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An investigation into aspects of resin retained bridge design on aesthetics and oral health related outcomes

Miss Claire Forbes-Haley

A dissertation submitted to the University of Bristol in accordance with the requirements for award of the degree of Master of Research in Bristol Dental School in the Faculty of Health Sciences

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Abstract

Objective: This thesis aims to determine if altering the design of an anterior resin-retained bridge (RRB) by removing the incisal edge metal extension, improves aesthetic outcomes without adversely affecting failure rates.

Methods: The study was carried out in two phases. Phase 1 was a randomised, controlled, two treatment, parallel study in 40 dental patients attending a Dental Hospital with an anterior missing tooth requiring replacement. Phase 1 participants received one of two RRB designs, original or adjusted and completed a quality-of-life questionnaire (OHRQoL) before and after treatment. Photographs of tooth replacement outcomes were taken, and a questionnaire (containing 5 images of each RRB design selected at random and randomly presented) was generated. In phase two aesthetic outcomes of the 2 RRB designs were compared by three participant groups (hypodontia patients, The Public, dental care professionals) who rated the attractiveness of each image on a 5-point likert scale.

Results: For phase 1 there was statistical evidence for an improvement in OHRQoL after treatment, for both participant groups ($p < 0.001$), but not for a difference in improvement in OHRQoL between them. To date, no failures have been reported for either group. When phase 2 data from all three participant groups were combined, the two-outcome analysis demonstrated that there was statistical evidence for a preference for the adjusted RRB ($p < 0.001$), however there were no differences between groups. Females showed a greater preference for the adjusted RRB than males.

Conclusions: A RRB design that reduces the visible incisal metal rim improves aesthetic outcomes and to date shows no adverse effect on bridge survival. OHRQoL scores were improved irrespective of RRB design when patients transfer from removable to fixed prosthesis. The aesthetic questionnaire was used successfully and shows merit as an aesthetic assessment tool for comparison of fixed prosthetic dental treatments.

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Dedication and acknowledgements

I dedicate my thesis to my hard-working colleagues, my patient family, long suffering friends and neglected dog.

With special feelings of gratitude to my clinical mentors, Professor Nicola West, Mr Paul King and Mr Roger Yates, who helped me to become the clinician and researcher I am today.

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I want to acknowledge my husband for all his support, encouragement, and belief in my abilities.

Author's declaration

I declare that the work in this dissertation was carried out in accordance with the requirements of the University's *Regulations and Code of Practice for Research Degree Programmes* and that it has not been submitted for any other academic award. Except where indicated by specific reference in the text, the work is the candidate's own work. Work done in collaboration with, or with the assistance of, others, is indicated as such. Any views expressed in the dissertation are those of the author.

SIGNED: DATE:01/12/2021....

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1. Introduction

Facial appearance has become important within our culture (Cunningham, 1999) and the demand for facial Botox and fillers is rising (Moreno et al., 2018). There has been an even sharper increase with the COVID-19 pandemic due to people seeing themselves more on virtual meetings. This leaves our society critiquing appearance on a daily sometimes hourly basis. With social media someone can now be looking at your image almost every second of the day and how they judge our image can affect our judgment of ourself (Wallace et al., 2012).

A large part of facial appearance is your smile. Studies have shown that those with malocclusion are perceived as being less attractive (Havens et al., 2010). It has also been reported that people who are missing teeth are seen as less attractive and that missing teeth affect their facial appearance negatively (Burrow, 2012). Therefore, people are aware of the impact their smile has on the way they are perceived. Having a “good” smile means different things to different people. This can be seen by the comparisons between North America and Europe as within orthodontics there is an “American” or “European” approach the positioning of anterior teeth (Menezes et al., 2017). Some people prefer whiter teeth, others focus on a wide smile, some like a gap at the front of their teeth while others want any spaces gone (Anderson et al., 2005).

