing inter-examiner assessments. Some disadvantages include difficulties in achieving consistency in relation to magnification, lighting and angulation of the images making it challenging to compare data and to assess progress accurately (Benson et al. 2004). The analysis of digital photographs has also been reported to be a valid and reliable method of quantifying demineralisation (Benson et al. 2003a). Further improvements on white light digital photography has been established in an aim for a more accurate assessment and analysis of plaque and caries detection.

2.10.4 Quantitative light induced fluorescence (QLF)

Quantitative light induced fluorescence (QLF) is a non-invasive diagnostic tool which allows for the quantification of enamel demineralisation, incipient carious lesions on smooth surfaces and the accumulation of dental plaque using visible fluorescent light (De Josselin De Jong et al. 1995; Angmar-Månsson & Ten Bosch 2001). The diagnostic capacity of QLF is dependent on the mechanism that the natural fluorescence (auto-fluorescence) of a tooth is decreased by scattering which occurs in carious lesions (demineralised tooth substance) (Angmar-Månsson & Ten Bosch 2001; Van der Veen et al. 2007). QLF can be used to calculate the severity of demineralisation by quantifying the size of the lesion and/or the extent of mineral loss in the affected area (Benson et al. 2003a). It has been shown to be a valid, sensitive and reproducible means of detecting early caries and for monitoring lesion progression (Stookey 2004).

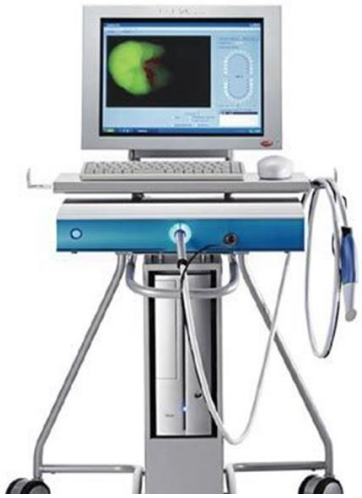


Figure 6 - QLF diagnostic system

Other methods using fluorescence have involved lasers or ultraviolet light, however because of potential eye damage these are deemed inappropriate in a clinical setting (Benson et al. *2003a)*. A portable QLF system was developed and first manufactured by Inspektor Research Systems in Amsterdam; it consisted of a charged couple device camera, filters and light sources which were connected to a computer (Figure 6, 7) (Al-Khateeb et al. 1997). The QLF images obtained were stored to allow for customised software analysis of the fluorescence levels present (Van der Veen et al. 2007). Heavy mature deposits of plaque appeared a deep red colour and were referred to as red fluorescent plaque (Sadeq et al. 2015). This red fluorescent plaque

(Figure 8) was thought to be red due to the presence of bacterial porphyrins present mainly in gram-negative anaerobes. The auto-fluorescence of these bacterial porphyrins (which are by-products of bacterial metabolism), means that both plaque and dental caries appear red using QLF images (Figure 8). The red colour is easier to identify in a more mature biofilm as a greater number of bacterial species are present. Hence, it can be suggested that the more intense the red is seen on the image, the higher the bacterial activity and thus the possibility of greater pathogenicity.

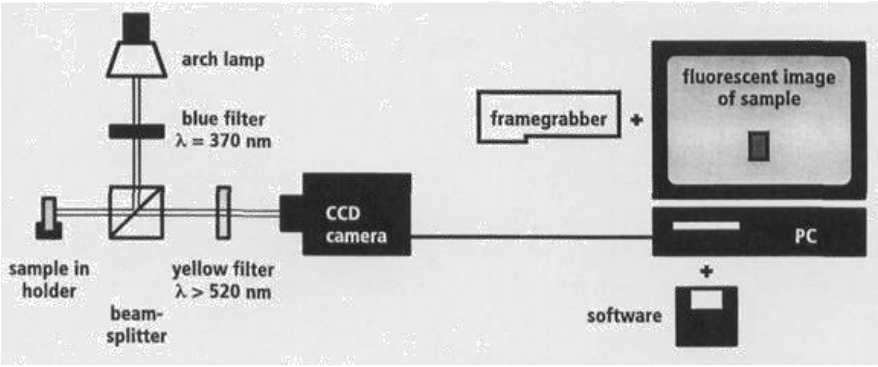


Figure 7 - The portable QLF diagnostic system (Al-Khateeb et al. 1997)

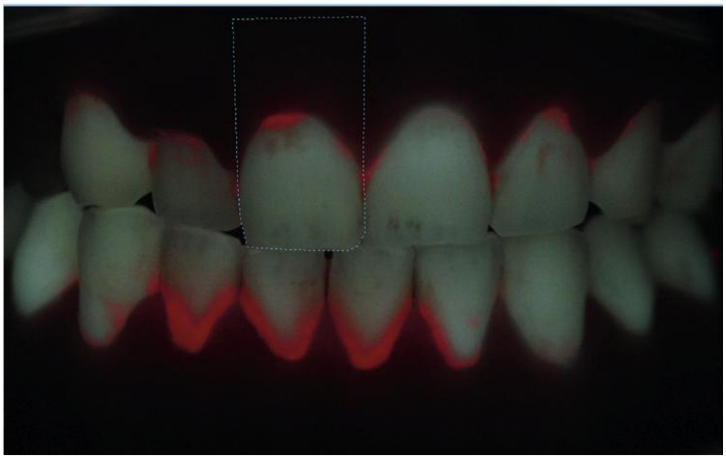


Figure 8 - Appearance of undisclosing plaque under QLF conditions (Han et al. 2015)

Plaque accumulation is graded using the customised QLF software according to amount of tooth coverage, which is based on the amount of red colour seen at various cut off points. The value of ΔR is representative of how many pixels are covered by red fluorescence. The fluorescence loss in the lesions is assessed relative to the surrounding enamel, therefore the outline of the analysis needs to be based on sound enamel to reduce the occurrence of false positives. Areas with fluorescence loss of over 5% are deemed part of the demineralised lesion (Pretty et al. 2003). Mean fluorescence loss is represented by ΔF which is determined by the level of demineralisation and the size of the lesion (ΔQ), it is based on the number of pixels involved (Pretty et al. 2002). QLF has been shown to be a valid and reliable tool for assessing plaque accumulation in vivo (Pretty et al. 2005) and in vitro (Benson et al. 2003a; 2003b).

QLF allows for plaque and demineralisation to be monitored more precisely than when descriptive indices are used (see section 2.10.1) and it detects demineralisation at an earlier stage than visual inspection or white light. Areas with greater than 15% fluorescence loss have been reported to be visible clinically (Boersma et al. 2005). The early detection of problems using QLF allows the clinician to reinforce oral hygiene and if appropriate to encourage remineralisation strategies.

Figure 9 - QLF-D camera and system

2.10.5 Quantitative Light Induced Fluorescence-Digital Biluminator (QLF-D)

This is an updated version of the original QLF device which examines plaque more clearly (Lee et al. 2013).

It was designed to enhance the features of the original system (Figure 6) and has a modified filter set and an enhanced light source (Ko et al. 2015). It is composed of a single-lens flex camera (SLR) attached to a laptop computer system with an automatic photo uploading system (Figure 9). The SLR camera has a built in extension which includes white and blue light emitting diode LED lights (Figure 10). It allows for automatic white light and blue light images to be taken. It still uses the principle of auto-fluorescence of teeth. When visible blue light of 405nm is emitted from the device there's a loss of fluorescence in the areas which have been demineralised. It is also designed to detect endogenous porphyrins which are represented as red fluorescence. It is thought to provide a clearer image of red fluorescence and to provide high resolution images when compared with the previous QLF system, (Kim et al. 2014) without the need for ambient light (Lee et al. 2013). The QLF-D was validated as a means of approximal caries identification in an in vitro study by Ko et al. in 2015. In that study it was shown to have high intra-examiner reliability, however the research did rely on one examiner for all methods. In addition to this the study was done *in vitro* resulting in the data lacking generalisability.

Figure 10 - White and Blue LED lights to take both white light photographs and QLF photographs (Blue arrow representing the blue LED and the white arrow representing white LED)

Figure 11 - Transverse microradiography system

A recent study was conducted with an aim to assess the detailed analysis of QLF-D. It aimed to assess the mean fluorescence loss, the maximum fluorescence loss, the lesion area and the lesion volume following orthodontic treatment. The aim was to place fluoride varnish (0.1% fluoride) on the white spot lesions and assess whether the QLF-D system would be able to detect the subtle changes following remineralisation. The authors concluded that the system was very sensitive to the small levels of mineral changes. Unfortunately this paper was considered as a pilot study with a small sample size, and used a technique that is not often practiced. The immediate fluoride varnish application may limit the reduction of the lesions volume and size. The study was simply used to show a reduction and change in demineralisation though no evidence in the validity or reliability of the change seen. There was also no comparison to any other measures of demineralisation detection (Kang et al. 2017).

The gold standard form of demineralisation detection and assessment is with the use of transverse microradiography (Ten Bosch et al. 1991) (Figure 11). This has been assessed in relation to the use of QLF-D in vitro. A study conducted by Cochrane et al. (2012) aimed to assess these changes following an in vitro lesion formation and remineralisation detected by the use of QLF-D and transverse microradiography. The results showed that there was an evident correlation between the use of QLF-D and transverse microradiography. Therefore in comparison to the gold standard QLF-D showed promising results of detection. This however was conducted in vitro and mounting curved crowns in a lab based setting with the detection systems is a

very delicate process. Previous research has shown that this occasionally results in glaring due to the curvature of the crowns, which results in areas of high reflectance and non-uniform reflectance. This can directly affect the outcome and detection levels.

QLF-D has also been shown in vitro to differentiate between early and more mature plaque as fluorescence intensity increases with maturity of the biofilm (Kim et al. 2014). Other research papers have reported that QLF-D can determine the cariogenicity of biofilms by assessing the intensity of red fluorescence (Lee et al. 2013; Kim et al. 2014). The severity of demineralisation was significantly correlated with biofilm maturation levels. Therefore, identification of these areas and investigation of preventive methods and increased patient motivation, possibly has the potential to halt the cariogenic process. This particular study used bovine enamel which is thought to be an acceptable comparison for human tooth enamel (Kim et al. 2014).

2.10.6 DIAGNOdent pen (KaVo, Biberach, Germany)

The DIAGNOdent pen (Figure 12) uses a laser light (655nm wavelength) to illuminate the tooth surface and detect dental caries. Normal healthy tooth substance demonstrates little fluorescence. In each person the score will be different so the pen must be calibrated using each individuals healthy tooth structure as a reference. As the teeth are examined, any area with greater bacterial activity will demonstrate more fluorescence, a higher pitched frequency will be produced and the number on the dial will be elevated. Hence it’s a simple, chair-side, non-invasive means of differentiating between carious and healthy tooth substance. The fluorescence is readily quantified and represented as a number displayed on the panel of the device

itself (Shi et al. 2001). This means there is reduced operator input and thus less potential for operator bias. Studies in vitro have reported the DIAGNOdent as effective in detecting smooth surface caries (Shi et al. 2001) and demineralisation adjacent to Orthodontic fixed appliances (Staudt et al. 2004).

Figure 12 - DIAGNOdent pen (Kavo dental 2019)

2.10.7 Toothcare (All In One Bio Inc, Seoul, Korea)

Toothcare is similar to QLF (see 2.10.4) as it also allows for the detection of both plaque and demineralisation. It's a handheld device which uses a 450nm light-emitting diode (LED) to illuminate the tooth surface with a blue light. Filters may then be used resulting in green and red fluorescence which filter the yellow and red light with transmission peaks of 500-630nm. This instrument is very useable chair-side as it is compact and relatively inexpensive. The main disadvantage is that unlike QLF, there is no means of directly quantifying the plaque or demineralisation levels and thus descriptive indices are used, resulting in an increased potential for bias during attempts at quantification.

2.10.8 QScan Device (Inspektor Technology, The Netherlands)

See Appendix 2 for detailed images of QScan device.

See Appendix 3 for instructions on how to use the QScan device at home.

The Q-Scan oral hygiene device (Figure 13) is a Conformité Européenne (CE) approved hand held device which incorporates QLF technology to enable fluorescent plaque examination. The device illuminates the mouth using blue light and filters which can identify plaque and white spot lesions. QScan can allow the identification of more mature and potentially damaging plaque without the need for using dyes or disclosing agents, which can be time consuming and stain the oral soft tissues temporarily. It is specifically designed to allow patients to check their oral health status at-home. The battery lasts for 120 minutes and takes an hour to charge optimally. This means the device will need to be re-charged relatively infrequently. The developers, Inspektor Technology, report its advantages to include:

Figure 13 - QScan Device (Inspektor Technology)

i. No additional equipment required.

ii. Easy to use for people without clinical experience.

iii. Easy to use both in a clinical and non-clinical setting.

iv. Uses rechargeable batteries.

However, the device does not allow for the recording of photographs or videos, or for the analysis of plaque present, but it is hoped to be of particular benefit to Orthodontic patients to highlight any plaque left behind after cleaning.

There are many local factors that have been established to cause the accumulation of plaque which may lead to periodontal disease. The presence of faulty restorations and overhangs can accumulate plaque which is also the case with badly designed partial dentures. Orthodontic appliances have also been stressed as a local factor which causes the accumulation of plaque (Van der Veen et al. 2007). Whether it is the specific, non-specific or unified theories that are addressed, adequate oral hygiene is key especially in situations where local factors may make the removal of plaque more challenging.

A recent study oral health education program was conducted using the QScan device in an aim to educate school children on the importance of adequate oral hygiene. One hundred adolescents were divided into two groups in which one group was provided with traditional oral hygiene instructions and the experimental group was provided with QScan device based learning. The authors concluded that the use of QLF based learning resulted in a significant improvement of oral hygiene in the participants compared to the control group. However this was over an 8 week period which is a short period of assessment. In addition there is a risk of the Hawthorne effect with school children in the same school divided into two groups (Khudanov et al. 2018).

2.11 Plaque and periodontal disease:

It has been well documented that one of the primary cause of periodontal disease is bacteria. Studies have concluded that there is an increase in the number of bacteria present in inflamed gingivae when compared to an area of stable periodontium (Eley 2010). This was also evident when assessing the number of bacteria in the oral cavity with patients presenting with periodontal disease. In an experiment conducted by Loe (1965) 12 students were asked to refrain from the use of oral hygiene measures. This resulted in the accumulation of plaque around the gingivae and gingival inflammation was evident in all of the students. For completion, the students then returned to their normal oral hygiene routine reducing the accumulation of plaque which drastically improved their periodontal status.

There has been much debate about the aetiology of periodontal disease. The main theories proposed are the specific theory, the non-specific theory and the unified theory. The 'specific theory' states that there is a specific pathogen that causes periodontal disease. This theory follows the single pathogen concept in diseases such as typhoid and tuberculosis. Therefore, if this specific pathogen is eliminated then periodontal disease is controlled (Loesche 1979). The 'non-specific theory' states that the inflammatory process of periodontal disease occurs when the pathogens exceed the threshold of host resistance. Therefore, in this theory the concept of total plaque control is key to ensure the control of gum inflammation and in severe cases, periodontal disease (Theilade 1986). The 'ecological theory' states that periodontal disease is triggered when an imbalance occurs between the environment and the microflora (Marsh 1994). There is evidence to support that specific bacteria are present in severe cases of gum disease such as *Prophomonas Gingivalis, Prevotella Intermedia, Bacteroides forsythus, Fusobacterium Nucleatum* and *A. Actinomycetecomitans*. These bacteria have been associated with

periodontal disease and are seen in sites with attachment loss and inflammation. Regardless of which theory is applied in relation to the aetiology of periodontal disease, one must emphasise the importance of adequate oral hygiene. Plaque control would ensure maintaining a stable periodontium (Walker 1979, van Winkelhoff et al 2002).

2.11.1 Indices of periodontal disease:

The most common indicies are the gingival index and the bleeding on probing index. The gingival index focusses on the severity of the condition on a scale of 0-3. The mesial, buccal, distal and lingual gingival units are scored separately as follows:

Gingival Index (Loe and Silness 1963):

Normal gingivae

0- Mild inflammation, slight change in colour, slight oedema and no bleeding on probing

1- Moderate inflammation, redness, oedema and glazing. Bleeding on probing

2- Severe inflammation. Marked redness and oedema, ulceration. Tendency on spontaneous bleeding.

The Bleeding on probing index uses the same areas of assessment for all the teeth and also a scale from 0-3 as follows:

Bleeding on Probing Index (Loe 1967):

0- Normal gingivae

1- Signs of gingival inflammation but no bleeding on gentle probing

2- Bleeding on probing

3- Spontaneous gingival bleeding

The two indicies above mainly assessed areas for gingivitis rather than periodontitis. The main periodontal destruction indices used are the periodontal index (Russell 1956), the periodontal disease index (Ramjford 1959) and the community

periodontal index of treatment needs (CPITN) developed by Ainamo et al. (1983). The CPITN has been known as the most widely used system due to its ability to integrate the treatment need in a community setting (British Society of Periodontology - The good practitioner's guide to periodontology 2016). The dentition is divided into six sextants and coded depending on the score using a specially banded probe known as the basic periodontal examination probe. The scores are as follows:

Score Description

0 No pockets >3.5 mm, no calculus/overhangs, no bleeding after probing (black band completely visible)

1 No pockets >3.5 mm, no calculus/overhangs, but bleeding after probing (black band completely visible)

2 No pockets >3.5 mm, but supra- or subgingival calculus/overhangs (black band completely visible)

3 Probing depth 3.5-5.5 mm (black band partially visible, indicating pocket of 4-5 mm)

4 Probing depth >5.5 mm (black band entirely within the pocket, indicating pocket of 6 mm or more)

* Furcation involvement

The codes are clinically related to recommended treatment plans which are as follows:

Score	Description
0	No need for periodontal treatment
1	Oral hygiene instruction (OHI)
2	As in code 1, OHI, removal of plaque retentive factors, including all supra- and subgingival calculus
3	As in code 2, OHI, root surface debridement (RSD)
4	OHI, RSD. Assess the need for more complex treatment; referral to a specialist may be indicated.
*	To be treated according to BPE 0-4, OHI, RSD. Assess the need for more complex treatment; referral to a specialist may be indicated.

Table 9 - Treatment recommendations related to the BPE scoring system (British Society of Periodontology - The good practitioner's guide to periodontology 2016)

Separate plaque indices have also been established to assess plaque accumulation. This index developed by Loe and Silness (1963) is rarely used alone and it is usually used alongside the gingival index to assess causal relationship. The plaque index is as follows:

Plaque index (PI):

0- No plaque
1- Film of plaque visible only by removal on probe or by disclosing
2- Moderate accumulation of plaque which can be seen by the naked eye
3- Abundance of soft matter within the gingival pocket and/or on the tooth and gingival margin

These indices have clear limitations which must be taken under consideration when used in research. The scores may be very subjective with various terminologies used such as redness, slight redness and marked redness. They are also subjective in relation to the degrees of inflammation and pocket depth. In a number of these indicies the pocket depth is mainly assessed to provide a score. Pocket depth may be an assessment of past disease and not current disease, especially when there is no bleeding. Furthermore, the absence of bleeding on probing may be established as the presence of a stable periodontium though the presence of bleeding may not necessarily indicate the presence of disease (Lang et al. 1990). Nevins (1989) pointed out that bleeding on probing has a predictive ‘disease activity value’ of no more than 30%. At times bleeding on probing occurs due to the excessive force applied by the examiner, which effects the true representation of disease activity in the area. Therefore these indices must be used with caution due to the evident limitations associated with them.

2.12 Adjuncts to oral hygiene instructions

2.12.1 Behavioural management

One of the major clinical adjuncts to improving patient's oral hygiene is behavioural management which can be done in a clinical setting (British Society of Periodontology - The good practitioner's guide to periodontology 2016). This would not only aim to ensure patients comply with the advice given, but also to ensure consistency in their behaviour. The Department of Health in England released a toolkit in 2017 for general dental practitioners titled 'Delivering better oral health – an evidence based toolkit for prevention'. This toolkit covered the main aspects of behavioural management in regards to OHI. It provided evidence based techniques to general dental practitioners to further develop their understanding of behavioural management. The main role of dental practitioners in promoting behavioural change and maintaining it was described in a cycle which focussed on (Figure 14):

1) Deciding on the message – providing the patient with clear and concise information which is personalised to their circumstances.
2) Ensuring effective communication using various methods – active listening, open questions, motivational interviewing, using non-verbal communication etc.
3) Goal setting by using 'SMART':
    a) S – Specific – clear and precise goal set and clarified
    b) M – Measurable – a goal which can be measured and quantified
    c) A – Achievable – set a goal within a patients reach and achievable. Goals which are unachievable may demotivate the patient
    d) R – Relevant – has to be relevant to patients circumstances of they will not be motivated enough to stick to the behaviour
    e) T – Timely – the timing is right at the moment to achieve the goal with a clear timeframe

4) Monitoring progress – supporting the behaviour change and encouraging patients to continue doing so
5) Sign posting – ensuring to repeat and warn patients when needed

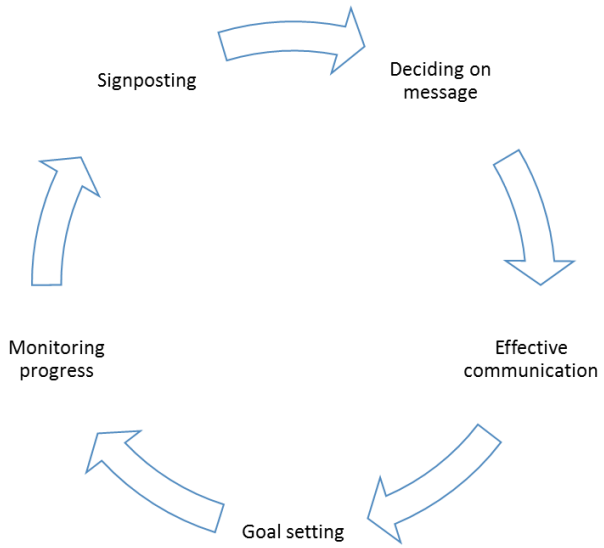


Figure 14 - Behavioral managment cycle for patient compliance (Public Health England - Delivering better oral health - an evidence based toolkit for prevention 2017)

2.12.2 Manual toothbrush and the electric toothbrush

One of the most frequently asked questions patients in relation to oral hygiene is in regards to toothbrush use. The type of toothbrush has always been an area of debate. Manual tooth brushing has been established as an adequate measure to reducing plaque and ensuring adequate oral hygiene. Various techniques have been proposed to ensure adequate brushing techniques such as the roll technique, bass, modified bass, Stillman's, vertical, Charter's and scrub brush. These techniques aim to ensure adequate plaque removal in a straightforward fashion with minimal long-term damage to the gingivae (Eley 2010).

