The use of QLF-D (Quantitative Light-induced Fluorescence-Digital^{TM}) as an oral hygiene evaluation tool to assess plaque accumulation and enamel demineralisation in orthodontics

Thesis submitted in accordance with the requirements of the University of Liverpool for the Degree of Doctor of Dental Science (Orthodontics)

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1.0 ACKNOWLEDGEMENTS

2.0 ABSTRACT

Aim: To assess the use of the Quantitative Light-induced Fluorescence-Digital Biluminator™ (QLF-D™) as an oral hygiene evaluation tool to detect demineralisation and plaque during orthodontics

Design: Randomised clinical trial

Settings: Liverpool University Dental Hospital

Subjects: 33 patients (21 females, 12 males) currently undergoing upper and lower fixed orthodontic appliance treatment were recruited. The median age of patients was 14.6 years with a range from 11.0 to 37.4 years.

Methods: The patients were randomly allocated, stratified by the presence of demineralisation at baseline (T0), to receiving oral hygiene reinforcement (OHR) at four consecutive appointments (T1-T4) using the White light (WL) or Quantitative Light-induced Fluorescence (QLF) images, taken with the QLF-D™ device (Inspektor Research Systems BV, Amsterdam, The Netherlands), as visual aids. The standard of oral hygiene was assessed on the QLF images using customised software to provide quantitative scoring of fluorescence loss (ΔF) and plaque coverage ($\Delta R30$) at each appointment. Inter-examiner reliability assessments were conducted by 4 examiners using QLF and WL images from 7 patients. One examiner assessed the images on a second occasion two weeks later to ascertain the intra-examiner reliability. A debriefing questionnaire, distributed on completion of the study, was used to ascertain the patients' perspectives of the QLF-D™ images.

Results: There were no significant differences in demineralisation (ΔF: P=0.56) or plaque accumulation (ΔR30; P=0.95) between the WL and QLF groups from T0 to T4. There were no significant reductions in ΔF in the WL or the QLF group from T0-T4 (P>0.05), however there was a significant reduction in ΔR30 (P<0.05).

The inter-examiner reliability of QLF image assessment, using ICC, was 0.994 and 0.998 for ΔF and ΔR30 respectively. The inter-examiner reliability of WL image assessment, using kappa, ranged from 0.504 to 0.785. The intra-examiner reliability scores were additionally high with an ICC of 0.988 and 1.0 for ΔF and ΔR30 respectively on the QLF images. The kappa score of demineralisation assessment on the WL images was 1.0.

All of the participants found being shown the images helpful and were able to see areas of demineralisation and plaque accumulation. 100% of the QLF group thought it would be useful to be given OHR for the full duration of orthodontic treatment compared to 81% of the WL group (OR 2.3, 95% CI: 1.5-3.5).

Conclusion: QLF-D^{TM} can be used to detect and monitor demineralisation and plaque during orthodontics. The image analysis demonstrated high levels of inter- and intra-examiner reliability. OHR at consecutive appointments using the WL or QLF images as visual aids is effective in reducing plaque coverage. Whilst there was no apparent statistical benefit in terms of reducing levels of demineralisation or plaque of using QLF images over WL images, patients reported that they were more informative.

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4.0 LITERATURE REVIEW

4.1 Dental enamel

Dental enamel consists of a highly crystalline structure arranged in rods. It is largely inorganic, with the main component being hydroxyapatite crystal of calcium phosphate, $Ca_{10}(PO_4)_6(OH)_2$. This inorganic component comprises 86-95% of the volume, which results in enamel being highly susceptible to demineralisation. The organic component, largely proteinaceous material, comprises 1-2% of the volume, with water constituting the remaining component (Weatherell, 1975). This results in spaces, termed as pores, which allow the movement of ions within enamel and the surrounding oral environment.

4.2 Plaque

4.2.1 Description

Plaque is a biofilm consisting of bacteria and an extracellular matrix of host and microbial polymers. It forms on oral tissues, including teeth, in layers (Marsh, 2004). Initially pioneer species adhere to the pellicle although with time many other species also adhere. This ultimately leads to a complex collection of microrganisms (Pretty et al. 2005). The phases of development have been described in stages (Marsh, 2004).

- Adsorption of host and bacterial molecules

  After a tooth erupts non-selective host salivary protein molecules adhere to the enamel to form the acquired pellicle of 50-150nm thickness. This additionally occurs after a tooth surface is cleaned.

- Bacterial adhesion

Physicochemical interactions occur between oral bacteria present in the saliva and the acquired pellicle tooth surface. This results in a net attraction of bacteria, which can adhere to the tooth surface via surface adhesions present. These attachments can be reversible or irreversible. The pioneer species, frequently streptococci strains, adhere to the acquired pellicle and colonise (Donlan and Costerton, 2002).

- Co-adhesion

Co-adhesion or co-aggregation is cell-cell recognition and this can occur between different bacterial species. Early colonising bacterial species have specific receptors to enable interactions with other bacterial species. This results in the adherence of many other species to the acquired pellicle and a diverse biofilm of a complex collection of microorganisms (Pretty et al. 2005).

- Multiplication

Cell growth occurs by cell division resulting in the formation of microcolonies. Polymers, such as polysaccharides, are produced by the bacteria. These, in addition the adsorbed proteins of salivary origin lead to a complex extracellular matrix. This contributes to a mature biofilm and increases the structural integrity.

- Detachment

The bacteria can detach and colonise in other areas.

Plaque is a contributing aetiological factor for the development and pathogenesis of various dental diseases including caries and periodontal disease (Cugini et al. 2006). Hence, an excellent standard of oral hygiene is required to ensure all plaque is removed from the teeth to reduce the risk of developing such diseases.

4.2.2 Plaque and orthodontic treatment

Plaque accumulation starts and is greatest at plaque stagnation sites, which tend to be at the gingival margins (Van der Veen et al. 2006). Saliva has a protective effect due to its buffering and antimicrobial properties, however as the plaque deposits increase, such factors have less of an influence (Donlan and Costerton, 2002). In orthodontic treatment, the brackets and archwires are significant plaque stagnation sites. Additionally, conventional oral hygiene is more difficult compounding the increased plaque accumulation and retention. Furthermore, the natural clearance of plaque by saliva and the cheeks is reduced (Mattousch et al. 2007).

It is imperative that patients learn to detect any plaque present to ensure they achieve satisfactory levels of oral hygiene (Pretty et al. 2005). Although plaque deposits are usually easily visible to clinicians, patients frequently have difficulty localising the deposits to enable optimal levels of oral hygiene to consistently be achieved.

4.2.3 Methods of quantification

Direct visual assessment is the most commonly used method of assessing the presence of plaque and several indices exist which enable quantification of the amount observed. These include the modified Ramfjord index (Shick and Ash, 1961), the Quigley and Hein (1962) plaque index and the Silness and Loe (1962) index.

The Bonded-Bracket Index, devised by Ciancio et al. (1984) can be used to assess plaque accumulation during fixed orthodontic treatment (Pretty et al. 2005; Fischman, 1986).

1. No plaque on the bracket or tooth surface

2. Plaque on bracket

3. Plaque on brackets, tooth, no extension to gingiva

4. Plaque on bracket, tooth, extension to papilla

5. Plaque on bracket, tooth, partial coverage to gingiva

6. Plaque on bracket, tooth, full coverage to gingival

However, despite this index being directly related to orthodontics, the Silness and Loe and Turesky indices are more frequently used. They have been demonstrated to provide a reliable quantitative assessment of the plaque coverage (Pretty et al. 2005; Fischman, 1986.) Strong correlations are noted between these ordinal indices for assessing the plaque scoring. However, they have been criticised for lacking precision and having low sensitivity and specificity scores (Cugini et al. 2006). Calibration of the examiners involved in the assessment process improves this, although there are cost implications associated with conducting such calibration sessions. Other methods of plaque detection, such as using Quantitative Light-induced Fluorescence (QLF), are more sensitive and able to detect very small amounts of plaque. This is not only useful from a clinical perspective but it is useful to improve the precision of the research being undertaken (Cugini et al. 2006).

4.3 Demineralisation

4.3.1 Description

Demineralisation of teeth occurs due to the bacterial fermentation of dietary sugars, which produces organic acids. Bacteria present in plaque, such as mutans streptococci and lactobacilli (Chang et al. 1997), lower the pH of the tooth surface to below the critical level, which causes dissolution of the mineral component. Calcium, phosphate and hydroxyl ions

diffuse into the surroundings. This can be demonstrated by the Stephan curve, which represents the decrease in pH that occurs following consumption of sugary foods. Stephen (1944) conducted an *in vivo* study involving patients with and without the presence of caries. The participants rinsed with a glucose solution and had longitudinal pH readings taken. The results demonstrated that the pH immediately fell on rinsing and took 30-60 minutes to return to normal. Additionally, patients with active caries had significantly lower pH values throughout, suggesting a greater amount of acid was being produced as a result of the ongoing bacterial cariogenic process.

A greater frequency of fermentable carbohydrate intake will result in a greater number of periods when the pH of the oral cavity is below the critical level, hence this will result in more demineralisation.

The structure of early enamel caries consists of four zones, which can be visualised under polarised light. The zones are related to the degree of demineralisation and changes in mineral content that have occurred (Gorelick et al. 1982; Arends and Christoffersen, 1986).

- Translucent zone

  This is the deepest part of the lesion. Dissolution of mainly magnesium and calcium ions occurs from the peripheral rod structures. The porosity is about 1%.

- Dark zone

  The mineral dissolution is mainly calcium and phosphate ions and a greater number of rod structures and cross striations are involved. The porosity is 2-4%.

- Body

    The body of the lesion is just below the surface and has a porosity that ranges from 5-25%. A greater amount of dissolution has occurred in this area, involving destruction largely of all of the rods. The spaces are filled with water and bacteria. The area of demineralisation in the region can often be seen as a white spot, hence frequently it is termed as a 'white spot lesion'. However, extrinsic stains from tobacco, food and bacteria can accumulate in this area and cause the demineralisation to be brown in appearance.

- Surface zone

    This is the outer layer which is continuously undergoing changes in mineral composition as a result of the changes in pH. Remineralisation may occur, resulting in the surface zone being porous although mineral rich. This allows the tooth surface to remain relatively intact despite substantial subsurface mineral having been lost.

Demineralisation is the first stage of dental caries. Early demineralisation is reversible (Angmar-Mansson and ten Bosch, 1993), whereby when the pH in the oral cavity is restored to neutral, enamel remineralisation will occur. This process is aided by the protective components of saliva, including bicarbonate ions and proteins, which increase the pH. Remineralisation is also aided by fluoride ions supplied from external sources such as toothpaste and mouthwash. The enamel surface undergoes a regular dynamic process of ion exchange as the pH in the oral cavity varies. Caries may progress if the rate of ion loss from enamel, namely demineralisation, occurs at a greater rate than remineralisation. This would lead to dentinal involvement and ultimately the total destruction of the tooth structure.

4.3.2 Demineralisation and orthodontic treatment

The risk of demineralisation is greater with orthodontics due to the tendency for increased plaque accumulation and retention around the appliances (van der Veen et al. 2007). The sequence of events and associated contributing factors are outlined in Figure 4.1. The progression rate around fixed orthodontic appliances is greater than traditional caries formation, with demineralisation having been demonstrated to be able to present within 4 weeks of appliance placement (Ogaard and ten Bosch, 1994). It can be seen as white and brown areas, of varing size, around the appliance. The severity must be quantified in terms of the size of these areas but also the extent of mineral loss (Benson et al. 2003).
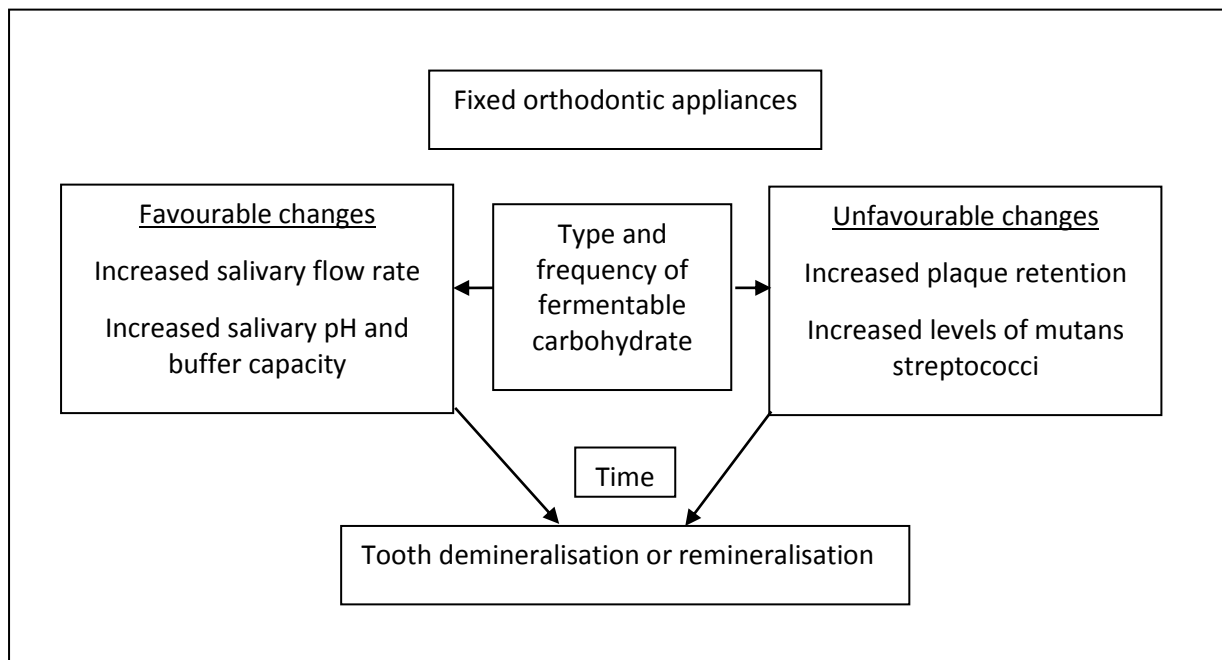
Figure 4.1: The sequence of events and influencing factors in the demineralisation and remineralisation processes, reproduced from Chang et al. 1997

The prevalence of demineralisation around fixed orthodontic appliances varies widely with documented rates varying in the literature between 2-96% (Gorelick et al. 1982; Mizrahi, 1982; Mitchell, 1992; Ogaard, 1989). Gorelick et al. (1982) conducted a retrospective cross-sectional study and found that 50% of patients undergoing fixed orthodontic treatment

developed at least one white spot lesion. However, the study did not discuss how developmental white spot lesions were distinguished. Mizrahi (1982), in a similar cross sectional study, found a significant 12% increase in the number of white spot lesions in a group of patients who had undergone fixed orthodontic treatment compared to untreated controls. The severity of lesions, assessed using the opacity index, was also significantly greater. However, this study involved the use of multibanded appliances, which is no longer commonly conducted. An RCT by Stecksen-Blicks et al. (2007) on the use of a fluoridated varnish versus placebo varnish during fixed orthodontic treatment, found 25% of the participants in the control group developed demineralisation over the duration of their treatment. Ogaard (1989), compared 51 patients, aged 19 years, who had received orthodontic treatment an average of 5.7 years previously to a matched untreated control group of 47 patients. The prevalence of white spots was 96% and 85% in the orthodontic treatment and control groups respectively, representing an 11% increase. This study also highlights that demineralisation that develops during orthodontic treatment can be permanent, as white spots were still present and visible in a large number of the subjects.

The variation in the documented prevalence of demineralisation in the studies is largely due to differences in standardising clinical examinations. Developmental white areas, such as fluorosis and enamel hypoplasia, are often incorrectly diagnosed. Demineralisation may also be present at baseline, having occurred prior to orthodontic treatment due to suboptimal general mouth care (Figure 4.2). Such pre-treatment white areas should be distinguished, noted at the outset of orthodontic treatment and be excluded from study values. This is to ensure there are minimal false positive results (Benson et al. 2003b) which would lead to an overestimation of the prevalence.
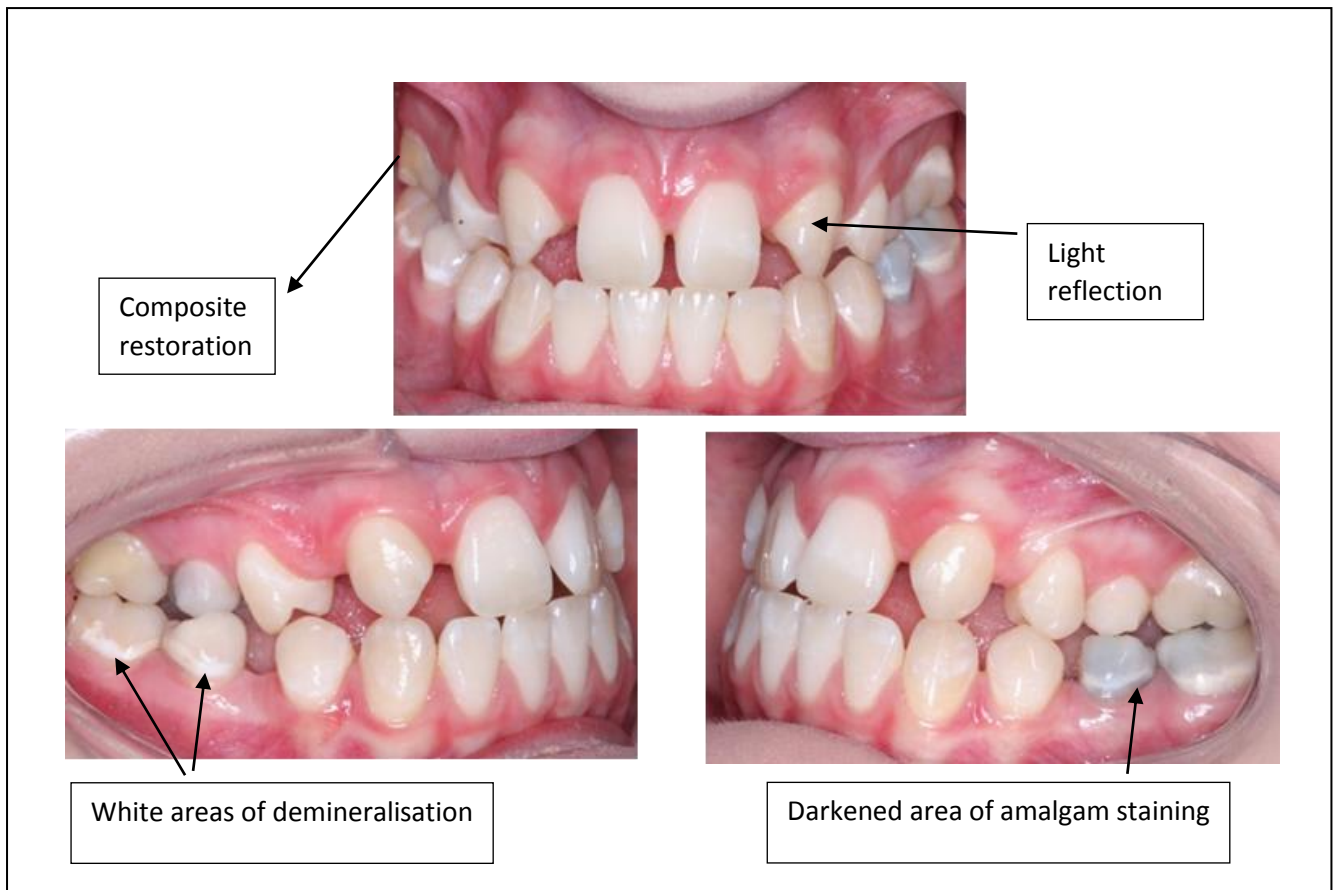
Figure 4.2: Clinical photographs taken prior to fixed appliances demonstrating demineralisation and other features that can be incorrectly diagnosed

Additionally, differences in prevalence may result due to the use of various detection tools, which differ in their ability to diagnose demineralisation (Boersma et al. 2005). Earlier studies frequently used direct visual examination as a method of assessment. More recent studies have reported on the newer equipment available. Al Maaitah et al. (2011), found the prevalence of white spot lesions was 71.7% in 230 subjects post orthodontic treatment assessed using Quantitative light-induced fluorescence (QLF). This is clearly much greater than the 25% noted by Stecksen-Blicks et al. (2007) on assessing digital images.

Any tooth can be affected by demineralisation, which will lead to poorer aesthetics and can impact on patient satisfaction. In severe cases restorative treatment may be warranted (Al

Maaitah et al. 2011). The canines and molars tend to be the most severely affected. van der Veen et al. (2007) found on debond that the number of areas of demineralisation was significantly greater on these teeth than on anterior teeth. The severity of the demineralisation was also significantly greater in the mandible than in the maxilla. Other studies have demonstrated that the maxillary lateral incisor is the most commonly affected tooth with an incidence of 23% (Gorelick et al. 1982). This may be due to the anatomical shape or because the brackets are often placed closer to the gingival margins leading to greater plaque retention (Ogaard, 1989). Additionally, frequently the maxillary lateral incisors are crowded palatally. Thus, particularly in the early stages of treatment, access to brushing can be difficult.

Orthodontics is elective treatment, thus clinicians must adequately assess whether a patient has a satisfactory level of oral health to be considered suitable to undertake treatment. This includes exhibiting sufficiently good levels of oral hygiene and having excellent dietary control. It is imperative that if demineralisation develops during treatment, it is detected as early as possible to prevent irreversible damage from occurring. Thus, methods for detecting early demineralisation and monitoring the lesions to ensure that they do not progress, are of a significant benefit for both clinicians and indeed patients.

The regression of demineralised areas post orthodontic treatment varies. Once the appliances are removed, the oral hygiene should improve and this may enable the lesions present to regress (van der Veen et al. 2007). In the early stages, when the lesions are largely softening of the outer enamel surface zone, there is a greater ability for these areas to regress and completely remineralise. However, subsurface loss of enamel structure, which is more common in demineralised areas that are present following a full course of orthodontic treatment, is less likely to regress. Often slow remineralisation, if any, may occur after the

appliance is removed (Ogaard and ten Bosch, 1994). At this stage, fluoride application may allow precipitation in the surface layer halting the subsurface demineralisation (Arends and Christoffersen, 1986), although unfortunately the white mark may remain permanently.