The opinions of others and their positive or negative feedback “likes” or “comment” on social media can impact on a person’s self-worth (Sabik et al., 2020). There is a belief that if you have poor or missing teeth you are seen as unkept and unattractive (Al-Omiri et al., 2009) and there is a link between populations with tooth loss and socio-economic deprivation (Eklund et al., 1994). However, unfortunately acquired tooth loss is not uncommon, and can be a result of poor oral hygiene, trauma, a result of diseases, but can also be inherited or developmental due to genetics and/or treatments such as chemotherapy during tooth development. An example of a genetic condition resulting in missing teeth is hypodontia where individuals are born without adult teeth. The prevalence of hypodontia varies between 2.6-11.3% of the UK population (McSwiney et al., 2017) with England at 4.3-4.4% (Rose, 1966) and frequently the adult teeth that are missing are anterior incisors (Nieminen, 2009). The tooth replacement option of choice for these individuals is usually a Resin Retained Bridge (RRB), the design of which has evolved over time with improvements in dental materials.

This thesis examines how the aesthetic appearance of the current design (original) RRB used at Bristol Dental Hospital, which results in a visible incisal edge metal extension, is perceived by the

Public, patients with hypodontia and Dental Care Professionals as compared to that of an adjusted design in which a metal rim is hidden. Oral health related quality of life (OHRQoL) in participants receiving the RRBs was also determined before and after bridge fit, and RRB failure rates monitored.

1.1 Tooth loss

Over the last 10 years there has been a rise in the proportion of older adults within the UK (Office for National Statistics, 2019). Some of this rise is due to increased life expectancy, and in the UK 1 in 6 individuals are over 65, that is roughly 10 million people. Through estimation it is believed that there will be 5.5 million more elderly in 2040, and 19 million more in 2050, this is almost double the number we had in 2010 (House of Commons Library Research, 2010). Furthermore, if the UK and Europe were ranked by age, we are currently and are likely to continue to be the oldest region in the world (Kulik et al., 2014). An impact of increased life expectancy is greater demand for health care, which is of increasing concern (Spillman et al., 2000). Increased health care costs are strongly associated with the increasing age of the population (Alemayehu et al., 2004).

As, due to increased life expectancy, people live with their teeth for longer they need more dental care, be it check-ups, fillings or tooth replacements. In addition, the number of adults aged 16 years and older, who are edentulous (have no teeth) is falling, adult dental health surveys in the UK showing a steady decline from 37% (1968), to 21% (1988), to 13% (1998) and 6% (2009) (Kelly et al., 2000)(Hill et al., 2013). Similarly, between 1990 and 2010, the global age-standardized prevalence of edentate people decreased from 4.4% to 2.4% (Kassebaum et al., 2014). This decrease in the edentulous population in turn increases the proportion of population who are dentate or partially dentate. Stability and tooth replacement needs for these patients are greater than for patients without teeth (edentulous) and a larger population with teeth also increases the number of complex cases. This need to care for more people with teeth is likely to increase pressures on primary and secondary dental care, therefore there is a need to ensure that treatments are efficient, cost effective, reliable, and meet patient demands.

As people age there is a higher chance, they may require tooth replacement (Boscato et al., 2016), the reasons for this vary with acquired tooth loss being the most common, but trauma, developmental tooth absence and loss due to interventional surgery for malignant/benign tumours of the jaw or soft tissues are also causes.

Acquired tooth loss is when a patient requires removal (extraction) of a tooth they were born with, this is usually due to disease on the tooth which cannot be treated or stabilised. In line with the findings on edentulism, there was an overall reduction in the number of tooth extractions between 1984 and 1999 with 25% fewer teeth extracted per patient and 30% fewer per dentist per week (McCaul et al., 2001). In England research has indicated that the main reasons for tooth extraction are dental caries (37%) and periodontal disease (29%) (Hull et al., 1997), these have also been indicated as the main causes in Wales with figures for dental caries of 59% and periodontal disease of 29.1% (Richards et al., 2005). Prevalence figures specific to acquired tooth loss are lacking, studies focussing on total edentulism. However participants aged 55 and over in the UK Adult Dental Health survey in 2009 had on average only 21 teeth (Hill et al., 2013), and in a more recent study undertaken in UK dental practices participants in the 35-44 age group had 1 missing tooth on average, the number rising steadily with age (National Dental Public Health Team, 2020). However, these figures will include the other forms of tooth loss described below.