Patients are usually overwhelmed with the number of choices in regards to manual toothbrushes. Therefore dentists are encouraged to guide patients with regards to the basics needed for a manual toothbrush which includes (Prevention and Management of Dental Caries in Children SDCEP guidelines 2010):

1) Small head with a length of about 2.5cm for an adult to ensure reaching all areas in the mouth
2) Bristles should be of even length so that they may act simultaneously
3) Soft to medium soft stiffness to ensure no damage to hard or soft tissue
4) Brush should be easy to clean
5) Handle must be comfortable to hold and manipulate

Many studies have now been published on the subject of manual vs electric toothbrushes. Some studies have concluded that electric toothbrushes have no added benefit to the manual toothbrushes (Niemi 1987; Boyd et al 1989; Walsh et al 1989). Others however have concluded that electric toothbrushes are more effective at plaque removal than manual toothbrushes (Stoltze & Bay 1994; Ainamo 1997) and that they are less abrasive to the gingivae (Niemi 1987). Some researchers have concluded that manual toothbrushes are better and have later changed their views following further research. A Cochrane review by Yaacob et al (2014) concluded that electric toothbrushes reduce plaque more than manual toothbrushes in the short and long term. Though this level of reduction will need further research to assess its clinical relevance. Therefore electric toothbrushes may be an oral hygiene adjunct for plaque control.

2.12.3 Dental floss and interdental cleaning

Brushing in addition to the use of dental floss is a recommendation presented to patients by dentists on a regular basis. This is due to theory that using a toothbrush

alone will only clean three out of the five sides of a tooth leaving the mesial and distal surfaces. For small spaces between teeth it is very difficult to ensure plaque removal. In a Cochrane review conducted in 2011 the effectiveness of flossing combined with toothbrushing was assessed in comparison with toothbrushing alone. The highest level of clinical evidence was assessed and twelve randomised control trials were assessed which met the search criteria. The authors concluded that there is some evidence to show that flossing may reduce gingivitis compared with toothbrushing alone, though no strong evidence to show the effectiveness of flossing on the reduction of dental caries (Sambinjak et al. 2011).

The development of interdental brushes has helped many patients in improving their oral hygiene and removal of plaque in large interdental spaces. This becomes a factor in areas of space closure during orthodontic treatment. Though there is limited high quality evidence to show the effectiveness of interdental brushes and their use in comparison to toothbrushing alone. There is weak evidence in the literature reporting the reduction of gingivitis when using interdental brushes. The authors of a systematic review which aimed to assess the effectiveness of interdental brushes concluded that the evidence was insufficient. The evidence was not sufficient enough to determine whether interdental brushes were better in plaque control when compared with floss (Poklepovic et al 2013).

When looking at patient prefrences, there was clear evidence to suggest that patients had more problems when using dental floss when compared with the use of interdental brushes. Patients generally preferred the use of interndental brushes and according to an RCT had more of an effect on plaque levels. The theory is that patients would most likely use an interdental cleaning method that they prefer. The consistency of use would eventually result in consistent plaque reduction and the improvement of periodontal

health (Christou et al. 1998). Though as mentioned in the systematic review the evidence is not sufficient to conclude that interdental brushes are more effective (Poklepovic et al 2013).

Other studies focussed on the psychological aspect of oral hygiene and interdental cleaning. Whether one decides to use floss or interdental brushes the most effective method to ensure patient compliance and use was using a combination of behavioural, cognitive and clinical management. This combination would aim in ensuring an adequate method, timing and duration of use. It would also improve patient's confidence and planning which results collectively in the reduction of plaque and therefore periodontal disease (Clarkson et al. 2009).

2.12.4 Mouthwash

The remineralisation potential of fluoride use has been investigated in depth, and the guidelines have recommended its use in a number of different methods. One of which is in the form of fluoride mouthwash. A Cochrane review was conducted with the aim to investigate the effect of fluoride mouthwash with the two main available concentrations of 230 ppm daily or 900 ppm once every two weeks. After assessing a total of 48 trials that met the criteria, the combined results reported a reduction in decayed, missing and filled tooth surfaces (DMFT) by 23%. The systematic review concluded that fluoride mouthwash can reduce tooth decay in both children's and adolescent's permanent teeth. The studies assessed in this systematic review were at a school setting, and therefore the use of mouthwash was supervised. This directly effects the generalisability of the results and conclusions. The author however has concluded that the effects may be generalised in a supervised or non-supervised setting (Marinho et al. 2016).

Chlorohexidine (CHX) mouthwashes have also been suggested to reduce periodontal inflammation. In a recently updated systematic review the use of CHX mouthwash has suggested an improvement using the Loe and Silness gingival index (see periodontal indices section 2.11.1) though its clinical relevance is questionable. The use of CHX mouthwash in conjunction with routine OH measures has shown a reduction in levels of plaque, though the clinical relevance in the level of plaque reduction is questionable. CHX mouthwash has also been suggested as having a number of negative side effects when used for four weeks, which includes staining and calculus build-up. Therefore there is a questionable benefit to the routine use of CHX mouthwash and its recommendation according to this systematic review (James et al. 2017).

2.12.5 Disclosing tablets

The main definition of a disclosing agent and its use was described by Raybin as an agent which when applied on the tooth, makes visible the foreign matter (Raybin, 1943). The first disclosing solution was introduced by Skinner in 1914 with the use of iodine solution. Patients were asked to use the solution at home and ensure removing plaque. Berkwin in 1920 further developed a dye with a combination of brilliant green and crystal violet. Easlick in 1953 used bismark brown and Raybin in 1943 decided on a non-iodine dye of gentian violet (Cohen et al 1972). The main aims of a disclosing dye is to accurately dye plaque and locate the areas of accumulation. This would not only be beneficial for clinical use but also for at home use. This can also be an indication of the current level of plaque control. The ideal properties would include staining plaque, adequate colour intensity (to differentiate plaque with surroundings) and adequate duration of this colour intensity, adequate taste, non-allergic, non-irritating to the mucosa and water soluble (Sharma 2010). Plaque has the ability to retain dye constituents due to the polarity difference, electrostatic interactions (with proteins) and hydrogen bonds (polysaccharides) made between the dye and plaque (Chetrus & Ion

2013). Whether solutions or tablets are used the dye should be absorbed by the pellicle layers (light colour and thin covering) and bacterial plaque layers (darker colour, thicker covering and more opaque). The disclosing material should not stain tooth or enamel.

Disclosing agents have been used on clinics in an aim to locate areas which the patient is finding difficult to clean. This has been shown to be a very valuable adjunct to the basic verbal or written oral hygiene instructions given. In a survey conducted in 1993 through the British Association for Orthodontists and the British Society for the Study of Orthodontics, 84% of orthodontists reported advising the use of disclosing tablets (Hobson & Clark 1998). In a single blinded randomised control trial participants were divided into four groups, where one group was shown images of plaque accumulation and its negative effects including demineralisation and gingival inflammation. The other participants were either in a disclosing tablets alone group, disclosing tablets and images group or a control group. The authors concluded that when images were provided there was a significant difference in plaque index and gingival scores. Though no significant difference was observed when disclosing tablets were used alone in relation to the control group (Peng et al 2014)**.**

Therefore, numerous oral hygiene adjuncts are available. These have all been studied in depth to assess their effectiveness. Though systematic reviews continue to conclude that the clinical relevance is questionable with most adjuncts, the results may aid clinicians in advising patients on which adjunct may be effective. The recommendations must be individually catered to the patient to ensure their use in an aim for adequate plaque control.

3.0 Aims and Objectives

3.1 Aims

The principal research aim is to test the efficacy of the QScan oral hygiene device as an adjunct to at-home oral hygiene measures in Orthodontic patients (11 years of age or older) wearing upper and lower fixed Orthodontic appliances.

3.2 Objectives

3.2.1 Primary objective

1. To assess if the oral hygiene regime using QScan results in a change related to plaque accumulation when compared to a control group who receive oral hygiene instructions and a fixed appliance starter pack only.

3.2.2 Secondary objectives

2. To assess if the oral hygiene regime using the QScan affects the occurrence of new demineralisation when compared to a control group who receive oral hygiene instructions and a fixed appliance starter pack only.

3. To evaluate intra and inter-examiner reliability of the QLFD assessment.

4.0 Trial design and methodology

4.1 Design

This study was conducted as a randomised controlled clinical trial. This design type was selected as it will help to produce data of high quality (Rosner 2012).

4.2 Sample

Consecutive patients attending Liverpool University Dental Hospital Orthodontic Department for fixed appliance Orthodontic treatment were considered for participation in the research. There was a systematic approach to patient selection. A random method of patient selection would have been preferable; however, this would have complicated the recruitment process and make it more difficult to gain the adequate number of participants within the available timeframe.

4.3 Inclusion criteria

- Subjects in good health with no medications.
- Aged 11 years or older.
- Planned for maxillary (upper) and mandibular (lower) fixed orthodontic appliances.
- Adequate oral hygiene and dental health to commence Orthodontic treatment.

4.4 Exclusion criteria

- Patients that has significant disabilities which may influence manual dexterity.
- These conditions would have influenced the patients' ability to carry out oral hygiene measures and thus could have impacted plaque scores
- Patients who had taken antibiotics within the two months immediately preceding the beginning of the study were excluded as this could alter the normal oral flora.

Patients who were given antibiotics during the study weren't excluded but the details of the medication was recorded in relation to: antibiotic type; dose; indication for administration and duration of treatment.

- Subjects with restorations affecting more than one tooth surface due to the potential surface roughness influencing plaque retention (Bollenl *et al.* 1997).
- Patients with active caries or periodontal disease as they would not have been considered appropriate for fixed Orthodontic treatment.

4.5 Setting

The trial was completed in the Orthodontic department at the Liverpool University Dental Hospital. Data was collected by the treating clinician at:

i) **T0**- Baseline QLF-D photographs with patients undergoing fixed orthodontic treatment;

ii) **T1**- At the first routine Orthodontic fixed-adjust appointment, approximately 6-8 weeks from the baseline QLF-D photographs at T0;

iii) **T2**- At the second Orthodontic fixed-adjust appointment, approximately 12-16 weeks from the baseline QLF-D photographs at T0.

Information obtained was analysed at the Liverpool University Dental Hospital research wing. All images were taken using white light followed by an automatic QLF-D photograph generated by the QLF-D camera (Canon EOS 550D Digital SLR Camera – equipped with lens containing 8 blue and 4 white LEDs). This was done after the teeth were dried with the use of an air-syringe for 5 seconds. The following settings were used: shutter speed of 1/20s, aperture value of 13.0 and ISO speed of 1600. The distance from the lens to the teeth was approximately 10cm.

4.6 Sponsorship, insurance and funding

The protocol was peer reviewed and edited following the feedback provided. Sponsorship and insurance cover was approved by the University of Liverpool (see Appendices 14 and 15). Doctorate of Dental Science (DDSc) Liverpool University funding was used for this trial.

4.7 Recruitment and anonymisation of data

Consecutive patients attending for their routine fix/adjustment Orthodontic appointments were included. Written information was given to patients in relation to participating in the study, and for those under 16 years of age a parent or guardian was given written information. This was explained in the participation information sheets for children 11-13, 14-15, over 16 and parents/guardians (Appendices 4, 5, 6 and 7). This information was given before the initial baseline session. The main aims and basic information about the study was explained verbally (in addition to in writing) by the clinician to the patient and their parent/guardian where relevant. This included approximately a 15 minute verbal explanation, and 15 minutes in private to read the information leaflet. An opportunity was given to ask questions at any stage. If they wanted to proceed with participation in the research, consent was obtained by the lead clinician or chief investigator on the same day from either the patient or parent/guardian. Anyone who was unsure was given until their next appointment to decide whether they wanted to partake in the study.

4.8 Randomisation

After participants agreed to partake and consent was obtained, a base line QLF-D assessment was completed (T0). This was done at the baseline appointment and involved photographs being taken using the QLF-D device for both the maxillary and mandibular dentition. This was initially done to assess for plaque deposits (Figure 15). The incisors were in an edge-to-edge relationship for frontal and buccal views, and out of occlusion for the lingual and palatal views. Plaque deposits noted were removed and another photograph was taken to allow for the assessment of demineralisation (Figure 16).

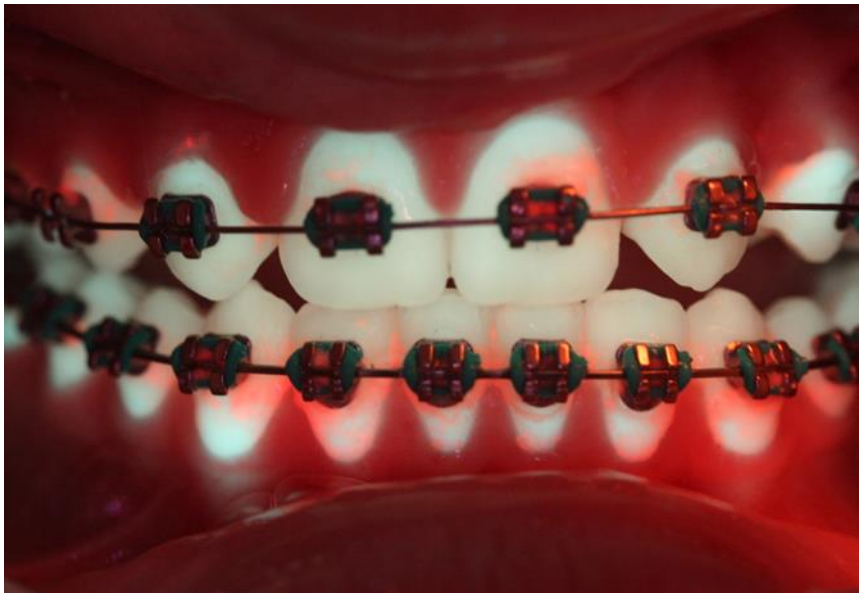


Figure 15 - QLF-D photo showing plaque deposits in florescent pink before removal for demineralisation

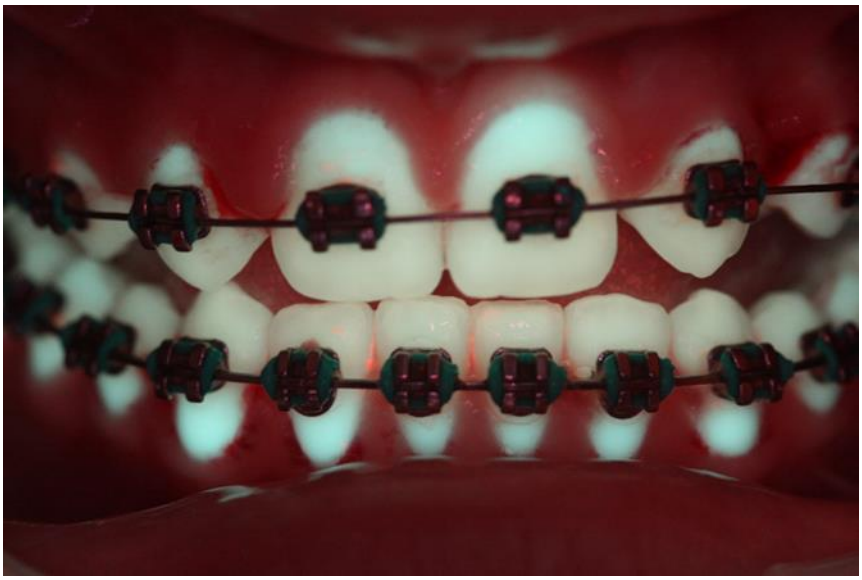


Figure 16 - QLF photo following plaque removal to assess for demineralisation that may be found below the plaque deposits evident in the previous photo (figure

QLF-D images were formally assessed for plaque presence and demineralisation and classed as low or high risk of demineralisation by QLF Researcher (SS). If a single area of demineralisation was evident the patient was considered as being at high risk for demineralisation.

Patients were randomly divided into two groups by an independent statistician (GB). This was done by the generation of a random number sequence by a computer generated programme. The randomisation process was stratified by demineralisation risk into high and low risk groups following assessment of the baseline QLF-D data. Allocation concealment was completed using consecutively numbered, sealed opaque envelopes. At the baseline appointment the envelope was opened based on the demineralisation risk, and the patient was allocated to one of the two parallel groups. Blinding of the participant or operator to the group allocation was not possible. All participants were treated by the same lead operator (DDSc student – SS – supervised by Orthodontic consultants at Liverpool University Dental Hospital).

Group 1 (intervention group) received the fixed appliance starter pack as per normal hospital procedure (see Appendix 1 for list of components) as well as a QScan device (see Appendix 2 - Inspektor Technology, The Netherlands) to take home with them. The QScan written instructions were provided and are included in the appendix section of this thesis (Appendix 3). Those who receive the QScan device were also given verbal instructions on how and when to use the device when at home. Group 2 (control) received the fixed appliance starter pack only. All patients received verbal and written oral hygiene instructions advising brushing twice a day: first thing in the morning and before bed. They were also advised to use a fluoridated mouthwash once a day at a different time to brushing. It was not possible to blind the clinician or patient, but the data (QLF-D photographs) was randomly coded when

saved. The random coding was revealed at a later stage by an independent investigator for data analysis. This was done so that there was no indication to the investigator on which group the patient was allocated to.

4.9 Data collection

The baseline data (QLF-D photographs) were collected on the day the patient formally agreed to participate in the study (T0), which allowed for stratification of the participants according to the risk of demineralisation as outlined above. The patients were assigned to their groups after the baseline photos. Oral hygiene was assessed as per normal procedure at every appointment. QLF-D images were taken at the first fixed adjust appointment following baseline (6-8 weeks) and then following another fixed adjust appointment (12-16 weeks from baseline).

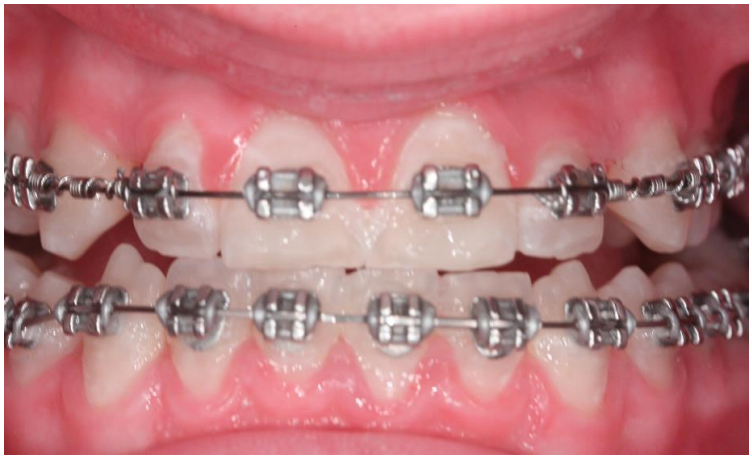


Figure 17 - White light photo using QLF-D

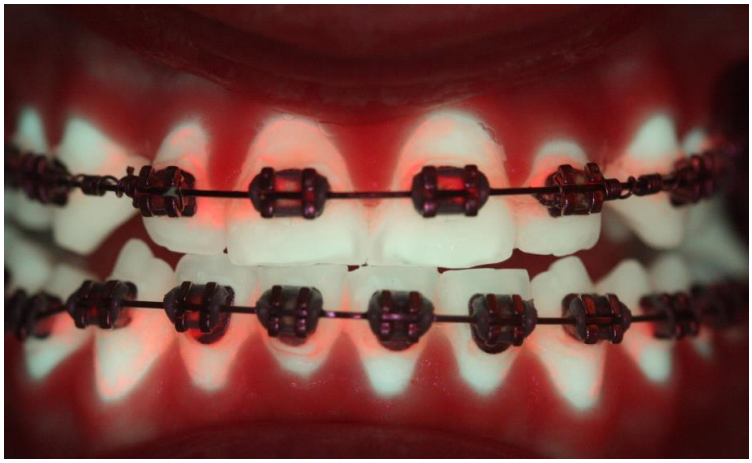


Figure 18 - QLF photo using QLF-D

As the QLF-D takes both QLF and white light photos at the same time (see Figures 17 and 18), white light photos were also available to use as a clinical reference to accompany the QLF data. At each visit the archwires were kept in place and the QLF-D device was used to take photographs of maxillary and mandibular teeth. The patient's teeth were in an edge-to-edge position for the frontal/buccal views (where appropriate) and not in occlusion for the palatal and lingual (Figure 19). The patients in the intervention group were required to bring their Q-Scan device to each appointment so that the operator could make sure it was functioning correctly. At each appointment participants in both groups were given feedback from the operator in relation to their oral hygiene/plaque control, using the QLF-D images as a visual aid. These images were at the same magnification, focus and direction as the baseline photos. The oral hygiene instructions given were standardised to be the same as that which was explained at the initial appointment, but will also highlight any specific areas demonstrating plaque stagnation. As per normal procedure within the Orthodontic Department if a participants' oral hygiene was consecutively of a poor standard deeming the patient at high risk of progressing demineralisation, the appliances were removed.