Ogaard and ten Bosch (1994) found that regression can occur rapidly in early lesions without the use of fluoride. Their study involved assessing seven patients with two premolars planned for later extraction. Customised plaque retentive orthodontic bands were placed, which ensured plaque accumulation buccally over the short-term four week period whilst a non-fluoridated toothpaste was used. This resulted in varying size areas of demineralisation. The bands were then removed, the use of non-fluoridated toothpaste was continued and the teeth were extracted after two or four weeks. At these time points, all of the areas of demineralisation were noted to have regressed. However, the authors discussed that due to the small sample size and large standard error of the results, the findings are not definitive and can only be used as an indication of the potential levels of regression that may be possible. Furthermore, as routine orthodontic treatment cases frequently take 18 months to 2 years, limited inferences can be made from this short-term study to the clinical setting. However, it does demonstrate the importance of careful monitoring being undertaken as if early demineralisation is noted and plaque control is improved or the localised part of the appliance is removed, the lesions may regress.

An *in vivo* study assessing the potential regression of demineralised areas post debond when no active remineralisation treatment was undertaken, found that lesion regression was only seen in approximately one third of cases over the six month period. Nevertheless, regression did occur irrespective of the lesion severity (van der Veen et al. 2007). Mattousch et al. (2007) noted 370 lesions in 51 patients at debond. There was a statistically significant

improvement seen in the severity of the lesions using QLF assessment after six months. However, only ten lesions underwent complete remineralisation and were unable to be seen clinically at the study's end point.

Additional remineralisation agents exist and can be enforced, such as MI Paste (GC America), which contains casein phosphopeptide stabilised amorphous calcium phosphate (CPP-ACP). Its proposed action is in the stabilisation of calcium and phosphate ions adjacent to the enamel surface, which allows a greater potential for remineralisation of the white spot lesions of mineral loss. A recent randomised controlled study (Huang et al. 2013), assessed 135 patients who had completed fixed orthodontic treatment at least two months previously having developed at least one area of demineralisation affecting the maxillary incisors. All of the study participants were given standardised oral hygiene instructions to use 1100ppm fluoride toothpaste with a manual toothbrush and dental floss. Allocation was to one of 3 groups; (1) a control group of routine mouth care; (2) to using a pea sized amount of MI Paste Plus twice daily, which is an advancement of the original MI Paste, whereby it additionally contains 900ppm Fluoride or (3) having a single application of PreviDent fluoride varnish (Colgate Oral Pharmaceuticals) of 22,600ppm fluoride placed at the start of the trial. WL photographs were assessed at baseline and at 8 weeks by dental professionals and a lay panel. The professional assessors noted reductions in the white spot lesions in each of the groups, with mean improvements of 21%, 29% and 27% in the MI Paste Plus, fluoride varnish and control groups respectively. No statistically significant differences were detected to suggest that the routine oral hygiene protocol was any less effective than the use of MI Paste Plus or Prevident fluoride varnish. Commendably, the image assessment was conducted in a blinded manner, however there was a 15% drop out rate with a greater proportion in the MI Paste Plus subjects, which could have led to attrition bias.

Other studies have shown MI Paste results in greater remineralisation. Bailey et al. (2009) allocated 45 patients, with 408 areas of demineralisation present, to using MI Paste or a placebo paste twice daily in a 12-week, double-blind RCT on completion of fixed orthodontic treatment. Demineralisation, which was assessed as code 2 or 3 on the ICDAS II scale, accounted for 92% of the lesions. Of these, there was a 31% greater remineralisation potential (OR: 2.3, P=0.04) with the use MI paste at 12 weeks.

4.4 Methods of detecting plaque and demineralisation

4.4.1 Clinical examination

This is the most commonly undertaken method for assessing plaque accumulation and enamel demineralisation, undertaken routinely at each clinical appointment. The advantage of measuring plaque and demineralisation by clinical examination is the simplicity of the non-invasive method and the low costs associated as no special equipment is required.

As discussed, many indices exist for assessment of plaque levels including the Quigley and Hein (1962) and the Silness and Loe (1962) indices. Additionally, disclosing tablets can be used to aid plaque identification by staining the plaque deposits and acquired pellicle. This is advantageous as plaque may be colourless (Pretty et al. 2005) and the disclosing tablets often contain erythrosine dye, which stain the concerned areas red, allowing easier visual assessment. This method is useful for patient educational purposes and patients can use such disclosing tablets at home.

Fluorescein disclosing can also be undertaken. It involves using a UV fluorescent dye that is colourless on application but adheres to plaque deposits present and fluoresces allowing

digital plaque image analysis to be conducted. This allows a greater assessment of the quantity of plaque present. However, a disadvantage is the expense of the system (Pretty et al. 2005).

Frequently used indices for the assessment of demineralisation by clinical examination include the International Caries Detection and Assessment System (ICDAS) scale, which differentiates between cavitated and non-cavitated lesions (Pitts, 2004). Additionally, the index of Gorelick et al. (1982) is commonly used, which allows classification of the severity of demineralisation into the following categories:

1. No white spot formation
2. Slight white spot formation (thin rim)
3. Severe white spot formation (thicker band)
4. White spot formation with cavitation

However, the disadvantage is that it is less sensitive and subclinical lesions will not be evident. Thus clinical examination alone may not be the suitable for monitoring small changes in demineralisation. Furthermore, as demineralisation is only seen clinically when at the white spot lesion stage, the level of mineral loss that has occurred by that time point, can be advanced.

4.4.2 Clinical photography

Photographs are a widely used method of monitoring patients during orthodontic treatment. Sandler and Murray (2002) advise that the minimum number of photographs that should be taken during a course of orthodontic treatment is nine pre-treatment images and nine post-

treatment images. Ideally, thirty six photographs are recommended to ensure the full photographic documentation of a course treatment (Sandler and Murray, 2002).

Photographs are an easy and efficient method of recording the progress of treatment to obtain a permanent record (Benson et al. 1998). They also record the optical appearance of enamel (Benson et al. 2003a) and hence aid diagnosis of any areas of demineralisation present. In terms of research, an additional benefit of photographs over direct clinical examination assessment, is that the images can be stored and analysed at a later time point, which if anonymised, can reduce any observer bias. Intra and inter-examiner assessments can be easily arranged. However, it can be difficult for photographs to be consistent in terms of lighting, magnification and the angulation that the images are taken (Benson et al. 2004).

Benson et al. (2003) found that computerised analysis of digitally converted photographic slides was a reliable and valid method of analysing and quantifying levels of demineralisation. The mean grey levels detected on human molars exposed to demineralising gel showed good repeatability with only small differences noted between the repeated readings and good validity (Benson et al. 2003a; 2003b). These studies compared the use of digital photographs with QLF. A similar *in vitro* study conducted by Benson et al. (1998) compared direct visual assessment with photographic assessment. The measurements made using the photographs were found to be a more reliable means of measuring demineralisation (Benson et al. 1998). However, the need for a more objective method of assessing the mineral content levels of enamel was discussed.

4.4.3 Transverse microradiography

Transverse microradiography (TMR) is a valid and reliable technique for detecting demineralisation. It is considered to be the gold standard method for quantitative measurement of mineral content levels. Hence, other techniques are often compared and validated against TMR results (van der Veen et al. 2007).

It involves thin transverse sections of tooth tissue being cut and prepared to 80 to 100μm thickness. These sections are radiographed alongside a calibrated step wedge, frequently made of aluminium. This allows determination of the optical density and hence mineral content levels present (ten Bosch and Angmar-Mansson, 1991). However, due to it being destructive in nature, its use in the clinical setting is limited to extracted teeth. Thus, the technique is largely only employed for laboratory research.

4.4.4 Quantitative Light-induced Fluorescence (QLF)

QLF is a technique that uses visible light to detect enamel demineralisation and dental caries (de Josselin de Jong et al. 1995). The concept is based on the fact that under normal conditions enamel fluoresces when illuminated by light, a property known as autofluorescence. Fluorescence occurs due to changes in the wavelength of the light following reflection from the surface. Initially, laser light-induced fluorescence was introduced in 1982 to detect early enamel caries (Al-Khateeb et al. 1998). It was conducted using a laser source and was validated against longitudinal microradiography. A high correlation (r=0.73) was noted between the amount of fluorescence loss and mineral loss (Emani et al. 1996). However, there were potential dangers of eye damage using such lasers (Benson et al. 2003).

A portable system was then created comprising an external light source, filter system and camera. It was manufactured by Inspektor Research Systems in Amsterdam and consists of a single-lens reflex (SLR) camera, filters and light sources, which are connected to a computer (Figure 4.3). The light is produced from a xenon lamp and passes through a blue filter producing a peak intensity of 370nm (Al Maaitah et al. 2011). The handpiece can be directed to illuminate the particular surface of interest (Benson et al. 2003). The reflected light from the teeth is detected by a camera after passing a yellow filter which excludes light below the frequency of 520nm. This allows exclusion of back-scattered light. The resultant QLF images are then stored for customised software analysis of the fluorescence levels present (Benson et al. 2003, van der Veen et al. 2006). The system was validated and found to be a valid and reliable method for assessment of enamel demineralisation severity. A significantly high positive correlation ($r=0.84$) was observed between the fluorescence changes noted and TMR observed mineral loss (Al-Khateeb et al. 1997).
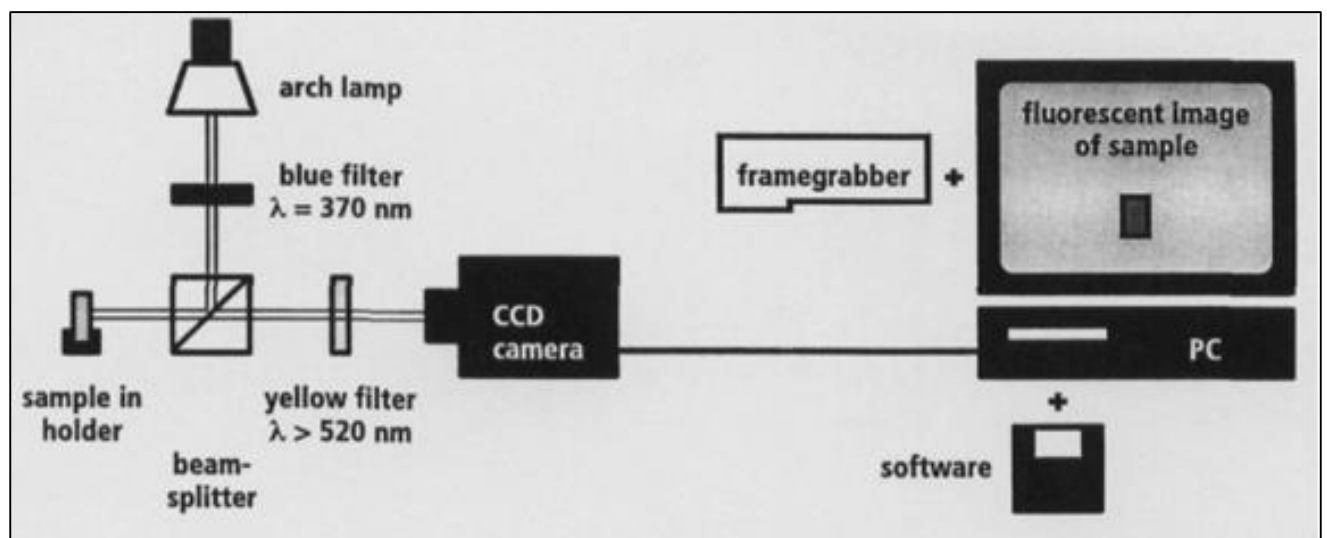
Figure 4.3: The portable QLF diagnostic system, reproduced from Al-Khateeb et al. 1997

Plaque and dental caries can be seen on QLF images as red due to the autofluorescence of bacterial porphyrins. Using the QLF customised software, plaque accumulation on the teeth

can be graded as the percentage tooth coverage, which is based on the levels of red fluorescence evident at different cut off points. The value of ΔR, which is a value related to how many pixels are covered with red fluorescence, must be greater than 30% for it be assessed as plaque. Pretty et al. (2005) demonstrated QLF was a reliable tool for assessing plaque accumulation present *in vivo*. It can be used longitudinally to assess levels present and hence monitor the success of any interventions aimed at reducing plaque accumulation.

Demineralisation is detected by assessing changes in the autofluorescence of enamel. There is a reduced fluorescence radiance compared to sound enamel, hence demineralisation and areas of dental caries appear as darker (Figure 4.4). The mechanism for this is that there is a greater degree of light scattering in demineralised enamel. The minerals have been replaced by water resulting in a decrease in light transmission and light absorption (Al-Khateeb et al. 1998).

| Demineralisation on digital images | Demineralisation on QLF images |
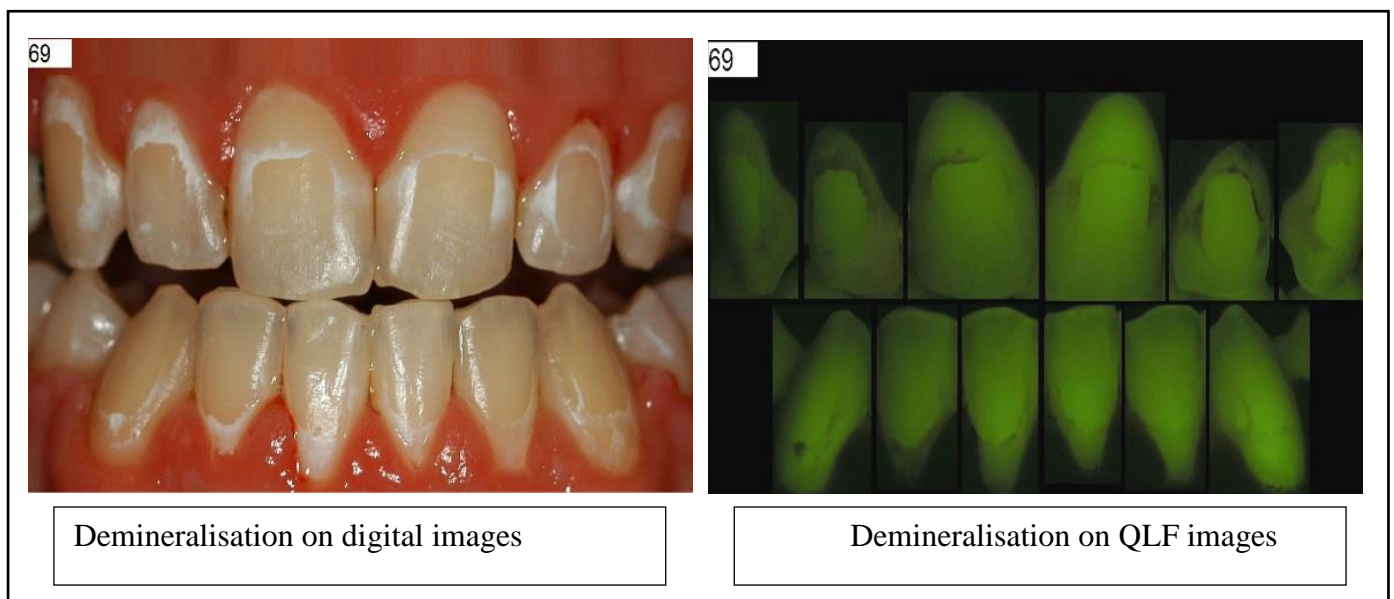
Figure 4.4: Digital photographic and QLF images highlighting demineralisation

The fluorescence loss in the lesion is assessed in comparison to the fluorescence of the surrounding sound enamel to provide a quantitative assessment of the severity of the

demineralisation. The outline of the analysis should therefore be adjusted so that it is based on sound enamel to reduce false positives. Any areas with relative fluorescence loss greater than the 5% threshold are deemed part of the lesion (Pretty et al. 2003). Data is obtained on the degree of demineralisation and the extent of the area affected (Benson et al. 2003), graded as ΔF and ΔQ. ΔF is a measure of the mean percentage fluorescence loss which is based on the amount of mineral loss from the enamel. ΔQ is indicative of the lesion size and severity. It is a measurement of the fluorescence loss over the total surface area affected, thus involving the number of pixels and the area involved (Pretty et al. 2002).

Understandably, it is preferable if the individual analysing the images has experience in using the image analysis software equipment. Pretty et al. (2002) demonstrated that QLF image analysis was reliable and reproducible, based on the high intra- and inter-examiner agreements found in an *in vitro* study. Only small differences were detected between the results of the ten examiners involved. One individual was largely responsible for majority of the detected discrepancies and had higher levels of intra examiner disagreement. This examiner was a novice in the technique, hence stressing the importance of assessors undergoing substantial training in the analysis techniques to reduce measurement error. Additionally, Pretty et al. (2002) reported that due to the subjectivity of the image analysis process, there is a risk of operator bias associated with the technique. Nevertheless, QLF has been found to be a reproducible (Benson et al. 2003a) and valid method (Benson et al. 2003b). *In vitro* (Pretty et al. 2003; Benson et al. 2003a; 2003b) and *in vivo* studies (van der Veen et al. 2007; Al-Khateeb et al. 1998; Al Maaitah et al. 2011) have demonstrated that it is appropriate for identifying demineralisation and longitudinal monitoring of mineral changes. van der Veen et al. (2007) undertook a longitudinal study monitoring 406 carious lesions in 58 subjects for six months post debond. The average ΔF at debond was 10.3%.

An advantage of QLF is that it provides a quantitative score of plaque accumulation and demineralisation. Thus, changes in fluorescence levels and the size of lesions may be monitored more precisely than would be possible by using descriptive indices (Boersma et al. 2005). Additionally, QLF demonstrates demineralisation before it is evident on white light digital images. Pretty et al. (2003) conducted an *in vitro* study of bonded orthodontic cleats on 13 human premolars placed in a demineralising solution. The level of fluorescence loss on QLF images, ΔQ, increased from 0.17 at baseline to 5.2, 29.7 and 68.2 at 24hours, 144 hours and 288 hours respectively. However, visual evidence of demineralisation was only evident on 5 of the 13 teeth at 144 hours and on 8 teeth at 288 hours, indicating the greater sensitivity of QLF image assessment. *In vivo* studies (Boersma et al. 2005; Thomas, 2010) have also found that QLF demonstrated a greater amount of demineralisation and noted it an earlier stage than conventional photographic analysis. Boersma et al. (2005) found that only lesions which had greater than 15% fluorescence loss, scored by QLF, were visible clinically. This ability of QLF to detect subclinical lesions is of great benefit to clinicians in reinforcing oral hygiene control and if appropriate, knowledge that it may be appropriate to initiate remineralisation therapies.

4.4.5 Diagnodont^{TM}

This technique can additionally be used to assess dental caries. A laser light of 655nm wavelength is used to illuminate the surface. The resultant fluorescence detected is in the infrared region. The amount of fluorescence noted increases with greater bacterial activity. Hence, the device can readily demonstrate sound from carious tooth tissue. The resultant value is displayed directly on a panel of the device as a number (Shi et al. 2001). This means further assessment by the operator is avoided, which is advantageous to reduce possible operator bias. *In vitro* studies have demonstrated the effective use of the device in assessing

smooth-surface caries (Shi et al. 2001) and demineralisation adjacent to orthodontic brackets (Straudt et al. 2004).

4.4.6 Toothcare^{TM}

The Toothcare^{TM} device is based on the same principal as QLF and can be used to assess plaque accumulation and demineralisation. It consists of a hand-held device that transmits blue light from a 450nm LED to illuminate the tooth surface. Green and red fluorescence can then be observed with the use of filters. These filter the yellow and red light with transmission peaks of 500 to 630nm.

The advantage is that the device is compact and inexpensive. Thus, it is more easily transportable, allowing chairside use with relative ease. However, it does not provide a direct quantitative measurement of the plaque accumulation and enamel demineralisation present. Subsequently, a standardised methodology with the use of appropriate indices must be used.

Thomas (2010) found Toothcare^{TM} demonstrated plaque deposits more readily than QLF in an *in vivo* study assessing 29 patients during fixed orthodontic treatment. This may be due to the device being more compact and easier to use. However, on assessing demineralisation, Toothcare^{TM} had poorer sensitivity scores. Using QLF assessment, 43% of patients were noted to have demineralisation, whilst in comparison, no lesions were detected using the Toothcare^{TM} device.

4.4.7 Quantitative Light-induced Fluoroscence-Digital (QLF-D)

The QLF-D Biluminator^{TM} is a novel device (Figure 4.5), based on QLF and Toothcare technology. It takes two successive images, a white light (WL) image, which is a conventional digital photograph, and a QLF fluorescent image.

Figure 4.5: The QLF-D Biluminator^{TM} software

This is advantageous as the two images are taken almost simultaneously, ensuring consistency with regards to magnification and angulation, hence allowing comparisons between the images to be made. Additionally, unlike with the Toothcare device, the images taken can be stored. This allows greater precision in terms of research design by enabling image randomisation to be undertaken if desired. Analysis can then be conducted at a later time point, which will reduce observer recall bias.