Dental trauma is injury to the teeth and/or periodontium (gums, periodontal ligament, alveolar bone) and nearby soft tissues (Andreasen et al., 2018). Some teeth during the trauma are avulsed (knocked out completely) and cannot be reimplanted. Other teeth that suffer trauma may be damaged in a way that reduces their life span such that they eventually require extraction, thus falling into the acquired tooth loss category. It has been reported that as many as 1 in 5 children suffer a traumatic dental injury to their permanent dentition (Kelly et al., 2000). Further, it has been shown that 11.9% of traumatised teeth require extraction (acquired tooth loss through trauma) and 34.7% require endodontic treatment at the first review appointment after the injury (Kallel et al., 2020). Avulsion of permanent teeth accounts for 0.5–3% of all dental injuries (Andreasen et al., 2018) and studies have reported that the prevalence of the root resorption varies between 57-80% in avulsed and replanted teeth (Chappuis et al., 2005). Endodontic treatment is effective in managing inflammatory resorption related to infection in the main root canal but is not successful in handling teeth where replacement root resorption is evident (Zaleckiene et al., 2014); 49.3% of teeth that suffer an avulsion injury are lost at 5 years (Andersson et al., 2017). Overall, in the UK tooth trauma, resulting in immediate or future loss (acquired tooth loss from trauma) occurs in around 17% of the adult population (Marcenes et al., 2002).

Tumours of the jaw and soft tissue come in many forms and many require interventions with potential removal of teeth in the dentoalveolar region (Balaji et al., 2018). A US study reported that 13.13% of all oral lesions biopsied required resection of the jaw and teeth (Dovigi et al., 2016). In the

UK 1-4% of all malignant neoplasms are oral cancers (Johnson et al., 1993), and an ongoing South West of England service evaluation indicates that 64% of patients with Head and Neck Cancer who are undergoing radiotherapy (roughly 500-700 patients a year) require tooth extraction (NHS England, 2021).

1.1.1 Hypodontia

Developmental tooth absence (hypodontia) is a condition characterised by developmentally missing teeth (Bloch-Zupan et al., 2012). In the UK hypodontia can be classified into three categories for missing teeth: Mild (3 or less) Moderate (4-5) Severe (6 or more) (Hobkirk et al., 1980). Teeth can fail to grow due to familial/genetic conditions such as hypodontia or Ectodermal Dysplasia, and at least 181 syndromes are known to be associated with hypodontia (Neville et al., 2019). Illnesses while teeth are developing which require treatments such as chemotherapy or radiotherapy can also lead to hypodontia (D'Dharan et al., 2015).

The prevalence of hypodontia has been reported to vary by country, from 2.6% in Saudi Arabia to 15% in Hungary (Hashem et al., 2013), and varies with gender, within Europe around 4.6% males and 6.3% female are missing one or more teeth (not including third molars) (Polder et al., 2004).

Maxillary laterals are commonly missing in patients with mild hypodontia (Sisman et al., 2007) and are often missing bilaterally (Polder et al., 2004). Therefore, a symmetrical, pattern of missing teeth in the upper anterior region of the mouth is common for hypodontia patients. This data indicates that the prevalence of hypodontia is relatively high in the population, and in these individuals the missing tooth is frequently in the anterior region usually visible when a person smiles.

When the prevalence of acquired tooth loss, tooth loss resulting from oral cancers and hypodontia are combined, and then considered together with an ever-aging population, it is clear that cost effective, reliable ways of replacing teeth are important.

1.2 Consequences of tooth loss

Patients see tooth loss as a negative event and have difficulties in accepting it as it commonly leads to a loss of confidence, limitations in food choice, reduced enjoyment of food, avoidance of laughing in public and reluctance to form close relationships (Davis et al., 2000).

1.2.1 Function

Having good oral function is an important factor in quality of life and for many years there has been evidence that maintaining a full arch of teeth is important (Angeles, 1937; Elias et al., 1998).

Furthermore, failing to replace a missing tooth can result in surrounding teeth tipping into the space the removed tooth has left behind, this can make oral hygiene more difficult leading to an increased chance of caries and periodontal problems (Hirschfeld, 1937).