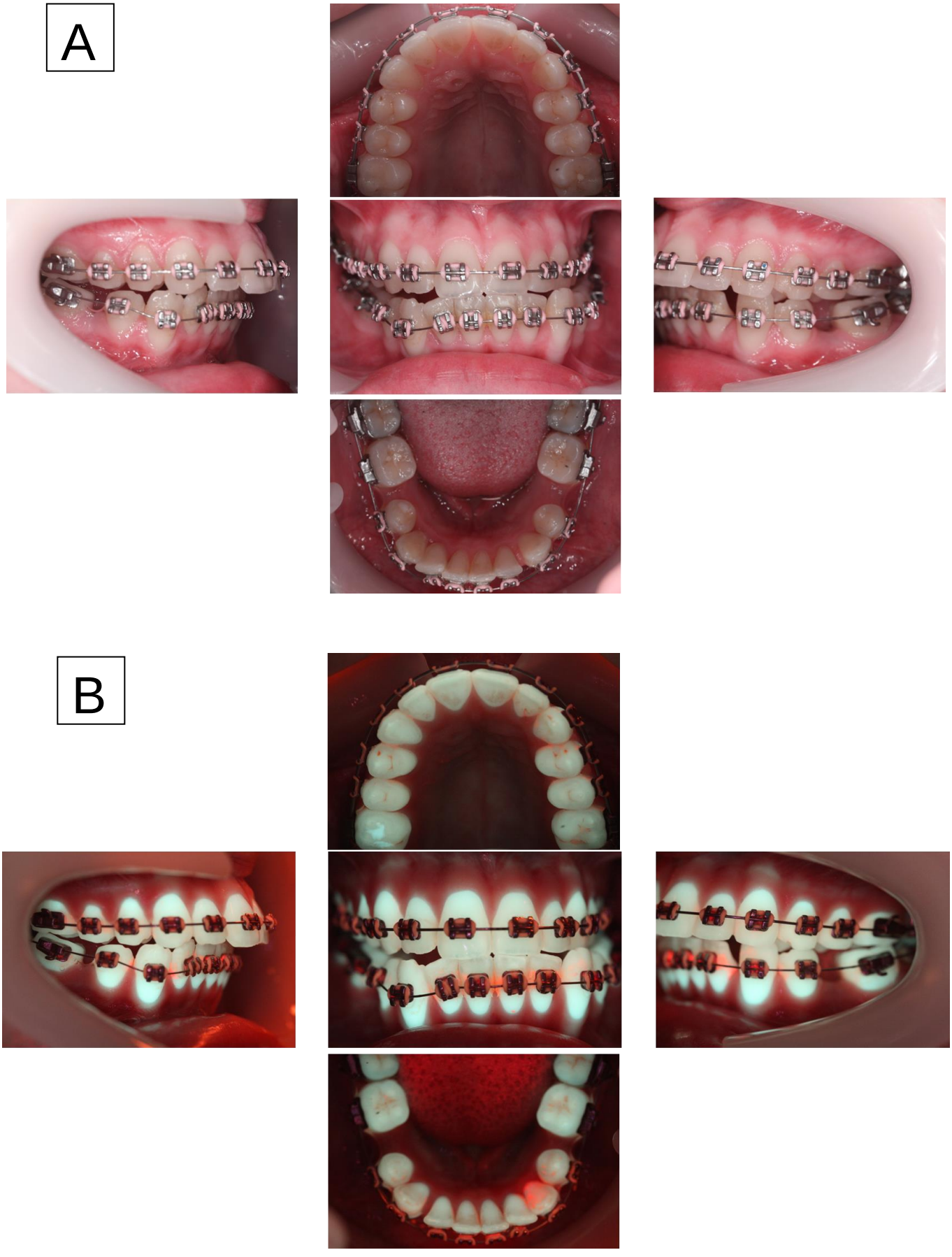


Figure 19 - Complete set of photos taken for plaque assessment which included a frontal, right buccal, left buccal, palatal and lingual photograph using white light (A) followed by automatic QLF photographs (B).

4.10 Image analysis

Images were stored using the patients' allocated random number on an electronic database. An independent investigator randomised the coding and images to allow for analysis to be free of any recall bias.

Plaque accumulation was measured on each tooth and represented as a percentage of tooth coverage demonstrating red fluorescence. For analysis purposes, this was graded at ΔR30. The teeth to be assessed were outlined using a cursor to limit the teeth to be assessed at each photo (Figure 20). A decision was made to divide the teeth to be assessed as follows to ensure no duplication of the measurements:

1) Frontal photo (F) – Assessing the upper and lower incisors including the canines
2) Buccal photos (A/B) – Assessing the first premolar, second premolar and first molar on the left hand side with the photo assessing the left buccal surfaces and on the right hand side with the photo assessing the opposite buccal surfaces
3) Palatal and lingual photos (P/L) – Assessing all the occlusal, palatal and lingual surfaces on all of the teeth up to and including the first molars

Demineralisation was calculated by initially drawing an outline around each lesion with borders resting on sound enamel (Figure 21). If the adjacent structure was not sound enamel, such as a bracket edge, the outline was adjusted to account for this. The mean fluorescence loss (ΔF) and maximum fluorescence loss was assessed and compared to the fluorescence of the surrounding sound enamel. This was assessed per pixel, comparing the lesion area involved and the surrounding sound

enamel. If there was more than one demineralised lesion on a tooth the total fluorescence loss was calculated as two separate areas on the tooth.

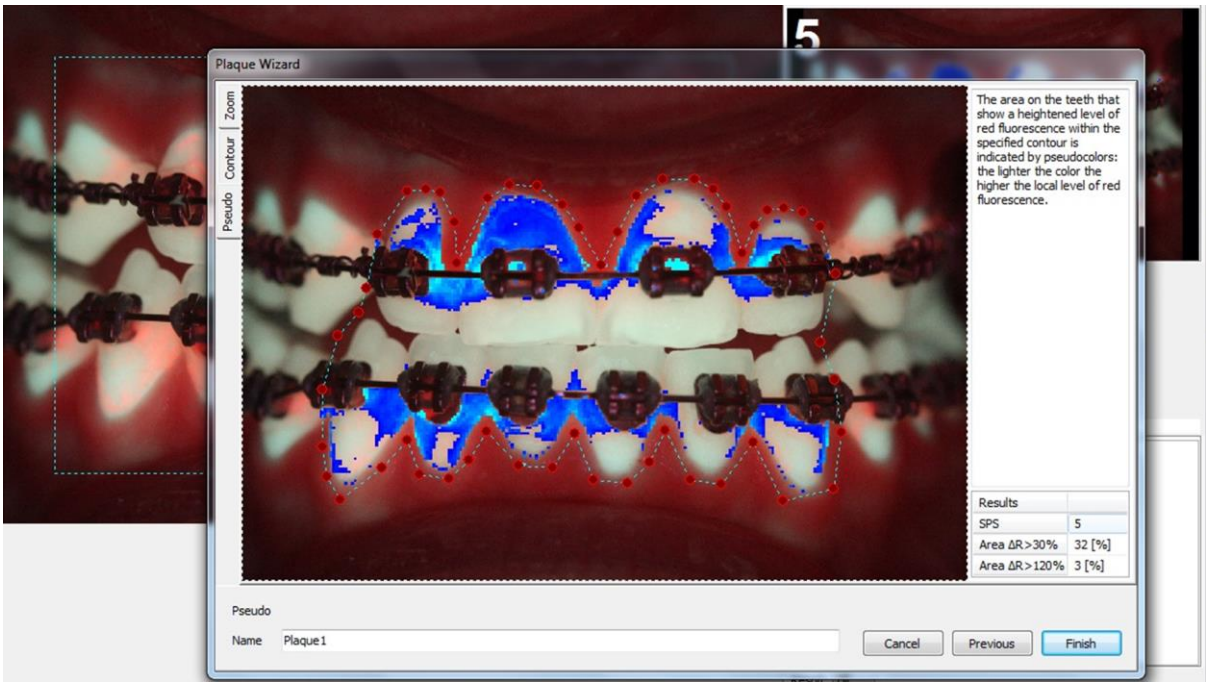


Figure 20 - Image analysis for plaque involves outlining the teeth to be assessed and the system detects areas of plaque accumulation evident.

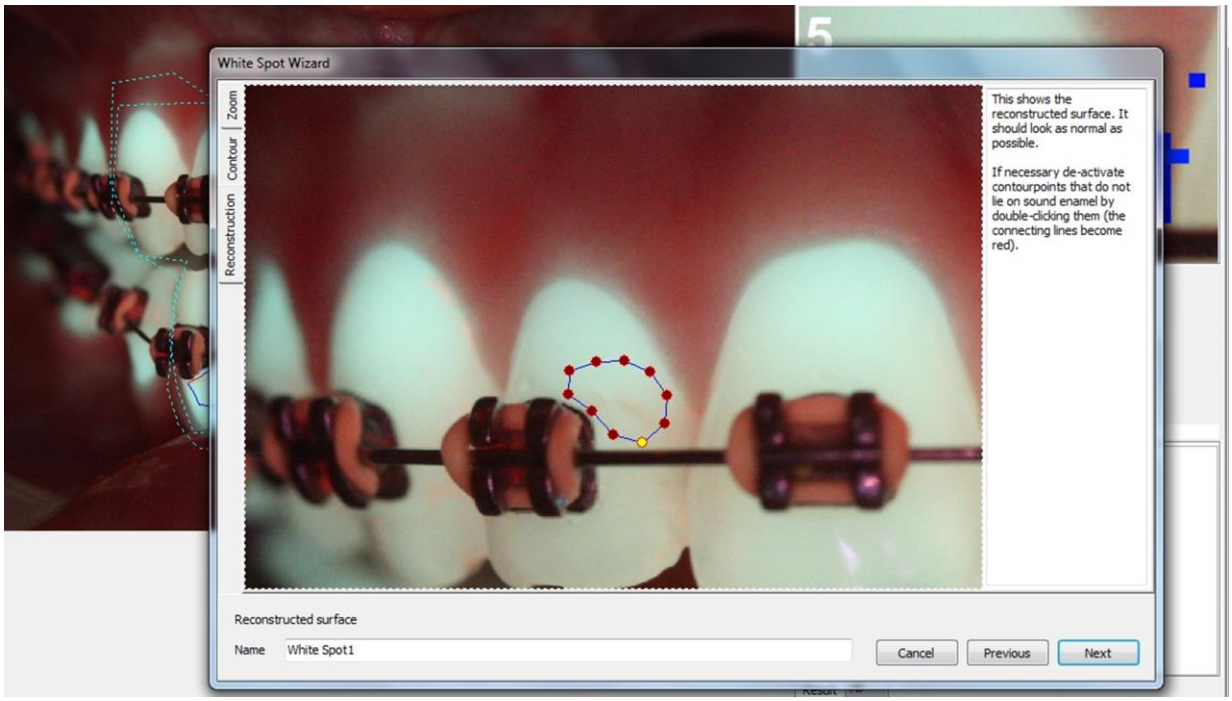


Figure 21 - Areas of demineralisation is outlined and assessed in relation to the change in florescence between the demineralised tissue and surrounding sound enamel

5.0 Statistical analysis

5.1 Reliability, sensitivity and specificity assessments

To determine if the examiners had the ability to correctly identify the presence or absence of demineralisation, 10 QLF-D images were assessed by 2 examiners. These selected images were displayed at random and assessed independently to avoid any recall bias influencing outcomes. The results were compared to the main assessor's analysis (GK), which was assumed to be the gold standard. This was to assess for inter-examiner reliability. This examiner had previous experience using the software and analysing the experimental data type. To assess intra-examiner reliability, the main investigator (SS) repeated analysis of 10 randomly selected QLF-D images 2 weeks apart. Intra and inter-examiner reliability was conducted using the Stats Direct (version 3.0) program using the inter class correlation coefficient (ICC). This was completed under the supervision of an experienced statistician (GB).

5.2 Sample size calculation

To our knowledge there has been no previous randomised controlled trials on the use of Q-Scan oral hygiene device at the start of the experiment to allow for a sample size calculation. A sample size of 60 was deemed appropriate, allowing for 30 participants in each group (intervention and control). The information gained, was used to assist in the estimation of parameters for a sample size calculation to be conducted. This in turn, could be used for future definitive studies.

5.3 Normality testing and hypothesis testing

The primary outcome variable was the change in plaque accumulation at tooth level measured on 3 occasions: from the baseline appointment (T0) and during the continuing treatment of patients with upper and lower fixed appliances. This meant assessing the participants at the following 2 adjustment appointments (T1-T2) using the QLF-D photographs. Plaque accumulation was represented as a percentage of tooth coverage demonstrating red fluorescence at ΔR30.

The secondary outcome was the development of demineralisation at tooth level also measured on the same 3 occasions, as in the primary outcome assessment: from the baseline appointment (T0) and during the continuing treatment of patients with upper and lower fixed appliances. This meant assessing the participants at the following 2 adjustment appointments (T1-T2) using the QLF-D photographs. This was measured as ΔF using the QLF-D photographs. A statistical comparison was carried out between the two groups to give estimates of the effect of size and variability, which could be used to assist in the design of future research.

5.4 Receiver operating characteristic (ROC) curves

These were used to assess the loss of fluorescence on QLF-D images and to evaluate the performance of QLF as a diagnostic method. These ROC curves give an indication of the overall value of this test for demineralisation quantification and their use is reported to be appropriate when a test is based on an *'observed variable that lies on a continuous or graded scale'* (DeLong *et al.* 1988).

5.5 Reliability data

Using the QLF-D images, data on plaque accumulation and demineralisation was continuous and both intra and inter-examiner reliability was evaluated using intra-class correlation coefficient (ICC).

5.5 Sensitivity and specificity of data

Sensitivity was calculated by assessing the level of demineralisation in relation to the gold standard, which was the main assessors' analysis of the QLF-D images. This will act to provide a measure of QLFs' diagnostic accuracy of demineralisation.

6.0 Results

6.1 Recruited participants

The participants were recruited according to the inclusion and exclusion criteria with originally 60 patients agreeing to take part in the study. Four participants were removed from the study due to poor attendance missing multiple back to back appointments. The missed appointments affected their orthodontic treatment and data collection for this study. These participants were contacted on the phone and a letter was later sent to them and their general dental practitioner, asking to contact the department to arrange for an appointment. Contacting the patients with a letter following multiple appointments missed is an NHS trust policy, and the four participants did not respond to the letters and did not contact the department. Therefore, a total of 56 participants completed the trial. The participant's details are outlined in table 10. The QScan group had a near equal number of male to female participants (15M/13F) whilst the control group had more females than males (6M/22F). The average age for the patients was around 16 years for both groups.

Participant Details		
	QScan	Control
Number of participants	28	28
Gender (M/F)	15M/13F (46% Female)	6M/22F (79% Female)
Age (mean)	16.014 (SD = 5.87)	16.085 (SD = 5.29)

Table 10 - Participant details in relation to the number of participants in each group, gender and the mean age range

6.2 Appointment duration

Data was collected at three consecutive orthodontic appointments at the dental hospital. Patients undergoing orthodontic treatment had appointments arranged every 6-8 weeks in an aim to readjust their fixed orthodontic appliances. The two groups on average had the same time period between appointments. There was a difference of 3.5 days between the two groups from T0-T1 with the QScan group being seen on an average 51 day period and the control group at 54 days. At T1-T2 the total difference was 2.1 days. The QScan group were seen on an average 59 day period and the control group at 57 days, following their previous appointment. Therefore the total difference from T0-T2 between the two groups was less than a day. The mean duration between appointments is outlined in the table below (Table 11):

Duration between appointments			
Group	T0-T1	T1-T2	T0-T3
QScan - Mean (SD)	51.5 (16.9)	59.4 (15.1)	110.9 (28.0)
Control - Mean (SD)	54.0 (22.9)	57.3 (13.9)	111.3 (26.4)

Table 11 – Appointment duration between appointments in both the QScan and Control groups from T0-T3

6.3 Intra and inter reliability assessment:

Prior to data analysis, reliability assessment was completed. Intra reliability was completed with researcher SS in an aim to assess reliability in quantifying plaque accumulation ΔR. This was completed following a two week washout period assessing a total of 10 records. The intra reliability score using the inter class correlation coefficient (ICC) was 0.997. This is considered excellent according to the interpretation by Ko and Lee (2016). Inter reliability was also assessed starting with

plaque accumulation in coordination with researcher GK. As in the intra-reliability a total of 10 records were assessed. This was also in an aim to assess the reliability associated with quantifying plaque accumulation ΔR. A comparison was made in relation to the results of the primary researcher SS. The inter reliability was completed using ICC with a score of 0.997 (excellent). The intra and inter reliability assessments were repeated for quantifying demineralisation ΔF. The intra reliability resulted in a score of 0.997 (excellent) and the inter reliability with a score of 0.937 (excellent) also assessing 10 records. Therefore the intra and inter reliability assessment resulted in high scores with an interpretation of excellent reliability for quantifying plaque ΔR and demineralisation ΔF. The detailed intra and inter reliability scores are outlined in table 12.

Intra and inter reliability for plaque accumulation and demineralisation (ICC)		
Assessment	Plaque accumulation	Demineralisation
Intra reliability	0.998	0.997
Inter reliability	0.997	0.937

Table 12 - Intra and inter reliability scores for plaque accumulation and demineralisation

6.4 Flowchart of the clinical phase

In total 61 patients were approached to take part in the study. Only one of which declined to take part due to the understanding that the QLF photos taken would add time to their orthodontic appointment. Therefore 60 patients were randomised to the two groups (QScan and control). Two patients in each group were lost to follow up due to poor attendance to the orthodontic appointments. The four patients did not attend any appointments throughout the period of the trail following their initial appointment. The data for the 56 patients remaining were all analysed (Figure 22).

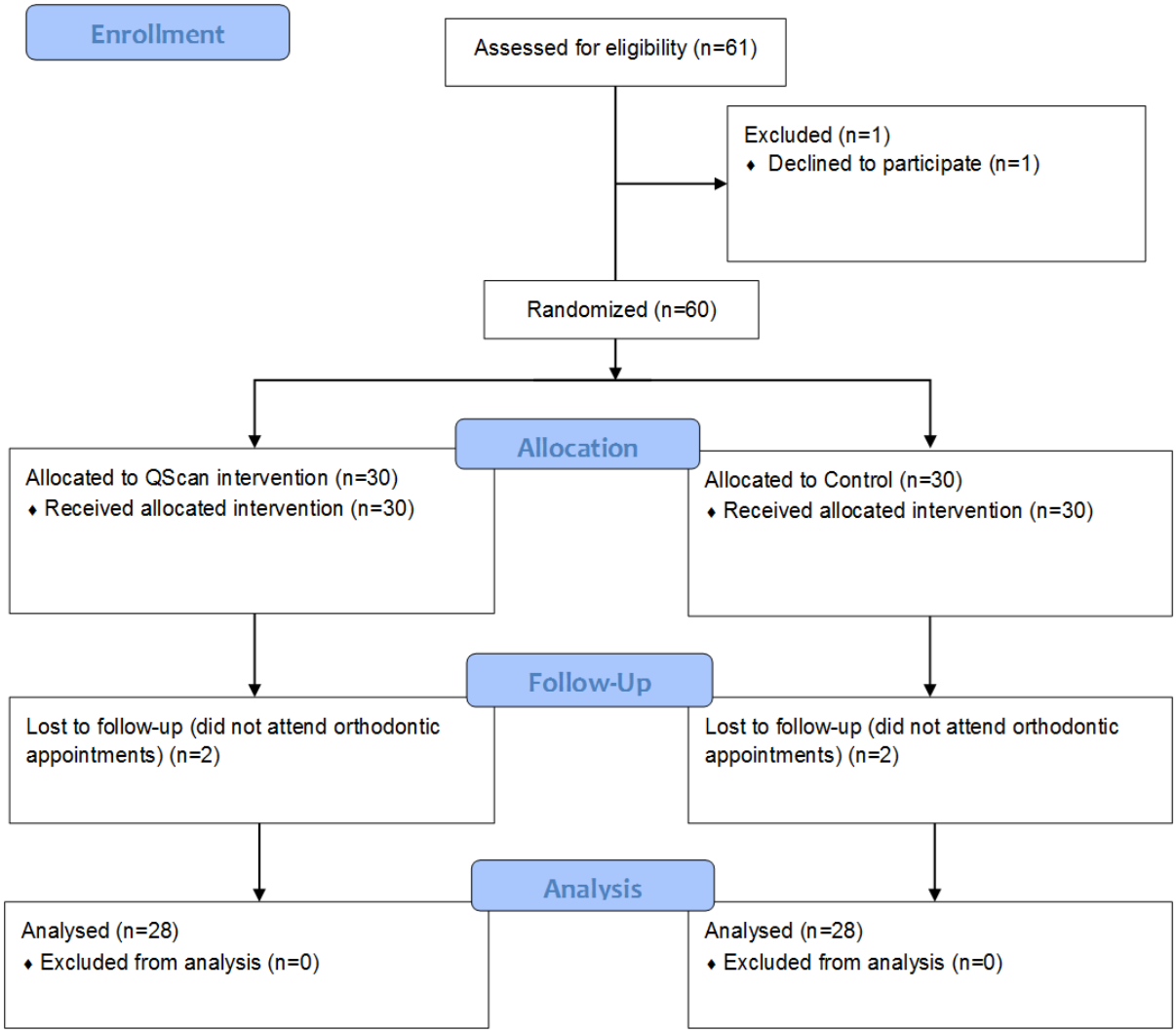


Figure 22 - The Consort participant flow diagram for patients' recruitment, allocation and analysis

6.5 Plaque accumulation

Following inter and intra reliability the data was analysed in an aim to assess the primary outcome which was the changes in plaque accumulation for patients in both the QScan group and the control group. This was done in relation to the changes of plaque accumulation between T0-T1, T1-T2 and T0-T2 within each group using a t-test. Following the assessment of changes within each group a t-test was completed in an aim to assess the significance of the changes between both groups. This test was chosen due to the normal distribution of the continuous data in ΔR. The assessment was made in relation to surfaces; frontal (F), right buccal (A), left buccal (B), palatal (P) and lingual (L). The assessments aimed to assess changes not only as a whole but also in sections between the QScan group and control group at changes in time points T1, T2 and T3. These sections were divided as follows:

1) FABPL (Frontal, right Buccal, left Buccal, Palatal and Lingual sections)
2) FAB (Frontal, right Buccal and left Buccal sections)
3) PL (Palatal and Lingual sections)
4) F (Frontal section)
5) A (Right Buccal section)
6) B (Left Buccal section)
7) P (Palatal section)
8) L (Lingual section)

This was done in an aim to assess the effect and changes observed not only as a whole (FABPL) in relation to the total change in plaque accumulation but also in relation to smaller sections (FAB and PL) and individual ones (F, A, B, P and L). The statistical analysis was completed using SPSS (version 24.0, IBM Corporation, Armonk, NY, USA) under the supervision of an experienced statistician (GB). The results for the sections above were as follows:

1) **FABPL - Frontal, Right Buccal, Left Buccal, Palatal and Lingual sections**

The plaque accumulation and assessment was as mentioned above assessed in relation to the time points T0-T1, T1-T2 and T0-T2 between the two groups. The average changes looking at all the surfaces (Figure 23) from T0-T1 in the QScan was greater (3.6) than the control group (-1.53). The changes showed a reduction in plaque accumulation in the QScan group when compared with the control group which had an increase in the amount of plaque from T0-T1. These changes when assessed revealed a significant difference following a t-test analysis ($p<0.001$ – 95% CI for difference 3.27-6.51). The same pattern was apparent when assessing the changes at T1-T2 in which the QScan group plaque scores reduced (0.59) whilst the control group plaque levels increased (-0.49) which also revealed a significant difference ($p<0.05$ – 95% CI for difference 0.51-2.41). With both groups showing significant changes when compared at points T0-T1 and T1-T2, the overall changes between T0-T2 revealed a substantial reduction in plaque accumulation in the QScan group (4.19) and an increase in plaque accumulation in the control group (-2.02) which was also statistically significant revealing a $p<0.001$ on a 95% CI for difference 4.78-7.65 (Table 13, Figure 24).