The WL and QLF images (Figure 4.6, Figure 4.7) are taken successively and stored on the camera prior to being transferred to the computer for customised software analysis.

| WL image plaque accumulation | QLF image plaque accumulation |
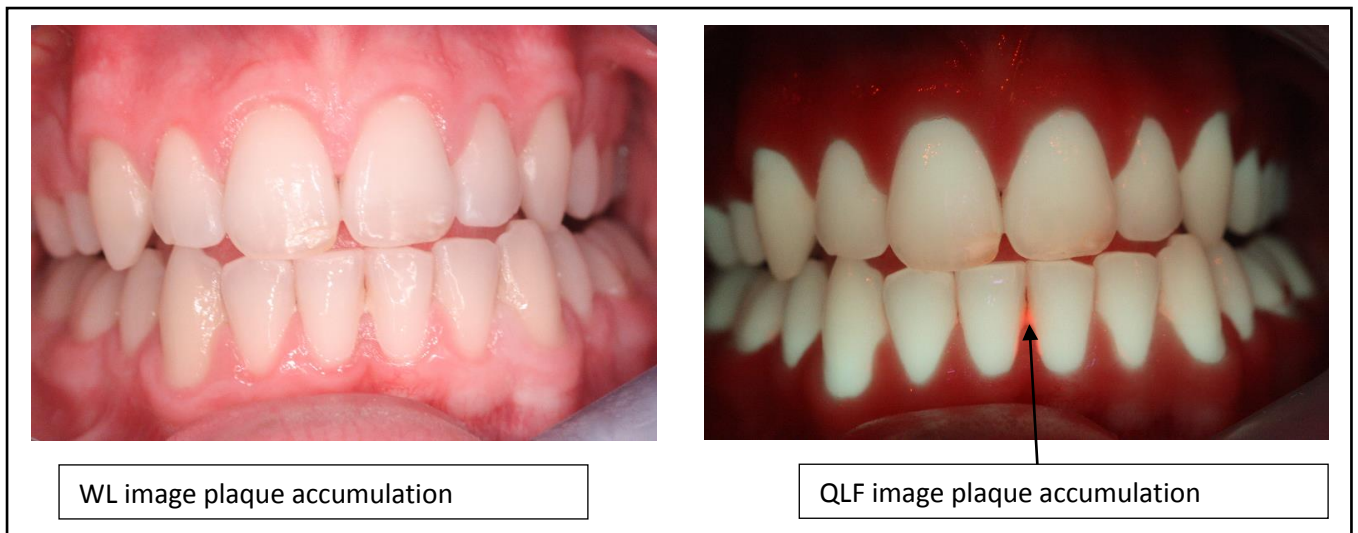
Figure 4.6: WL and QLF images demonstrating plaque accumulation

| Demineralisation on the WL image | Demineralisation evident on the QLF image |
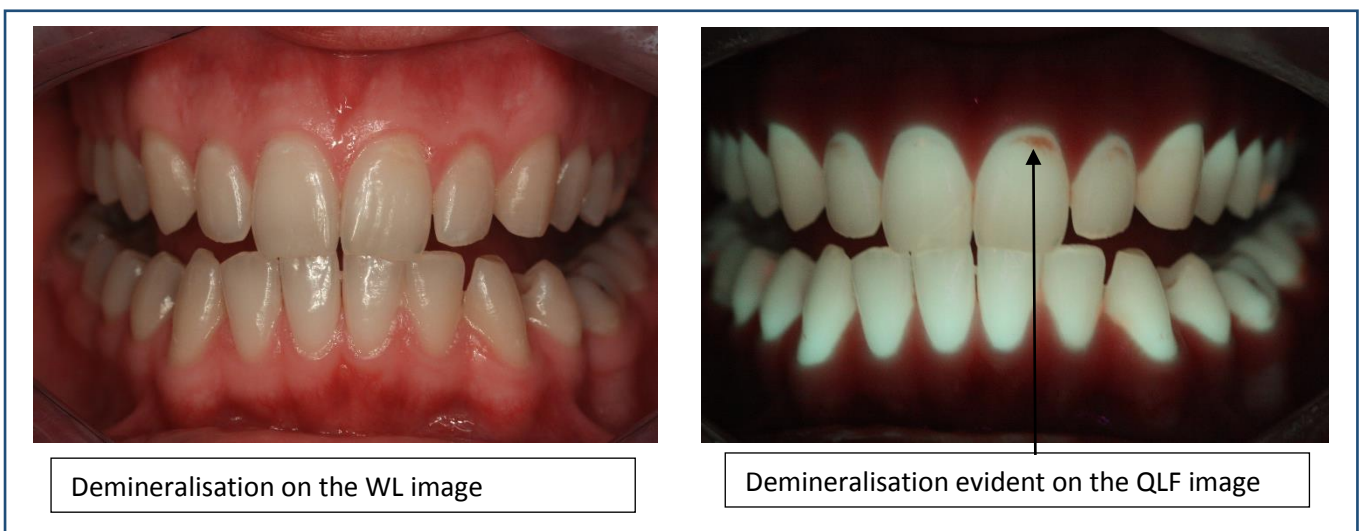
Figure 4.7: WL and QLF images demonstrating demineralisation

The WL images require direct visual assessment to assess the plaque accumulation and demineralisation present. This can be conducted using qualitative or quantitative scoring criteria. The QLF images are analysed using the customised software to provide quantitative data. Plaque accumulation is graded as the percentage tooth coverage demonstrating red fluorescence, ΔR, at different cut off points. The value $\Delta R30$ is most commonly recorded, whereby the number of pixels covered with red fluorescence must be greater than 30%. Areas

of demineralisation must be identified and assessed individually. Data are obtained regarding changes in the enamel fluorescence of the lesions, recorded as ΔF and ΔQ.

4.5 Management of oral hygiene during orthodontics

It is essential that patients maintain adequate levels of oral hygiene during orthodontic treatment to ensure plaque accumulation is controlled and to prevent demineralisation from developing (van der Veen et al. 2007). During orthodontics, the use of fluoride is a key factor to preventing demineralisation (Benson et al. 2004) and encouraging remineralisation of early enamel lesions. Fluoride ions can be taken up into the mineralised tooth tissue and incorporated into the crystalline structure forming fluorapatite. This structure is less soluble and affects the diffusion potential of calcium and phosphate ions, resulting in the enamel being more resistant to dissolution (Chang et al. 1997). The protective effect is related to the amount of time the tooth crystals have been exposed to fluoride, as this enables the fluoride ions to become incorporated to a deeper level (Arends and Christoffersen, 1986). Fluoride can also have a direct effect on bacterial growth by inhibiting the bacterial enzyme enolase, which is involved in the metabolism process.

Fluoridated toothpaste must be used during orthodontics and is a key intervention in the prevention of dental caries. The Cochrane review by Marinho et al. (2003) highlights that the associated benefits of fluoride toothpastes have been firmly established by numerous clinical trials. Recently, higher concentrations of fluoride in toothpaste have been advocated for individuals at a higher caries risk. Toothpaste containing 0.619% fluoride is recommended for children aged 10-15 years and 1.1% fluoride for adults and children of 16 years or older. The benefit of using high fluoride toothpaste, containing 5000ppm fluoride, rather than conventional toothpaste containing 1450ppm fluoride during upper and lower fixed

orthodontic treatment has been highlighted in the multicentre RCT conducted by Sonesson et al. (2013). The maxillary incisors, canines and premolars were assessed by blinded clinicians on digital images at baseline and upon debonding. The incidence of demineralisation in the high-fluoride group and control group was 18.1% and 26.6% respectively, equating to a 32% risk reduction.

Clinical studies also support the recommendation of patients using a daily 0.05% sodium fluoride mouthwash during orthodontic treatment (Boyd et al. 1994; Geiger et al. 1992; Benson et al. 1994). Geiger et al. (1992) found that the use of a daily fluoridated mouthwash led to a statistically significant 25% reduction in the number of patients with white spots. Only 13% of the 206 patients fully complied with the rinsing regime of once daily, however there was a significant dose response relationship between compliance and white spots.

Regular fluoride varnish application has been advised during orthodontic treatment. Stecksen-Blicks (2007) undertook a well-designed double-blinded RCT. The 273 participants were randomised to receiving a placebo varnish or a 0.1% fluoride varnish (Fluor-Protector), at routine orthodontic adjustment appointments, held at a 6-week intervals, during the full course of maxillary fixed orthodontic treatment. Digital photographs, taken at baseline and on debond, were assessed by independent examiners and indicated a statistically significant difference in the incidence of white spot lesions of 7.4% and 25.3% in the fluoride varnish group and placebo groups respectively. This translated into an 18% risk reduction, highlighting the potential benefit of such an intervention being routinely undertaken.

Remineralisation agents containing CPP-ACP may also be used to prevent demineralisation. An RCT by Robertson et al. (2011) assessed the use of MI Paste Plus (GC America) in

patients undergoing fixed orthodontic treatment. Applications were placed at four week intervals over a three month period and compared to the use of a placebo paste. In the placebo group, the demineralisation score increased by 91.1% whereas use of MI Paste plus resulted in a 53.5% reduction in demineralisation.

Fluoride-releasing orthodontic materials can also aid the prevention of demineralisation. Glass ionomer and resin modified glass ionomer cements for bonding can release fluoride and have been shown to reduce demineralisation compared to the use of conventional composite resin (Marcusson, 1997; Gorton, 2003). Fluoride-releasing elastomerics have also shown potential. A split-mouth RCT which randomly allocated 21 patients to having fluoride releasing modules on one side and conventional modules on the contralateral side over the full course of fixed orthodontic treatment found that the former developed significantly less demineralisation. Additionally, any lesions that did present were less severe, assessed on digital images using a modification of the enamel defect score (Mattick et al. 2001).

A suitable tooth brushing technique should be advised and emphasis placed on the commonly missed areas. Boyd et al. (1994) demonstrated electric toothbrushes may be more effective. In the RCT, participants were assessed clinically prior to having fixed orthodontic treatment and 3 months following debond. Individuals allocated to using a rotary electric toothbrush developed significantly less demineralisation than those who used a manual toothbrush. The groups were matched for gender and age, however, the allocation was not randomised, which could have led to selection bias.

Interdental brushes are often recommended in addition to conventional toothbrushing during orthodontics. Although, the Cochrane review by Goh et al. (2007) stated that their use was

not supported by clinical studies and that greater wear occurs on the brushes from the fixed appliances which increases the financial burden placed on patients of having to repeatedly purchase such oral hygiene products. Nevertheless, such products are commonly advised.

Longitudinal monitoring of a patient's standard of oral hygiene is essential at each appointment. If oral hygiene control is suboptimal, additional OHR should be provided, focusing on the areas of teeth that are frequently being missed. A systematic review (Gray and McIntyre, 2008) found oral health promotion during fixed orthodontic treatment led to short term improvements in plaque control and/or gingival health in 4 of the 6 studies. However, a meta-analysis was unable to be performed due to the heterogeneity in outcome measures included.

There are many available techniques for OHR. One of the most frequently advised is the use of disclosing agents on the clinics chairside and the use of such products at home. Boyd (1983), assessed the effectiveness using Plaklite, a disclosing agent, as an adjunct to oral hygiene instruction in 24 patients undergoing fixed orthodontic treatment. Participants were randomly allocated to receiving verbal plaque control instructions using the modified Bass technique, the above with the additional use of Plaklite disclosant or a control group of no oral hygiene instructions. The intervention groups received oral hygiene reinforcement on a monthly basis for the first 5 months of treatment. The results found that participants allocated to the group with the additional use of plaklite, which enabled patients to monitor their own plaque levels, resulted in the lower plaque and gingivitis scores being maintained when the routine oral hygiene reinforcement was discontinued. This indicates that visual reinforcement of the effectiveness of plaque removal may lead to continued improvement in oral hygiene behaviour long term.

Oral health counselling has been found to be beneficial (Lalic, 2012). Plaque and gingivitis levels were assessed in 99 patients undergoing fixed orthodontic treatment who had been randomly allocated to either receiving verbal oral hygiene instructions using a model tooth brushing demonstration or the former with an additional personalised oral health counselling session. The overall level of oral hygiene improved from baseline to 6 months after the education and counselling sessions with statistically significant reductions in plaque in both groups. However, gingival inflammation was only significantly lower in the counselling group, suggesting counselling in addition to routine education may be an effective tool.

Computer-based methods, such videotapes with oral hygiene instructions (Lees and Rock, 2000) have been investigated and were found to be more effective than the provision of written instructions alone. The initial manufacturing costs of such methods can be high, however once produced the videos can subsequently be used repeatedly with minimal associated costs. Indeed, such information in DVD format could easily be circulated in an orthodontic waiting room.

The use of rewards as an adjunct to improve oral hygiene compliance in patients who lack adequate compliance has been evaluated. Richter and Nanda (1998) assessed 144 patients, 72 were classed as above average compliers based on their score using a patient cooperation scale and 72 were below average. Twenty-four patients in each category were allocated to 3 groups. These consisted of an award group receiving monthly verbal instructions and a report card with written feedback evaluating their compliance, a reward group of the above and eligibility to receive rewards of gifts, or a control group receiving standardised verbal oral hygiene instructions. The patients' compliance levels, encompassed by the standard of oral hygiene that was being maintained, appointment punctuality, appliance wear and appliance

maintenance were assessed at monthly appointments. There was no statistically significant improvement in the patients with above average compliance scores. In the below average compliers, a significant improvement in the oral hygiene was noted between the reward and control groups in months 5 and 6. Thus, generally, the study demonstrated that the use of rewards had minimal effect on the oral hygiene levels of the patients assessed.

Oral hygiene reminders using text messaging (Eppright et al. 2014) have been found to improve oral hygiene compliance during orthodontics. In this RCT, patients aged 11-19 years were randomly assigned to their parent or guardians receiving a text message once weekly at 17:15 reinforcing the necessity of maintaining good levels of oral hygiene or a control group who did not receive such a text message. There were no statistical differences noted at T1, 2 months from baseline. However, the text message group had significantly lower bleeding, gingival, and plaque indices scores at T2, four appointments from baseline. The authors suggested that this delay may be due to length of time for improved oral hygiene habits to be adopted as normal behaviour. Thus inferring that any study of a short duration, investigating an OHR technique may not be able to fully demonstrate any benefits. Additionally, there was no difference noted between the two groups with regards to the development of demineralisation. Nevertheless, the study demonstrates that regular OHR by the use of text messaging can be advantageous in improving oral hygiene compliance.

It has been suggested that to gain long-term improvements in oral hygiene, repetition of the OHR method is more important than the process itself. Peng et al. (2014) found that the plaque and gingival scores of patients allocated to having their plaque disclosed at a single time point for educational purposes failed to have better oral hygiene levels than the routine oral hygiene instruction (OHI) group. Thus, approaches where the OHR instruction is

repeated- such as using regular reminder text messages (Eppright et al. 2014), reinforcement sessions (Marini et al. 2014; Boyd, 1983) and dental health lectures (Emler et al. 1980) may be the most effective means.

This study aimed to use the QLF-D^{TM} device as an oral hygiene evaluation tool to assess the patients' standard of oral hygiene compliance longitudinally during fixed orthodontic treatment. As discussed, research has shown that various methods of OHR may improve oral hygiene compliance in the short term during fixed orthodontic treatment. However, the majority of the studies reported on ordinal indices, such as the plaque index of Silness and Loe, (1964) and white spot lesion measurements, namely whether demineralisation was present or absent. The advantage of using the QLF-D^{TM} device and thereby obtaining QLF images is that they can be assessed to provide a quantitative measure of plaque accumulation and of any demineralisation present, hence increasing the precision of the research and ascertainment of the effect of the oral hygiene intervention being provided.

Furthermore, although the literature is abound with studies on the effect of OHR on plaque accumulation and gingival health, there is limited information available on its impact on demineralisation. The systematic review by Derks et al. (2004) on preventative measures that can be used during fixed orthodontic treatment to reduce the potential for caries development focused on four measures- fluoride, chlorhexidine, sealants and bonding materials. It was concluded that many publications required exclusion due to inadequate research design and the authors advocated that additional clinical trials were required to provide evidence-based recommendations on which to base our practice, to ensure the best strategies are in place to prevent demineralisation.

In this study, OHR would be undertaken using WL or QLF images, taken with the QLF-D^{TM} device, as personalised visual aids. The OHR would focus on the areas of plaque accumulation or demineralisation present to ascertain if by improving patient awareness this would lead to better oral hygiene control. The study would also assess the patients' opinions of having being shown the images to determine if they felt the protocol was an advantageous aid to their routine oral hygiene management.

5.0 AIMS AND OBJECTIVES

5.1 Aims

1. To assess the use of the QLF-D^{TM} as an oral hygiene evaluation tool to detect plaque accumulation during orthodontics.

2. To assess the use of the QLF-D^{TM} as an oral hygiene evaluation tool to detect demineralisation during orthodontics.

5.2 Objectives

1. To quantify plaque accumulation on the surfaces of teeth using QLF-D^{TM}.

2. To quantify demineralisation on the surfaces of teeth present using QLF-D^{TM}.

3. To assess if OHR using the QLF-D^{TM} device reduces plaque accumulation and the development of demineralisation during orthodontic treatment.

4. To assess the level of demineralisation that occurs and can be visualised on QLF images before being seen on WL images.

5. To evaluate the intra and inter-examiner reliability of QLF and WL image assessment.

6. To ascertain the patients' perspectives of QLF-D^{TM} as oral hygiene evaluation tool.

7. To provide data on QLF-D^{TM} as an oral hygiene evaluation tool to aid the design and methodology of future studies.

6.0 MATERIALS AND METHODS

6.1 Ethical approval

Ethical approval was gained from the North West Research Ethics Committee- Liverpool Central (REC reference: 13/NW/0005). The project was also registered with the Royal Liverpool and Broadgreen University Hospital Trust Research and Development Department (REF: 4415).

6.2 Design

The study was a randomised clinical trial.

6.3 Sample

Consecutive patients attending Liverpool University Dental Hospital orthodontic department for fixed orthodontic appliance treatment, conducted by the same clinician (CCM), who met the required inclusion and exclusion criteria were asked to participate.

6.3.1 Inclusion criteria

1. All subjects were consented

2. All subjects were in good health

3. At least 11 years of age

4. Patients undergoing upper and lower fixed appliance orthodontic treatment

6.3.2 Exclusion criteria

1. Patients with significant disabilities that may affect manual dexterity and oral hygiene practice

2. Patients who had antibiotics in the last two months

3. Patients with full coronal coverage restorations

4. Patients with visually cavitated lesions

6.4 Setting

The study was conducted at Liverpool University Dental Hospital where patients were being seen for fixed orthodontic appliance treatment by CCM. Data were collected at the patients' routine orthodontic adjust appointments.

6.5 Methods

6.5.1 Recruitment and anonymisation of data

Consecutive patients attending Liverpool University Dental Hospital orthodontic department for orthodontic appliance treatment by the same clinician (CCM), who had at least 4 appointments worth of treatment time remaining were asked to participate. Written patient information sheets were provided to the patients outlining involvement in the study (Appendix 14.1, Appendix 14.2). For individuals under 16 years of age, information sheets were additionally provided to a parent or guardian (Appendix 14.3).

The participants were given until the next routine appointment to read the information leaflet and decide decision whether or not to participate. Additional time was offered if the patient was still undecided. Informed written consent was then obtained by CCM from the patient

(Appendix 14.4) or parent (Appendix 14.5). Assent forms were completed if the patient was under 16 years of age (Appendix 14.6).

Following recruitment, each participant was given a unique study number so that the data could be pseudo-anonymised. The personal details of each subject were not used in conjunction with the research project to ensure anonymity.

6.5.2 Randomisation

After consent had been gained, a baseline assessment (T0), was taken using the QLF-D^{TM} device (Inspektor Research Systems BV, Amsterdam, The Netherlands). The archwires were removed and the QLF-D^{TM} device was used to photograph the maxillary and mandibular dentition when the patient was occluding edge to edge in frontal and buccal views. If required, a prophylaxis was conducted to remove plaque deposits present. The photographs were then repeated to allow an assessment of any demineralisation present.

The QLF images were assessed by CCM at least a week later for the presence of demineralisation. If there was at least 1 area of demineralisation present, the individual was classed as high risk (HR). If no areas of demineralisation were present, the individual was classed as low risk (LR).

The randomisation was conducted by an independent statistician. A random number sequence was produced by a computer generated programme. The randomisation process was stratified by demineralisation risk into HR and LR groups. Allocation concealment was with consecutively numbered, sealed opaque envelopes. At the subsequent routine orthodontic appointment (T1), the next envelope was opened based on the participant's demineralisation

risk at T0 and the patient was allocated into one of the two parallel groups. Blinding of the patient or operator to the group allocation was not possible. All of the patients were treated by one operator (CCM).

6.5.3 Data collection

The standard of oral hygiene was re-assessed at four consecutive routine orthodontic appointments (T1-T4), at approximately 6-8 week intervals. The arch wires were removed at the start of the appointment and the QLF-D™ device was used to photograph the maxillary and mandibular dentition when the patient was occluding edge to edge in frontal and buccal views.

At each visit, the subjects were given OHR using the WL or QLF images as visual aids depending on their group allocation. These images were at the same magnification, focus and direction. The OHI was a standardised reinforcement of the instructions given at the start of the orthodontic treatment, although focused on the areas of poorer plaque control or where demineralisation was present. At the start of orthodontic treatment, patients are advised to brush their teeth twice a day, after breakfast and at bedtime. They are additionally advised to use a fluoridated mouthwash once a day at a different time to brushing. These instructions are given verbally and on a written information leaflet. As is normal clinical practice, if a subject's oral hygiene was continually poor and severe, or progressing demineralisation was noted, the orthodontic treatment would be terminated early.

On completion of the study, the participants were given a debriefing questionnaire (Appendix 14.7) to complete, which focused on their perception of being shown the images and their opinion of whether seeing them was a useful tool to aid their oral hygiene control.

6.5.4 Image analysis

The images taken were stored anonymously on a database based on the participants study number. The images were all analysed by one clinician (CCM) at least one week later from the appointment to avoid recall bias. The reliability study on QLF image assessment conducted by Pretty et al. (2002) used a 'washout' period of 7 days between each of the 3 assessments that were undertaken by the examiners. Similarly, Huang et al. (2013) also used an interval period of at least a week between repeat WL demineralisation image assessments. Thus, an interval of 1 week was employed in this study.

The WL images were assessed for the number of areas of demineralisation present in addition to the number of teeth an assessment was made on. The QLF images were assessed using the customised computer software. A measurement of the plaque accumulation on each tooth (Figure 6.1) as the percentage tooth coverage demonstrating red fluorescence at $\Delta R30$ was graded as $\Delta R30$.
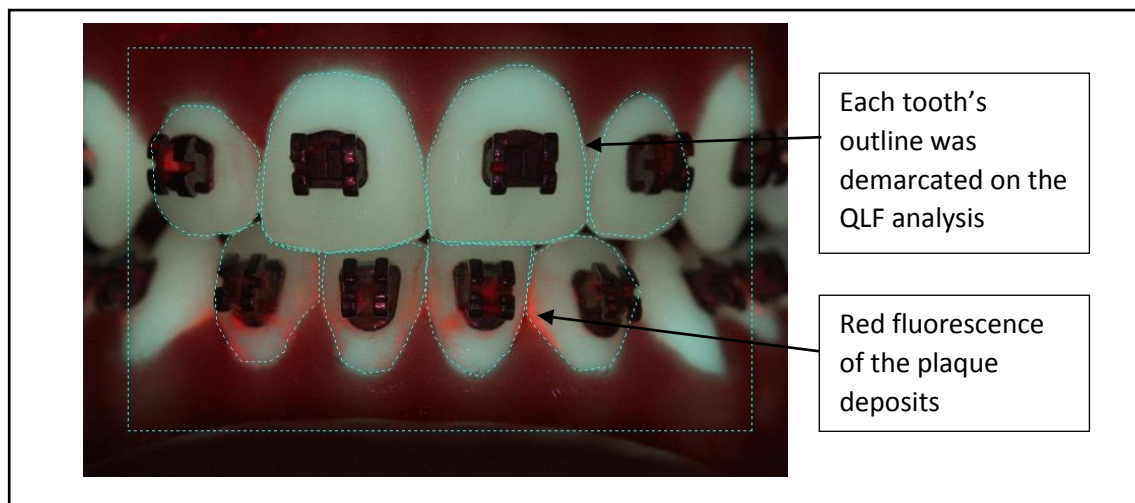
Figure 6.1: Customised computer analysis of the plaque accumulation

For areas of demineralisation, an outline was drawn around each lesion with borders on sound enamel (Figure 6.2). The mean fluorescence loss (ΔF), maximum fluorescence loss

(ΔF Max) were assessed in comparison to the fluorescence of the surrounding enamel. ΔQ, was also ascertained, which enabled an assessment of the amount of fluorescence loss ΔF and the lesion area involved per pixel). If there was no sound enamel adjacent to the lesion on one side, such as when the lesion was adjacent to the edge of the bracket, the outline was adjusted for this. The total fluorescence loss was calculated for each tooth when more than 1 lesion was present.