Studies based in the UK have shown that there is a link between the number of remaining teeth and a person's diet, and that the number of occluding pairs of teeth influences the selection of food stuffs (Sheiham et al., 1999). However, the shortened dental arch concept suggests that missing all posterior molars does not statistically affect the function and chewing ability of patients (Käyser, 1981). By contrast, severely shortened dental arches, missing all molars and second premolars, are shown to cause the greatest dietary limitations due to reduced tooth contacts (Sarita et al., 2003), the choice these patients have with respect to their diet being dependent on the contacts between their upper and lower front teeth. It has been shown that for those patients with only anterior dentition, or less than 20 teeth, some foods such as nuts, apples and raw carrots cannot be eaten easily (Lin et al., 2021 a). Interestingly, it has also been shown that eating intake values on all food stuffs were higher for dentate individuals (any number of teeth) than for those with no teeth at all, suggesting that even a few natural teeth are of some value (Sheiham et al., 2001). This indicates that anterior tooth contact is important not only for aesthetics but also for function. Persistent low diet quality has been associated with higher risk of tooth loss and accumulation of oral health problems (Kotronia et al., 2021), reinforcing the importance of tooth replacement to retain tooth contacts and maintain a healthy diet.

1.2.2 Patient perceptions of tooth loss

Evidence indicates that in the UK there has been increasing patient dissatisfaction with the appearance of their teeth over time due to gaps and spaces, a study showing this number has risen steadily from 5% in 1988 to 18% in 1998 to 42% in 2018 (National Dental Public Health Team, 2020). This is against a background of diminishing rates of edentulousness and reflects patients' reluctance to accept missing teeth. It has been reported that patients who lose front teeth are more interested in finding replacements than those who lose back teeth, and that they also rate aesthetics above function as reason for their tooth replacement (Elias et al., 1999). Demand for treatment which is aesthetically pleasing is increasing due to patient awareness fuelled by the media (Wong et al., 2006).

Quality of life measurements show that patients suffer not only with functional but also with psychological compromises following tooth loss (Brennan et al., 2008), with a positive correlation demonstrated between oral health quality of life (OHIP-14 score) and satisfaction with dental aesthetics (Park et al., 2011). It has been shown that having missing anterior teeth in particular, as well as the number and distribution of missing teeth affects oral health quality of life scores negatively (Gerritsen et al., 2010). Imperfections and missing anterior teeth also have been shown to have a negative impact on the psychological and social well-being of children (Gupta et al., 2019), and have negative effects on the emotional state of an individual (Khan et al., 2008). In agreement with these findings, the replacement of missing anterior teeth resulted in a significant improvement in psychosocial state (Chen et al., 2012) and OHRQoL and satisfaction were also positively affected by the replacement of anterior teeth using removable partial dentures (De Kok et al., 2017). Furthermore, when considering tooth replacement options such as dentures there is evidence that aesthetics is the predominant factor in success as judged by the patient and observers (Vallittu et al., 1996). Thus, to provide desirable outcomes for patients the aesthetics of partial dentures is as important as aesthetics is in any other contemporary modality of treatment (Shah and Aras, 2013).

It has been shown that lay people can reliably identify ideal smile characteristics but the range of acceptable smile characteristics is large (Ker et al., 2008). Witt and Flores-Mir (2011) demonstrated that an adult layperson's perception of anterior tooth aesthetics is determined by certain preferences such as for tooth shape, tooth size/proportion, and incisor position. In another study of anterior crown and bridge aesthetics, the shade and colour of the restorations were the most important factors in the patients' assessments of the outcome (Rimmer et al., 1996). Interestingly, dental professionals can be more critical of smile aesthetic outcomes than patients/laypersons (Arunyanak et al., 2017), and no correlation between dentist and patient assessments of dental appearance using an aesthetic satisfaction questionnaire could be found, although both groups reported an overall improvement after oral rehabilitation (Mehl et al., 2011). In another study it was shown that orthodontists were clearly more critical than prosthodontists, oral surgeons and dental students when looking at the pink esthetic score (PES) for evaluating soft tissue around a single-tooth (Fürhauser et al., 2005).

There is currently insufficient data to determine which factors are most important in children/adolescents smile perception but smile aesthetics do influence social perception during childhood and adolescence (Rossini et al., 2016). It was shown that children and adolescents felt those with a more ideal smile also had better athletic performance, were more popular, and were better leaders (Henson et al., 2011). These social influences can play an important role in behaviour

and the replacement of missing teeth can, therefore, provide social benefits for children and adolescent patients.