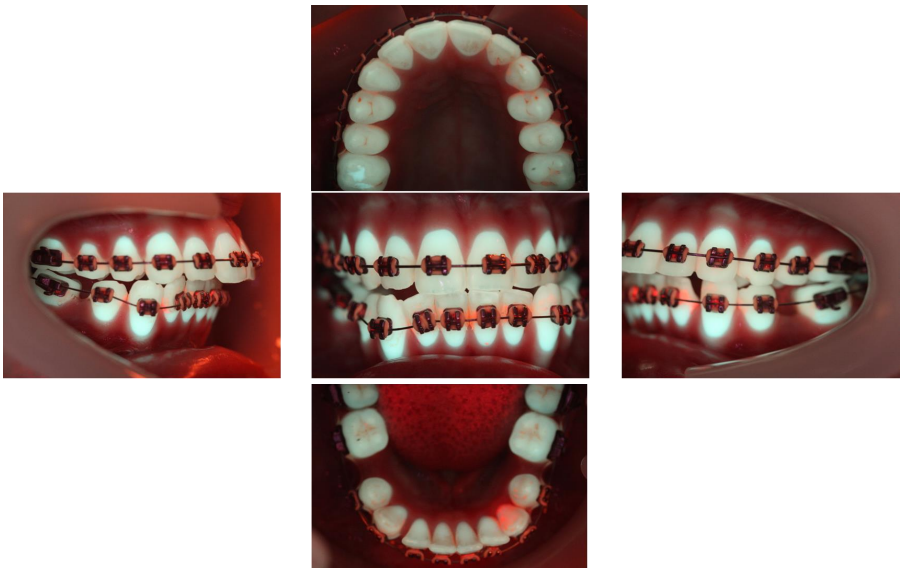


Figure 23 - FABPL (Frontal, right Buccal. left Buccal, Palatal and Lingual)

Plaque accumulation (ΔR) all surfaces (FABPL)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Mean Difference (95% CI)	P - value
Plaque T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	10.11 (7.91)	6.51 (4.61)	3.28 (4.85)	4.89 (3.27-6.51)	<0.001
Control	7.76 (6.25)	9.29 (8.30)	-1.61 (6.51)		
Plaque T1-T2	T1	T2	T1-T2	T1-T2	T1-T2
QScan	6.51 (4.61)	5.92 (3.76)	0.52 (1.09)	0.92 (0.51-2.41)	0.030
Control	9.29 (8.30)	9.78 (8.52)	-0.39 (1.62)		
Plaque T0-T2	T0	T2	T0-T2	T0-T2	T0-T2
QScan	10.11 (7.91)	5.92 (3.76)	4.19 (6.03)	6.21 (4.78-7.65)	<0.001
Control	7.76 (6.25)	9.78 (8.52)	-2.02 (6.19)		

Table 13 - Plaque accumulation (ΔR) all surfaces (FABPL) means, standard deviations and effects.

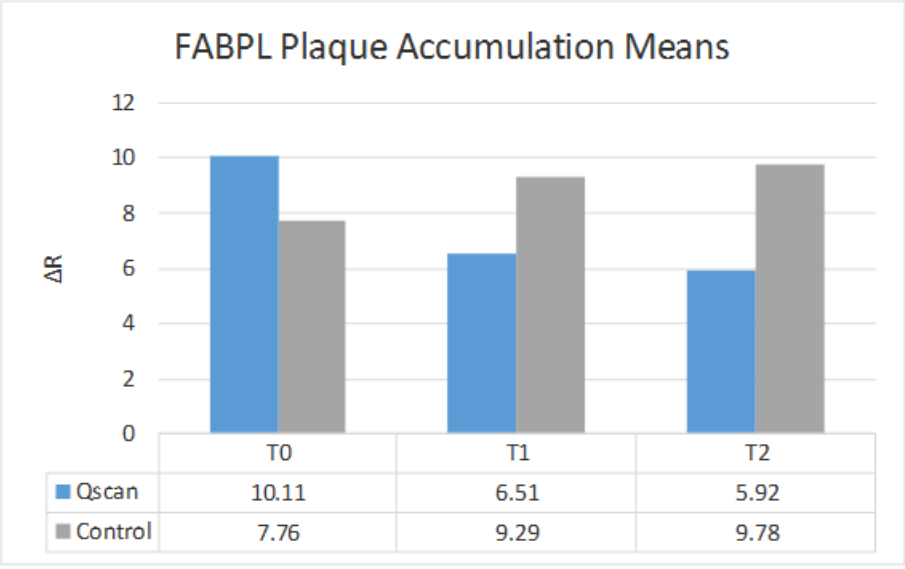


Figure 24 – Chart of the Plaque accumulation levels (ΔR) of all surfaces (FABPL).

2) FAB - Frontal, Right Buccal and Left Buccal sections

The average changes looking at the frontal and buccal surfaces (Figure 25) from T0-T1 in the QScan was greater (5.01) than the control group (-1.56). The changes also showed a reduction in plaque accumulation in the QScan group when compared with the control group which had a slight increase in plaque accumulation. These changes when assessed revealed a significant difference following a t-test analysis ($p<0.001$ – 95% CI for difference = 2.93 – 10.78). The same pattern was apparent when assessing the changes at T1-T2 in which the QScan group scores reduced (1.09) whilst the control group increased (-0.88) which also revealed a significant difference ($p<0.05$ – 95% CI for difference = 0.35 – 3.29). With both groups showing significant changes when compared at points T0-T1 and T1-T2, the overall changes between T0-T2 revealed a substantial reduction in plaque accumulation in the QScan group (6.1) and an increase in plaque accumulation in the control group (-2.44) which was also statistically significant revealing a $p<0.001$ on a 95% confidence interval which was between 5.00 – 12.07 (Table 14, Figure 26).

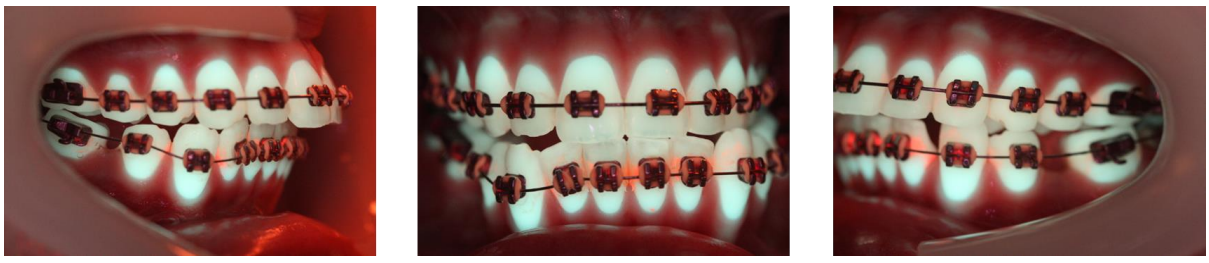


Figure 25 - FAB (Frontal, right Buccal and left Buccal)

Plaque accumulation (ΔR) for the frontal and buccal surfaces (F/A/B)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Mean Difference (95% CI)	P- value
Plaque T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	13.25 (8.04)	8.24 (4.29)	5.01 (4.26)	8.54 (2.93 – 10.78)	0.001
Control	9.30 (6.16)	10.86 (8.74)	-1.56 (7.30)		
Plaque T1-T2	T1	T2	T1-T2	T1-T2	T1-T2
QScan	8.24 (4.29)	7.15 (3.58)	1.09 (2.94)	1.46 (0.35 – 3.29)	0.016
Control	10.86 (8.74)	11.74 (9.008)	-0.88 (3.76)		
Plaque T0-T2	T0	T2	T0-T2	T0-T2	T0-T2
QScan	13.25 (8.04)	7.15 (3.58)	6.10 (5.77)	6.86 (5.00 – 12.07)	<0.001
Control	9.30 (6.16)	11.74 (9.008)	-2.44 (7.33)		

Table 14 - Plaque accumulation (ΔR) for the frontal and buccal surfaces (F/A/B) means, standard deviations and effects.

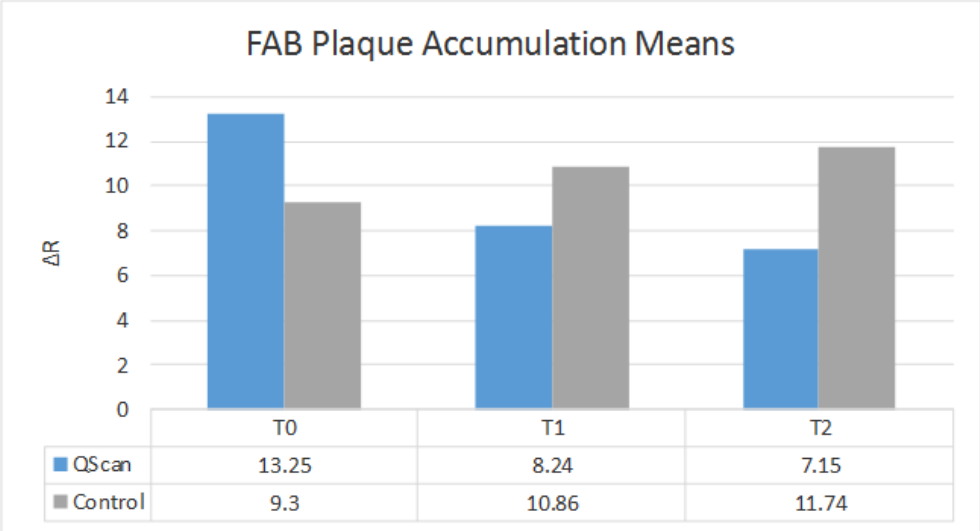


Figure 26 – Chart of the Plaque accumulation (ΔR) for the frontal and buccal surfaces (F/A/B).

3) PL - Palatal and Lingual sections

Finally the last joint surface assessment was looking at the palatal and the lingual surfaces (Figure 27). The average changes looking at all the surfaces from T0-T1 in the QScan was near the same (1.49) as in the control group (-1.48). The QScan group had a reduction in plaque accumulation and the control group had an increase in plaque by around the same amount. These changes when assessed revealed a significant difference following a t-test analysis ($p<0.001$ – 95% CI for difference = 0.36 – 3.51). This pattern was reversed when assessing the changes at T1-T2 in which the QScan group scores increased (-0.15) and the control group decreased (0.09) which also revealed a significant difference ($p<0.05$ – 95% CI for difference = 0.02 – 1.82). With both groups showing significant changes when compared at points T0-T1 and T1-T2, the overall changes between T0-T2 revealed a reduction in plaque accumulation in the QScan group (1.34) and an increase in plaque accumulation in the control group (-1.39) which was also statistically significant revealing a $p<0.001$ on a 95% confidence interval for difference between 3.87 – 9.01 (Table 15, Figure 28).

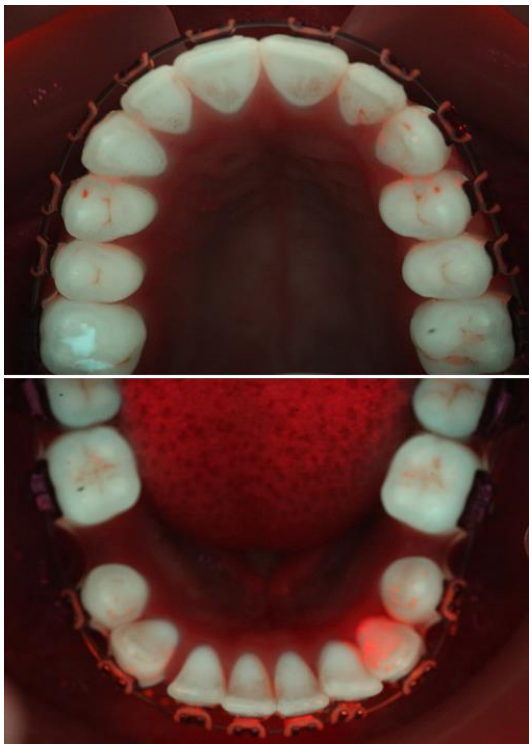


Figure 27 - PL (Palatal and Lingual)

Plaque accumulation (ΔR) for the frontal and buccal surfaces (P/L)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Mean Difference (CI 95%)	P-Value
Plaque T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	5.41 (4.78)	3.92 (3.83)	0.69 (1.66)	1.93 (0.36 – 3.51)	0.017
Control	5.45 (5.70)	6.93 (7.04)	-1.24 (2.95)		
Plaque T1-T2	T1	T2	T1-T2	T1-T2	T1-T2
QScan	3.92 (3.83)	4.07 (3.27)	0.53 (1.09)	0.92 (0.02 – 1.82)	0.045
Control	6.93 (7.04)	6.84 (6.81)	-0.39 (1.62)		
Plaque T0-T2	T0	T2	T0-T2	T0-T2	T0-T2
QScan	5.41 (4.78)	4.07 (3.27)	1.34 (2.13)	2.73 (3.87 – 9.01)	<0.001
Control	5.45 (5.70)	6.84 (6.81)	-1.39 (2.29)		

Table 15 – Plaque accumulation (ΔR) for the palatal and lingual surfaces (P/L) means, standard deviations and effects.

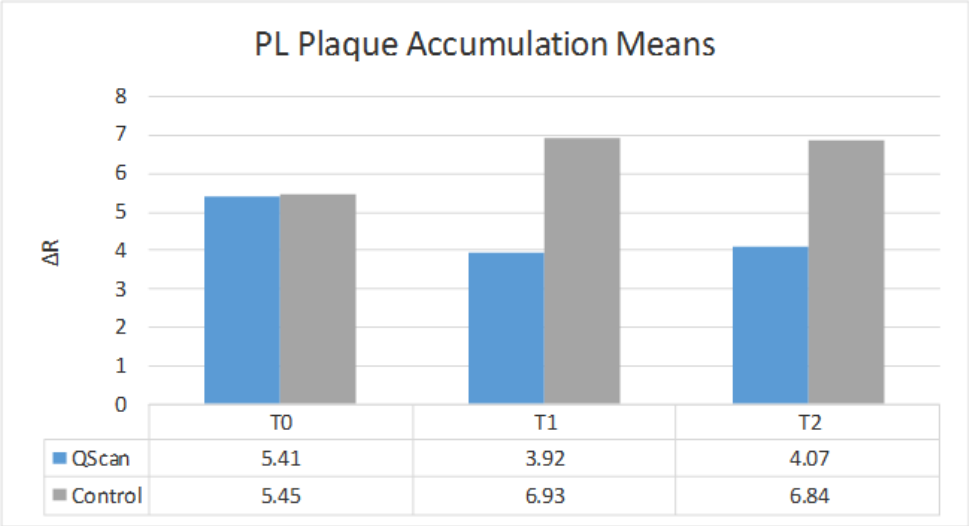


Figure 28 - Chart of the Plaque accumulation (ΔR) for the palatal and lingual surfaces (P/L).

4) F – Frontal section

The average changes looking at the frontal surfaces (Figure 29) from T0-T1 in the QScan group was greater (3.94) than the control group (-1.65). The changes also showed a reduction in plaque accumulation in the QScan group when compared with the control group which showed an increase in plaque. These changes when assessed revealed a significant difference following a t-test analysis ($p<0.05$ – 95% CI for difference = 1.82 – 9.37). This same pattern was apparent when assessing the changes at T1-T2 in which the QScan group scores reduced (1.44) whilst the control group increased (-0.96) which also revealed a non-significant difference ($p>0.05$ – 95% CI for difference = -0.36 – 5.16). The overall changes between T0-T2 revealed a substantial reduction in plaque accumulation in the QScan group (5.46) and an increase in plaque accumulation in the control group (-2.43) which was also statistically significant revealing a $p<0.001$ on a 95% confidence interval for difference between 4.31 – 11.47 (Table 16, Figure 30).

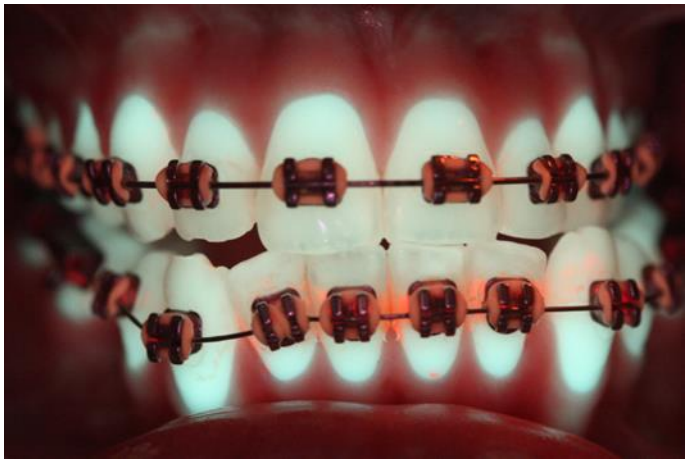


Figure 29 - F (Frontal)

Plaque accumulation (ΔR) for the frontal surface (F)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Mean Difference (CI 95%)	P- Value
Plaque T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	11.11 (6.97)	6.94 (3.70)	3.94 (4.67)	5.60 (1.82 – 9.37)	0.005
Control	7.86 (5.77)	9.61 (7.43)	-1.65 (6.75)		
Plaque T2-T3	T1	T2	T1-T2	T1-T2	T1-T2
QScan	6.94 (3.70)	5.64 (3.22)	1.44 (2.18)	2.40 (-0.36 – 5.16)	0.086
Control	9.61 (7.43)	10.29 (8.70)	-0.96 (5.44		
Plaque T1-T3	T0	T2	T0-T2	T0-T2	T0-T2
QScan	11.11 (6.97)	5.64 (3.22)	5.46 (6.35)	7.90 (4.31 – 11.47)	<0.001
Control	7.86 (5.77)	10.29 (8.70)	-2.43 (7.01)		

Table 16 - Plaque accumulation (ΔR) for the frontal surfaces (F) means, standard deviations and effects.

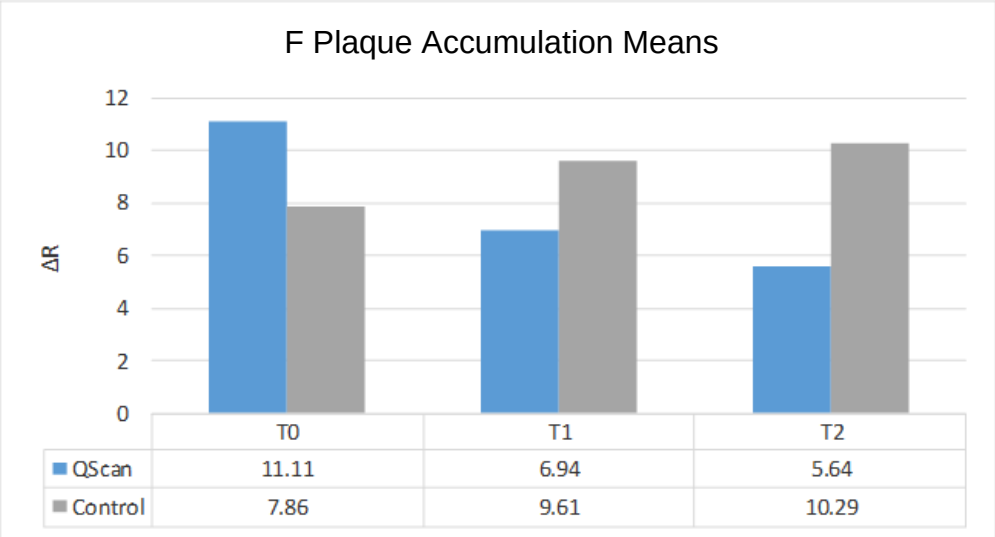


Figure 30 - Chart of the Plaque accumulation (ΔR) for the frontal surfaces (F).