An area of demineralisation present on a WL image, which is difficult to fully visualise.

An area of demineralisation appears darker on a QLF image. It can be demarcated to allow assessment.
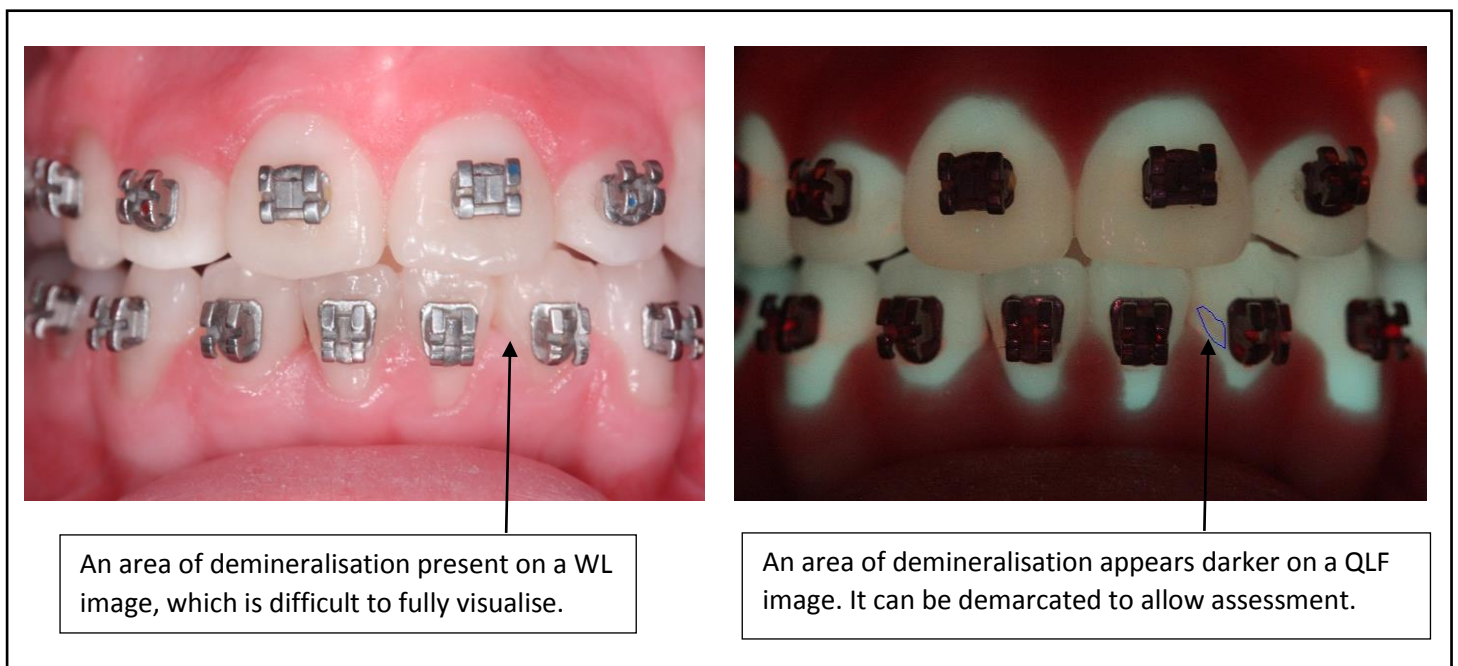
Figure 6.2: Customised computer analysis of demineralisation

6.5.5 Reliability assessments

To assess inter-examiner reliability, the WL and QLF images from 7 patients were analysed by the main examiner and three additional examiners (Appendix 14.8). These examiners all had previous experience with the software and analysing experimental data. The main examiner examined the images on a second occasion two weeks later to allow assessment of the intra-examiner reliability.

Stecksen-Blicks (2007) assessed intra- and inter-examiner reliability in their study. Images from 50 cases out of the 273 patients were reanalysed. From this information and calculating the proportion that were evaluated, it was felt appropriate to use some of the data obtained from 7 of the 33 patients to enable an appropriate assessment to be undertaken.

6.5.6 Sensitivity and specificity assessments

The sensitivity of a diagnostic test is its ability to correctly diagnose the presence of an outcome when the outcome is present, thereby whether the presence of demineralisation can be correctly diagnosed on the images. The specificity of a diagnostic test is the ability of a test to correctly confirm a negative outcome, such as the absence of demineralisation (Bewick et al. 2004). Seven WL images and their corresponding QLF images (Appendix 14.9) were assessed for the presence of demineralisation by three examiners to determine the ability of the examiners to correctly identify the presence and absence of demineralisation. The QLF and WL images were displayed in a random order to ensure each image was assessed independently and to avoid recall bias. The results were compared to an additional main assessor's analysis, which was taken to be the gold standard.

7.0 STATISTICAL ANALYSIS

All of the data was analysed using SPSS Version 20.0 software.

7.1 Sample size calculation

There were no previous studies available on which to base a sample size calculation, thus a formal sample size calculation was not carried out. Expert statistical advice was sought and a sample size of 30 was deemed appropriate to allow estimation of parameters for a sample size calculation to be conducted for future definitive studies. Browne (1995) advocate assessing at least 30 participants when estimating the effect of a specific factor during a pilot study (Browne, 1995; Lancaster et al. 2004). Hence, this was deemed to be an appropriate number of patients to recruit.

7.2 Normality testing and hypothesis testing

The primary outcome variable was the percentage change in demineralisation from the baseline visit (T0) to the final visit of OHR (T4), measured as ΔF from the QLF images. The measurement was taken at the tooth level, over all areas of demineralisation. Although the study was not powered to detect a difference between groups, a statistical comparison would be carried out to give initial estimates of effect size and variability for use in the design of future studies (Lancaster et al. 2004).

As the outcome was measured at tooth level, but the randomisation was at a participant level, the analysis of the primary outcome controlled for the clustering of teeth within participants using multilevel modelling (Harrison and Burnside, 2012). This allowed estimation of the intracluster correlation coefficient (ICC) for use in the design of future studies.

The percentage change in plaque accumulation, measured from the QLF images as tooth coverage demonstrating red fluorescence at ΔR30, was analysed similarly to the demineralisation data.

7.3 Receiver operating characteristic curves

Receiving operator curves assess the relationship between the sensitivity of a test, which is the number of true positives and 1-specificity. As specificity is the correct diagnosis of true negatives, 1-specificity is the number of false positives detected. A perfect test would have a sensitivity and specificity of 1. Graphically, when a diagnostic test is as likely to produce a true positive result as a false positive result, there would be a linear diagonal line from (0,0) to (1,1). The more steep the line the greater the sensitivity and specificity. Alongside this, the area under the curve (AUC) can be calculated to assess the performance of a diagnostic test with the best test having a value of 1. These factors were used to assess the level of demineralisation measured on QLF images and that could be visualised on the WL images (Bewick et al. 2004).

7.4 Reliability data

For the WL images, the demineralisation data collated were categorical, whereby demineralisation was assessed as being present or absent, thus intra and inter-examiner reliability was assessed using Cohen's kappa statistics. For the QLF images, the plaque and demineralisation data collated were continuous, whereby a precise score was given using the QLF software, thus intra and inter-examiner reliability was evaluated using intra-class correlation coefficient (ICC).

7.5 Sensitivity and specificity of demineralisation data

The sensitivity and specificity of demineralisation assessment on the QLF and WL images would be calculated by assessing the demineralisation data results obtained from the 3 examiners in comparison to the results of the gold standard, which was the main assessor's analysis of the QLF images. This would provide a measure of QLF and WL diagnostic accuracy of demineralisation.

8.0 RESULTS

8.1 Description of subjects

A total of 33 patients were recruited. The first patient enrolled in March 2013 and the last patient completed the study in November 2013. Baseline records were taken of the 33 patients at T0 and the images were assessed for the presence of demineralisation on the QLF images. All image assessments were taken at least 1 week following the appointment to reduce the risk of recall bias. 17 patients were noted to have demineralisation present and were classed as high risk. 16 patients were classed as low risk, having no areas of demineralisation present. The baseline mean $\Delta R30$ was 10.4 (SD 5.33) and 7.55 (SD 5.84) for the high and low risk group participants respectively, which was not statistically significant (P=0.15, t-test).

The 33 patients were randomly allocated to the WL or QLF groups stratified on the presence of demineralisation at baseline, T0. This resulted in 16 participants being allocated to the WL group and 17 to the QLF group. Figure 8.1 highlights the flow of patients through the trial. There were no drop-outs. All of the patients completed the trial and had their data fully analysed.

There were 21 females and 12 males recruited into the study (Table 8.1). In the WL group there were 10 females (62.5%) and 6 males (37.5%). In the QLF group, there were 11 females (64.7%) and 6 males (35.3%). Almost two thirds of the sample were female (64%). The data for age were assessed and found to be skewed, thus medians were used. The median

age of the sample was 14.6 years (IQR 3.5; minimum 11.0yrs; maximum 37.4yrs). In the WL group the median age was 14.5 years (IQR 2; minimum 12.9yrs; maximum 17.6yrs) and QLF group was 15.7 years (IQR 4.9; minimum 11yrs; maximum 37.4yrs). The larger IQR was due to 1 participant being 37.4 years of age, which affected the distribution of the data. There were no significant differences between the groups at baseline for gender (P=0.90, chi-square test) and age (P=0.42, Mann-Whitney U-test).
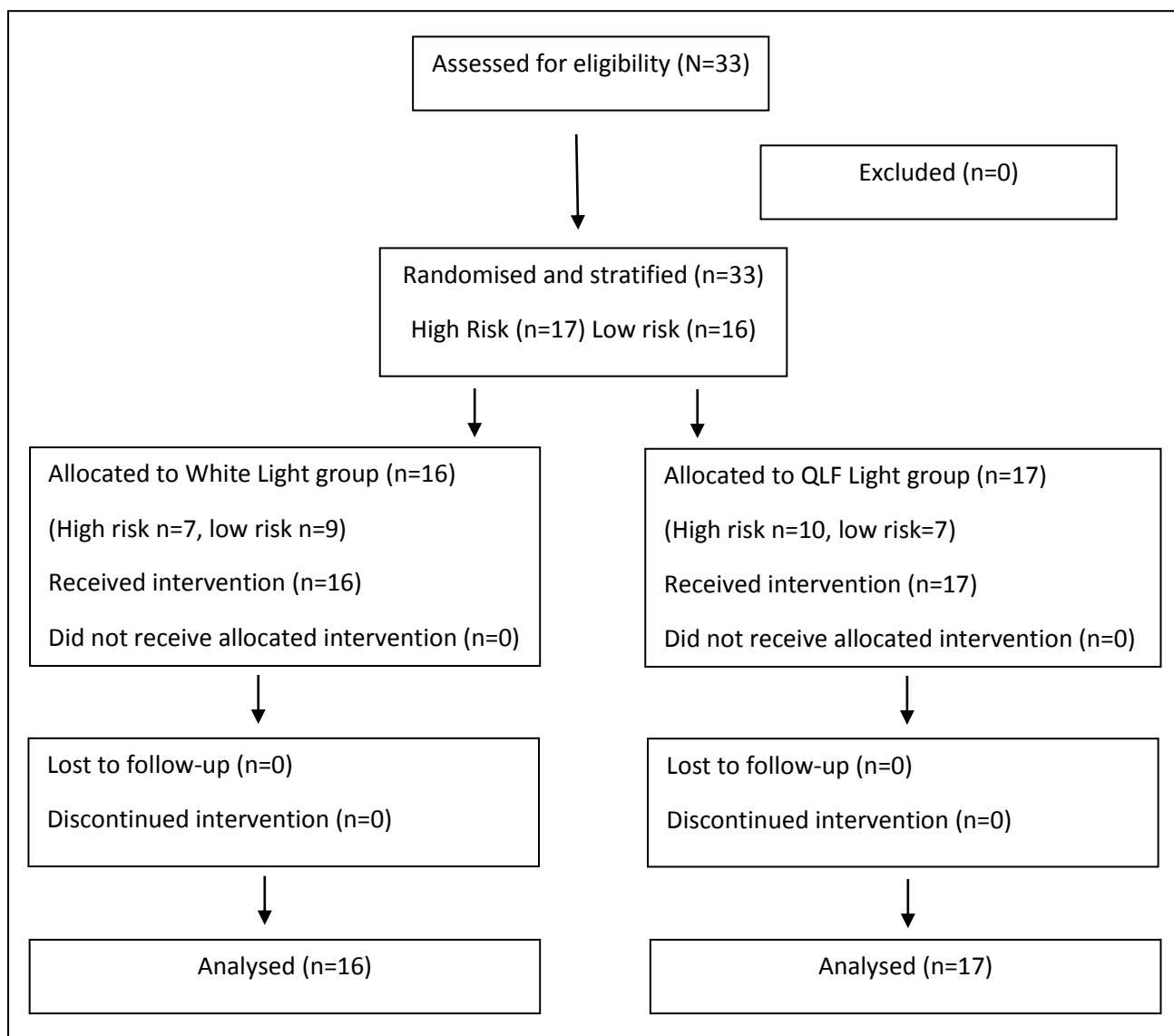
Figure 8.1: Flow of participants through the study

	WL group	QLF group	All participants
Participants	n=16	n=17	N=33
Median Age (IQR)	14.5 (2)	15.7 (4.9)	14.6 (3.5)
Gender- Female	10	11	21
Gender- Male	6	6	12

Table 8.1: Baseline characteristics of the participants

The overall mean number of teeth assessed per participant was 18 (SD 3.1). In the WL group, the mean number of teeth assessed was 19 (SD 2.9) and in QLF group was 18 (SD 3.2). There was no statistical difference between the two groups (P=0.43, t-test).

8.2 Demineralisation data

Assessing the total number of lesions present at a patient level, 21 participants had the same number of lesions present at T4 as T0 (Figure 8.2). In the high risk group, four participants had less lesions and seven participants had a greater number. In the low risk group, one participant had a greater number. The remaining 15 individuals had no change in the number of lesions. As these individuals did not have any areas of demineralisation pre-treatment, this indicated that they did not develop any lesions. Comparing the high risk and low risk groups with regard to the total number of lesions present, there was a statistically significant change in their number from T0-T4 (P=0.001, chi-square test). This confirms the need for the randomisation process to be stratified on the baseline demineralisation risk to account for such a confounding factor.
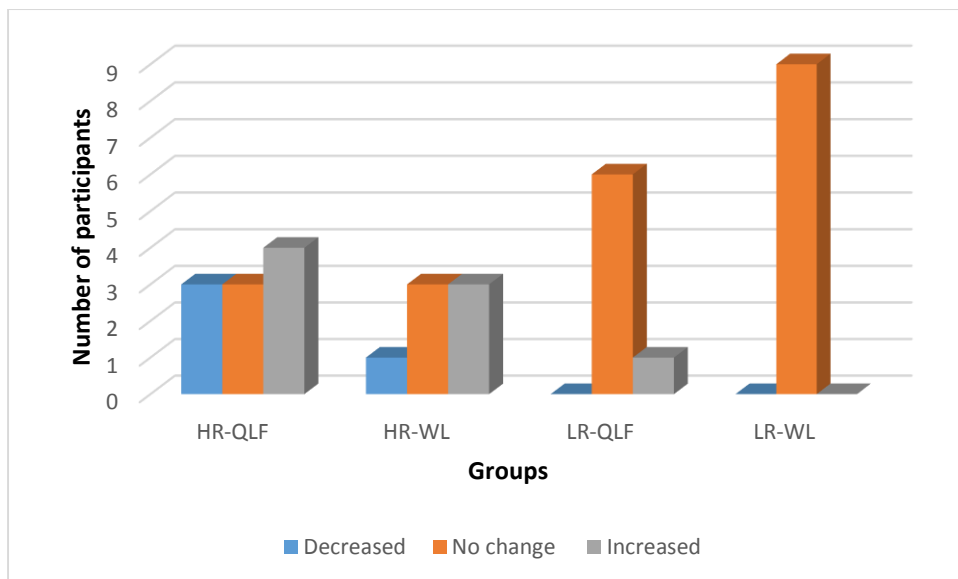
Figure 8.2: Participant level change in the number of demineralisation lesions from T0-T4

In the QLF group, 3 participants had less areas of demineralisation, 5 had a greater number and in 9 the number of lesions remained constant. In the WL group, 1 participant had less lesions, 3 developed a greater number and in the remaining 12 the number of lesions present did not change. There were no statistically significant differences noted in the change of number of lesions present between the groups from T0 to T4 (P=0.39, chi-square test). The subgroup analysis by stratification of the participants into the high risk and low risk groups additionally showed no statistically significant differences (HR-QLF participants compared to HR-WL participants, P=0.84; LR-QLF participants compared to LR-WL participants, P=0.44, chi-square test).

At a tooth level, there were 41 teeth noted at T0 to have areas of demineralisation present on the QLF images of which 25 were in the QLF group and 16 in the WL group. The most commonly affected teeth were the maxillary central and lateral incisors which accounted for 47.4% of the lesions detected (Figure 8.3).
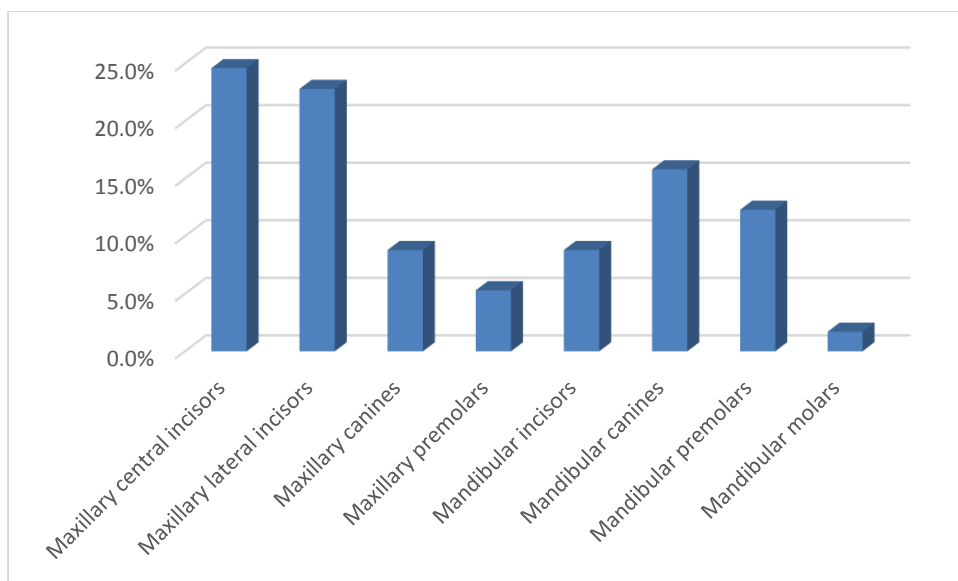
Figure 8.3: Teeth affected by demineralisation

At T4 there were 4 more teeth with demineralisation present than at T0 (Table 8.2). These teeth were evenly distributed between the treatment groups. In the QLF group, the upper right canine and lower left canine had demineralisation observed that was not present at T0. In the WL group, the teeth involved were the upper left lateral incisor and lower left first premolar.

	Appointment			
	Baseline		Visit 4 (T4)	
Total number of teeth with demineralisation	41		45	
Allocated group	QLF	WL	QLF	WL
Teeth with demineralisation	21	16	23	18

Table 8.2: Teeth with demineralisation on QLF images and their group allocation

With regards to the outcome, percentage change in ΔF at a tooth level, from T0-T4, the 16 individuals in the LR group who presented with no demineralisation at baseline could not be assessed as a percentage change calculation cannot be undertaken when the value initially is

0. Of the 16 participants in the LR group, 15 had the same number of lesions present at T4 as at T0- in that they had did not have any areas of demineralisation. Only one individual developed a lesion. However, as previously discussed, the data for the LR individuals was included in the participant level analysis, with no statistically significant difference noted in the number of lesions present from T0 to T4 between the WL and QLF groups (P=0.39, chi-square test). The percentage change in ΔF assessment was therefore based on the data from the 17 high risk individuals who had demineralisation present at baseline. Of these individuals, 10 had been randomly allocated to the QLF group and 7 to the WL group. With regards to the unadjusted means, not taking into account clustering within patients, the mean percentage change in ΔF was -17.4% (SD 37.4%). In the QLF and WL groups the percentage change was -20.2% (SD 37.5%) and -12.9% (SD 38.0%) respectively. This 7.3% greater reduction in the QLF group was not statistically significant (P>0.05).