Hypodontia patients have the same issues as patients who suffer acquired tooth loss, additionally it has to be considered that hypodontia patients not only have missing teeth but have to learn how to manage this issue from a young age. Hypodontia becomes apparent as soon as the primary dentition begins to be lost and is not replaced, from roughly age 6 ending at around 15 years old. The most common issues hypodontia patients face are generalised spaces in their arches around their teeth, missing teeth and poor appearance (Hobkirk et al., 1980). Many patients are not treated in general dental practice and to start managing hypodontia many need to wait until they have developed enough adult teeth (from around 12 years old), this delay between age 6 and 12 can have educational and social consequences leading to increasing concerns for children and their parents (Hobkirk et al., 1994). The treatment of hypodontia regularly requires multidisciplinary treatment (MDT) between Orthodontic specialists and Paediatric/Restorative Specialists. Joint planning is required to give patients and their families the options for management of their hypodontia (Barber, 2019). The aim of many treatment plans for hypodontia are to redistribute the spacing between teeth and either close all spaces or collect spaces in planned locations (using orthodontics), if spaces are left the plan is to then fill them with replacement teeth, using restorative techniques (McSwiney et al., 2017). Many patients cannot start treatment until all their adult teeth have erupted as this is required for orthodontic phase and this can be as late as 15-16 years old as hypodontia patients show delayed eruption of adult teeth (Uslenghi et al., 2006). It has been shown that among dental students one of the most distracting characteristics of a smile when determining its attractiveness is hypodontia (Armalaite et al., 2018).

Considering the literature together, studies support the need for anterior tooth replacement for function where teeth are limited in number, but it also recognises the importance of improving aesthetics, due to the associated effects on quality of life and social impacts of visibly missing teeth.

1.2.3 Measurement scales for oral health quality of life and dental aesthetics

1.2.3.1 *Oral health related quality of life scales (OHRQoL)*

After years of research and many publications the definition of oral health related quality of life (OHRQoL) is still quite vague yet the patient's perception about their OHRQoL is significant in clinical dentistry, dental education and dental research (Baiju et al., 2017). OHRQoL scales have been developed to assess the impact of dental diseases or disorders on daily life and are essential for

capturing the patient perception of their oral condition and outcome of any treatment (Reissmann, 2021). They allow patients to score different impacts of their oral condition, for example functional or social, in a standardised way, and several OHRQoL questionnaires now exist. All OHRQoL questionnaires contain questions covering 4 main dimensions, oral function, oro-facial pain, oro-facial appearance and psychosocial impact, which are the suggested areas that cover the concept of OHRQoL (Larsson et al., 2010 a). Requirements for health status questionnaires were considered by Stewart et al (1988) who showed that to be effective, OHRQoL questionnaires should represent multiple health concepts with a range of health states including general functioning and well-being, have good psychometric properties (reliability, validity and precision), be constructed for use in clinical settings and be suitably concise/simple.

Current questionnaires to measure OHRQoL can be split into instruments of different lengths. There are several long instruments such as the Dental Impacts on Daily Living (DIDL) 36 questions (Leao et al., 1996), Subjective Oral Health Status Indicator (SOHSI) 43 questions (Locker et al., 1994), and Oral Health Impact Profile (OHIP-49) 49 questions (Sierwald et al., 2011). Short instruments include Oral Impacts on Daily Performance (OIDP) 8 questions (Adulyanon et al., 1997), Geriatric Oral Health Assessment Index (GOHAI) 12 questions (Atchison et al., 1990), Oral Health Impact Profile (OHIP-14) 14 questions (Slade, 1997 a), Oral Health Impact Profile (OHIP-EDENT) 19 questions (Allen et al., 2002), and Dental Impact Profile (DIP) 25 questions (Strauss, 1996). Then there are some ultra-short instruments: Rand Dental Health Index (RDHI) 3 questions long (Gooch et al., 1989), Oral Health-related Quality of Life measure (OHQOL) 3 questions (Kressin, 1996), Oral Health Impact Profile (OHIP-5) 5 questions (John et al., 2006).

The length of OHRQoL questionnaire is relevant as ideally the system used should be concise and collect the relevant information with lowest burden for the respondent. There is no perfect questionnaire to measure OHRQoL as setting and study size does affect the appropriateness of the questionnaire length. Shorter assessments can be well suited to larger studies, but where assessment of an individual impairment for a specific patient is considered, an instrument with a larger number of questions could be more effective as it can standardise for confounding factors better. The amount of information collected in a setting should be comparable, similar to other studies of a similar nature, to allow for comparison of findings (Reissmann, 2021).