5) A – Right Buccal section

The average changes looking at the right buccal surfaces (Figure 31) from T0-T1 in the QScan group was greater (6.67) than the control group (-1.35). The changes displayed a reduction in plaque accumulation in the QScan group when compared with the control group which showed an increase in plaque. These changes when assessed revealed a significant difference following a t-test analysis ($p<0.05$ – 95% CI for difference = 2.75 – 13.28). This same pattern was apparent when assessing the changes at T1-T2 in which the QScan group scores reduced (1.89) whilst the control group increased (-1.09) which also revealed a significant difference ($p<0.05$ – 95% CI for difference = 0.30 – 5.66). The overall changes between T0-T2 revealed a substantial reduction in plaque accumulation in the QScan group (7.68) and an increase in plaque accumulation in the control group (-2.21) which was also statistically significant revealing a $p<0.001$ on a 95% confidence interval for difference between 5.50 – 14.30 (Table 17, Figure 32).

Figure 31 - A (right Buccal)

Plaque accumulation (ΔR) for the buccal surface on the right hand side (A)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Difference Mean (CI 95%)	P- value
Plaque T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	15.32 (8.17)	9.44 (4.72)	6.67 (5.89)	8.01 (2.75 – 13.28)	0.004
Control	10.75 (6.26)	11.70 (9.69)	-1.35 (9.73)		
Plaque T2-T3	T1	T2	T1-T2	T1-T2	T1-T2
QScan	9.44 (4.72)	7.64 (3.32)	1.89 (4.20)	2.98 (0.30 – 5.66)	0.030
Control	11.70 (9.69)	12.96 (9.40)	-1.09 (4.22)		
Plaque T1-T3	T0	T2	T0-T2	T0-T2	T0-T2
QScan	15.32 (8.17)	7.64 (3.32)	7.68 (7.07)	9.89 (5.50 – 14.30)	<0.001
Control	10.75 (6.26)	12.96 (9.40)	-2.21 (9.21)		

Table 17 - Plaque accumulation (ΔR) for the right buccal surfaces (A) means, standard deviations and effects.

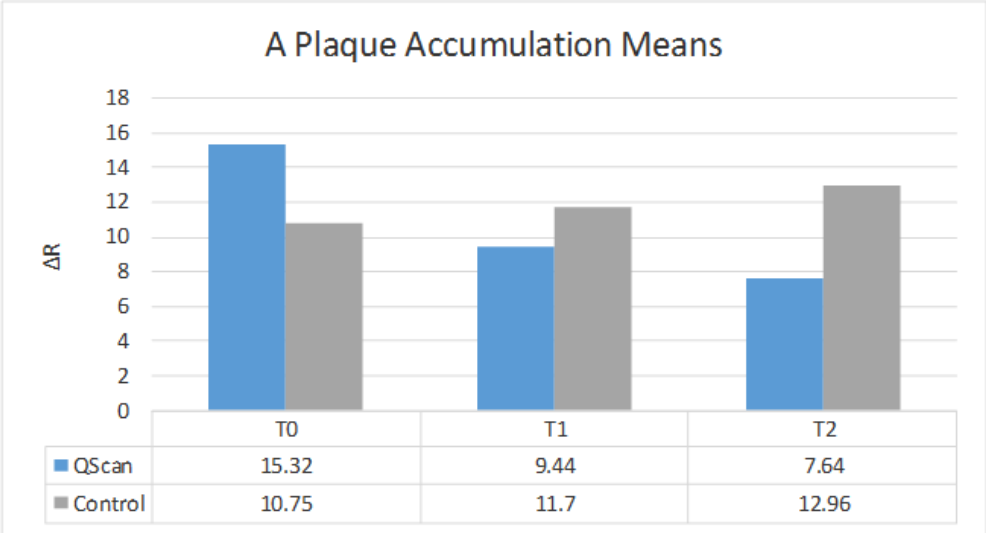


Figure 32 - Chart of the Plaque accumulation (ΔR) for the right buccal surfaces (A).

6) B – Left Buccal section

The average changes looking at the left buccal surfaces (Figure 33) from T0-T1 in the QScan group was greater (4.39) than the control group (-2.57). The changes displayed a reduction in plaque accumulation in the QScan group when compared with the control group which showed an increase in plaque. These changes when assessed revealed a significant difference following a t-test analysis ($p<0.05$ – 95% CI for difference = 2.90 – 11.05). The same pattern was apparent when assessing the changes at T1-T2 in which the QScan group scores reduced (0.22) whilst the control group increased (-0.30) which also revealed a non-significant difference ($p>0.05$ – 95% CI for difference = -2.32 – 2.48) due to a reduction and increase of no more than a single unit in both groups. The overall changes between T0-T2 revealed a substantial reduction in plaque accumulation in the QScan group (5.14) and an increase in plaque accumulation in the control group (-2.68) which was also statistically significant revealing a $p<0.001$ on a 95% confidence interval for difference between 4.30 – 11.35 (Table 18, Figure 34).

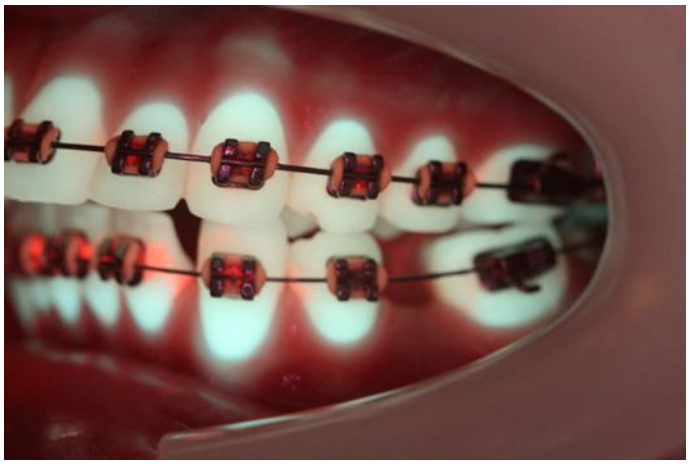


Figure 33 - B (left Buccal)

Plaque accumulation (ΔR) for the buccal surfaces on the left hand side (B)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Difference Mean (CI 95%)	P- value
Plaque T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	13.32 (8.62)	8.33 (4.26)	4.39 (5.30)	6.95 (2.90 – 11.05)	0.001
Control	9.29 (6.30)	11.26 (9.20)	-2.57 (7.19)		
Plaque T1-T2	T1	T2	T1-T2	T1-T2	T1-T2
QScan	8.33 (4.26)	8.18 (3.76)	0.22 (3.80)	0.082 (-2.32 – 2.48)	0.945
Control	11.26 (9.20)	11.96 (9.03)	-0.30		
Plqaue T0-T2	T0	T2	T0-T2	T0-T2	T0-T2
QScan	13.32 (8.62)	8.18 (3.76)	5.14 (6.45)	7.82 (4.30 – 11.35)	<0.001
Control	9.29 (6.30)	11.96 (9.03)	-2.68 (6.74)		

Table 18 - Plaque accumulation (ΔR) for the left buccal surfaces (B) means, standard deviations and effects.

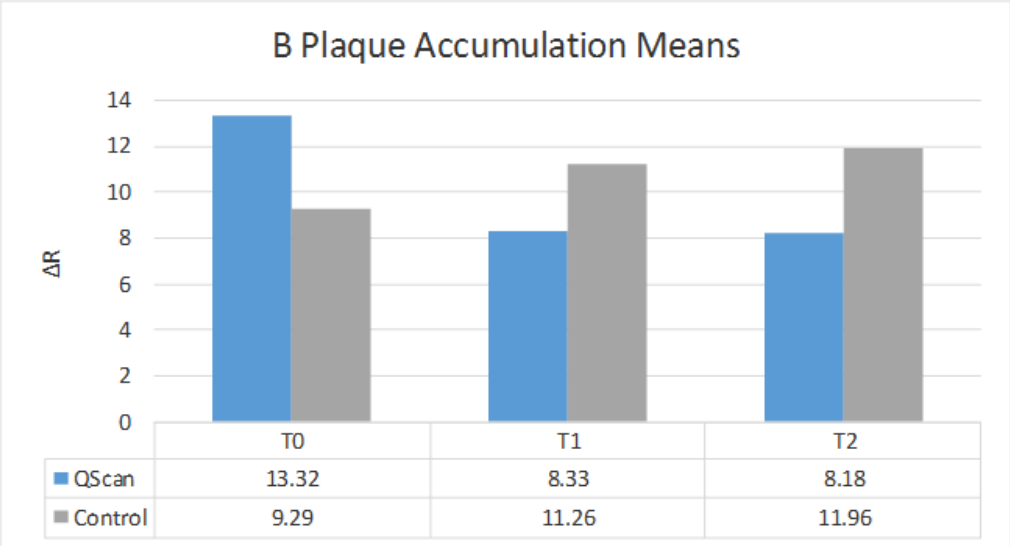


Figure 34 - Chart of the Plaque accumulation (ΔR) for the left buccal surfaces (B).

7) P – Palatal section

The changes looking at the palatal surfaces (Figure 35) from T0-T1 was a reduction in the QScan (0.92) and an increase in the control group (-0.99). The changes displayed a reduction in plaque accumulation in the QScan group when compared with the control group which showed an increase in plaque. These changes when assessed revealed a non-significant difference following a t-test analysis ($p>0.05$ – 95% CI for difference = -0.50 – 2.22). The opposite pattern was apparent when assessing the changes at T1-T2 in which the QScan group scores increased (-0.71) whilst the control group reduced (0.42) which also revealed a non-significant difference ($p>0.05$ – 95% CI for difference = -0.78 – 0.88). The overall changes between T0-T2 revealed a slight reduction in plaque accumulation in the QScan group (0.21) and an increase in plaque accumulation in the control group (-0.57) which was also non-significant revealing a $p>0.05$ on a 95% confidence interval for difference between -0.41 – 1.71 (Table 19, Figure 36).

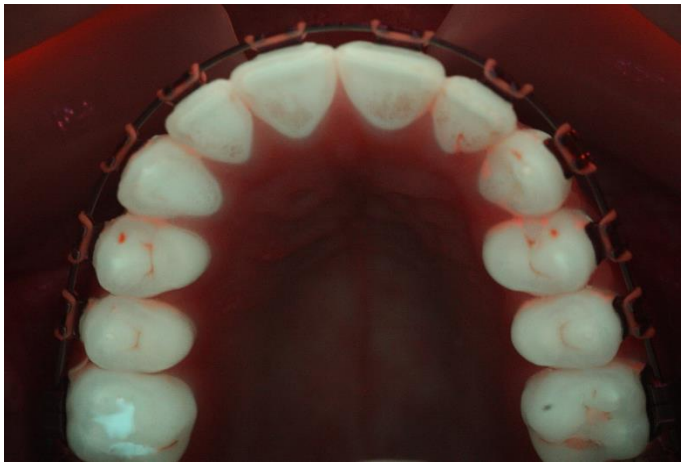


Figure 35 - P (Palatal)

Plaque accumulation (ΔR) for the palatal surface (P)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Difference Mean (CI 95%)	P- value
Plaque T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	3.64 (2.53)	2.72 (2.87)	0.92 (1.66)	0.857 (-0.50 – 2.22)	0.211
Control	3.75 (5.32)	4.74 (5.60)	-0.91 (2.45)		
Plaque T1-T2	T1	T2	T1-T2	T1-T2	T1-T2
QScan	2.72 (2.87)	3.43 (3.06)	-0.71 (1.21)	0.048 (-0.78 – 0.88)	0.907
Control	4.74 (5.60)	4.32 (5.60)	0.42 (1.37)		
Plqaue T0-T2	T0	T2	T0-T2	T0-T2	T0-T2
QScan	3.64 (2.53)	3.43 (3.06)	0.21 (1.31)	0.79 (-0.14 – 1.71)	0.093
Control	3.75 (5.32)	4.32 (5.60)	-0.57 (2.04)		

Table 19 - Plaque accumulation (ΔR) for the palatal surfaces (P) means, standard deviations and effects.

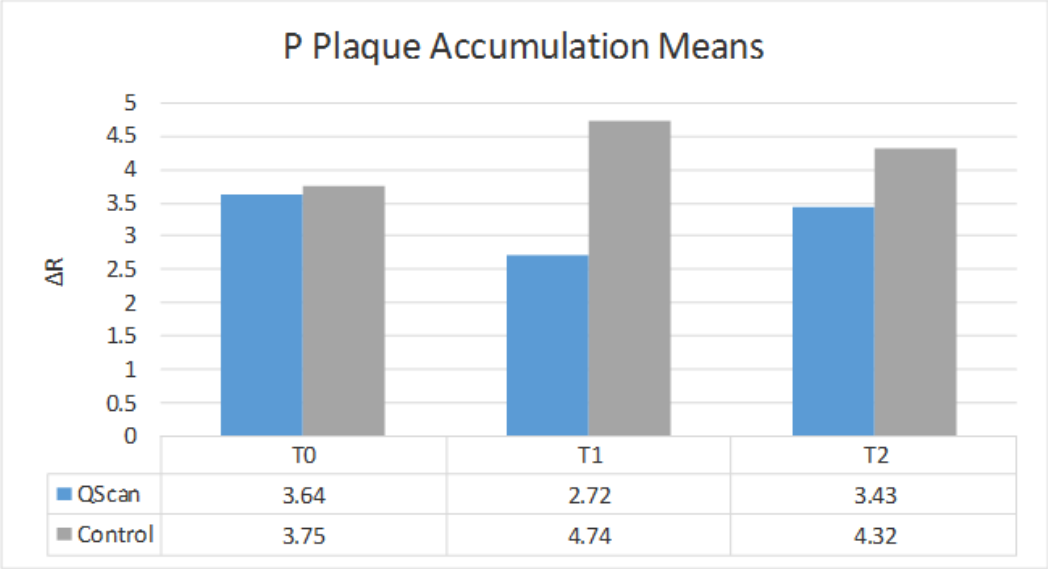


Figure 36 - Chart of the Plaque accumulation (ΔR) for the palatal surfaces (P).

8) L – Lingual section

The changes looking at the lingual surfaces (Figure 37) from T0-T1 was a reduction in the QScan (7.18 to 5.11) and an increase in the control group (7.14 to 9.13). The changes displayed a reduction in plaque accumulation in the QScan group when compared with the control group which showed an increase in plaque. These changes when assessed revealed a significant difference following a t-test analysis ($p<0.05$ – 95% CI for difference = 0.59 – 5.44). The same pattern was apparent when assessing the changes at T1-T2 in which the QScan group scores reduced (5.11 to 4.71) whilst the control group increased (9.13 to 9.36) which also revealed a significant difference ($p<0.05$ – 95% CI for difference = 0.17 – 3.41). The overall changes between T0-T2 revealed a substantial reduction in plaque accumulation in the QScan group (7.18 to 4.71) and an increase in plaque accumulation in the control group (7.14 to 9.36) which was also significant revealing a $p<0.05$ on a 95% confidence interval for difference between 2.61 – 6.7 (Table 20, Figure 38).

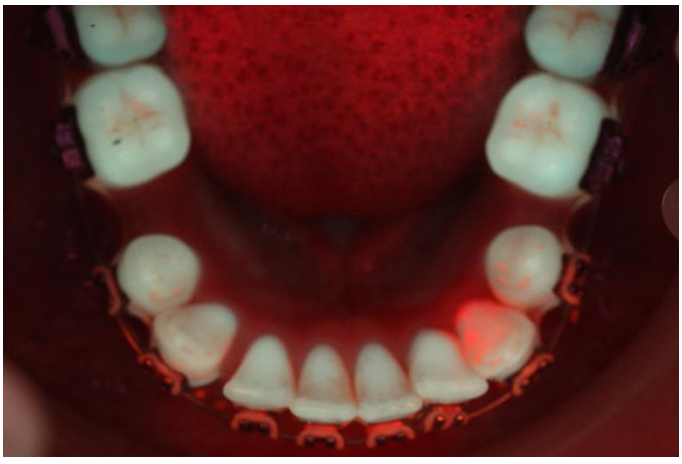


Figure 37 - L (Lingual)

Plaque accumulation (ΔR) for the lingual surface (L)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Difference Mean (CI 95%)	P- value
Plaque T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	7.18 (5.80)	5.11 (4.35)	2.07 (2.60)	3.01 (0.59 – 5.44)	0.016
Control	7.14 (5.65)	9.13 (7.16)	-1.99 (4.53)		
Plaque T1-T2	T1	T2	T1-T2	T1-T2	T1-T2
QScan	5.11 (4.35)	4.71 (3.40)	0.4 (1.92)	1.79 (0.17 – 3.41)	0.031
Control	9.13 (7.16)	9.36 (7.07)	-0.23 (2.93)		
Plqaue T0-T2	T0	T2	T0-T2	T0-T2	T0-T2
QScan	7.18 (5.80)	4.71 (3.40)	2.47 (4.34)	4.68 (2.61 – 6.75)	<0.001
Control	7.14 (5.65)	9.36 (7.07)	-2.22 (3.30)		

Table 20 - Plaque accumulation (ΔR) for the lingual (L) means, standard deviations and effects.

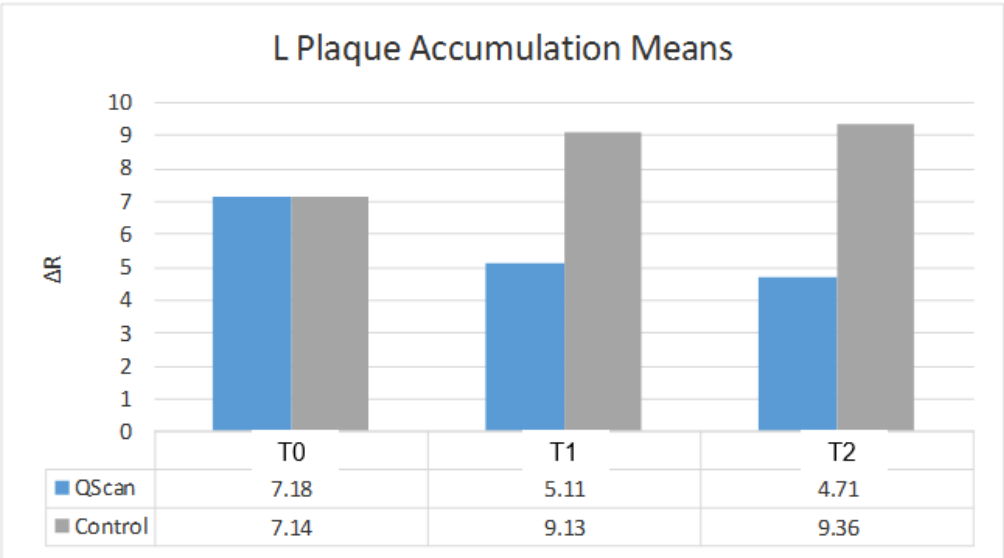


Figure 38 - Chart of the Plaque accumulation (ΔR) for the lingual surface (L).

6.6 Demineralisation

Following the assessment of the primary outcome in relation to the plaque accumulation an assessment was completed to look at the changes in demineralisation. The changes in demineralisation were assessed in relation to all the surfaces combined for each patient. Not all the patients had areas of demineralisation though they were stratified originally in relation to high or low risk of demineralisation. As mentioned in the methods this was assessed in relation to the current demineralisation status of each patient and the number of demineralisation sites. The demineralisation score was (ΔF) which is the change in fluorescence between the area of demineralisation and sound tooth tissue. An area of demineralisation would have a reduction in fluorescence and therefore a negative score. The mean demineralisation score at T0 was -7.87 which increased even further at T1 and a ΔF score of -8.49 (increase in demineralisation). The demineralisation improved at T2 with an increase in the ΔF score and a reduction in demineralisation revealing a score of -8.26. The changes in demineralisation of the control group was an initial reduction of demineralisation of 0.62 from T0 to T1. There was then an increase in demineralisation from T1-T2 with ΔF score reduction and increase in demineralisation of -0.62. The overall change from T0-T2 was an improvement of demineralisation by 0.31. When assessing the changes in the means and the fluctuation apparent between the groups at the different time points, the t tests revealed the following: a non-significant difference between the two groups from T0-T1, T1-T2 and from T0-T2 with a $p>0.05$ (Table 21, Figure 39).

Demineralisation (ΔF)					
Group	Mean (SD)	Mean (SD)	Difference (SD)	Difference Mean (CI 95%)	
Demin T0-T1	T0	T1	T0-T1	T0-T1	T0-T1
QScan	-7.87 (2.52)	-8.49 (2.59)	-0.62 (1.09)	0.37 (-0.97 – 1.72)	0.576
Control	-11.43 (6.73)	-10.81 (6.65)	0.62 (2.03)		
Demin T1-T2	T1	T2	T1-T2	T1-T2	T1-T2
QScan	-8.49 (2.59)	-8.26 (2.44)	0.23 (0.80)	-0.72 (-1.61 – 1.47)	0.924
Control	-10.81 (6.65)	-11.43 (6.03)	-0.62 (2.42)		
Demin T0-T2	T0	T2	T0-T2	T0-T2	T0-T2
QScan	-7.87 (2.52)	-8.26 (2.44)	-0.39 (0.68)	0.17 (-9.71 – 1.748)	0.561
Control	-11.43 (6.73)	-11.12 (6.03)	0.31 (2.24)		

Table 21 - Demineralisation (ΔF) for all the surfaces combined and a detailed description of the means, standard deviations and the effects.