The largest percentage change in ΔF at a tooth level in both the QLF and WL groups was from 0 to -20%, indicating an improvement in the extent of mineral loss of the lesions (Figure 8.4). The frequency of having a change in ΔF from 0 to -20% and -20% to -40% was greater in the QLF group, suggesting a trend towards greater levels of improvement in the participants who were given OHR based on the QLF images. However, the spread of the data was wide. Five teeth showed a 100% improvement such that the lesions present were no longer detectable using the QLF image assessment. These teeth, which were the upper right central incisor in two cases, the upper right canine, lower right canine and the lower right lateral incisor. The five teeth were in five different individuals, three of which were allocated to the QLF group and two to the WL group. The mean ΔF of these teeth was 6.20 (SD 0.48).
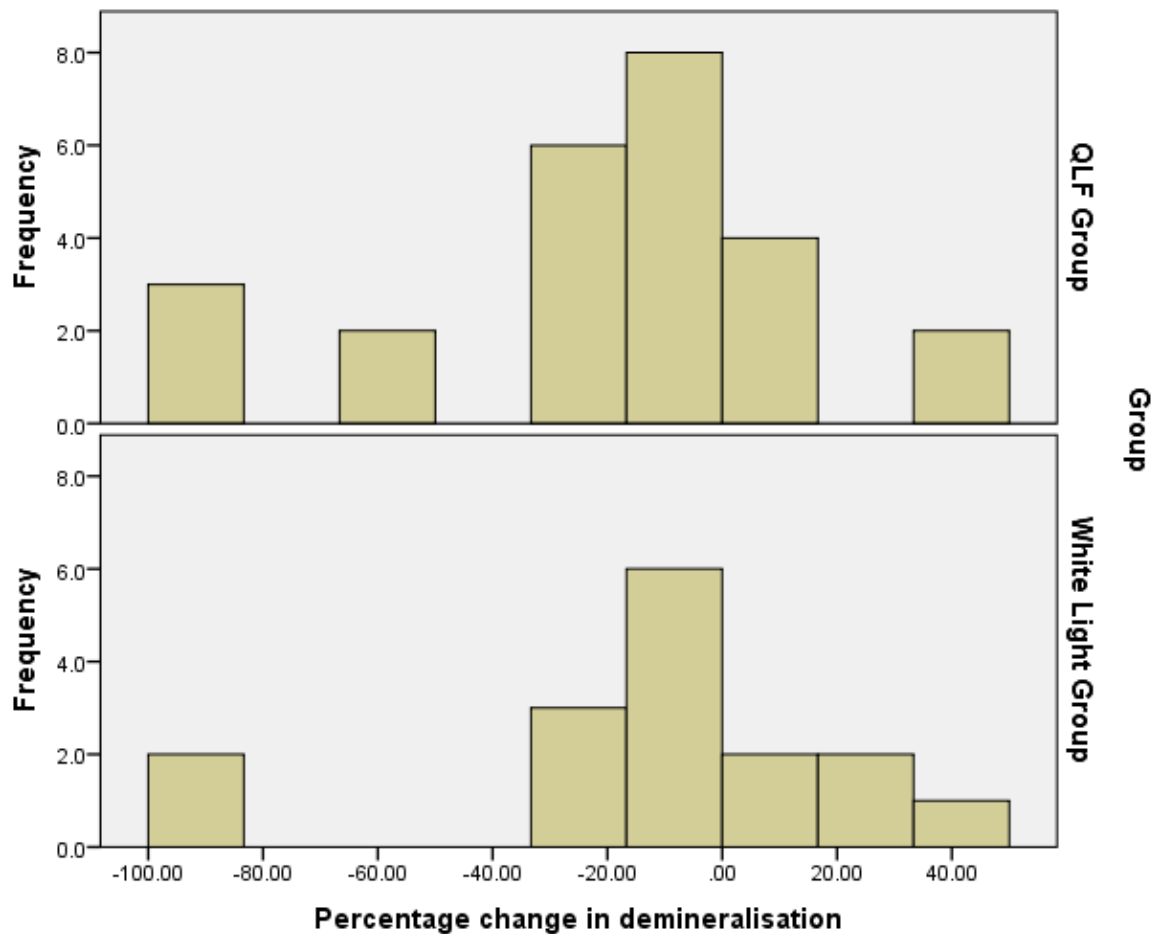
Figure 8.4: Mean percentage changes in ΔF at a tooth level from T0-T4

Assessment of the mean ΔF of the lesions present in the participants (Figure 8.5) suggests there was a reduction in ΔF as the study progressed. A repeated measures of analysis of variance using the baseline visit as a covariate indicated this was not significant from T0 to T4 (P=0.577). Additionally, there was no difference between the WL and QLF participants (P=0.498). There appeared to be an increase in ΔF between T0 and T1 when no intervention was provided, although this was not significant using a paired t-test for all participants (P=0.472).
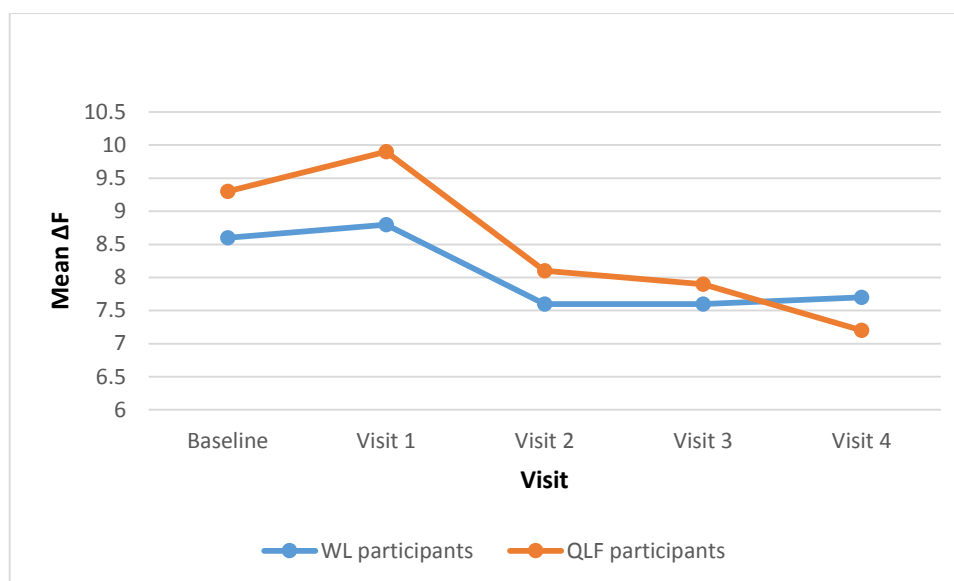
Figure 8.5: Mean ΔF of the lesions in each participant in the allocated groups

The outcome measures in the study were measured at tooth level, but the randomisation was at participant level, thus multilevel linear regression analysis was undertaken to control for the clustering of teeth within the participants. The mean percentage reduction in the adjusted mean ΔF was -21.8% (SE 9.1) and -13.3% (SE 10.6) in the QLF and WL groups respectively (Table 8.3). The 95% confidence intervals (CIs) demonstrate the wide spread of the results and indicate no statistically significant differences in either the QLF or WL groups (P>0.05).

	WL group	QLF group
Mean	-13.3%	-21.8%
95% Confidence Interval	10.8% to -37.4%	1.8% to -45.4%
SE	10.6	9.1

Table 8.3: Adjusted mean percentage change in ΔF from T0-T4

The difference in the adjusted means was 8.5 (SE 13.9). The 95% CI, -41.0 to 24.8, indicates this was not statistically significant (P>0.05). The test of the fixed effect of the intervention

showed no significant difference in the percentage change in ΔF, from T0-T4, between the QLF and WL groups (P=0.56).

An analysis was also undertaken at tooth level to include the results of all of the participants, including those in the low risk group that had no demineralisation at baseline and did not develop any lesions. There were 792 teeth assessed at T4, of which 751 had no lesions present. The estimated mean total ΔF per tooth at T4, adjusted to account for the total ΔF at baseline and the risk of demineralisation, whether the participant was assessed as HR or LR at baseline, was 0.56 (95% CI 0.44-0.67, SE 0.06) and 0.51 (95% CI 0.40-0.62, SE 0.06) for the WL and QLF groups respectively (P=0.552).

Assessing the covariance parameters to determine the error variance of teeth being present within the same participant gave an intracluster correlation coefficient (ICC) of 18.5%, indicating that 18.5% of the variance in the outcome was between patients and the majority of the variation, 81.5%, was at a tooth level. This ICC estimation will be advantageous in planning the design and sample size required in future studies.

The maximum level of mineral loss noted within a lesion, ΔF Max, was additionally assessed to determine the extent of the lesion's severity. The overall unadjusted mean percentage change in ΔF Max from T0-T4 was -7.5% (SD 62%). In the QLF and WL groups the percentage change was -9.5% (SD 68.4%) and -4.3% (SD 52.4%) respectively. Adjusting for clustering of teeth at a participant level (Table 8.4), the mean percentage change in ΔF Max was -8.5 (SE 15.9) and -6.2 (SE 18.3) in the QLF and WL groups respectively. The CIs

indicate the mean reductions noted were not significantly lower in either the QLF or WL groups at T4 (P>0.05).

	WL group	QLF group
Mean	-6.2%	-8.5%
95% Confidence Interval	33.1% to -45.5%	27.6% to -44.6%
SE	18.3	15.9

Table 8.4: Adjusted mean percentage change in ΔF Max

The difference in the adjusted means between the QLF and WL groups was 2.3 (SE 24.2) with a wide 95% CI of -55.5 to 50.9 (P>0.05). Additionally, the test of the fixed effect of the intervention showed no statistically significant difference between the QLF and WL groups (P=0.93).

ΔQ indicated the severity of the demineralisation with respect to the degree of mineral loss in conjunction with the lesion area involved, per pixel. The overall unadjusted mean percentage change in ΔQ from T0-T4 was 45.8% (SD 267.3%). In the QLF and WL groups the percentage change was 34.2% (SD 272.8%) and 63.9% (SD 266.1%) respectively. Adjusting for clustering of teeth at a participant level (Table 8.5), the mean percentage change in ΔQ was 40.3 (SE 52.7) and 54.5 (SE 65.9) in the QLF and WL groups respectively. This suggests that there was an increase in ΔQ in both groups, however the CIs indicate the wide variation within the groups from T0 to T4 and no statistically significant changes were noted (P>0.05).

	WL group	QLF group
Mean	54.5%	40.3%
95% Confidence Interval	187.9% to -79.0%	146.9% to -66.4%
SE	65.9	52.7

Table 8.5: Adjusted mean percentage change in ΔQ

The difference in the adjusted means between the QLF and WL groups was 14.2 (SE 84.6) with a wide 95% confidence interval of -185.5 to 157.1 (P>0.05). Additionally, the test of the fixed effect of the intervention showed no statistically significant difference between the QLF and WL groups (P=0.87).

Participants were seen at 6-8 weekly intervals for the four appointments when OHR was provided. An assumption was made that, unlike ΔR30, changes in ΔF would occur linearly over time with the four visits of OHR. Thus, an assessment was required to ensure any variation in participants' duration in the study did not lead to differences in the potential development of demineralisation. The mean duration of the participants in the study from T0 to T4 was 163 days. The SD was low in relation to the mean at 16 days, indicating there was limited variation between the subjects.

8.3 Plaque data

The assessment of plaque accumulation was measured by ΔR30 on QLF images. On assessing the groups in terms of their baseline risk of demineralisation, wide variations in the mean ΔR30 values were noted. However, there were no statistically significant differences

detected between the HR and LR individuals in terms of their baseline R30 values (P=0.15, t-test).

Figure 8.6 demonstrates the mean ΔR30 scores for the participants at each of the visits in the stratified groups. As noted, there was a reduction in all of the patient groups as the study progressed. The change in mean ΔR30 was greatest in the HR participants who were shown QLF images. These individuals had a reduction of 80% from baseline to T4. The HR participants who were shown the WL images had a 57% reduction. Conversely, the opposite findings were observed for the LR participants, whereby those who were shown the QLF images had a reduction of 60% whereas the individuals being shown the WL images had a slightly greater mean ΔR30 reduction of 67%. However, due to the nature of the study, these results were based on groups of very low sample sizes and thus the findings should be viewed with caution.
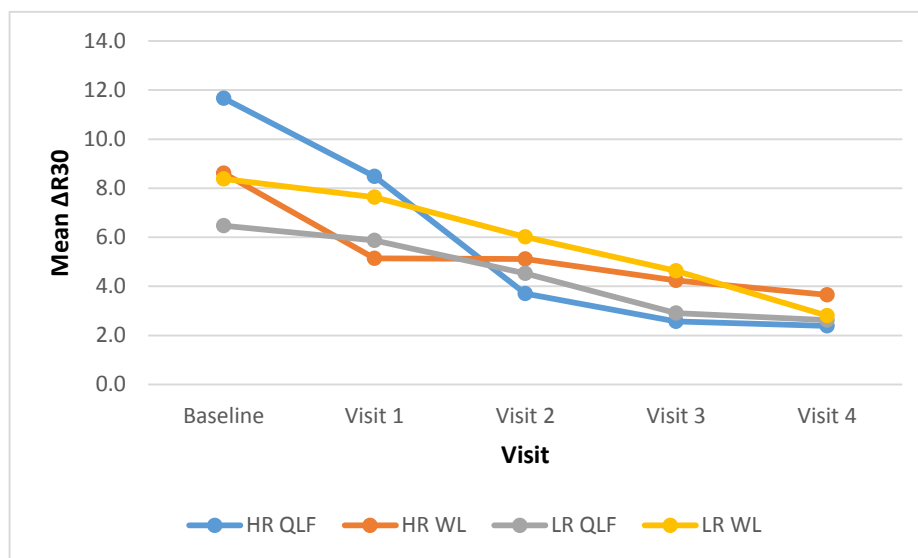
Figure 8.6: Mean ΔR30 level for the participants in their stratified subgroups

A repeated measures of analysis of variance was conducted for the overall mean ΔR30 for the participants at T1 to T4 using the baseline visit and the demineralisation risk (HR or LR) as covariates. This assessment, accounting for demineralisation risk, allowed the individuals to be analysed in the WL and QLF groups (Figure 8.7). The analysis found that there was a reduction in the mean ΔR30 values over the four visits as the study progressed, although this was not statistically significant (P=0.054). The QLF participants appeared to have a greater reduction in mean ΔR30 from baseline to T4, yet again the difference between WL and QLF participants was not significant (P=0.120).

A reduction in ΔR30 was additionally noted between baseline, T0, and Visit 1, T1, when no intervention was provided. This was statistically significant for all participants (P=0.016, paired t-test). This may be due to the Hawthorne effect in that patients were aware they were being assessed as part of a clinical trial. Figure 8.8 highlights an example of the QLF images of a participant at T0 and T4, clearly indicating the improvement in plaque control following 4 sessions of OHR.
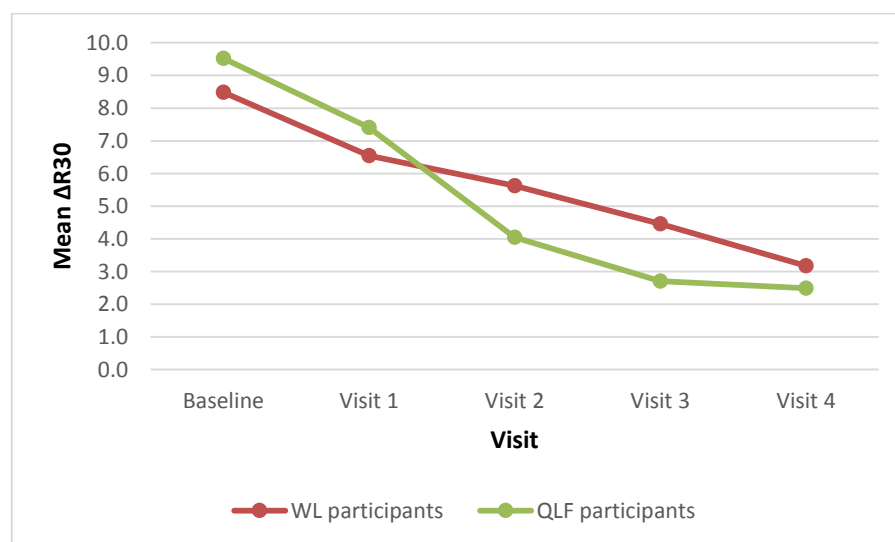
Figure 8.7: Mean ΔR30 level for the participants over the course of the study

Figure 8.8: QLF images demonstrating the difference in plaque accumulation of a participant at T0 and T4. Upper images taken at T0 and lower images taken at T4.

The primary outcome of the study with regards to levels of plaque accumulation observed on the QLF images was the tooth level data. The unadjusted mean percentage change in ΔR30 from T0-T4 based on the participants baseline risk of demineralisation was -57.3 (SD 102.2) and -44.4 (SD 161.5) in the HR and LR groups respectively. Accounting for clustering within participants, the adjusted mean percentage change in ΔR30 (Table 8.6), indicated that there were no statistically significant differences between the groups (P=0.372).

	High risk	Low risk
Mean	-56.3%	-41.6%
95% Confidence Interval	-33.3% to -79.4%	-18.0% to -65.2%
SE	11.2	11.5

Table 8.6: Mean ΔR30 level of the participants based on demineralisation risk

In the QLF and WL groups the unadjusted percentage change was -53.5% (SD 119%) and -48.4% (SD 148.8%) respectively. This demonstrates a definite reduction in the ΔR30,

however the standard deviation values were high. The adjusted mean percentage change in ΔR30, accounting for clustering within participants and including the risk of demineralisation as a factor within the analysis, was -49.5 (SE 11.1, df 28.6) and -48.4 (SE 11.4, df 26.9) in the QLF and WL groups respectively (Table 8.7). The confidence intervals indicate that the mean reductions noted were significantly lower in both groups at T4 than at T0 ($P<0.05$). Thus indicating that the mean ΔR30 levels for the participants reduced over the course of the study as a result of the OHR being given. This was the case for both groups, regardless of their group allocation.

	WL group	QLF group
Mean	-48.4%	-49.5%
95% Confidence Interval	-25.1% to -71.8%	-26.3% to -72.7%
SE	11.4	11.1

Table 8.7: Adjusted mean percentage change in ΔR30

The type 3 test of the fixed effect of the intervention indicated there was no statistically significant difference between the QLF and WL groups ($P=0.95$).

8.4 Level of demineralisation visible on WL images

The number of teeth observed with demineralisation present was consistently much greater on the QLF image assessment than on the WL images (Table 8.8), suggesting that the QLF software is a more sensitive detection tool.

	Appointment				
	T0	T1	T2	T3	T4
QLF Image	41	35	40	46	45
WL Image	25	23	25	24	26

Table 8.8: Number of teeth with areas of demineralisation noted on QLF and WL images

The reduction in the number of teeth with demineralisation at T1 in comparison to baseline (T0) may be due to improved oral hygiene control. There was a statistically significant reduction in the plaque levels for both groups. This could have led to remineralisation of any early areas of demineralisation that were present.

ROC curves were used to assess the level of demineralisation measured on QLF images and that could be visualised on WL images. There were 227 areas of demineralisation noted on the QLF images. All of these areas of demineralisation were included in the assessment (Figure 8.9).
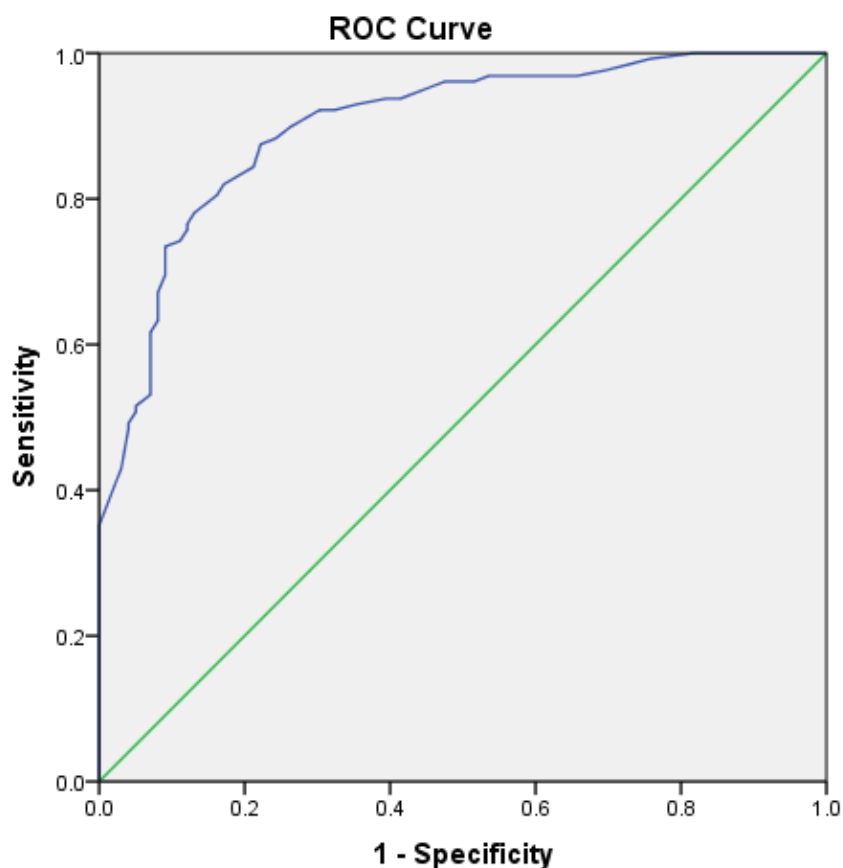
Figure 8.9: ROC of demineralisation assessed on WL and QLF images

A maximum combined sensitivity and specificity of 1.65 was noted at a level of demineralisation of ΔF 7.25. The area under the curve was 0.9 (SE 0.02, 95% CI 0.86-0.94). Thus, the level that one is likely to first visualise a lesion under WL conditions is at a ΔF of 7.25, with a narrow 95% confidence interval. Enamel mineral loss lower than this will only be visible on QLF images, highlighting the greater sensitivity of such an assessment in clinical practice. Figure 8.10 highlights areas of demineralisation on the upper left lateral incisor, upper left canine and lower left canine that are visible on both QLF and WL images. The area of demineralisation on the lower left canine, which is clearly visible on both the WL and QLF image assessment, had a ΔF of 9.

Figure 8.10: WL and QLF images showing demineralisation

8.5 Reliability assessments

8.5.1 QLF Images

The QLF images were analysed by the main assessor and 3 additional examiners who had previous experience in the software and in analysing experimental data. QLF images from 7 patients were used and the assessors were given a questionnaire (Appendix 14.8) outlining which specific teeth should be assessed. There were 12 teeth and 15 teeth assessed for demineralisation and plaque data respectively. The data obtained were continuous, thus an intraclass correlation coefficient (ICC) was used as a measure of inter-examiner reliability. The results (Table 8.9) indicate strong levels of agreement for assessing demineralisation, with ICC values of 0.994, 0.816 and 0.914 noted for ΔF, ΔF Max and ΔQ respectively. The inter-examiner agreement for the assessment of plaque accumulation, measured by $\Delta R30$ also indicated a strong level of agreement with an ICC 0.998.

To measure the intra-examiner reliability of the demineralisation and plaque assessments, the main assessor examined the same images, in an alternative random order, on a second occasion two weeks later. All of the data were noted to have strong levels of agreement (Table 8.9). The outcome measures, ΔF and $\Delta R30$, had ICC scores of 0.988 and 1.0 respectively.