Many OHRQoL questionnaires are generic, but items can be inappropriate or irrelevant for a specific dental condition or research aim. Therefore, more specific assessments were designed to increase sensitivity, detect impacts from specific conditions and to see changes induced by interventions, for

example tailoring to a specific dental condition such as dentine hypersensitivity (the Dentine Hypersensitivity Experience Questionnaire) (Boiko et al., 2010; Reissmann, 2021) or hypodontia the Bristol condition specific questionnaire (BCSQ) (Akram et al., 2011). These specific oral condition OHRQoL measures have been shown in systematic review to still assess the four major dimensions (Oral Function, Orofacial Pain, Orofacial Appearance and Psychosocial Impact) of OHRQoL (John et al., 2014; Mittal et al., 2019) but are for selective conditions.

The OHIP is the most commonly used reliable and validated OHRQoL measure and is available in several lengths. OHIP has been used on children, adolescents and adults within the literature and it has been shown that the OHRQoL dimensions measured can be used across an entire lifespan demonstrating its suitability for dentistry (Omara et al., 2021). OHIP-49 is the original full version of this questionnaire and has seven conceptual dimensions of function limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and social handicap (Slade et al., 1994). Each item is rated on a 5 point scale from 0 to 4 (with additional Not Applicable/Don't know option) and at 49 questions it takes time to complete which has been shown to be a limitation of its in use in clinical settings (Allen et al., 1999). As a result a shorter form of OHIP-49 was created, OHIP-14 which still contains questions from each of the seven domains (Slade, 1997 a) and when compared to OHIP-49 was shown to have good reliability, validity and precision (Slade, 1997 b). Despite being generic, OHIP is sensitive to the impacts of tooth loss and has shown itself to be responsive to the effects of different treatments for the condition (Anweigi et al., 2013 a). OHIP-14 has also been tested and shown to have good validity and reliability when used in studies that assess the self-perception of oral health in adolescents (Silveira et al., 2019). In addition, OHIP-14 has been shown to correlate positive OHRQoL with satisfaction with dental aesthetics for adults (Park et al., 2011) and also been shown to be effective at representing adolescents' self-perceived impact of dental aesthetics on OHRQoL (De Paula et al., 2009). The 5-item ultra-short form of OHIP, OHIP-5 can describe 90% of information assessed by OHIP-49 making OHIP-5 a very valuable instrument to assess OHRQoL in most settings but is not used often therefore less comparable to other studies (John et al., 2006).

In light of the current literature on the available OHRQoL questionnaires, OHIP-14 is perhaps the most suitable for assessing OHRQoL in younger individuals in clinical situations where time is not plentiful. The OHIP-14 questionnaire is a good length and the frequency with which it is used makes comparison to other similar studies straightforward. Although aesthetic questions are a part of OHIP-14, and the oro-facial appearance dimension of OHRQoL shows moderate impact for patients with different conditions which had aesthetically related treatment need (Larsson et al., 2010 a),

similar to the many other questionnaires discussed above it is specifically designed to measure OHRQoL and is no substitute for an aesthetic scale.

1.2.3.2 Aesthetic scales

There are a variety of systems that are used to specifically assess dental aesthetics, however many of these are clinically based rather than designed for patients/layerspersons to assess their own or others aesthetics outcomes.

Clinical indices are designed to be as objective as possible, and many used to assess the aesthetic success of tooth replacement strategies are based on measurements, different indices being more or less appropriate depending on the tooth replacement method employed. For example, the Papilla Index (PI) is based on measurement of the gingival papilla between teeth and implant crowns, it allows a scientific assessment of soft tissue contour adjacent to single restorations and helps to record any soft tissues changes in a systematic way from insertion of the crowns to follow-up (Jemt, 1997). By contrast, the Papilla Presence Index (PPI) system is used to assess interproximal papillary levels around teeth looking at the position of the papilla in relation to the height of natural teeth, lack of contact points and presence of diastemata (Cardaropoli et al., 2004). The Implant Crown Aesthetic Index (ICAI) is an objective tool for rating aesthetics of implant supported single crowns and adjacent soft tissues based on the anatomic form, colour and surface characteristics of the crown and peri-implant soft tissues (Meijer et al., 2005), while the Pink Esthetic Score (PES) reproducibly evaluates peri-implant soft tissue around single-tooth implants. The Pink and White Esthetic Score (PES/WES) is an extension of this in which the PES comprises the mesial papilla, distal papilla, curvature of the facial mucosa, level of the facial mucosa, and root convexity/soft tissue colour/texture at the facial aspect of the implant site. The WES specifically focuses on the visible part of the implant restoration and is based on general tooth form; clinical crown outline and volume; colour (hue and value); surface texture; and translucency and characterization (Belser et al., 2009).