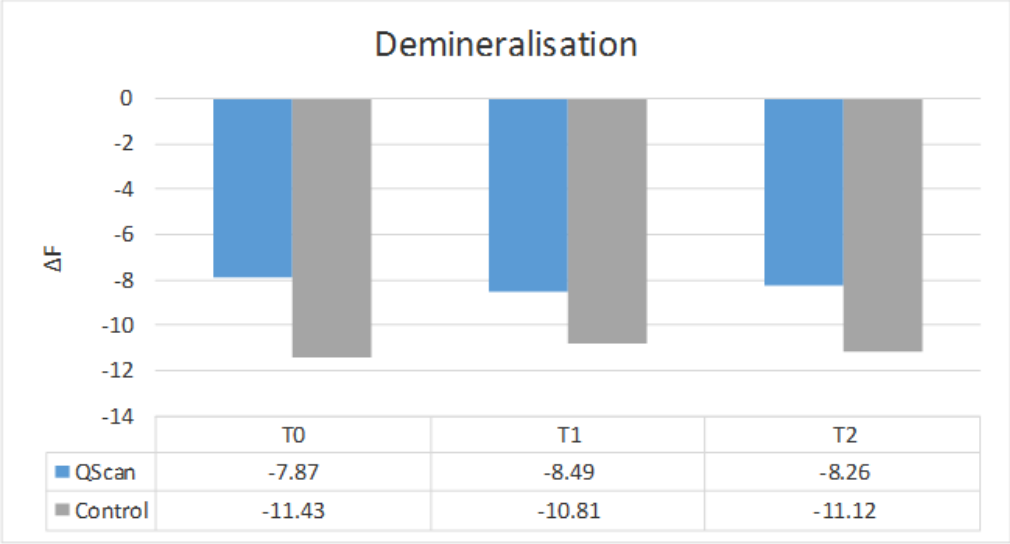


Figure 39 – Chart showing Demineralisation (ΔF) for all the surfaces combined.

7.0 Discussion

In this section the results will be interpreted with an aim to outline the main strengths and limitations of this study. These limitations may have a direct effect on the internal and external validity which will also be discussed. Following the above the applicability of this research in the field of dentistry and areas of future research will also be outlined.

The results defined the primary outcome assessing the effects of QScan use on plaque accumulation when compared to participants in the control group. The secondary outcome assessed the effects of QScan use on demineralisation when compared to participants in the control group.

7.1 Interpretation

The results were divided into the total effects on plaque accumulation as well as the effects on the defined segments (FAB, PL, F, A, B. P and L). This was done in an over three orthodontic visits. The results showed that there was a significant reduction in plaque accumulation following the collective assessment of all the segments with a p value of <0.001 from T0-T1. This was also apparent in from T1-T2 ($p<0.05$) and finally when assessing the total effect throughout the research from T0-T2 ($p<0.001$). This can be interpreted as a positive effect of QScan use. Patients that use the QScan can potentially benefit from a reduction in plaque which may theoretically have an effect on the adverse effects of plaque accumulation. However, this general effect on plaque reduction should be interpreted with caution, since this significant reduction was not apparent when the palatal segment was assessed independently. Though the frontal, buccal and palatal surfaces showed a significant reduction in plaque accumulation from T0-T2 this was not the case with the most difficult surface to use with QScan. The palatal surface showed an insignificant

difference in plaque accumulation when assessed at T0-T1, T1-T2 and T0-T2 ($p<0.05$).

One of the main adverse effects of plaque accumulation is demineralisation. This was assessed as the secondary outcome in the study. Unlike plaque accumulation demineralisation was not evident in all of the segments. Therefore, the areas of demineralisation were collectively assessed in all sections of the dentition (FABPL). Patients in the QScan group had an insignificant reduction of demineralisation when assessed at T0-T1, T1-T2 and T0-T2.

7.2 Limitations

Though statistically the results were significant as described, they must be interpreted with caution. Many limitations are apparent in this study. When assessing the recruitment process in detail, patients were all recruited from Liverpool University Dental Hospital which has a specific demographic of patients. This may potentially affect the generalisability of the study. There was an unequal number of males to females in both groups and no indication of socioeconomic status which has been shown to correlate with decayed, missing and filled teeth (DMFT) (Costa et al. 2012). They were all patients that currently had fixed orthodontic appliances and at different stages in their treatment. This may have an effect on their motivation to ensure adequate oral hygiene, with an expected reduction as the treatment progressed. Evidence has shown that increase in treatment duration has been associated with an increase in the development of white spot lesions (Khalaf 2014). Therefore, participants towards the end of their 2 year treatment would be expected to have more white spot lesions.

The participants weren't selected from a large sample but recruited consecutively at the start of the trial if they met the inclusion criteria. Most clinical trials follow this

method and recruit participants consecutively but they also ensure to randomly allocate them to groups in an aim to reduce confounding factors. This was also the case in this clinical trial. The patients were all treated by one investigator, though the oral hygiene instructions were standardised a risk of bias may appear to patients in one group or the other. The randomisation process was carried out by one investigator with the use of sealed envelopes. The same investigator allocated the participants to their groups and was therefore aware of which participants were in the QScan and control groups. This may subconsciously effect the management of these patients which may affect their oral hygiene. The stratification process though effective in ensuring that patients are equal in both groups with regards to demineralisation, it is however difficult to assess (Tranaeus et al. 2001). Patients with more than one area of demineralisation were considered high risk. Analysis with regards to demineralisation was completed on clinics to assign a patient to either being at high or low risk of demineralisation. This detailed analysis requires time which was limited, and therefore a generalised assessment was used rather than a detailed analysis on the number of demineralised areas. This may have affected the stratification process in this study.

During the study areas of plaque accumulation were assessed after the fixed adjust treatment. This may have a direct effect on the amount of plaque present. Elastomeric modules are known to be plaque retentive and changing the modules in some of the cases may have reduced the amount of plaque. Though this was consistently done with all patients, it may have potentially benefitted patients with poor oral hygiene more than ones with adequate oral hygiene, reducing the overall plaque content. In addition, when certain mechanics are used during orthodontic treatment some teeth may be ligated with stainless steel ligatures rather than elastomeric ligatures. Evidence has shown that elastomeric modules are more

plaque retentive than stainless steel ligatures and therefore may have played a role in the overall plaque accumulation (Türkkahraman et al. 2015). Though the mode of ligation in all cases was mainly elastomeric, there was an assumption that only a few teeth in both groups would have other forms of ligation, and therefore no stratification was done in that regards. This may have potentially had an effect on the general outcome.

The assessment of demineralisation requires all the plaque to be removed from the tooth surface. This is a long process in which not only plaque on the tooth surfaces must be removed but also around the fixed appliances. A small amount of plaque may alter the analysis in which if deemed as an area of demineralisation, would give a false positive. Areas of demineralisation and plaque accumulation following QLF-D photography are quite similar in their presentation. Therefore an area of plaque accumulation may be interpreted as an area of demineralisation and vice versa. Therefore any form of human error in the removal of plaque may have contributed to a false positive assessing demineralisation. The same scenario may occur when there are areas of staining and calculus which may also influence the QLF assessment. In an aim to overcome this, a detailed assessment of the white light images was completed prior to assessing the QLF photographs in an aim to remove any plaque present. This may be very difficult to do especially when pores of active demineralised sites are filled with plaque and other fluorescing substances (Tranaeus et al. 2001).

Data collection using the QLF-D photographs requires an accurate assessment of tooth surfaces and ensuring that any other noise in the photos are emitted. In this study the photographs were taken with fixed appliances on. Any areas of demineralisation around the fixed appliance would need to be interpreted with

caution. A common mistake would be to include part of the bracket, module, wire or band into the area to be assessed. This would affect the final assessment of fluorescence and the comparison between demineralised enamel and sound enamel. Human error in placement of the outline not to include any pixels of the fixed appliances is not uncommon, especially when assessment is made on a pixel level. This complication may again lead to inaccurate assessment of demineralisation. This is not only apparent around the orthodontic appliance but also when an assessment is made near the gingival margin. Demineralisation near the gingival margin would require a very accurate outline of the area to be assessed. As with the fixed appliances any coverage of the gingivae in the demineralisation outline would affect ΔF. Another common issue with the assessment of demineralisation in orthodontic patients using QLF-D imaging is with teeth rotating during the alignment phase of treatment. As teeth rotate the angle in which the photograph is taken changes. This has the potential to effect the assessment of florescence loss aswell as the size of the lesion from one visit to the next (Van der Kaaij et al. 2018).

Participants recruited in the study were fully aware of the outcomes to be assessed. When assessing plaque accumulation it is only a screenshot in time when the QLF-D photographs are taken. A participant may simply ensure to brush their teeth before the session. This would give an indication of adequate oral hygiene with reduced plaque levels in the photographs. However, the patient may have used the QScan device at home, but the device may not necessarily have had an impact on their plaque levels between their orthodontic appointments. The levels of plaque when the photos were taken may not necessarily represent the levels of plaque throughout the 6-8 week period between the QLF-D photographs. The Hawthorne effect may have played a role in this clinical trial which can directly affect its generalisability (McCarney et al. 2007). Patients who were in the intervention group may have

ensured that their oral hygiene was adequate throughout the trail knowing that they were in a study to assess the effects of QScan.

When a patient is provided with a new device especially in the average age range recruited in this study, they may go through a level of compliance at the start since it is a new device that they would aim to try out. This may soon fade away with time. This study was able to measure the changes over a short period of time when considering that orthodontic treatment may take up to 2-3 years in challenging cases. Due to the short period in which the study was conducted one cannot conclude that the effects of QScan in plaque accumulation may reduce plaque levels for orthodontic patients throughout their entire course of treatment.

7.3 Strengths

The study was conducted as a randomised control trial which aims to minimise bias, confounding factors with adequate statistical reliability (Rosner 2012). The investigators were blinded in which allocation to groups was conducted using sealed envelopes pre- prepared by investigator GB. In addition to random allocation the participants were also stratified in relation to the level of demineralisation. The patients in both groups were near equal in the average age and time between visits. The statistical analysis also revealed a non-statistically significant difference when assessing the difference in plaque accumulation between both groups at baseline. Therefore all measures were taken to ensure adequate randomisation and reduction of confounding factors.

The investigators were blinded in relation the participants' group allocation during data analysis. The photographs were labelled with random codes, and during analysis the photos were randomised once again to ensure limiting any recall of

patients and their assigned groups. The blinding was also completed throughout data analysis and only revealed once all the data was collected and presented to investigator GB for supervised statistical analysis.

All the instruments used in the study were the same throughout. This is in relation to the camera used, the instruments used for plaque removal, the computer system to initially assess demineralisation for stratification as well as the QScan devices given to the patients. The settings on the camera and focal distance was consistent throughout, as well as the settings in the data analysis system to analyse plaque and demineralisation. This aimed to ensure consistency in the data collection and analysis.

The participants had fixed orthodontic appliances and were at different stages of their treatment which as mentioned can be viewed as a limitation of the study. Though this may be interpreted differently. It may also be considered as a realistic use of an oral hygiene adjunct. Clinicians may advise their patients to use adjuncts at any stage of their treatment. The adjunct is usually recommended due to the patients' inadequate oral hygiene status that may drop at any time during treatment. The short period in which the study was conducted averaged 15 weeks, which has also been defined as a limitation, though data from previous research (Ogaard & Ten Bosch 1994) revealed that demineralisation may appear in less than 4 weeks. A 15 week period for such a study assessing a newly developed adjunct may provide the necessary information to further develop the device and its efficacy. A study with the same methodology may be done for a longer period though by the time it is completed, further alterations may have been made to the device. This has been evident with many oral hygiene adjuncts that are continuously being improved with new versions every year. If the data collection period is prolonged, upon completion

of the study there may be further developments of the QScan device which is currently available, and new/advanced versions maybe released. Therefore, labelling the trial as one which investigated a ‘dated/old’ version. Treatment in orthodontics may take up to 2 ½ - 3 years and therefore approximately 5 – 6 years to complete a study assessing plaque accumulation and demineralisation in patients prior to bond up until debond.

7.4 Implications of results in practice

The results of this study can have a considerate impact on clinical practice. As mentioned in the introduction the use of fixed orthodontic appliances makes the daily maintenance of oral hygiene much more of a challenge (Zachrisson & Zachrisson 1971). Therefore orthodontists advise their patient of the main risks associated with orthodontic treatment which includes demineralisation. This is as a result of plaque accumulation around the appliances. Orthodontists may also advise their patients to use oral hygiene adjuncts in an aim to reduce the risks of demineralisation with adequate oral hygiene. QScan has shown to be an effective adjunct in the reduction of plaque accumulation in patients with orthodontic appliances. Therefore, this may be one of the options that an orthodontist may consider.

During orthodontic treatment an orthodontist liaises with a number of clinicians in an aim to ensure that the patient has adequate oral hygiene throughout treatment. General dental practitioners, hygienists, therapists and orthodontic therapists can all play a role in ensuring patients have adequate oral hygiene throughout orthodontic treatment. Therefore, they may also advise patients about the use of QScan. This may be in conjunction with other oral hygiene adjuncts as well.

So far the clinical applications have been mentioned with regards to patients having fixed orthodontic appliances. This is not to say that the application of the device may not have an impact on patients without fixed appliances. During tooth brushing the areas of plaque accumulation are not only around the fixed appliances but also near the gum margin, interproximal, occlusal, lingual and palatal surfaces. All these surfaces were assessed during the study, and not only the labial and buccal surfaces where the fixed appliances were attached. Therefore the device has demonstrated to be effective on fixed appliance and non-fixed appliance surfaces. This may advocate the use of QScan in non-orthodontic patients in an aim to improve their oral hygiene. Whether these patients are aiming to have orthodontic treatment or not the application of such adjuncts may improve their oral hygiene. This has also been demonstrated in previous research (see applications of QScan in the literature review).

Patients in the study mentioned that some of the main advantages in the use of QScan was the ability to clearly see the areas of plaque accumulation. The identification of plaque using QScan can be utilised by clinicians on clinic when providing oral hygiene instructions. Classically disclosing tablets were used with an aim to identify areas of plaque accumulation, which have their disadvantages (Hobson & Clark 1998). The main disadvantages described included staining of soft tissues, clothes and teeth rather than simply staining plaque. The patient information leaflets provided on the use of disclosing tablets have advised washing clothes or towels immediately if the red colouring is in contact with them (Endekay disclosing tablets erythrosine 2019).

One of the other comments received by the participants was that the QScan device was utilised with younger members of the family. Participants with children used the

device in an aim to identify areas of plaque accumulation which may be difficult to do otherwise. Therefore, using the device as a tool to help them clean their children's teeth better. Some participants also mentioned using the device to see whether their children who have recently been cleaning their teeth on their own, are being efficient and accurate in their tooth brushing. Though this research focussed mainly on assessing patients with fixed appliances and the efficiency of the QScan device, the device may have a number of other applications. The effectiveness of QScan use in these various applications may warrant further research.

7.5 Future research applications

The future research applications may be divided into a number of different aspects related to this particular study. These include, future research applications related to QScan, QLF-D and their use with and without fixed orthodontic appliances.

7.5.1 Future research applications of QScan

One of the future research applications of QScan following this research, would be a continuation of the work done in this study. A complete follow up of patients starting orthodontic treatment who are then assessed throughout their 2-3 year treatment for plaque accumulation and demineralisation. This can be beneficial especially if patients are followed up following debond of the fixed appliance. A comparison may be made between the pre orthodontic demineralisation, and post orthodontic demineralisation with or without QScan use. It may be considered not only beneficial to demonstrate the effects before and after treatment, but it may also reduce bias ascribed to a variation in the rate of demineriIsation and decay between individuals (Alanen 2000). This can also be expanded to assess gingival disease and the effects of QScan on periodontal status at different stages of orthodontic treatment, up to and following removal of the appliance. This research would however require a long

period of time to conduct, in which time further versions of QScan will be made with improvements to increase its level of efficiency.

The QScan device as mentioned in section 7.4 of the discussion, may have a number of different applications. These can further be tested and researched. Starting off with patients using QScan without having fixed orthodontic appliances. This may or may not increase the effects of QScan on plaque accumulation.

Other applications of QScan has been mentioned in relation to the use with children, where parents are able to identify areas they have missed when aiding their children to brush their teeth. A randomised control trial can assess levels of plaque accumulation where parents use the QScan device when brushing their children's teeth. This can be compared with a control group where simple oral hygiene instructions are given.

The application of QScan in a clinical setting by specialists, general dental practitioners, therapists, hygienists and nurses in conjunction with oral hygiene can be further tested. This can be done by assessing patients' plaque levels when providing oral hygiene instructions with and without using QScan. This can also be assessed in relation to other measures of providing oral hygiene instructions. Verbal and video applications have been shown to be effective (Gray & McIntyre 2008) though never compared to educating patients with QLF applications or QScan.

The alternative and most widely used plaque detector currently is the disclosing tablet. A survey concluded that 84% of British orthodontists are currently recommending the use of disclosing tablets (Hobson & Clark 1998). Patients are asked to use the disclosing tablets on a regular basis to ensure that they are efficient

in their tooth brushing. A future research project can be conducted as a three arm randomised control trial assessing three different groups. The first would be given the QScan device as the main intervention. The second group would be provided with disclosing tablets and the third would be the control group. This again can be assessed with patients having orthodontic appliances and patients that don't.

As mentioned in the clinical application of this research, in clinical practice practitioners may advise their patients on the use of oral hygiene adjuncts at any stage of their treatment. The question is which one is more effective? Oral hygiene instructions and its application must be customised to the patient and simplistic (British Society of Periodontology - The good practitioner's guide to periodontology 2016). Many adjuncts are currently available in the market. A randomised control trial comparing the effects of different adjuncts may be of benefit. Adjuncts may have different aims and one is recommended over another depending on what the patient struggles with, it would be valuable to have a list of adjuncts depending on patient specific struggles. For example, if patients are struggling with cleaning interdental areas a specific adjunct can be recommended vs patients struggling to clean areas around the gingivae or orthodontic brackets etc. Whether a disclosing tablet, interdental brush, water flosser, air flosser, electric toothbrush or QScan is a better adjunct for the various complications mentioned above. This may be assessed in relation to plaque accumulation, gingival health and demineralisation. One of the most reliable methods of detecting demineralisation is known to be QLF-D, which has a number of research applications aswell.

7.5.2 Future research applications of QLF-D

The use of QLF technology with an aim to detect demineralisation has been viewed as a reliable method (Benson 2003a). Therefore its applications can be in a number of different clinical and academic settings. The aim would be to assess the effects of

different interventions on demineralisation and plaque accumulation with the use of QLF-D technology. The interventions may vary between different adjuncts to oral hygiene that are currently available and others that are being developed.

Demineralisation is one of the major adverse effects of poor oral hygiene and it may be considered as one of the most difficult adverse effects to assess. QLF technology has allowed demineralisation and plaque level assessment to be much more effective and efficient (Benson 2003a). Most research in the area of oral hygiene adjuncts has focused on plaque accumulation and gingival disease. Gingivitis can resolve due to its reversible nature though if demineralisation progresses further it may lead to cavities which will warrant restorations. Therefore it is important that if an adjunct is developed that it is assessed not only in relation to plaque accumulation but also in relation to demineralisation. An effective method as mentioned previously is with the use of QLF-D.

The use of QLF-D may be used on its own as an adjunct to oral hygiene instructions. Clinicians can provide patients with oral hygiene advice following the use of QLF-D to highlight the areas of plaque accumulation. This can be done on a big screen in a clinic or simply on the QLF-D program using the computer screen. This may be considered for future research projects assessing OH instructions for patients with or without orthodontic appliances with the use of QLF-D.

The recent advancements in technology has invited many dentists into the world of social media in an aim to aid in providing oral hygiene advice (Althunayan et al. 2018). This may be considered as an adjunct to oral hygiene instructions. A 3 minute explanation on clinic though short may contain a lot of information for a patient to grasp. This information can be further reviewed on social media whether through

video applications, short clips or text. . This can be further assessed to see whether utilising social media can play a role in the improvement of patient's oral hygiene. As with all QLF-D research this can be assessed in patients with or without fixed orthodontic appliances.

8.0 Conclusion

The use of QScan has demonstrated its effectiveness in the reduction of plaque accumulation. The significant reduction of plaque accumulation however did not translate to a reduction in demineralisation. This was evident after an average 15 week assessment of orthodontic patients with fixed appliances.

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10.Appendix

Appendix 1: Fixed appliance starter pack components

1. Three interdental brushes (Tepe™, Sweden).

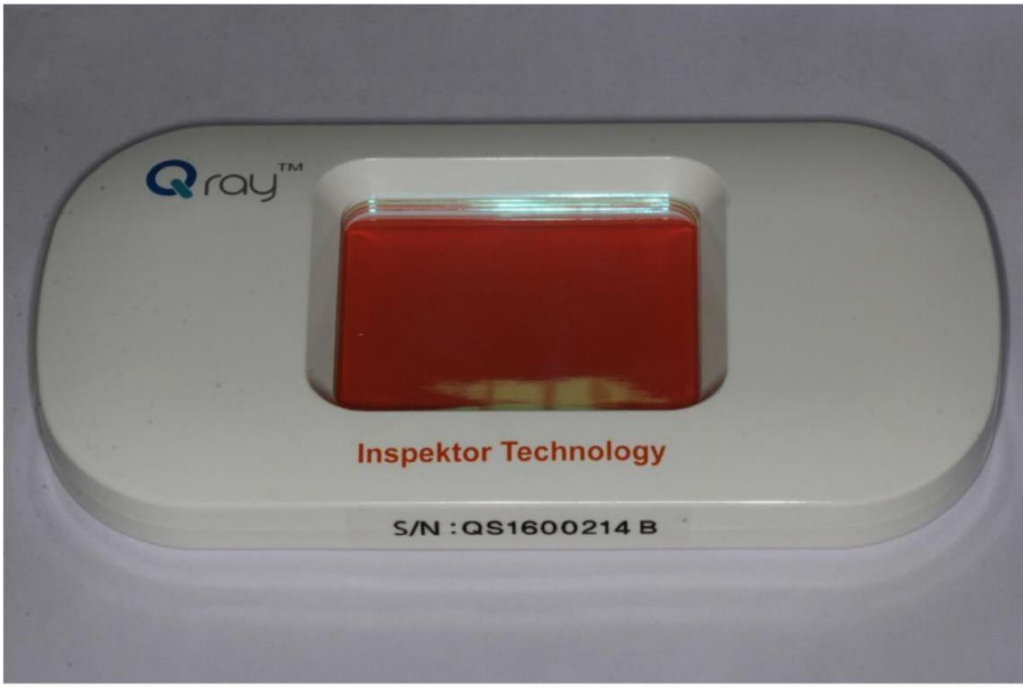
2. PlaqSearch™ (Tepe™, Sweden) four plaque disclosing tablets (to use at home to check to see if plaque remains after brushing).