	Inter-examiner reliability assessments	
	ICC	95% Confidence Interval
ΔF	0.994	0.986-0.998
ΔFMax	0.816	0.632-0.934
ΔQ	0.914	0.812-0.971
ΔR30	0.998	0.996-0.999
	Intra-examiner reliability assessments	
	ICC	95% Confidence Interval
ΔF	0.988	0.960-0.996
ΔFMax	0.924	0.766-0.977
ΔQ	0.945	0.827-0.984
ΔR30	1	0.99-1.0

Table 8.9: Inter- and Intra-examiner reliability assessment of the QLF images

8.5.2 WL images

In a similar manner, using a questionnaire to record the data (Appendix 14.8), seven WL images from 7 patients were assessed by the main assessor, examiner 1, and 3 additional examiners to determine the inter- and intra-reliability of assessing demineralisation on WL images. The categorical data, analysed using kappa statistic, demonstrated that the inter-examiner agreement ranged from 0.504 to 0.785 (Table 8.10). The intra-examiner assessment

of examiner 1, which was conducted in a similar manner as the QLF assessment after a two week interval, demonstrated a kappa score of 1.0.

Examiner	1	2	3	4
1	1.0	0.636	0.654	0.577
2	-	-	0.504	0.685
3	-	-	-	0.785
4	-	-	-	-

Table 8.10: Inter-examiner reliability assessment on the WL images

8.6 Sensitivity and specificity assessments

The WL and QLF images were assessed to determine the ability of the examiners to correctly identify the presence and absence of demineralisation. This was undertaken in addition to the ROC analysis primarily to ascertain the sensitivity of the WLF image assessment. Seven WL images and their corresponding QLF images were assessed for the presence of demineralisation by three examiners. The images (Appendix 14.9), were shown in a random order and the examiners were given proformas with photographs to mark the areas of demineralisation that they could observe. Their results were compared to an additional main assessor's analysis, which was assumed to be the gold standard. The main assessor noted 16 lesions on the QLF images, of which 9 could be identified on WL, giving the WL images a sensitivity of 0.56. The specificity of demineralisation detection by the main assessor on the WL images was 1.0.

The results (Table 8.11), demonstrate that the sensivity of the WL images was moderately poor. Examiner C correctly identified the same number of lesions as the gold standard with a sensitivity of 0.56. Examiner A and B had lower sensitivity scores of 0.31, each missing 4 lesions. The specificity of WL image assessment was higher, ranging from 0.92-1.0 with majority of sound images being correctly identified as such. Examiner A and C incorrectly diagnosed 2 and 4 additional areas as demineralisation respectively. The sources of error were incorrectly noting the presence of staining (33%), light reflection (50%) and composite to be demineralisation (17%).

The sensitivity and specificity of the QLF images was higher. The sensitivity scores were 0.75 and 0.81 with 4 and 3 lesions being missed respectively. Additionally, the specificity of QLF images was higher at 0.94-1.0. Examiner B and C incorrectly diagnosed 3 additional lesions, noting the appearance of staining to be demineralisation.

	Examiner A	Examiner B	Examiner C
WL Image Sensitivity	0.31	0.31	0.56
QLF Image Sensitivity	0.75	0.81	0.75
WL Image Specificity	0.96	1.0	0.92
QLF Image Specificity	1.0	0.94	0.94

Table 8.11: The sensitivity and specificity of demineralisation assessment

8.7 Patient Perspective

A debriefing questionnaire (Appendix 14.7) was provided to all participants on completion of the study. The patients were asked to identify whether they were shown WL or QLF images. This question, by asking patients to identify their allocation, was used to determine the validity of their answers. The results (Table 8.12), demonstrate that the patients were very positive about being shown the images. All of the participants found being shown the images helpful (100%), were able to see areas of food accumulation (100%) and tooth damage (100%). There were no problems reported (0%) with being shown the images. Interestingly, 100% of the participants allocated to the QLF group thought it would be useful to be given the OHR the whole way through treatment compared to 81% of the WL group, with an odds ratio of 2.3 (95% CI: 1.5-3.5) indicating that this opinion of the participants is statistically significant ($P<0.05$).

	All	WL group	QLF group
Number of participants	33	16	17
Reported having problems with the photographs	0%	0%	0%
Reported the photographs were helpful	100%	100%	100%
Reported tooth-brushing improved	100%	100%	100%
Reported able to see food accumulation	100%	100%	100%
Reported able to see tooth damage	100%	100%	100%
Reported it would be useful to be shown images for the whole duration of treatment	91%	81%	100%

Table 8.12: Patient perspectives of OHR with QLF-D[TM] images

9.0 DISCUSSION

9.1 Summary of the main findings

1. OHR provided at four consecutive routine orthodontic adjust appointments using WL or QLF images as visual aids does not significantly reduce the development of demineralisation.

2. OHR resulted in a reduction in plaque accumulation, assessed on the QLF images, from baseline to T4. This reduction was noted in all study participants, regardless of their allocation to the WL or QLF groups.

3. There was no advantage in terms of demineralisation or plaque accumulation of being given OHR using the QLF images as visual aids rather than the WL images.

4. The QLF images have a greater sensitivity, allowing subclinical lesions of demineralisation to be detected. The level of demineralisation that can first be viewed under conventional WL conditions is ΔF 7.25.

5. The WL and QLF image assessment displayed high levels of inter- and intra-examiner reliability.

6. The patients' perspectives of the use of both the WL and QLF images, as visual aids for OHR, were positive. This suggests that the QLF-D^{TM} Biluminator may be a suitable tool that could be used to supplement routine oral hygiene control measures in the orthodontic setting.

9.1.1 The relationship of OHR and demineralisation

Over the course of the study, there was a slight non-significant improvement in demineralisation in both the WL and QLF groups with an adjusted mean percentage change in ΔF of -13.3% (95% CI; -37.4 to 10.8%) and -21.8% (95% CI; -45.5 to 1.8%) respectively.

T0 was a time point in the middle of a course of upper and lower fixed appliance treatment rather than at the commencement of treatment. It is possible that demineralisation present at T0 may have been irreversible with limited potential for improvement. This would have led to any intervention, by means of the OHR, having minimal effect on improving the ΔF values. Mattousch et al. (2007) conducted a prospective longitudinal study using QLF-D^{TM} on 51 patients who had completed fixed orthodontic treatment. The median ΔF of lesions at debond was 8.5 (Quartiles 6.6%; 11.9%). In the two year post-treatment period assessed, 39% of lesions showed an improvement. There was a statistically significant improvement in ΔF within the first 6 months, however no further improvement was achieved after this. This suggests that lesions with a median ΔF 8.5 do have a potential for improvement, particularly immediately following debond. In this study, the median ΔF at baseline was 8.7 (Quartiles 6.2%; 11.0%), indicating similar findings may be accomplishable.

At a patient level, four individuals showed an improvement in the number of areas of demineralisation present, 3 of which were allocated to the QLF group and 1 to the WL group. In addition, 5 lesions underwent remineralisation so that no mineral loss was detectable on QLF images at T4. The teeth involved were the upper right central incisor, lower right canine and the lower right lateral incisor. The mean ΔF of the lesions which were fully remineralised was ΔF 6.20 (SD 0.48). This was slightly lower than Mattousch et al. (2007) had reported, suggesting the lesions in this study had a lower potential for remineralisation.

Although the number of patients that had remineralisation was minimal, as the participants were undergoing active fixed orthodontic appliance treatment, there is an increased risk of developing new areas of demineralisation during the trial's duration, T0-T4, rather than find

any improvements in ΔF. This is due to the ongoing risk factor of the patients still having active orthodontic treatment. Thus, the likelihood of gaining improvements in ΔF, as seen in the debond study by Mattousch et al. (2007) is limited. Hence, it may be more important to draw attention to the 21 individuals who did not develop additional lesions. Reported prevalence rates of demineralisation vary in the literature from 2-96% (Gorelick et al. 1982; Mizrahi, 1982; Mitchell, 1992; Ogaard, 1989). This variance is due to differences in the sensitivity of the assessment tool being used. Julien et al. (2013) assessed pre and post-treatment digital images and found 23.4% of 885 patients developed at least 1 lesion during fixed orthodontic treatment. Khalef (2014) found 42% of 45 patients developed demineralisation in a cross-sectional study. However, the post-treatment assessment was undertaken chairside whereas the pre-treatment assessment was made on photographs, which could have led to bias due to differences in the diagnostic ability of the methods. In comparison, using QLF assessment, a more sensitive tool, Al Maaitah et al. (2011) found 71.1% patients had 1 to 12 lesions following completion of fixed orthodontic treatment.

At T4, there were 4 more teeth with demineralisation present than at T0, however only 1 participant who did not have any evidence of demineralisation at baseline developed a lesion. At T4, 54.5% of patients had demineralisation present. This is a lower rate than observed by Al Maaitah et al. (2011). Although as the brackets are still in place, there is a risk that more lesions are indeed present that will not be fully detectable until removal of the appliances. Nevertheless, one would expect the number of individuals affected by demineralisation to increase with ongoing treatment duration. Lovrov et al. (2007) found 24.9% of teeth developed demineralisation or developed additional lesions in a retrospective study assessing 53 patients who had undergone fixed orthodontic appliance treatment with a mean duration of 14.9 years ±2.3 years. Thus, although the present study failed to demonstrate a significant

improvement in demineralisation, the OHR may have improved the standard of oral hygiene in such a way as to prevent the formation of additional lesions.

The most commonly affected teeth using QLF assessment were the maxillary central incisors (24.6%) and maxillary lateral incisors (22.8%). On the WL assessment, the most commonly affected teeth were the maxillary central incisors (32.1%), maxillary lateral incisors (17.9%) and mandibular canines (17.9%). It is slightly unusual for the maxillary central incisor to be affected to such a degree, which suggests there may have been difficulties in the diagnosing demineralisation more posteriorly on the standardised images resulting in a falsely elevated proportion of central incisors being affected in relation to the other teeth. However, the overall results are similar to other studies. Stecksen-Blicks (2007) found the maxillary lateral incisors were the most commonly affected tooth in their RCT comparing the application of a fluoridated varnish against a placebo varnish in the prevention of demineralisation using digital image assessment. The second most commonly affected tooth in their study was the maxillary cuspid and the maxillary central incisor in the fluoride and placebo varnish group respectively. The authors suggest that the maxillary lateral incisor may be more affected due to its frequently crowded position palatally at baseline which would lead to greater plaque levels and thus be at a higher risk of demineralisation. Maini (2011) found a weak inverse relationship between plaque accumulation, as assessed using the Toothcare[TM] device and labial segment crowding. This was a prospective observational cohort study assessing plaque accumulation and its association with labial segment crowding from the commencement of fixed appliances until the anterior teeth were aligned. However, in the present study, the pre-treatment malocclusion was not assessed, thus no inferences can be made that the degree of crowding affected the potential for improvements in plaque and demineralisation to be achieved.

Lovrov et al. (2007) assessed the relationship between oral hygiene, fluoride use and enamel demineralisation during fixed orthodontic treatment. Oral hygiene was scored on the frequency of brushing and whether interdental cleaning was conducted with the use of mini-brushes or dental floss. Fluoride use was scored on fluoridated table salt, fluoride tablets, toothpaste, gel and mouthwash use. A lower incidence of demineralisation was noted with increased frequency of brushing and fluoride exposure, reinforcing the importance of oral hygiene measures in prevention. This is supported by other studies, with Khalef (2014) finding poor oral hygiene was the highest risk factor for developing demineralisation with a RR of 8.55.

9.1.2 The relationship of OHR and plaque accumulation

Studies on OHR during orthodontics tend to focus on measures of periodontal health, such as bleeding on probing, gingival indices and plaque indices. A systematic review (Gray and McIntyre, 2008) found oral health promotion during fixed orthodontic treatment led to short term improvements in plaque levels and gingival health in 4 of the 6 studies included. These studies have largely used ordinal indices which may lack precision. In this study, plaque accumulation was assessed on the QLF images as $\Delta R30$. This is advantageous, as having a quantitative score may increase the validity of the true effect of the intervention. A significant reduction in the adjusted mean percentage change $\Delta R30$ at tooth level was found in both groups from T0 to T4, of -48.4 (95% CI; -25.1 to -71.8) and -49.5% (95% CI; -26.3 to -72.7%) in the WL and QLF groups respectively. Additionally, there was a reduction in the mean $\Delta R30$ scores of the participants in both groups as the study progressed. This was

initially statistically significant (P=0.034), however when the stratification process was accounted for in the analysis the findings just failed to reach significance (P=0.054).

The improvements noted in ΔR30 may be partly due to the patients being involved in a clinical trial. The statistically significant mean reduction in ΔR30 (P=0.016) of all the participants between T0-T1, a period when no intervention was provided, suggests this may be a contributory factor. However, the continued trend for reduction in ΔR30 scores in the subsequent visits (T1-T4) highlights that the overall result is unlikely to be due to this factor alone.

It is paramount that patients have adequate levels of oral hygiene to prevent caries and periodontal disease during orthodontic treatment. Hobson and Clark (1998) express it is an obligation of the treating clinician to ensure patients are advised about the importance of adequate plaque control and methods to ensure this is achieved. Additionally, it is their obligation to monitor the effectiveness of patient's oral hygiene throughout the course of treatment. If sufficient levels of oral hygiene are not being maintained to support treatment, the appliances should be removed in order to prevent progressing demineralisation and periodontal disease. A survey was distributed to 1038 UK orthodontists to determine the oral hygiene advice routinely given to patients (Hobson and Clark, 1998). There was a 46% response rate, with the results indicating that the majority of orthodontists routinely provide instruction on tooth-brushing, disclosing tablets and floss in addition to dietary advice (Table 9.1).

Option	Use advised (%)	Not advised (%)
Tooth-brushing	100	0
Floss	22	78.0
Disclosing tablets	84.1	15.9
Dietary advice	89.5	10.5
Chlorhexidine mouthwash	41.9	58.1
Fluoride rinse	73.6	26.4
Other methods	20.3	78.7

Table 9.13: Oral hygiene advice provided by orthodontists, reproduced from Hobson and Clark (1998)

Many oral health promotion techniques have been proposed during orthodontics, including the use of a specially made videotape (Lees and Rock, 2000), disclosing agents for patients' to self-assess the effectiveness of their plaque control (Boyd, 1983), the provision of regular report cards with written feedback (Richter and Nanda, 1998), a personalised 40-minute oral health counselling session (Lalic et al. 2012), rewards such as coupons for ice cream sundaes for clinical compliance (Richter and Nanda, 1998) and weekly text message oral hygiene reminders (Eppright et al. 2014). Additionally written instructions are often given alongside other techniques, although the former have been shown to be the least effective method of improving plaque scores (Lees and Rock, 2000).

This study demonstrated that regular verbal OHR with WL and QLF images as visual aids can be a useful technique in improving plaque control. Marini et al. (2014) found similar findings. In their study, 60 patients undergoing fixed orthodontic appliance treatment were randomly allocated to receiving repeated OHI and motivational reinforcement at six 4-weekly visits or just at 1 visit. Additionally the participants were randomly allocated to using an electric or manual toothbrush. The plaque coverage scores, graded using the modified Quigley-Hein index, were assessed at each visit by a blinded examiner, and demonstrated a statistically significant reduction with repeated OHI and motivation, regardless of the type of toothbrush allocation. This highlights that active reminder systems should be in place to reinforce the importance of adequate standards of oral hygiene throughout treatment. Maini (2011) observed that the plaque levels in 13 adolescents having upper and lower fixed appliances demonstrated large variability over time and no consistent trend was observed for plaque accumulation to reduce as labial crowding was relieved during the early alignment stages of treatment. The present study showed that plaque levels consistently reduced, highlighting the benefit of the OHR intervention that was being given.

9.1.3 OHR using the QLF images compared to the WL images

Whilst numerically there appeared to be an advantage in terms of demineralisation and plaque accumulation of being given OHR using the QLF images rather than the WL images, this was not statistically significant. QLF images are advantageous, particularly with regards to plaque accumulation, as deposits can be visualised more easily than on WL images (Figure 9.1). However, as not all of the plaque present will fluoresce, this may lead to a slight underestimation of the amount present in comparison to using direct disclosing techniques (van der Veen et al. 2006).
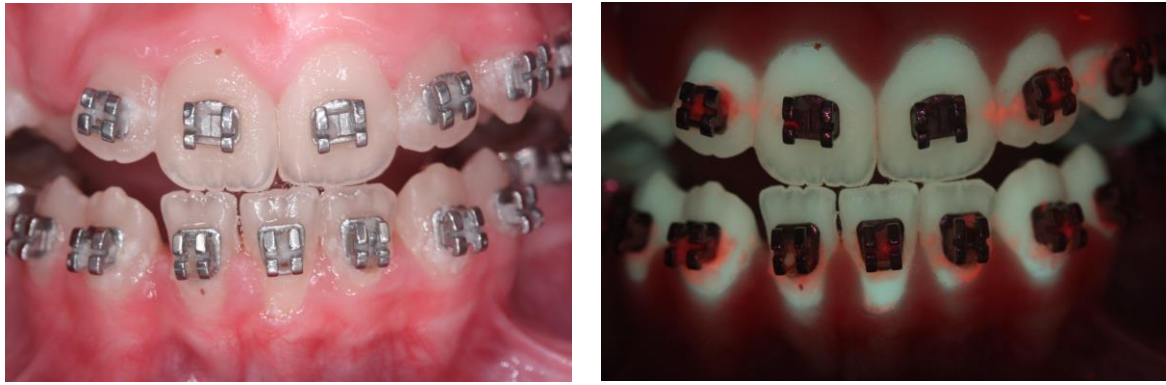
Figure 9.1: WL and QLF images taken of one of the participants for plaque assessment

A possible factor which may have contributed to no statistical difference being detected relates to patient motivation. Ericson et al. (2012) conducted a cross-sectional study and found that adolescents with more negative perceptions, attitudes and behaviours to oral health had poorer oral hygiene with higher plaque and gingivitis scores. Although it is important that patients are adequately informed, unless they display sufficient levels of motivation, the specific method used during the OHR session will be largely ineffective and will not necessarily result in reduced demineralisation and periodontal disease. Hadler-Olsen et al. (2012) assessed patient compliance following oral hygiene instructions using a questionnaire and found a relationship between the level of reported compliance and the number of areas of demineralisation that had developed during fixed orthodontic treatment, although this relationship failed to reach statistical significance.

It may be that patients do not fully comprehend the potential risks that may result from poorer oral hygiene and dietary control. Peng et al. (2014) demonstrated a significantly greater improvement in plaque and gingival indices in patients who were shown images of the severe potential consequences of plaque deposits compared to a group who were only provided with

routine OHI. This suggests that greater patient awareness of the risks and hence the importance of plaque control, improved their motivation, which led to better oral hygiene. In addition to motivation, self-application of the technique is important to ensure patients are aware of the level that they should aim for. A short duration study by Ay et al. (2007) assessed different oral hygiene motivation methods including verbal information with model demonstration, verbal communication with catalogue illustration and the former methods with patient self-application under the supervision of the treating clinician. The group who had verbal OHI with catalogue illustration alongside self-application had significantly lower plaque scores at 4 weeks. Self-application was not assessed in the current study as some of the individuals displayed excellent levels of plaque control throughout. Although it is likely that some of the participants would have benefitted from such a technique during the OHR process, it would have led to bias if this had been conducted on a selective basis.

It is apparent in the literature that repetition and reinforcement of dental health education instructions are key factors to improving oral hygiene performance long-term (Emler et al. 1980). However, it is possible that behavioural management needs additional focus (Hobson and Clark, 1998). Interestingly, one of the intervention groups in the study by Acharya et al. (2011) involved taking plaque samples from participants and showing the patients the live motile bacteria present in their own plaque using a phase contrast microscope. The authors found this, alongside conventional plaque disclosure and OHI was more effective than conventional plaque disclosure alone. They advocated this had a long-lasting effect on plaque levels, which would reduce the need for conducting regular OHR. However, only a 6 month period was assessed. Thus, any inferences that the single interventional input could maintain the improvements noted in oral hygiene, avoiding the need of regular reinforcement for a full course of orthodontic treatment are unsubstantiated.

9.1.4 The sensitivity and specificity of the QLF images

The main advantage of the QLF-D^{TM} device is that quantitative scores are produced, which allow precise monitoring of plaque coverage and demineralisation. Additionally, QLF has an ability to detect subclinical lesions (Pretty et al. 2003; Boersma et al. 2005; Thomas, 2010). This is of great benefit to clinicians in reinforcing oral hygiene and, if appropriate, initiating remineralisation therapies. ROC curves were used to determine that a maximum combined sensitivity and specificity of 1.65 was noted at a level of demineralisation of ΔF 7.25, indicating that this is the level demineralisation will become apparent using direct visual assessment. Boersma et al. (2005) found the mean fluorescence loss of lesions noted with direct vision was greater than 15% and those with QLF was 12.6%, indicating the results of this study are more sensitive.

The ability of QLF to detect more demineralisation was supported by the sensitivity assessments which demonstrated higher scores of 0.75-0.81 and 0.31-0.56 for the QLF and WL groups respectively. In contrast, the QLF and WL images had similar specificity scores. On the WL images, staining, light reflection and composite were incorrectly diagnosed as demineralisation. The incorrect diagnosis of light reflection as demineralisation is of particular concern as a large number of studies in the literature use digital images for demineralisation assessment and may suffer from this source of error. On the QLF images, staining was incorrectly diagnosed as demineralisation. This reinforces the need for a clinical assessment to be undertaken in addition to using visual aids such as digital or QLF images to allow a fully accurate diagnosis.

Although many studies on the use of remineralisation agents, such as CPP-ACP, have demonstrated their benefit in terms of reducing demineralisation (Robertson et al. 2011), others have only shown a weak or negligible effect (Huang et al. 2013). These studies have largely used digital photographs for the assessment. It is likely that by using a more sensitive detection tool, such as QLF, the advantage of using remineralisation agents may become more apparent and hence be advocated more routinely in clinical practice.

9.1.5. The inter- and intra-examiner reliability of the QLF and WL image assessment

The high inter- and intra-examiner ICC scores for ΔF and $\Delta R30$ on the QLF images demonstrate that QLF image assessment is reliable amongst different examiners. This study involved experienced examiners with substantial prior research experience. This is paramount as the reliability study by Pretty et al. (2002) found that a novice who had few hours of previous experience with the QLF analysis software had higher levels of disagreement than more experienced assessors.