When assessing for orthodontics, the Index of Orthodontic Treatment Need (IOTN), is used by clinicians to assess whether patients qualify for NHS orthodontic treatment and consists of a Dental Health Component (IOTN DHC) as well as an Aesthetic Component (IOTN AC) (Brook et al., 1989). To judge the aesthetic component the IOTN AC uses a 10 image scale (least to most attractive) to which the clinician matches the patients dentition (Evans et al., 1987), but this scale has its limitations as it does not measure patient perceived need (Shaw et al., 1991). To help manage this issue the patient also self-rates their IOTN AC.

These clinical indices allow an objective assessment of the outcome of different surgical or prosthodontic/periodontic protocols by clinicians, however they do not provide information on how aesthetics impacts a patient's quality of life when considering function and psychosocial well-being as can be assessed by OHRQoL instruments. In addition, apart from the patient self-rated IOTN AC they do not reflect the patient perspective, and there is evidence that clinician and patient perspectives of aesthetic outcomes differ (Arunyanak et al., 2017).

To determine patient responses to dental aesthetics a new Smile Aesthetics Satisfaction Scale (SASS) was developed which uses a three-point Likert scale (Likert, 1932) (1 = not satisfied, 2 = moderately satisfied and 3 = completely satisfied) for each of the following five dimensions of tooth aesthetics: tooth appearance, tooth colour, tooth shape, tooth position/alignment and the appearance of the gingiva (Lajnert et al., 2018). Assessments of smile aesthetics in adults and the elderly demonstrated that the SASS had good reliability and psychometric properties. However, although the SASS only uses a three point Likert scale, as five dimensions of tooth aesthetics have to be assessed per image this scale is quite complicated and time consuming.

The Orofacial Esthetic Scale (OES) developed in prosthodontic patients uses a questionnaire and 0-10 numerical scale (0 - "very dissatisfied", 10 - "very satisfied") or "not applicable"(if participants do not wish to respond) to assesses orofacial aesthetics (Tedesco et al., 1983). OES questions refer to 7 aesthetic areas for each image (face, facial profile, mouth, rows of teeth, tooth shape/form, tooth colour, gum). The 7 items are combined as a summary score from 0-70 and an 8th question gains patient's global assessment of orofacial aesthetics (Larsson et al., 2010 b). This scale collects feedback on many elements of aesthetics not just the teeth, with 8 ratings required per image, only 3 of which relate to teeth and thus it is also time consuming for participants to complete if assessment of more than one tooth id required.

Other scales such as prosthetic esthetic index (PEI) (Özhayat et al., 2014), Dental esthetic index (DEI) (Baca-Garcia et al., 2004), oral health impact scale aesthetic (OHIP-Aes) (Wong et al., 2007), psychosocial impact of dental aesthetic questionnaire (PIDAQ) (Klages et al., 2006), complex esthetic index (CEI) (Juodzbaly et al., 2010), smile esthetic index (SEI) (Rotundo et al., 2021), prosthetic and dental esthetic ,screening index (DESI) (Frese et al., 2019) have multiple questions, some are only about individual teeth and are focused on clinical and not patient based results.

A Visual Analogue Scale (VAS) is a measurement instrument which was originally a psychometric scale used to quantify subjective characteristics or attitudes that cannot be easily or directly measured (Hayes et al., 1921). The scale is a line 100mm long line on which the scorer marks where they feel their response lies from what is defined as '0' to what is defined as '100', it captures the idea of an underlying continuum which was why VAS was devised. It is often used in epidemiologic and clinical research to measure the intensity or frequency of symptoms (Grant et al., 1999). Over time it has been most used for ratings in mood and pain (Crichton, 2010) but VAS can be used for any assessments which fall along a scale, and it has been used to measure dental aesthetics, however studies suggest VAS has less validity and reliability when compared to other aesthetics scales (Schabel et al., 2009; Oliveira et al., 2015).