3. Orthodontic wax (to apply small piece to appliance should an area irritate the soft tissues).

4. British Orthodontic Society patient information leaflet outlining ‘Fixed Appliances’.

5. Colgate FluoriGard Alcohol Free Mouth Rinse 0.05% w/v sodium fluoride (to use once a day for 30 seconds at a different time than brushing) (Colgate™, United States).

Appendix 2: Images of Q---Scan device (front and back)



Appendix 3: Instructions on how to use the Q---Scan device at-home

HOW DO I USE THE QSCAN DEVICE

The Qscan device reveals the plaque on your teeth.

Plaque: What is it?

Plaque is a sticky, colourless film of bacteria that constantly forms on our teeth and causes tooth decay.

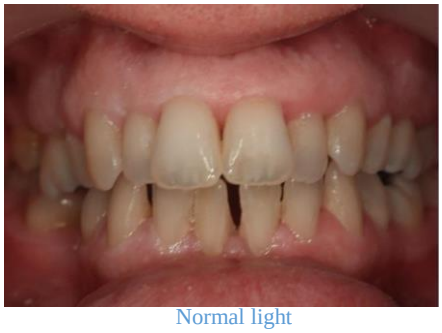
Dental plaque is difficult to see unless it's stained. You can stain plaque by chewing red "disclosing tablets," found at supermarkets and chemists. The red colour left on the teeth will show you where there is still plaque—and where you have to brush again to remove it.

However, some people don't like using disclosing tablets as it can be a bit time consuming and not everyone likes the taste of them.

What if you could see a build up of plaque without disclosing tablets – well now you can!

This device reveals the plaque without you having to use disclosing tablets.

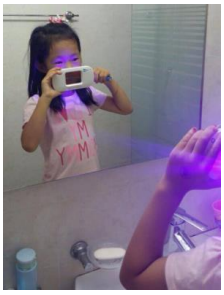
1



Normal light

Qscan (showing bright red plaque)

INSTRUCTIONS FOR USE



- Use after brushing to see if all the plaque has been removed. *(You should be brushing your teeth twice daily)*
- If red areas of plaque are visible, re-brush until it's gone.
- It's easiest to the use the Qscan looking in a mirror. *(See 'Operating your Qscan' on page 4)*

PARTS IDENTIFICATION

3 Optical Filter

4 LEDs

1

Power button (power on/off; control for LED mode light level)

Charging port

power supply adapter/charger (US)*

*Or similar model

STORING CONDITIONS

Should be used and stored at room temperature (32 to 86°F; 0 to 30°C), away from direct light and in a dry location.

IMPORTANT SAFETY INFORMATION

Keep this manual for future reference. It contains important information about maintenance and safe operation of your Qscan.

- Do not disassemble the unit by force
- Be careful not to scratch the filter
- Be sure to turn off the power after using the product

DANGERS

- To avoid risk of damage to eyes or eyesight, never look directly into the light when the light is on, nor shine it directly into another person's eyes
- To reduce the risk of electrocution:
  - Do not place or store the product while charging in an area where it can fall or be pulled into a bath or sink, or where it will sit or drop into water or other liquid
  - Do not reach for a power supply adapter/charger that has fallen into water or other liquid. Unplug immediately.
  - Never use a power supply adapter/charger with a damaged cord or plug
- Any battery may rupture or explode if put in a fire or otherwise exposed to excessive heat (direct sunlight, hot car). To avoid risk of injury, do not expose batteries to fire or excessive heat
- Never short-circuit a battery pack by bringing the terminals in contact with a metal object. Explosion, burns, other bodily injury or fire could result.

WARNINGS

- This appliance is not intended for use by persons (including children) with reduced physical, sensory or mental capabilities, or lack of experience of knowledge, unless they have been given supervision or instruction concerning the use of the product by a person responsible for their safety
- To reduce the risk of burns, electrocution, fire or physical injury:
  - Do not use any charging cradle, wall adapter, generic battery charger or other attachments other than those recommended by the manufacturer
  - This product is designed to be charged within a range of 100 to 240 volts
  - Never force the power supply adapter/charger plug into an outlet; if the plug does not easily fit into the outlet, discontinue use
  - Keep the product and power supply adapter/charger away from heated surfaces and liquids
- This product is not a toy. Do not allow children or pets to play with your Qscan product.
- Never force the plug into an electrical outlet; never force the power tip into the charging port
- LEDs get hot during extended usage. Personal injury or damage to heat sensitive materials may result, e.g. plastics, rubber, cloth fabrics, etc.

- Do not use a cell phone power supply adapter/charger. Use only the power supply adapter/charger provided with your Qscan
- The battery should be charged in a safe manner, and never overcharged or overdischarged.
- Disconnect Qscan from the power supply adapter/charger once fully charged
- If Qscan is to be stored unused for a long period of time, it should be charged up to 80% prior to storage

CHARGING YOUR QSCAN

Your Qscan features a built-in battery, which is not user replaceable. Tampering with your Qscan, or attempting to open it, will void the warranty and can result in a safety hazard. Use only the charger that was shipped with your product to charge the battery.

1. Connect the Qscan to the power supply adapter/charger by inserting the power tip into the charging port
2. Plug the charging cable into an electrical outlet
3. The light on the charger is lit red while the Qscan is charging; the light on the charger will be lit green when the charging is complete
4. It typically takes 2 hours to fully charge the Qscan
5. Qscan should be disconnected from the charger once charging is complete

OPERATING YOUR QSCAN

You can use your Qscan before and after you brush your teeth, in order to show how effectively you've cleaned your teeth. Your Qscan will work best in a low lit area**.**

Self Use:

1. While facing a mirror and with the Qscan off, with the LED strip on the bottom of the Qscan facing toward you, point the LEDs directly toward your mouth
2. Turn on the Qscan by pressing the power button. If power button is pressed once, the LEDs will be operating on HIGH level; if power button is pressed twice, the LEDs will be operating on LOW level; if power button is pressed a third time, the Qscan will be turned off.
3. While looking directly into the mirror, view the reflection of your mouth through the optical filter in the Qscan for visible signs of red fluorescence, which would indicate areas on your teeth that require additional self cleaning or, if red fluorescence persists, you may want to consider a professional cleaning.

CLEANING YOUR QSCAN

1. Use lens cleaning cloth to clean the Qscan filter. The casing can be cleaned with a damp cloth with mild detergent
2. Do not use isopropyl rubbing alcohol, vinegar, or essential oil based products to clean the Qscan
3. Do not clean the Qscan in the dishwasher

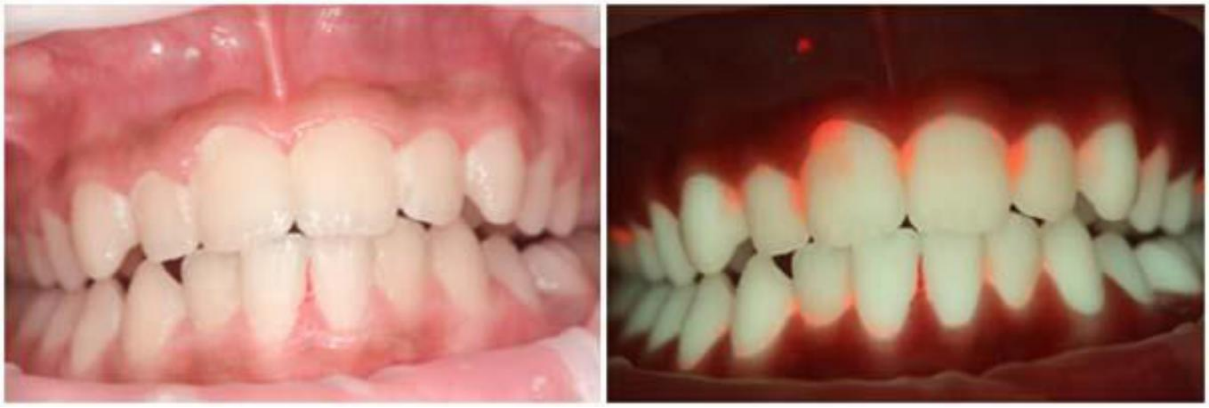
Appendix 4: Participant information sheet for 11-13yrs

INFORMATION SHEET FOR 11-13 yrs

The use of the Q-Scan device as an adjunct to "at-home" oral hygiene in Orthodontics

We want to tell you about a research study we are doing. A research study is a special way to find out about something. We would like you to join this study that looks at how clean your teeth are. Before you decide please read this information sheet.

We will be using a camera that records a photograph of your teeth. This camera takes a two photographs, a normal and a blue light photograph of the teeth. It will help us see how clean your teeth are. You will be given tooth brushing advice and shown the blue light photographs. These photographs will show you if you are missing any areas.



Some people who choose to take part will be given a device to use at home to check their tooth brushing. By pressing a simple on/off button you can highlight the teeth and using a mirror can see any plaque that's there as it will be red in colour. You can then go back and brush your teeth again to remove this. Only half of the people who take part in the study will be given one of these to use. Everyone who takes part will have the photographs taken to show them how their cleaning is and to give them tips on how to

improve their cleaning around the braces. These photos will only be used for the study, and your name will not be attached to them or mentioned (codes will be used instead of your name). They will be kept safe so that no one can see them except the dentists doing the study. The photos will be deleted 11 years after the study is done though will not be reused unless your permission is taken.

The study will not change your treatment. It will only make 5 of your appointments about 5 minutes longer.

What is the purpose of the study?
We would like to find out if the device (called Q-Scan) helps people with braces to clean their teeth better at home.

Q- Scan device:

Why have I been asked to take part?
You are the right age and are going to have upper and lower braces fitted.

What will happen if I say yes and what will happen during the study?
We will take the special QLF-D photographs when the braces have been fitted and at two check-up sessions after that. If we need to we will clean the teeth at these review appointments. We will show you the photographs and give you tooth brushing advice to focus on any areas that need better cleaning.
Half of the people that choose to take part will be given a Q-Scan device to take home and use twice a day after brushing. This will need to be brought to each review appointment so the dentist can check it is working. After treatment is finished and braces are removed you will be asked to give this device back to the dentist.

How long is the project?
It will last for four sessions in total.

What if I am not happy or have a problem?
You can stop taking part in this project at any time. Your brace treatment will continue as normal.

What if the Q-Scan device breaks?
If the Q-Scan breaks please stop using it, pack it away carefully and contact me to arrange to come into the clinic so we can see what the problem is (please see contact details below). It is important to keep in a safe place and ask your parent on which place is best so that it does not break.

What if I have a question?
If you have any questions, feel free to ask and I will be happy to answer them.
Thank you for taking the time to read this.
Contact email: qscan@liv.ac.uk Phone: 0044 (0)151 706 525

Appendix 5: Participant information sheet for 14-15yrs

INFORMATION SHEET FOR 14-15 yrs

The use of the Q-Scan device as an adjunct to "at-home" oral hygiene in Orthodontics

We want to tell you about a research study we are doing. A research study is a special way to find out about something. We would like you to join this study that looks at how clean your teeth are. Before you decide please read this information sheet. Please ask us if there is anything that is not clear or you have any questions.

Quantitative Light Induced Fluorescence digital (QLFD^{TM}) is a camera which records a photograph of your teeth. This camera takes a normal photograph and a blue light photograph of the teeth. It will help us monitor your teeth and see how clean they are. If there is plaque on your teeth we will be able to see it. You will be given tooth brushing advice and shown the blue light photographs. These photographs will show the areas of plaque on your teeth and help you know where to brush.

Some people who choose to take part will be given a device to use at home to check their tooth brushing. By pressing a simple on/off button you can highlight the teeth and using a mirror can see any plaque that's there as it will be red in colour. You can then go back and brush your teeth again to remove this. Only half of the people who take part in the study will be given one of these to use. Everyone who takes part will have the photographs taken to show them how their cleaning is and to give them tips on how to improve their cleaning around the braces. These photos will only be used for the study, and your name will not be attached to them or mentioned (codes will be used instead of your name). They will be secured so that no one has access to them except the dentists doing the study. The photos will be disposed of 11 years following the study completion though will not be reused unless your permission is taken.

The study will not change your treatment. It will only make 5 of your appointments about 5 minutes longer.

What is the purpose of the study?
We would like to find out if the device (called Q-Scan) helps people with braces to clean their teeth better at home.

We will be using a Quantitative Light Induced Fluorescence-Digital (QLF-D^{TM}) camera to take normal and blue light photographs of your teeth when you are in the clinic. We will be trying to find the areas where plaque as not been cleaned away or where there is any minor damage to your teeth.

We are aiming to find out if showing you the camera photographs, or if the use of the device at home, is useful for your tooth brushing. At the end of your brace treatment

we will ask you to complete a questionnaire to assess how useful you feel the photographs / Q-Scan device were.

Q- Scan device:

Why have I been asked to take part?
You are the right age and are going to have upper and lower braces fitted.

What will happen if I say yes?
We will take the special QLF-D photographs when your braces have been fitted and in 2 check ups visits following that. If we need to we will clean the teeth at these review appointments. We will show you the photographs and give you tooth brushing advice to focus on any areas that need better cleaning. Half of the people that choose to take part will be given a Q-Scan device to take home and use twice a day after brushing. This will need to be brought to each review appointment so the dentist can check it is working. After treatment is finished and braces are removed you will be asked to give this device back to the dentist.

How long is the project?
It will last for the same amount of time as your fixed brace treatment.

What if I am not happy or have a problem?
You can stop taking part in this project at any time. Your brace treatment will continue as normal.

What if the Q-Scan device breaks?
If the Q-Scan breaks please stop using it, pack it away carefully and contact me to arrange to come into the clinic so we can see what the problem is (please see contact details below).

What if I have a question?
If you have any questions, feel free to ask and I will be happy to answer them.

Thank you for taking the time to read this.

Contact email: qscan@liv.ac.uk
Phone: 0044 (0)151 706 5252

Appendix 6: Participant information sheet for over 16yrs

INFORMATION SHEET FOR THE PARTICIPANT (16 and over)

The use of the Q-Scan device as an adjunct to "at-home" oral hygiene in Orthodontics

You are being asked to participate in a research project, which is looking at a new way to help people with braces check their tooth brushing at home. People who decide to take part will be divided into two groups. One group will be given a hand held device (named Q-Scan) to take home and asked to use it twice daily to check their teeth after brushing. The other group will not be given a device.

Before deciding whether to take part in the study please take a little time to read this information sheet. Please ask us if there is anything that is unclear, if you have any questions or would like further information.

What is the purpose of the study?
Our aim is to find out if the Q-Scan device helps people with braces clean their teeth at-home. We also want to find out if the blue and white light photographs taken with a special digital camera help people with braces keep their teeth clean.

How will the study work?
In the Orthodontic clinic both groups will have photographs taken of their teeth in order to assess the level of cleanliness and also to identify areas which show early signs of minor damage which can appear like white spots on the teeth.

Quantitative Light Induced Fluorescence digital (QLFD^{TM}) is a digital camera which takes a normal photograph and a blue light photograph of the teeth. The blue light enables plaque to be seen as red areas on teeth. It is also able to show early enamel changes, which can leave permanent marks on teeth, at an earlier stage than eye sight alone. In this study both groups will have QLF-D photographs taken when the braces have been fitted and at two subsequent check-up visits. Taking clinical photographs is part of the normal course of Orthodontic treatment. Taking part in the study will lengthen your appointment time by approximately 5 minutes on 5 occasions. You will not be required to attend extra appointments. The photos will only be used for the study, and your name will not be attached to them or mentioned (codes will be used instead). They will be secured so that no one has access to them except the dentists doing the study. The photos will be disposed of 11 years following the study completion though will not be reused unless your permission is taken.

One group will be given the Q-Scan device to use at home. This device uses the same technology as the QLFD camera, allowing the person using it to check if there is any plaque on their teeth after brushing by simply turning the device on and looking in a mirror. Any areas with plaque still present will appear red. **The participant will then need to brush their teeth again to remove the red area (plaque) to make sure the teeth are completely clean.** After your braces have been removed the device will need to be given back to the Orthodontic Department.

The other group will not be given the Q-Scan device and will be asked to clean their teeth as they normally do.

Has the study been approved?
Ethical approval via IRAS has been completed.

Who is paying for the study?
The University of Liverpool will be funding this project.

Who will be conducting the study?
The study is being run by Dr Norah Flannigan (Senior Clinical Lecturer in Orthodontics) and a Postgraduate in Orthodontics (Salman Sarkhouh). The study will be done as part of a postgraduate program in orthodontics.

Why have I been asked to take part?
You have been asked to take part because we are looking for healthy volunteers aged 11-years or older who will be having upper and lower fixed braces.

How long will the study last?
The study will last for as long as the fixed brace treatment takes. The study ends when the braces are removed. However, should you wish to withdraw from the study you may do so at any stage and your Orthodontic care will continue as normal.

What if I do not want to take part?
Your treatment will continue as normal. You should not feel obliged to take part and you do not have to give a reason if you do not want to. If you do take part in the study, but later decide that you do not want to continue you can also withdraw at any time without giving a reason.

What if I have a question or if there is a problem during the study?
You may ask questions at any time, before and during the study. If you wish to make any enquiry, you may contact, the Orthodontic Department, Liverpool University Dental Hospital, Pembroke Place, Liverpool, L3 5PS. Email: gscan@liv.ac.uk.

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team on 0044 (0)1517065252. They will do their best to answer your questions. If you are still unhappy and wish to complain formally, you can do this through the Patient Advice Liaison Service or by emailing; complaints@rlbuht.nhs.uk.

It must be noted that it is important to keep the device in a safe place and ensure to follow the “How do I use the QScan device” document. The device should be monitored and if there are any problems with the device it is important to contact for advice or possible repair.

How will the information collected be managed?
Information about you will be stored anonymously. As soon as we have collected the information, we will replace any personal information with a code. The person responsible for security and access to your data is Dr Flannigan, the Chief investigator of the Study.

What do I do if I want to take part?
If you would like to take part, please sign all the relevant sections of the consent form that you will have been provided with.

Thank you for taking the time to read this.
Email: gscan@liv.ac.uk
Phone: 0044 (0)151 706 5252

Appendix 7: Information sheet for parents

INFORMATION SHEET FOR THE PARENT

The use of the Q-Scan device as an adjunct to at home oral hygiene in Orthodontics

Your child has been asked to participate in a research project which is:

1. Investigating if a new device (named Q-Scan) can help patients with fixed braces improve their "at-home" tooth brushing. One group will be given the Q-Scan device to use at home in addition to their normal oral hygiene advice. The other group will not receive the device but will still receive the normal oral hygiene instructions that are given to all patients with braces.
2. Both groups will have special photographs taken of their teeth when they attend the clinic. These photographs will be taken when the braces have been fitted and in the subsequent two check-up visits. In addition to providing information for the research, these images will be used to teach the patients about how to improve their tooth brushing skills.

Before deciding whether to take part in the study please take a little time to read this information sheet. Please ask us if there is anything that is unclear, if you have any questions or would like further information.

What is the purpose of the study?
Our aim is to find out if the Q-Scan device helps people with braces clean their teeth at home. We also want to find out if the blue and white light photographs taken with a special digital camera help people with braces keep their teeth clean.

How will the study work?
In the Orthodontic clinic participant will have photographs taken of their teeth in order to assess the level of cleanliness and also to identify areas which show early signs of minor damage which can appear like white spots on the teeth.

Quantitative Light Induced Fluorescence Digital (QLFD^{TM}) is a digital camera which takes a normal photograph and a blue light photograph of the teeth. The blue light enables plaque to be seen as red areas on teeth. It is also able to show early enamel changes, which can leave permanent marks on teeth, at an earlier stage than eye sight alone. In this study both groups will have these photographs taken when the braces have been fitted and in the following two subsequent check-up visits. Taking clinical photographs is part of the normal course of Orthodontic treatment and; taking part in the study will require a couple of extra minutes per appointment for the QLFD photographs to be taken in addition to the regular photographs. You will not be required to attend extra appointments. These photos will only be used for the study, and your name will not be attached to them or

mentioned (codes will be used instead). They will be secured so that no one has access except the dentists doing the study. The photos will be disposed of 11 years following the study completion though will not be reused unless your permission is taken.

Your child will be assigned to one of two groups. One group will be given the Q-Scan device to use at home. This device uses the same technology as the QLFD camera, allowing the person using it to check if there is any plaque on their teeth after brushing by simply turning the device on and looking in a mirror. Any areas with plaque still present will appear red. **The participant will then need to brush their teeth again to remove the red area (plaque) to make sure the teeth are completely clean.** After your braces have been removed the device will need to be given back to the Orthodontic Department.

The other group will not be given the Q-Scan device and will be asked to clean their teeth as they normally do.

There is no harmful risk to the use of the Q- Scan device and it is to be used in the morning and evening after brushing their teeth. Your child will be advised of this if the decision has been made to take part.

Has the study been approved?
Ethical approval via IRAS has been completed.

Who is paying for the study?
The University of Liverpool will be funding this project.