The outcomes for the study on which the conclusions were based were ΔF and $\Delta R30$. Although data were additionally collected on ΔF Max and ΔQ. The inter-examiner ICC for ΔQ was 0.914. Thus, it had slightly lower levels of agreement in comparison to results obtained for ΔF and $\Delta R30$, however, the overall reliability was noted as good. In contrast, the ΔQ values of the individual areas of demineralisation in the participants from T0-T4, had very large variations. This led to wide confidence intervals of the ΔQ data for each of the groups with an adjusted mean percentage change of 40.3 (95% CI 146.9% to -66.4%) and 54.5 (95% CI 187.9% to -79.0%) in the QLF and WL groups respectively. This variation is likely attributable to difficulties in outlining the extent of some of the demineralisation

lesions due to the presence of excess composite and the outline of the bracket. In addition, minor residual plaque deposits were occasionally present despite a prophylaxis having been performed which contributed to difficulties in ascertaining the outline of the lesions. Pretty et al. (2002) discuss similar difficulties in outlining lesions lying adjacent to confounding factors such as enamel defects and stain. They report these lesions raise the complexity of image analysis, although suggest that with a rigid instructions in place to ensure appropriate management of these areas, high levels of reliability can be achieved. Such difficulties are particularly relevant in this study, as the demineralisation areas were largely adjacent to the orthodontic brackets, thus the lesion outline required adjustment as there was no sound enamel adjacent on one side. This suspected poorer accuracy in ΔQ was not reflected in the ICC score for ΔQ. A possible explanation for this discrepancy is that the demineralisation lesions that were selected for the reliability assessments were well defined and easy to demarcate. In retrospect, to reduce this selection bias, it would have been advantageous to have randomly selected the demineralisation lesions to be used in the reliability assessment. Indeed, the non-random allocation of the demineralisation lesions used in the QLF and WL image reliability assessment may have affected the results of the other measures, ΔF, ΔF Max and $\Delta R30$, with perhaps a slight over-estimation of the reliability levels obtained.

The inter-examiner reliability of demineralisation assessment on WL images using kappa ranged from 0.504 to 0.785, indicating a slight reduction in reliability in comparison to the QLF image assessment. This confirms that often demineralisation can be difficult to accurately detect in routine clinical conditions. Stecksen-Blicks et al. (2007) had similar scores in their WL reliability measurements of demineralisation. Their intra- and inter-examiner assessment results, using kappa, were 0.77 and 0.69 respectively.

9.1.6. The positive patient perspective of the use of the QLF-D^{TM} images for OHR

The participants' perspectives of having regular OHR with the QLF and WL images as visual aids demonstrated a very positive response. All of the participants allocated to the QLF group felt it would be useful to have the OHR for the complete duration of treatment, compared to 81% of the WL group, with an odds ratio of 2.3 (95% CI: 1.5-3.5). This indicates a statistically significant difference in the participants' opinions between the groups (P<0.05), suggesting QLF images may be more useful as an oral hygiene aid.

Patients often have difficulty localising plaque deposits. WL images are essentially a direct visual assessment, equivalent to assessing one's self looking in the mirror. If patients struggle to detect the white plaque deposits by direct vision, it is understandable how the QLF images, where plaque is demonstrated as bright red areas, may be more helpful. Nevertheless, this did not result in any statistically significant differences being detected between the QLF or WL groups.

Questionnaires were distributed to 122 patients undergoing fixed orthodontic treatment in a study by Berlin-Broner et al. (2012) to ascertain their perspective of the oral hygiene support provided by the 38 treating orthodontists. Patients largely reported that their orthodontists had stressed the importance of toothbrushing at least once (94%), however 48% noted that their orthodontist had not checked they were continuing to attend routine dental examination appointments with their GDP and only 31.5% documented that they were advised to use a daily fluoridated mouthwash. It concluded emphasising the necessity of orthodontists to increase their commitment to providing thorough and comprehensive oral hygiene advice to patients so as to reduce the risk of developing caries and periodontal disease. This supports

Eppright et al. (2014) who advised that active patient reminder systems should be in place during the course of treatment to regularly reinforce the initial OHI given to optimise patient compliance.

Assessing the patients perspectives' of the methods of OHR used in this study is advantageous to gain their opinion. Wright et al. (2010) conducted an RCT whereby patients aged 12 to 16 years of age were randomly allocated to receiving verbal information about fixed appliances or verbal information with the supplementary use of a written leaflet prior to having fixed appliances. The study assessed differences in anxiety, motivation and apprehension by the use of a questionnaire and found that providing written information significantly improved patient motivation rates at the consent appointment, which was approximately 4 weeks later. There was also improved compliance rates; namely lower periodontal scores, better attendance rates and less breakages, although this was not statistically significant. Unfortunately, oral hygiene compliance was not assessed directly and the periodontal assessment was limited to a basic periodontal examination. Generally, investigations focussing on patient motivation levels are infrequently conducted in studies but indeed may be advisable to ascertain which method of OHR is the most effective, since ultimately any improvement in oral hygiene is related to the patients' enthusiasm and motivation.

9.2 Study Limitations

9.2.1 Sample size

The sample size was limited to 33 patients due to the clinical time-constraints of providing detailed OHR at four consecutive appointments. If an excessive number of subjects had been recruited it would not have been possible to see all of the patients at routine archwire adjust appointment intervals of six to eight weeks. There were no data in previous studies on which to base a sample size calculation, thus it was deemed acceptable to recruit at least 30 individuals to ensure adequate clinical time was available for standardised appointment intervals for all participants. However, due to the small sample size, there is a greater risk of a type 2 statistical error, with lack of statistical power to detect a difference.

A sample size calculation, with ΔF as the outcome variable, was undertaken to aid the design of future studies. This study detected a difference of 8% in ΔF between the QLF and WL groups, with a SD of 37 and an average of 2 lesions detected per patient. The intracluster correlation coefficient was 0.185. Using these data and the knowledge that future studies would be designed to only include participants with demineralisation at baseline, 200 individuals would be required per group to detect a difference of 8% with an 80% power and an alpha of 0.05. If the clinically significant effect size was increased to 15%, 58 individuals would be required per group.

9.2.2 Sample

Of the 33 patients, 64% were female. This could be a source of bias, as males have been shown to develop more demineralisation during fixed orthodontic treatment and of a greater severity (Al Maaitah et al. 2011; Boersma et al. 2005; Khalef, 2014). However, it is more

likely representative of the gender differences of individuals seeking orthodontic treatment. Al Maaitah et al. (2011) assessed 230 patients on completion of fixed orthodontic treatment, 65% of which were female.

Of the recruited patients, 16 did not have any areas of demineralisation present at baseline. These individuals were categorised as low risk. The remaining 17 participants had demineralisation at baseline and were categorised as high risk. The patient level changes in demineralisation were conducted on all of the individuals that were recruited. The primary tooth level change assessed was the percentage change in ΔF. Mathematically a percentage change cannot be undertaken when the baseline value is 0, thus this assessment was conducted on the high risk individuals who had demineralisation at baseline. This is unlikely to be a significant source of bias as the number of individuals who were excluded from the assessment who did not have lesions was 7 in the QLF group and 9 in the WL group, which is relatively similar. An additional analysis on demineralisation at tooth level, regarding the mean total ΔF per tooth, was undertaken to include the results of all of the participants to account for this. Furthermore, as mentioned, all of the sample were included in the participant level analysis.

9.2.3 Study duration

Another factor which may have led to the lack of any significant changes being noted in demineralisation, may be that the study was relatively short. An RCT by Eppright et al. (2014), involving the use of a weekly text message being sent to the parents of patients undergoing orthodontic treatment and a control group who did not receive such a text reminder found no difference in the prevalence of demineralisation, measured by direct visual

examination, between the two groups. However, there was a trend in the control group for increasing levels of demineralisation to occur between two and four appointments after baseline. The authors advised that to accurately assess the development of demineralisation with an intervention, longitudinal monitoring should be undertaken for greater than six months. They also found that the significant improvements that were noted in the gingival indices did not appear to influence the development of demineralisation. Although, again this could be due to the short duration of the study.

In this study, the participants were assessed over five visits (T0-T4), held at approximately six weekly intervals. The overall length of involvement in the study was on average 30 weeks, slightly over six months, in comparison to Eppright et al. (2014) where the time frame was 5.44 months. This similarly, may have been insufficient to assess significant differences in the development of new additional lesions.

The five visits assessed were at different stages during treatment depending on the length of time each participant had already been undergoing active treatment. This may have affected the baseline results in that participants who had been in treatment for longer may have had more areas of demineralisation present. Khalef (2014), found that increased treatment duration was correlated with significantly more areas of demineralisation with a RR of 3.65 when treatment length was >36 months compared with <24 months. Although, other studies (Al Maaitah et al. 2011; Boersma et al. 2005) do not support this. It would have been advantageous to assess the impact of OHR throughout the whole active orthodontic treatment. In addition, following the participants after the appliances were removed would have allowed assessment of post-debond changes that may occur. This limitation has been

recognised by other similar short-duration studies (Boyd, 1983). However, such research would be substantially more complex to undertake with associated staffing, clinical time and financial considerations requiring consideration.

9.2.4 Blinding

The allocation was concealed by the use of consecutively numbered, sealed opaque envelopes to reduce selection bias. The OHR was given to all participants by the same clinician. It was not possible to blind the clinician to the treatment allocation, which has the potential to lead to bias. However, the OHR advice was standardised instructions, with the only difference being the areas of focus, which were the plaque and demineralisation areas that could be visualised on either the QLF or WL images. Thus, there should be minimal bias as a result. Similar studies assessing OHR (Ay et al. 2014; Peng et al. 2014), have used the same clinician for standardisation purposes.

9.2.5 Time point of data collection

Participants were seen for OHR at their routine orthodontic adjust appointment which was at six to eight week intervals. Occasionally, patients cancelled or failed to attend their appointment which was out with the control of the study organisers and demonstrates the difficulties with conducting clinical trials. Such individuals were rebooked for the next available session, however assuming that changes in ΔF occur linearly over time, a short delay could have potentially lead to performance bias in that there was a greater time period for demineralisation to develop or improve. The mean duration from T0 to T4 was 163 days and the SD was low in relation to the mean at 16 days, indicating limited variation of the

participants' study duration. This is likely due to the meticulous organisation of the study with imminent rescheduling of such patients.

9.2.6 Data analysis

The mean number of teeth assessed per patient was 18 (SD 3.1) with no statistical difference noted between the WL or QLF groups. The variation was related to the number of teeth present in the arches, in that some individuals had undergone extractions or had hypodontia. It was necessary to exclude teeth that could not be fully assessed. It may have been more appropriate to have completely standardised the process. Bailey et al. (2009) assessed upper and lower incisors, canines and first premolars in their RCT. Other studies have limited the assessment to maxillary anterior teeth (Huang et al. 2013) or maxillary incisors, canines and premolars (Stecksen-Blicks, 2007; Sonesson et al. 2013). In this study, there was no limitation placed on which teeth to assess for demineralisation and plaque coverage. It was possible to assess the first molars and second premolars on the QLF and WL images of some participants, allowing their inclusion. Should these teeth have been excluded it would have allowed the assessment to be more standardised, although it would have reduced the amount of data obtained.

The participants were given a unique identification number on enrolment which was used throughout. Thus, the images were anonymised during the analysis process. However, the images were analysed by the same assessor who provided the OHR, thus there is a risk of recall bias regarding the group of allocation.

Despite the use of customised software for image analysis, there is also a risk of measurement bias as the assessor has to subjectively demarcate the lesion or tooth for QLF assessment (Pretty et al. 2002). This is unlikely to be significant in this study as strict guidelines were in place regarding the assessment of lesions. However, there is also a risk of such subjectivity in direct clinical or digital image assessment. The RCT by Eppright et al. (2014) used the following scale for assessing demineralisation clinically:

1. No visible white spots or surface disruption
2. Visible white spot without surface disruption
3. Visible white spot lesion with roughened surface
4. Visible white spot requiring restoration

Clearly, not only is there similar risks of subjectivity associated with such a scoring system, but there is poorer accuracy with regards to the classification of the severity of the demineralisation present. Histological examination of areas of demineralisation in sacrificed teeth is the most effective method of assessment (Robertson et al. 2007), although clearly this is obviously infeasible in clinical studies. However, QLF has been validated against such lab-based studies, suggesting it is a valid assessment tool. Al-Khateeb et al. (1997) demonstrated a strong correlation between QLF fluorescence changes and TMR observed mineral loss.

The data analysis was standardised by the same assessor conducting all of the image analysis. Intra-examiner reliability assessment of this examiner demonstrated high levels of consistency, suggesting such a source of bias would be limited. In addition, the inter-examiner reliability assessments conducted demonstrated high levels of agreement, as has

been reported in previous studies (Pretty et al. 2002). Although, the present study's scores may be a slightly exaggerated due to the non-random selection of the reliability image assessment process. Pretty et al. (2002) selected 16 demineralisation lesions of varying size and severity to be assessed by 10 examiners using QLF software. This provided a sample with a range of difficulty. Similarly, this was the case in this study with the images that were chosen to be used. However, randomly selecting the images would have reduced any associated bias. Indeed, other studies have randomly selected patients (Stecksen-Blicks, 2007) or images (Huang et al. 2013) for WL image assessment.

9.2.7 Bias associated with the method

Due to the restrictions in the amount of time allocated for each of the participants' routine archwire adjust appointment, the length of time available to conduct the OHR at each of the four consecutive visits was limited. As this was the case for all of the individuals regardless of their treatment allocation, it is unlikely this would have significantly affected the between-group results. However, it could have reduced the impact the OHR had on the plaque accumulation and demineralisation levels of all the participants. It would have been interesting to ascertain if allocating more time to give further detailed OHR instructions affected the results and led to greater improvement. Hobson and Clark (1998) have advocated that it may be more cost-effective for oral hygiene measures to be provided by trained auxiliaries.

A prophylaxis was conducted if required to remove plaque deposits present before the QLF-D^{TM} images were taken for demineralisation assessment. Despite this, occasionally, residual plaque deposits remained or calculus was present that was not removed during the

prophylaxis. This contributed to difficulties visualising demineralisation during QLF image analysis. It may have been advantageous for the prophylaxis to have included including ultrasonic scaling, although there would have been time implications associated with including this.

9.2.8 Performance bias

As in any clinical research study, there is a risk of performance bias when the participants are aware of being assessed. This is highlighted by the statistically significant reduction in $\Delta R30$ noted in both groups from T0 to T1, despite no active intervention being given.

9.2.9 Confounding factors

The participants were randomly allocated to the QLF and WL groups at baseline, stratified for the presence of demineralisation. It is assumed patients with baseline demineralisation present a higher risk of developing additional lesions, which would have the potential to confound the results if not controlled for. Comparing the high risk and low risk groups there was a statistically significant change in the number of lesions from T0-T4 (P=0.001, chi-square test) which confirms the need for the randomisation process to have been stratified on the baseline demineralisation risk. Al Maaitah et al. (2011) found the pre-treatment oral hygiene status and the presence of diseased first molars were related to the number of areas of demineralisation and the severity of demineralisation respectively. There were no statistical differences between the WL and QLF groups in terms of age or gender, which demonstrates the groups were well balanced in terms of these potentially confounding variables.

A potential confounding factor was the variation in oral hygiene practice between the individuals. Some of the individuals routinely brushed their teeth in the waiting room prior to the appointment, which would have led to differences in the plaque accumulation. The time of the day that the appointment was held may also have been a potential factor, in that if the appointment was after lunch, residual food deposits may have been present. This was often the case when patients attended straight from school. However, by not standardising the above, this study allowed an assessment of real-life everyday oral hygiene levels Additionally, the oral hygiene products that were used at home were not controlled. All of the participants were given standardised OHI prior to commencing fixed orthodontic treatment on tooth brushing techniques and the daily use of mouthwash, alongside the frequency and duration of the above. However, compliance levels regarding any products that were being used were not assessed. The RCT by Peng et al. (2014) supplied participants with toothbrushes and toothpaste to standardise this. In addition, wire ligatures were used instead of elastomeric modules to reduce the potential risk of plaque stagnation that can occur from the latter (Garcez et al. 2011).

10.0 CONCLUSION

This study assessed the use of QLF-D^{TM} images as visual aids for OHR in a sample of patients undergoing fixed orthodontic treatment. Data was collected at five consecutive routine adjust appointments, with OHR being provided at three time points. The following conclusions were drawn:

1. The QLF-D^{TM} device is straight-forward and easy to use. The QLF images allow quantitative data to be obtained on demineralisation and plaque coverage. Analysis of the WL and QLF images has high levels of inter- and intra-examiner reliability.

2. Whilst OHR using the QLF-D^{TM} images as visual aids did not reduce the demineralisation over the mean 6 month period of assessment, there was a reduction in plaque noted. This was significant in both the QLF and WL groups.

3. There was no clinical benefit of having OHR with the QLF images than with the WL images, although the patient perspective questionnaires indicated that the QLF images may be more useful. For both groups, the response of being shown the images was positive and no problems were reported.

4. The sensitivity of QLF images in assessing demineralisation is greater. The level of demineralisation that can first be viewed under conventional WL conditions is ΔF 7.25.

11.0 CLINICAL RECOMMENDATIONS

This study demonstrates clinician led OHR is effective. Photographic records are taken regularly throughout treatment to monitor changes in the occlusion, thus they should be readily available. It may be worthwhile for these to be used as direct visual aids to provide regular personalised focused OHR.

Whilst there was no apparent clinical benefit of using QLF images over WL images as oral hygiene aids, the patient perspective suggested that the QLF images may be more useful. It may be advantageous to use a QLF-D^{TM} device instead of a conventional camera during orthodontics. WL clinical photographs, which are needed for patient records can still be taken and the benefits of having access to QLF images can be additionally gained.

12.0 RESEARCH RECOMMENDATIONS

As a result of this study, the recommendations for future studies are:

1. It would be beneficial to conduct a similar study using the QLF and WL images taken with the QLF-D^{TM} Biluminator for OHR with minor modifications being made to the protocol

- Conduct a sample size calculation based on the results of this study and thereby recruit a sufficient number of participants to ensure the study is adequately powered to detect a difference.

- Have the addition of a group who would receive OHI alone, to allow comparisons to be made against the standard of oral hygiene care which is routinely provided.

- Extend the length of the study's duration to incorporate the full course of fixed orthodontic treatment, with the participants being assessed prior to commencing treatment and at debond.

2. In light of recent studies and recommendations regarding regular fluoride application during orthodontic treatment (Benson et al. 2013), the QLF-D^{TM} Biluminator could be used to assess improvements in demineralisation and plaque during RCTs involving such treatment. QLF images have a greater sensitivity in detecting demineralisation, which would allow a more detailed and precise analysis process.

3. Further investigation, by use of an expanded questionnaires or a framework approach, into the opinions of patients regarding their motivation in relation to oral hygiene care and dietary habits. This would enable correlations to be assessed between oral health control, plaque accumulation and demineralisation experience. Additionally, understanding patients' knowledge and attitudes would help determine the direction that future OHR techniques should focus.

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14.0 APPENDICES

14.1 Information sheet for adults

UNIVERSITY OF
LIVERPOOL

V1.2 October 2012

INFORMATION SHEET FOR THE STUDY

The use of QLFD in orthodontics

You are being asked to participate in a research study which is looking at a new way to assess the level of cleanliness of your teeth and any damage present. Before you decide to take part in the study please take 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.

Quantitative Light-induced Fluorescence digital (QLFD^{TM}) is a digital camera which can record images of teeth. It takes a normal photograph and a blue light photograph of the teeth. The blue light enables plaque debris to be seen as fluorescent areas on teeth. It is also able to show enamel damage, which can leave permanent marks on teeth, at an earlier stage than eye sight alone. This camera will help us monitor the health of the teeth and assess the cleanliness and damage to the teeth more accurately.

The investigation will not involve any alteration to the orthodontic treatment apart from a slight extension of the appointment times.

What is the purpose of the study?
We are investigating a method used to assess the level of cleanliness of your teeth and any damage present. We will study the cleanliness of teeth using a digital camera under blue light conditions, which is a recognised technology, called Quantitative Light-induced Fluorescence (QLF), and has been used in many previous clinical trials as well as in dental practice. We will either show you the white light or blue light images taken with the QLFD camera and give tooth brushing advice to determine if seeing these images helps reduce plaque debris build up and reduce any enamel damage.

Has the study been approved?
The project was reviewed by NRES Committee North West- Liverpool Central.

Who is paying for the study?
The University of Liverpool is providing funds for this study.

Who will be conducting the study?
The study is being run by Prof. Susan Higham (Professor of Oral Biology), Dr Norah Flannigan (Senior Clinical Lecturer in Orthodontics) and Cara Miller (Specialist Registrar in Orthodontics).

Why have I been asked to take part?
You have been asked because we are looking for healthy volunteers who are currently having fixed brace treatment.

What will happen if I take part?
The QLFD camera will be used to take normal photographs and blue light photographs of the teeth. This will be repeated at four consecutive appointments. Your teeth will also be given a polish to remove any plaque deposits present, if required. This will lengthen the appointment time by no more than 15 minutes. You will then be shown either the normal or blue light images of your teeth on a screen and given tooth brushing instruction. Photographs will also be taken at your final appointment when your fixed brace is removed.

How long will the study last?
You will be monitored for four consecutive appointments of fixed orthodontic treatment and at the appointment when your fixed brace is removed.

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 of there is a problem on the trial?
You may ask questions at any time, before and during the study. If you wish to make any enquiry subsequently, you may contact, Cara Miller, Orthodontic Department, Liverpool University Dental Hospital, Pembroke Place, Liverpool, L3 5PS.
Email: cara.miller@liverpool.ac.uk

How will the data collected be managed?
All information about you will be processed and analysed by the research staff involved in the study. Data will be stored for ten years. As soon as we have collected the necessary data all information, which identifies you, will be removed and replaced by a code. The person responsible for security and access to your data is Prof Susan Higham, 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.

UNIVERSITY OF
LIVERPOOL

V1.2 October 2012

INFORMATION SHEET FOR THE STUDY

<u>The use of QLFD in orthodontics</u>

Children are being asked to participate in a research study which is looking at a new way to assess the level of cleanliness of teeth. Before deciding to take part in the study, please take 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.

Quantitative Light-induced Fluorescence digital (QLFD^{TM}) is a digital camera which can record images of teeth. It takes a normal photograph and a blue light photograph. The blue light enables plaque debris to be seen as fluorescent areas on teeth. It is also able to show enamel damage, which can leave permanent marks on teeth, at an earlier stage than eye sight alone. The child will either be shown the normal or blue light photographs and be given tooth brushing advice based on these images. This will help us monitor the health of the teeth and assess the cleanliness and damage to the teeth more accurately.

The investigation will not involve any alteration to the orthodontic treatment apart from a slight extension of the appointment times.