Who will be conducting the study?
The study is being led by Dr Norah Flannigan (Senior Clinical Lecturer in Orthodontics) and a Specialist Registrar in Orthodontics (to be appointed).

Why has my child been asked to take part?
We are looking for healthy volunteers, 11 years of age or older, who are planned for upper and lower fixed braces.

What will happen if my child takes part?
They will be assigned to one of two groups. One group will receive the Q-Scan device to use at home. The other group will receive the usual oral hygiene advise but will not be given a device. All of the participants will have the special blue and white light photographs taken at 4 different appointments during their brace treatment. Your child's teeth will also be given a clean if required. This will lengthen the appointment time by approximately 5 minutes on 5 occasions. At the end of the study we will ask your child to complete a questionnaire to assess how useful the study has been to your child. Taking part in the study will not require any extra appointments.

How long will the study last?
The study will last for as long as the fixed brace treatment takes. The study ends when the braces are removed. However, should you or your child wish to withdraw

from the study you may do so at any stage and their Orthodontic care will continue as normal.

What if I do not want my child to take part?
Your child's treatment will continue as normal. You should not feel obliged to consent to taking part in you do consent but later decide that you do not want to continue you can also withdraw at any time without giving a reason.

What if I have a question of there is a problem during the study?
You may ask questions at any time, before and during the study. If you wish to make any enquiry, you may contact, the Orthodontic Department, Liverpool University Dental Hospital, Pembroke Place, Liverpool, L3 5PS. Email: qscan@liv.ac.uk.

If you have a concern about any aspect of this study, you should ask to speak to a member of the research team on +44 (0)1517065252. They will do their best to answer your questions. If you are still unhappy and wish to complain formally, you can do this through the Patient Advice Liaison Service or by emailing; complaints@rlbuht.nhs.uk.

How will the data collected be managed?
Information about participants will be stored anonymously. As soon as we have collected the information, we will replace any personal information with a code. The person responsible for security and access to the data is Dr Flannigan, the Chief investigator of the Study.

What do I do if I am happy for my child to take part?
If you are happy for your child to take part, please sign all the relevant sections of the consent form that you will have been provided with.

Thank you for taking the time to read this.

Email: qscan@liv.ac.uk
Tel: +44 (0)1517065252
this udy and o not have to give a reason if you do not want to. If

Appendix 8: Consent form 1 – Patients agreement for participation in research under 16

Patient Identification Number for this trial:

CONSENT FORM 1
Patient's agreement for participation in research Under 16

Research project: The use of the Q-Scan device as an adjunct to "at-home" oral hygiene in Orthodontics

Researcher: Dr Norah Flannigan

Please initial box

1. I confirm that I have read and understood the information sheet dated 10/10/2017 (Version 1.4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that the data collected during the study will be analysed by the study investigators and that relevant sections of data may be looked at by individuals from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

Appendix 9: Consent form 2 – Patients agreement for participation in research over 16

Patient Identification Number for this trial:

CONSENT FORM 2
Patient's agreement for participation in research
Over 16

Research project: The use of the Q-Scan device as an adjunct to "at-home" oral hygiene in Orthodontics

Researcher: Dr Norah Flannigan

Please initial box

1. I confirm that I have read and understood the information sheet dated 10/10/2017 (Version 1.4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that the data collected during the study will be analysed by the study investigators and that relevant sections of data may be looked at by individuals from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I agree to take part in the above study. ☐

_____	_____	_____
Name of Volunteer	Date	Signature

_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix 10: Consent form 3 – Parental agreement for participation in research

Patient Identification Number for this trial:

CONSENT FORM 3
Parental agreement for participation in research

Research project: The use of the Q-Scan device as an adjunct to “at-home” oral hygiene in Orthodontics

Researcher: Dr Norah Flannigan

Please initial box

1. I confirm that I have read and understood the information sheet dated 10/10/2017 (Version 1.4) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my child’s participation is voluntary and that I am free to withdraw them at any time without giving any reason, without their medical care or legal rights being affected. ☐

3. I understand that the data collected during the study will be analysed by the study investigators and that relevant sections of data may be looked at by individuals from regulatory authorities, where it is relevant to my child’s taking part in this research. I give permission for these individuals to have access to my child’s records. ☐

4. I agree to my child taking part in the above study. ☐

_____	_____	_____
Parent / Guardian	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix 11: Debriefing questionnaire

Patient Identification Number for this trial:

Debriefing questionnaire

Research project: The use of the Q-Scan device as an adjunct to “at-home” oral hygiene in Orthodontics

Researcher: Dr Norah Flannigan

We would be grateful if you can provide us with the following information

Please initial box

1. How many times a day on average are you using the QScan device? ☐
2. How many days a week on average are you using the QScan device? ☐
3. For how many weeks/ days have you been using the device? ☐ /

_____ _____ _____

Name of Volunteer Date Signature

Admin use - number of weeks/days since device was given ☐ /

Views sheet:

Appendix 12: Ethical approval

NHS
Health Research Authority

North West - Liverpool Central Research Ethics Committee
3rd Floor
Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 020 71048008

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 February 2017

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

Dear Dr Flannigan

Study title:	**The use of the Q-Scan oral hygiene device for plaque identification as part of an "at-home" oral hygiene routine and to assess its influence on plaque accumulation and enamel demineralisation using the QLF-Dâ„¢ (Quantitative Light Induced Fluorescence-Digitalâ„¢) in patients undergoing fixed appliance orthodontic treatment at Liverpool University Dental Hospital.**
REC reference:	**16/NW/0695**
Protocol number:	**UoL001233**
IRAS project ID:	**210553**

Thank you for responding to the Committee's request for further information on the above research and submitting revised documentation.

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

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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

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

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

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

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

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
IRAS Application Form [IRAS_Form_12092016]		12 September 2016
IRAS Application Form XML file [IRAS_Form_12092016]		12 September 2016
Non-validated questionnaire [Debriefing]	1.2	07 February 2017
Other [CE evidence for Q-Scan device]		28 March 2016
Other [user manual]		
Participant consent form [under 16]	1.2	07 February 2017
Participant consent form [over 16]	1.2	07 February 2017
Participant consent form [parent]	1.2	07 February 2017
Participant information sheet (PIS) [11-13]	1.2	07 February 2017
Participant information sheet (PIS) [14-15]	1.2	07 February 2017
Participant information sheet (PIS) [over 16]	1.2	07 February 2017
Participant information sheet (PIS) [Parent]	1.2	07 February 2017
Referee's report or other scientific critique report [Peer review form 1]		10 June 2016
Referee's report or other scientific critique report [Peer review form 2]		10 June 2016
Research protocol or project proposal	1.1	06 August 2016
Summary CV for Chief Investigator (CI) [CI CV]	V1.1	10 June 2016
Summary CV for student		

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:

1. Notifying substantial amendments
2. Adding new sites and investigators
3. Notification of serious breaches of the protocol
4. Progress and safety reports
5. Notifying the end of the study

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

16/NW/0695	**Please quote this number on all correspondence**

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

Yours sincerely

Mrs Julie Brake
Chair

Email:nrescommittee.northwest-liverpoolcentral@nhs.net

Enclosures: "After ethical review – guidance for researchers

Appendix 12: HRA approval

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

Email: hra.approval@nhs.net

16 February 2017

Dear Dr Flannigan

Letter of HRA Approval

Study title:	**The use of the Q-Scan oral hygiene device for plaque identification as part of an "at-home" oral hygiene routine and to assess its influence on plaque accumulation and enamel demineralisation using the QLF-Dâ„¢ (Quantitative Light Induced Fluorescence-Digitalâ„¢) in patients undergoing fixed appliance orthodontic treatment at Liverpool University Dental Hospital.**
IRAS project ID:	**210553**
Protocol number:	**UoL001233**
REC reference:	**16/NW/0695**
Sponsor	**University of Liverpool**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

6. *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities

7. *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

6. *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

9. A – List of documents reviewed during HRA assessment
10. B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

3. Registration of research
4. Notifying amendments
5. Notifying the end of the study

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

In addition to the guidance in the above, please note the following:

ϕ) HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.

g) Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.

h) The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

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

Your IRAS project ID is **210553**. Please quote this on all correspondence.

Yours sincerely

Dr Claire Cole

Senior Assessor

Email: hra.approval@nhs.net

Copy to: Mr Alex Astor
Prof Rebecca Harris, The University of Liverpool

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
IRAS Application Form [IRAS_Form_12092016]		12 September 2016
IRAS Application Form XML file [IRAS_Form_12092016]		12 September 2016
Non-validated questionnaire [Debriefing]	1.3	15 February 2017
Other [user manual]		
Other [Statement of Activities]	1.0	08 February 2017
Other [Schedule of Events]	1.0	08 February 2017
Other [CE evidence for Q-Scan device]		28 March 2016
Participant consent form [over 16]	1.3	15 February 2017
Participant consent form [parent]	1.3	15 February 2017
Participant consent form [under 16]	1.3	15 February 2017
Participant information sheet (PIS) [11-13]	1.3	15 February 2017
Participant information sheet (PIS) [14-15]	1.3	15 February 2017
Participant information sheet (PIS) [over 16]	1.3	15 February 2017
Participant information sheet (PIS) [Parent]	1.3	15 February 2017
Referee's report or other scientific critique report [Peer review form 1]		10 June 2016
Referee's report or other scientific critique report [Peer review form 2]		10 June 2016
Research protocol or project proposal	1.1	06 August 2016
Summary CV for Chief Investigator (CI) [CI CV]	V1.1	10 June 2016
Summary CV for student		

IRAS project ID	210553

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Mr Alex Astor

Tel: 01517948739

Email: sponsor@liv.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	The information sheets, consent forms and non-validated questionnaire have been changed to comply with HRA standards. These changes are non-substantial therefore have not been submitted for REC review.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A statement of activities will act as the agreement between the sponsor and the site. Schedule of Events has been submitted which does not have any cost attributions completed.

Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No funding provided to sites as detailed in the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Not Applicable	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is one site involved in this study, all research activities as detailed in the study documents will take place at site. The Chief Investigator or sponsor should share relevant study documents with participating NHS

organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If Chief Investigators, sponsors or Principal Investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the Chief Investigator, sponsor or Principal Investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**.

2. Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix.
3. The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).

A PI is expected at site and this will be the CI.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken

The student working on the project should be covered as part of a healthcare placement and the CI is already employed at the site. Therefore no honorary research contracts or letters of access are expected for this study.

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Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 13: Sponsorship approval

Dr Flannigan
School of Dentistry
University of Liverpool
Pembroke Place
Liverpool
Merseyside
L3 5PS

Mr Alex Astor
Head of Liverpool Joint Research Office

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

Tel: 0151 794 8739
Email: sponsor@liv.ac.uk

02 August 2016

Sponsor Ref: UoL001233

Re: Sponsorship Approval

"The use of the Q-Scan oral hygiene device for plaque identification as part of an at-home oral hygiene routine and to assess its influence on plaque accumulation and enamel"

Dear Dr Flannigan

After consideration at the JRO Non Interventional Sponsorship Sub Committee on 18th July 2016 I am pleased to confirm that the University of Liverpool is prepared to act as Sponsor under the Department of Health's Research Governance Framework for Health and Social Care 2nd Edition (2005) for the above study.

The following documents have been received by the Joint Research Office

Document title	Version	Date
Protocol	1	10/06/2016
QScan CE certificate	1	20/06/2016
Information Sheet (Children)	1	20/06/2016
Information Sheet (Parents)	1	20/06/2016
Information Sheet (Participant)	1	20/06/2016
Assent Form	1	20/06/2016
Consent Form 1	1	20/06/2016
Consent Form 2	1	20/06/2016
Debriefing Form	1	20/06/2016

Please note this letter does NOT allow you to commence recruitment to your study.

requirements have been met. Please see Appendix 1 to this letter for a list of the documents required.

If you have not already applied for regulatory approvals through IRAS you may now do so at https://www.myresearchproject.org.uk/Home.aspx.

In order to meet the requirements of the Research Governance Framework 2nd Ed 2005, the University requires you to agree to the following Chief Investigator responsibilities:

1. Comply with the Research Governance Framework 2nd Ed 2005 and all relevant legislation, including but not limited to the Data Protection Act 1998, the Mental Capacity Act 2005 and the Human Tissue Act 2004;

2. Inform the Research Support Office as soon as possible of any adverse events especially SUSARs and SAE's, Serious Breaches to protocol or relevant legislation or any concerns regarding research conduct;

3. Approval must be gained from the Research Support Office for any amendments to, or changes of status in the study **prior to** submission to REC and any other regulatory authorities;

4. It is a requirement that Annual Progress Reports are sent to the NHS Research Ethics Committee (REC) annually following the date of Favourable Ethical Approval. You must provide copies of any reports submitted to REC and other regulatory authorities to the Research Support Office;

5. Maintain the study master file;

6. Make available for review any study documentation when requested by the sponsors and regulatory authorities;

7. Upon the completion of the study it is a requirement to submit and an End of Study Declaration (within 90 days of the end of the study) and End of Study Report to REC (within 12 months of the end of the study). You must provide copies of this to the Research Support Office;

8. Ensure you and your study team are up to date with the current RSO SOPs throughout the duration of the study.

The University also requires you to comply with the following:

1. University professional indemnity and clinical trials insurances will apply to the study as appropriate. This is on the assumption that no part of the clinical trial will take place

you wish to sub-contract any part of the study to a third party specific approvals and consideration of appropriate indemnity would be required.

If you have any queries regarding the sponsorship of the study or the above conditions, please do not hesitate to contact the Joint Research Office governance team on 0151 794 8373 (email sponsor@liv.ac.uk).

Yours sincerely

pp Karen Wilding
Mr Alex Astor
Head of Liverpool Joint Research Office

Appendix 14: Insurance cover

Katie Booth
Client Advisor
National Corporate Practice
Marsh Ltd
Belvedere
12 Booth Street
Manchester
M2 4AW
+44 (0) 161 954 7200
Fax +44 (0) 161 954 7210
Katie.X.Dalton@marsh.com
www.marsh.com

2 August 2016

To whom it may concern

Dear Sirs

CONFIRMATION OF INSURANCE – The University of Liverpool

As requested by the above client, we are writing to confirm that we act as Insurance Brokers to the client and that we have arranged insurance(s) on its behalf as detailed below:

CLINICAL TRIALS

INSURER:	Novae Underwriting Limited
POLICY NUMBER:	019540MMA16C
PERIOD OF INSURANCE:	1 August 2016 – 31 July 2017
INDEMNITY LIMIT:	GBP5,000,000 any one event and in all the period of Insurance or any applicable Extended Discovery period.
DEDUCTIBLES:	GBP5,000 any one claim including costs and expenses.

We have placed the insurance which is the subject of this letter after consultation with the client and based upon the client's instructions only. Terms of coverage, including limits and deductibles, are based upon information furnished to us by the client, which information we have not

independently verified.

This letter is issued as a matter of information only and confers no right upon you other than those provided by the policy. This letter does not amend, extend or alter the coverage afforded by the policies described herein. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this letter may be issued or pertain, the insurance afforded by the policy (policies) described herein is subject to all terms, conditions, limitations, exclusions and cancellation provisions and may also be subject to warranties. Limits shown may have been reduced by paid claims.

We express no view and assume no liability with respect to the solvency or future ability to pay of any of the insurance companies which have issued the insurance(s).

We assume no obligation to advise yourselves of any developments regarding the insurance(s) subsequent to the date hereof. This letter is given on the condition that you forever waive any liability against us based upon the placement of the insurance(s) and/or the statements made herein with the exception only of wilful default, recklessness or fraud.

This letter may not be reproduced by you or used for any other purpose without our prior written consent.

This letter shall be governed by and shall be construed in accordance with English law.

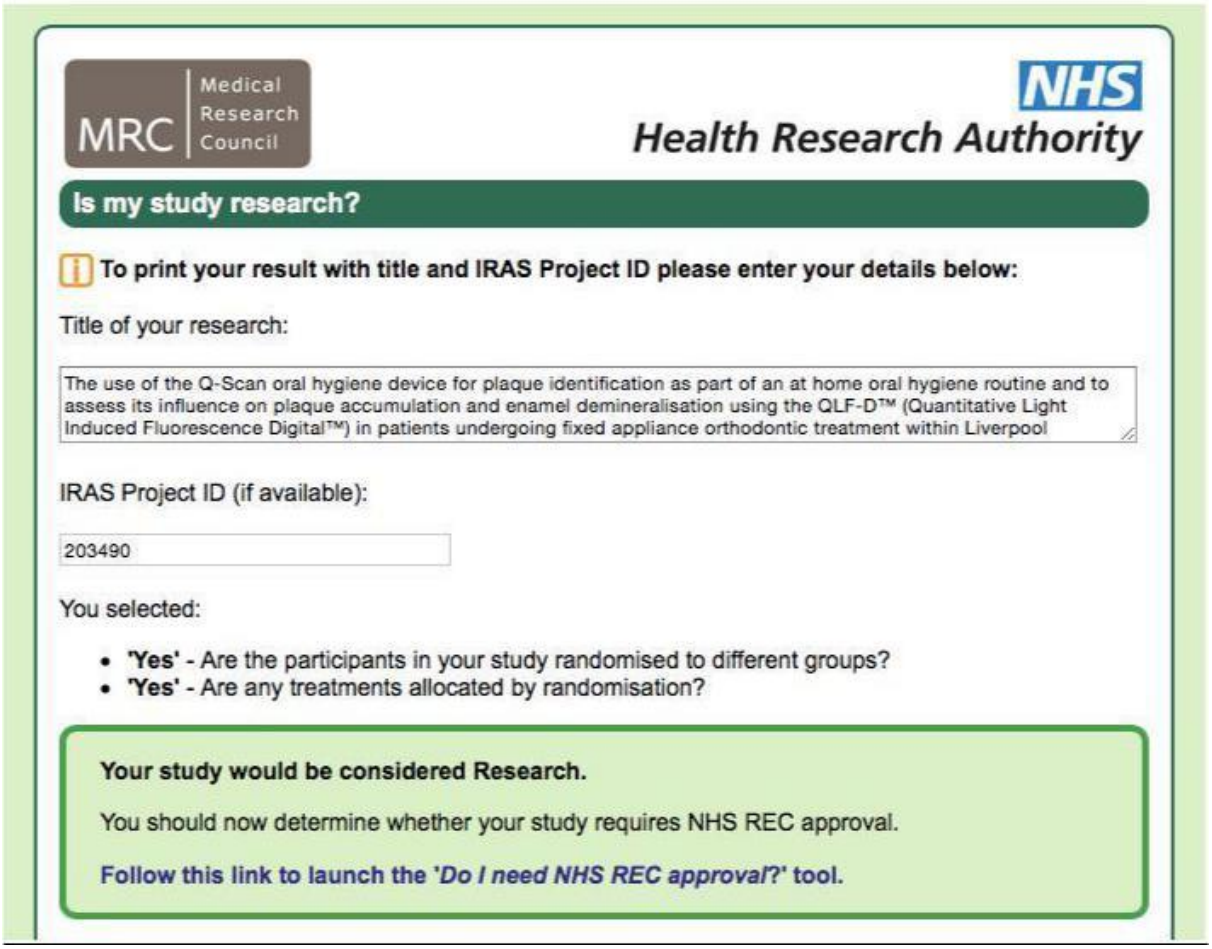
Yours faithfully,

Katie Booth

Katie Booth
Client Advisor

document2

Appendix 15: Medical Research Council (MRC) tool



MRC Medical Research Council

NHS Health Research Authority

Is my study research?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

The use of the Q-Scan oral hygiene device for plaque identification as part of an at home oral hygiene routine and to assess its influence on plaque accumulation and enamel demineralisation using the QLF-D™ (Quantitative Light Induced Fluorescence Digital™) in patients undergoing fixed appliance orthodontic treatment within Liverpool

IRAS Project ID (if available):

203490

You selected:

- **'Yes'** - Are the participants in your study randomised to different groups?
- **'Yes'** - Are any treatments allocated by randomisation?

Your study would be considered Research.

You should now determine whether your study requires NHS REC approval.

Follow this link to launch the '*Do I need NHS REC approval*?' tool.

MRC Medical Research Council

NHS Health Research Authority

Do I need NHS REC approval?

To print your result with title and IRAS Project ID please enter your details below:

Title of your research:

The use of the Q-Scan oral hygiene device for plaque identification as part of an at-home oral hygiene routine and to assess its influence on plaque accumulation and enamel demineralisation using the QLF-D™ (Quantitative Light Induced Fluorescence Digital™) in patients undergoing fixed appliance Orthodontic treatment at the Liverpool University Dental Hospital.

IRAS Project ID (if available):

210553

Your answers to the following questions indicate that **you need NHS REC approval for sites in England and you may also need other approvals**:

You have answered ***'YES'*** to: Is your study research?

Question Set 1
You answered ***'NO'*** to all of these questions:

- Is your study a clinical trial of an investigational medicinal product?
- Is your study one or more of the following: A non-CE marked medical device, or a device which has been modified or is being used outside of its CE mark intended purpose, and the study is conducted by or with the support of the manufacturer or another commercial company (including university spin-out company) to provide data for CE marking purposes?
- Does your study involve exposure to any ionising radiation?
- Does your study involve the processing of disclosable protected information on the Register of the Human Fertilisation and Embryology Authority by researchers, without consent?
- Is your study a clinical trial involving the participation of practising midwives?

You answered ***'England'*** to: Where is your study taking place?

Question Set 2

You have answered ***'YES'*** to: Will your study involve research participants identified from, or because of their past or present use of services (adult and children's healthcare within the NHS and adult social care), for which the UK health departments are responsible (including services provided under contract with the private or voluntary sectors), including participants recruited through these services as healthy controls?

Applications must be made using the **Integrated Research Application System (IRAS)**.

To understand the reasons why your research requires NHS REC review, please visit the **HRA algorithm**.

Follow this link to start again.

Print This Page