What is the purpose of the study?
We are investigating a method used to assess the level of cleanliness of teeth and any damage present. We will study the cleanliness of teeth using a digital camera under blue light conditions, which is a recognised technology, called Quantitative Light-induced Fluorescence (QLF), and has been used in many previous clinical trials as well as in dental practice. We will show the child either the white light or blue light images taken with the QLFD camera and give tooth brushing advice to determine if seeing these images helps reduce plaque debris build up and reduce any enamel damage.

Has the study been approved?
The project was reviewed by NRES Committee North West- Liverpool Central.

Who is paying for the study?
The University of Liverpool is providing funds for this study.

Who will be conducting the study?
The study is being run by Prof Susan Higham (Professor of Oral Biology), Dr Norah Flannigan (Senior Clinical Lecturer in Orthodontics) and Cara Miller (Specialist Registrar in Orthodontics).

Why has my child been asked to take part?
We are looking for healthy volunteers who are currently having fixed brace treatment.

What will happen if my child takes part?
The QLFD camera will be used to take normal photographs and blue light photographs of the teeth. This will be repeated at four consecutive appointments. The child's teeth will also be given a clean if required. This will lengthen the appointment time by no more than 15 minutes. The child will be shown either the normal or blue light images of your teeth on a screen and given tooth brushing instruction. Photographs with the QLFD camera will also be taken at the appointment when your child's fixed brace is removed.

How long will the study last?
You will be monitored for four consecutive appointments of fixed orthodontic treatment and at the appointment when your fixed brace is removed.

What if I do not want my child to take part?
The child's treatment will continue as normal. You should not feel obliged to consent to your child taking part in this study and do not have to give a reason if you do not want to. If 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 on the trial?
You may ask questions at any time, before and during the study. If you wish to make any enquiry subsequently, you may contact, Cara Miller, Orthodontic Department, Liverpool University Dental Hospital, Pembroke Place, Liverpool, L3 5PS.
Email: cara.miller@liverpool.ac.uk

How will the data collected by managed?
All information about your child will be processed and analysed by the research staff involved in the study. Data will be stored for ten years. As soon as we have collected the necessary data all information, which identifies you, will be removed and replaced by a code. The person responsible for security and access to your data is Prof Susan Higham, 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.

14.3 Information sheet for parents

V1.1 October 2012

INFORMATION SHEET FOR UNDER 16s

The use of QLFD in orthodontics

You are being asked to be part of a research project looking at a new way which shows if food is stuck on your teeth or your teeth have any damage. Before you decide please read this information sheet. Please ask us if you anything is not clear or you have any questions.

Quantitative Light-induced Fluorescence digital (QLFD^{TM}) is a digital camera which records a picture of your teeth. This camera takes a normal photograph and a blue light photograph of the teeth. It will help us monitor your the teeth and see how clean they are or if there is any damage. You will be given tooth brushing advice and shown either the normal or blue light photographs. These photographs will show the areas of food stuck on your teeth and help you know where to brush.

The project will not change your brace treatment. It will only make your appointments a few minutes longer.

What is the point of the project?
We are using a Quantitative Light-induced Fluorescence digital (QLFD^{TM}) camera to take normal and blue light photographs of your teeth. We are trying to find the areas where food has not been cleaned away or there is damage to your teeth. We are also trying to find out if showing you the camera photographs is useful for your tooth brushing.

Why have I been asked to take part?
You are the right age and are having fixed brace treatment.

What will happen if I say yes?
At every visit we will take photographs of your teeth and will clean them if required. We will show you either the normal or blue light photographs and give you tooth brushing advice on the areas that need better cleaning.

How long is the project?
It will last for four of your normal brace appointments and at the appointment your brace is removed.

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 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.

14.4 Consent form for adults

UNIVERSITY OF LIVERPOOL

V1.1 October 2012

Patient Identification Number for this trial:

CONSENT FORM

Research project: The use of QLFD in orthodontics

Researcher: Cara Miller

Please initial box

1. I confirm that I have read and understand the information
   sheet dated October 2012 (Version 1.1) 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   Date   Signature
taking consent

14.5 Consent form for parents

UNIVERSITY OF
LIVERPOOL

V1.1 October 2012

Patient Identification Number for this trial:

CONSENT FORM

Research project: The use of QLFD in orthodontics
Researcher: Cara Miller

Please initial box

1. I confirm that I have read and understand the information sheet dated October 2012 (Version 1.1) 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 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 child's records.

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

_____ _____ _____
Parent / Guardian   Date   Signature

_____ _____ _____
Name of Person   Date   Signature
taking consent

14.6 Assent form

V1.1 October 2012
Patient Identification Number for this trial
:

ASSENT FORM FOR UNDER 16s

Research project: The use of QLFD in orthodontics

Researcher: Cara Miller

Please circle YES or NO

1. I have read the information sheet dated October 2012 (V1.1).   YES   NO

2. The project has been explained to me.   YES   NO

3. I have been able to ask questions and have had these answered. YES   NO

4. I understand what the project is about and what I need to do.   YES   NO

5. I understand that I can stop taking part at any time.   YES   NO

6. I am happy to take part in the project.   YES   NO

_____ _____ _____
Name of patient   Date   Signature

_____ _____ _____
Name of Person   Date   Signature
taking assent

14.7 Debriefing questionnaire

DEBRIEFING QUESTIONNAIRE

Research project: The use of QLFD in orthodontics

Researcher: Cara Miller

Please circle answer

1. Which photographs were you shown?

NORMAL PHOTO   BLUE LIGHT PHOTO   NOT SURE

2. Did you have any problems with the additional photographs that were taken?

YES   NO   NOT SURE

3. Were you able to see the areas of food accumulation on the photographs?

YES   NO   NOT SURE

4. Were you able to see the areas of tooth damage on the photographs?

YES   NO   NOT SURE

5. Did you find it helpful to be shown the photographs?

YES   NO   NOT SURE

6. Do you think it would be useful to have the photographs taken the whole way through treatment?

YES   NO   NOT SURE

7. Do you think your tooth brushing improved over the appointments?

YES   NO   NOT SURE

_____   _____   _____
Name of patient   Date   Signature

14.8 Reliability assessment data collection proforma

UNIVERSITY OF
LIVERPOOL

RELIABILITY ASSESSMENT DATA COLLECTION PROFORMA

Research project: The use of QLFD in orthodontics
Researcher: Cara Miller

Examiner number:

White light Image 1:

Assess LR3, LR4, UR3 and UR4 for demineralisation

QLF Image 10:

Assess the plaque accumulation on UR3?

Assess the plaque accumulation on UR2?

Assess the plaque accumulation on LR4?

Assess the plaque accumulation on LR3?

Assess the plaque accumulation on LR2?

QLF Image 11:

Assess the demineralisation on LR3

Assess the plaque accumulation on UR3

White light Image 12:

Assess UL2 and LR3 for demineralisation

QLF Image 13:

Assess the demineralisation on distal surface of UR1

Assess the demineralisation on distal surface of UR1

Assess the plaque accumulation on UR4

QLF Image 14:

Assess the plaque accumulation on LR4

Assess the plaque accumulation on LR3

QLF Image 17:

Assess the plaque accumulation on LR1

Assess the plaque accumulation on LL1

Assess the plaque accumulation on LL2

QLF Image 18:

Assess the plaque accumulation for UR4

Assess the plaque accumulation for UR5

QLF image 20:

Assess the plaque accumulation on UR3

QLF image 21:

Assess the plaque accumulation on UL3

QLF image 22

Assess the demineralisation on UL1

Assess the plaque accumulation for LR1

White light Image 3:

Assess UR3, UR4, UR5, LR3 and LR4 for demineralisation

White light Image 6:

Assess UL2, UL3, UL4 and LL3 for demineralisation

White light Image 7:

Assess UR2, UR1, UL1, UL2, LR1, LR2, LL1 and LL2 for demineralisation

QLF Image 8:

Assess the plaque accumulation for UR3

Assess the plaque accumulation for UR2

Assess the demineralisation on LR3

Assess the demineralisation on LL3

14.9 Sensitivity assessment data A

SENSITIVITY ASSESSEMENT IMAGES

14.9 Sensitivity assessment data B

SENSITIVITY ASSESSMENT IMAGES

14.9 Sensitivity assessment data C

SENSITIVITY ASSESSMENT IMAGES

14.9 Sensitivity assessment data D

SENSITIVITY ASSESSMENT IMAGES
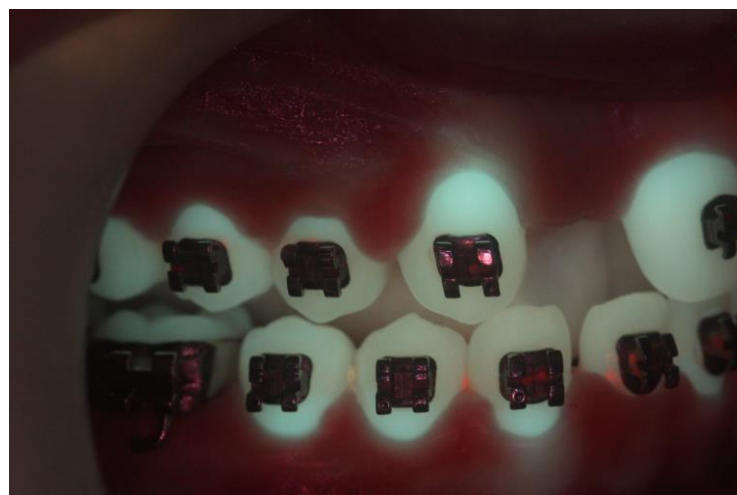
14.9 Sensitivity assessment data E

SENSITIVITY ASSESSMENT IMAGES
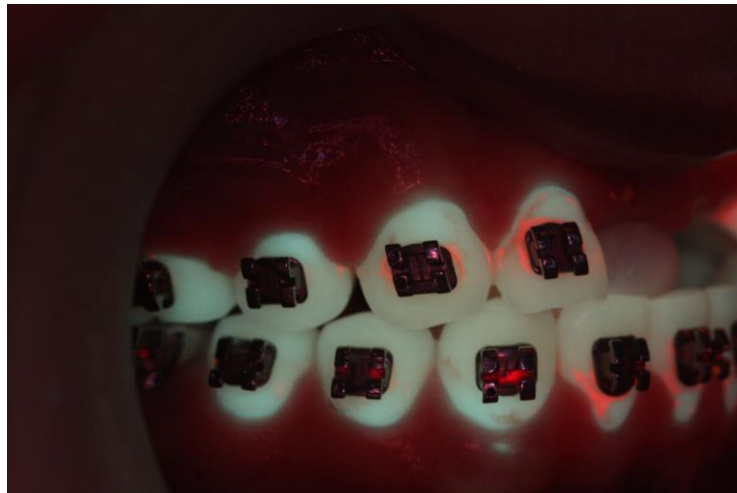
14.10 Mean Delta F results per patient

Subject number	Visit				
	Baseline	Visit 1	Visit 2	Visit 3	Visit 4
1	10.4	9.3	8.0	9.0	9.3
2					
3					
4	8.9	6.4	3.1	7.1	7.4
5	5.6	6.7	6.0	7.0	7.3
6					
7					
8	6.0	5.4	6.0	0.0	0.0
9	20.8	28.0	20.0	19.4	17.3
10					
11	9.6	12.0	10.8	7.5	7.2
12	8.9	10.7	8.3	8.9	9.8
13	6.5	5.3	0.0	0.0	0.0
14	6.5	7.8	7.2	3.4	3.9
15					
16					
17					
18					
19	6.8	7.4	7.4	7.7	6.6
20					
21					
22					
23	5.8	5.4	5.2	0.0	5.7
24	0.0	0.0	0.0	0.0	5.5
25	5.8	7.0	7.6	8.7	5.6
26	11.0	10.0	11.0	7.7	12.0
27					
28	12.4	10.6	8.5	9.4	7.1

29	9.2	10.3	13.5	10.9	8.5
30					
31					
32	8.8	8.3	9.5	7.5	7.5
33	6.9	6.1	6.4	7.0	6.8

14.11 Mean Delta R30 results per patient

Subject number	Visit				
	T0	T1	T2	T3	T4
1	10.4	6.0	4.9	4.5	2.0
2	6.7	3.1	2.6	1.0	0.3
3	4.9	3.9	7.8	2.7	2.0
4	4.4	1.3	1.4	2.4	1.3
5	14.8	8.1	5.2	3.7	1.9
6	4.2	7.7	1.7	3.0	1.6
7	6.1	8.8	3.4	2.4	2.3
8	16.9	15.2	5.4	2.1	4.9
9	12.1	10.3	5.0	3.5	3.1
10	0.2	0.5	0.7	0.3	0.3
11	16.6	5.6	6.5	3.8	2.1
12	17.2	7.3	11.5	12.2	8.9
13	12.5	13.6	6.1	0.9	0.9
14	12.8	13.9	4.6	2.8	3.0
15	6.6	6.4	4.2	6.0	4.0
16	9.9	6.8	5.7	5.1	4.3
17	5.9	10.8	4.1	2.4	1.2
18	23.9	11.2	13.8	8.7	4.4
19	9.4	4.4	7.6	4.0	4.1
20	0.8	7.2	4.3	5.8	0.3
21	3.1	3.7	3.6	2.3	1.4
22	7.8	4.6	3.1	2.2	0.6
23	3.3	3.5	1.2	1.3	0.6
24	8.6	10.7	9.4	4.3	4.5
25	16.9	5.5	1.6	0.4	1.8
26	8.9	12.7	6.2	5.7	8.4
27	14.4	11.8	14.2	7.4	7.8
28	3.5	1.6	1.0	2.2	0.7

29	0.5	1.2	1.4	0.3	0.2
30	4.2	4.1	3.6	3.0	1.8
31	13.5	8.5	3.7	5.5	6.9
33	6.3	4.0	1.8	1.5	1.3
33	10.4	6.6	1.5	4.1	4.3

14.12 ROC Data

Delta F	Sensitivity	1 - Specificity	Specificity	Combined sensitivity and specificity
-1.00	1.00	1.00	0.00	1.00
2.50	1.00	0.90	0.10	1.10
5.05	1.00	0.89	0.11	1.11
5.15	1.00	0.87	0.13	1.13
5.25	1.00	0.86	0.14	1.14
5.35	1.00	0.84	0.16	1.16
5.45	1.00	0.82	0.18	1.18
5.55	0.99	0.76	0.24	1.23
5.65	0.98	0.73	0.27	1.26
5.75	0.98	0.70	0.30	1.28
5.85	0.97	0.66	0.34	1.31
5.95	0.97	0.65	0.35	1.32
6.05	0.97	0.56	0.44	1.41
6.15	0.97	0.54	0.46	1.43
6.25	0.96	0.52	0.48	1.45
6.35	0.96	0.47	0.53	1.49
6.45	0.95	0.45	0.55	1.50
6.55	0.94	0.41	0.59	1.52
6.65	0.94	0.39	0.61	1.54
6.75	0.93	0.35	0.65	1.58
6.85	0.92	0.32	0.68	1.60
6.95	0.92	0.30	0.70	1.62
7.05	0.90	0.26	0.74	1.64
7.15	0.88	0.24	0.76	1.64
7.25	0.88	0.22	0.78	1.65
7.35	0.84	0.21	0.79	1.63
7.45	0.82	0.17	0.83	1.65
7.55	0.80	0.16	0.84	1.64

7.65	0.78	0.13	0.87	1.65
7.75	0.77	0.12	0.88	1.64
7.90	0.76	0.12	0.88	1.64
8.05	0.74	0.11	0.89	1.63
8.15	0.73	0.09	0.91	1.64
8.25	0.71	0.09	0.91	1.62
8.35	0.70	0.09	0.91	1.60
8.45	0.67	0.08	0.92	1.59
8.55	0.66	0.08	0.92	1.58
8.65	0.66	0.08	0.92	1.58
8.80	0.63	0.08	0.92	1.55
8.95	0.62	0.07	0.93	1.55
9.05	0.60	0.07	0.93	1.53
9.15	0.58	0.07	0.93	1.51
9.25	0.56	0.07	0.93	1.49
9.35	0.55	0.07	0.93	1.48
9.45	0.53	0.07	0.93	1.46
9.55	0.52	0.05	0.95	1.47
9.65	0.51	0.05	0.95	1.46
9.75	0.49	0.04	0.96	1.45
9.90	0.48	0.04	0.96	1.44
10.50	0.43	0.03	0.97	1.40
11.50	0.35	0.00	1.00	1.35
12.50	0.26	0.00	1.00	1.26
13.50	0.17	0.00	1.00	1.17
14.50	0.13	0.00	1.00	1.13
15.50	0.13	0.00	1.00	1.13
16.50	0.10	0.00	1.00	1.10
17.50	0.09	0.00	1.00	1.09
18.50	0.06	0.00	1.00	1.06
19.50	0.05	0.00	1.00	1.05

20.50	0.05	0.00	1.00	1.05
29.50	0.04	0.00	1.00	1.04
38.50	0.03	0.00	1.00	1.03
40.50	0.02	0.00	1.00	1.02
44.00	0.02	0.00	1.00	1.02
46.50	0.01	0.00	1.00	1.01
48.00	0.00	0.00	1.00	1.00

RCT Using QLF-D To Assess Demineralisation And Plaque During Orthodontics

#575

UNIVERSITY OF LIVERPOOL

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Background

- Demineralisation during fixed orthodontic appliance treatment affects between 2-96% of patients.[1]
- Plaque control is made more difficult by the presence of orthodontic appliances and demineralisation may develop within 4 weeks of appliance placement.[2]
- It is essential patients have a good level of oral hygiene, minimising plaque during treatment to prevent periodontal disease and caries.[3]
- The Quantitative Light-induced Fluorescence-Digital (QLF-D) device, Figure 1, allows White Light (WL) and Quantitative Light-Induced Fluorescence (QLF) images to be taken.
- On the QLF images, demineralisation is seen as darker due to the reduced fluorescence (Figure 2). Plaque is seen as red due to the autofluorescence of bacterial porphyrins (Figure 3).

Figure1: The QLF-D Device

Figure 2. WL and QLF images taken for demineralisation assessment

Figure 3. WL and QLF images taken for plaque assessment

Aims

- To assess the use of the Quantitative Light-induced Fluorescence-Digital (QLF-D) device as an oral hygiene evaluation tool to detect demineralisation and plaque during orthodontics.

Materials and Methods

- A prospective randomised clinical trial was conducted.
- 33 patients currently undergoing upper and lower fixed orthodontic appliance treatment were randomly allocated to receiving oral hygiene reinforcement (OHR) at four consecutive appointments using the WL or QLF images, as visual aids.
- The standard of oral hygiene was assessed on the QLF images to provide quantitative scoring of demineralisation (ΔF) and plaque coverage ($\Delta R30$) at each appointment (T0-T4).
- A debriefing questionnaire, distributed on completion of the study, was used to ascertain the patients' perspectives of the QLF-D images.

Results

- There were no significant differences in demineralisation (ΔF: $P=0.56$; ΔF Max: $P=0.93$) or plaque accumulation ($\Delta R30$; $P=0.82$) between the WL and QLF groups from T0 to T4.
- There were no significant reductions in ΔF in the WL or the QLF group from T0-T4 ($P>0.05$), however there was a significant reduction in $\Delta R30$ ($P<0.05$).
- All of the participants found being shown the images helpful and were able to see areas of demineralisation and plaque accumulation.
- 100% of the QLF group thought it would be useful to be given OHR for the full duration of orthodontic treatment compared to 81% of the WL group.
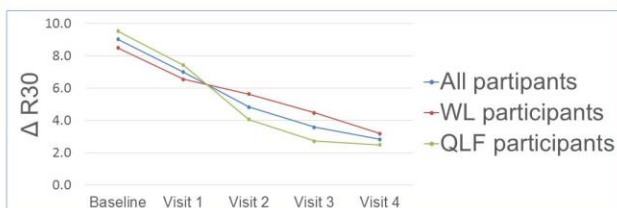

Figure 4: The reduction in plaque coverage between T0 and T4

Discussion

- Whilst there was no statistical benefit in terms of reducing levels of demineralisation or plaque using QLF images over WL images, a greater number of patients allocated to the QLF group felt it would be useful to have this OHR for the whole duration of treatment, suggesting that the QLF images may be more useful.
- It may be advantageous to consider using a QLF-D device instead of a conventional camera during orthodontics. This would allow one to be able to take clinical photos and additionally QLF images, which could be used for OHR.
- The main limitation of the study was that it was not possible to blind the treating clinician, who provided the OHR and undertook the image analysis.

Conclusions

QLF-D can be used to detect and monitor demineralisation and plaque during orthodontics. OHR at consecutive appointments using the WL or QLF images as visual aids is effective in reducing plaque coverage. Whilst there was no apparent benefit in terms of reducing levels of demineralisation or plaque using QLF images over WL images, patients reported that QLF images were more informative.

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14.14 British Orthodontic Conference- oral presentation

UTG ORAL PRESENTATION SESSION EDINBURGH (18th –20th September 2014)

Use of QLF-D to assess demineralisation and plaque during orthodontics

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Objective: To assess the use of Quantitative Light-induced Fluorescence-Digital (QLF-D) to detect demineralisation and plaque coverage during fixed orthodontic treatment.

Design and Setting: A prospective RCT was conducted at Liverpool University Dental Hospital.

Materials and Methods: 33 patients undergoing fixed orthodontic treatment were randomly allocated to receiving oral hygiene reinforcement (R) at four consecutive appointments using white light (WL) or QLF-D images as visual aids. For both groups, change in demineralisation, measured by the degree of fluorescence loss, ΔF, and plaque coverage, $\Delta R30$, were assessed on QLF-D images from the baseline to the final appointment. A questionnaire was used to ascertain the patients' perspectives of the images being used as oral hygiene aids.

Results: There were no significant differences in demineralisation (P=0.56) or plaque accumulation (P=0.82) between the WL and QLF-D groups. There was no significant change in demineralisation over the four visits in either group, however there was a significant reduction in plaque in both groups at a tooth level (P<0.05). At a participant level, there was a trend for a reduction in plaque coverage in both groups (P=0.034), although when the risk of demineralisation was included in the analysis this was no longer significant (P=0.054). 100% of the QLF-D group and 81% of the WL group expressed it would be useful to be given such OHR for the full duration of orthodontic treatment.

Conclusions: OHR using WL or QLF-D images as visual aids was effective in reducing plaque coverage. There was no difference in the level of demineralisation or plaque coverage between the QLF-D and WL groups. Patients reported that the QLF-D images were more informative than WL images.