Other studies in which participants rather than clinicians have assessed oral aesthetic appearance have used a 5 point scale to rate attractiveness of images. Armalaite et al. (2018) looked at smile aesthetics and evaluated 3 different aspects of aesthetics; dentolabial, dentogingival, and dental arch characteristics for each using a numeric rating scale (1, best; 5, worst) with a score ≥ 3.5 indicating a smile that was no longer aesthetically acceptable. Similarly, Ong et al (2006) used a 5-point Likert attractiveness scale to rate the relative importance of various dental features that contribute to overall dental attractiveness. Support for the acceptability of 5 point scales for rating aesthetics was provided by a study which compared different scales ranging from 5 to 101 points to rate physical attractiveness, and showed that the 5 point scale was as effective as the 12 and 101 point scale (Wedell et al., 1987). Generally research indicates that most surveys should be completed in under 10 minutes to keep participant interest and that 5 minute surveys have higher completion rates, especially if they are customer satisfaction or feedback surveys (Crawford et al., 2001)(Evans et al., 2018). In addition, evidence has demonstrated that, selecting a choice in online surveys by clicking creates better engagement of participants compared to writing an answer in paper surveys, and that overall the fewer clicks required the better (Beer et al., 2010), suggesting this should be taken into consideration when designing surveys for study participants.

Based on the literature it is difficult to select the ideal survey for aesthetics in every situation. The best choice will be influenced by each specific study and the aesthetic measurement wanted. For an aesthetic study based in a clinical situation it is important that the chosen assessment method is suitably short, scoring easy to complete for adults and adolescents, Likert scales being a good choice for this.

1.3 Replacement strategies for tooth loss

Even though there are functional and aesthetic reasons for replacing missing teeth, perhaps surprisingly, not everyone wants to replace them. Most patients know that teeth can be replaced, a 2016 survey indicated that up to 98% of participants were aware there were replacement options, however only 90% of them wanted the replacement (John Rozar Raj, 2016). This finding could reflect the location of the missing tooth and/or patient understanding of replacement options. Another recent survey showed that 23.8% of study groups did not feel that teeth should be replaced by a prosthesis and that while 77.9% patients knew about removable prostheses, only 32.9% patients knew about implants and fewer (25.2%) patients knew about tooth supported bridges (Jayasinghe et al., 2017). This data indicates that more could be done to improve patient's knowledge regarding the negative effect missing teeth can have on oral and general health, and the options available to them. Increased awareness of dentists toward the indications and contraindications of the options available for replacement of missing teeth, which satisfy both aesthetic and functional needs, is also important. To achieve this, the importance of different types of media cannot be overlooked and communication programs for patients and dental professionals should be strengthened at district and local levels.

There are several tooth replacements options available for patients. Not all options will be possible for every case, but the following: accepting the space, a metal or acrylic removable prosthesis, a tooth supported by adhesive wing (RRB), a tooth supported by another tooth which has been crowned or a tooth supported by an implant (fixed or removable) is a comprehensive list of the treatment options (Breeze et al., 2017).

1.3.2 Removable Prosthesis

Removable prosthodontics is tooth and soft tissue replacement with a prosthesis that can be removed. These removable prostheses are usually called dentures and can replace a full arch of teeth (complete dentures), or less than a full arch of teeth (partial dentures). Dentures can be made from acrylic, metal acrylic, flexible acrylics, and other plastic materials and utilise tooth support to reduce pressure on the gum and bone, and to aid retention (Harrison et al., 1990). The design, materials, ease of repair, patient education, and follow-up for dentures all have a significant impact on their success (Campbell et al., 2017).

There are very few restrictions to wearing a denture which makes them a good choice for people of all ages or medical backgrounds. Removable dentures require little or no preparation of teeth, there are no post treatment delays in eating, drinking, or working as there is no local anaesthetic or

surgical recovery needed. Dentures can be made quickly compared to some alternative fixed options, are completely reversible as they can be removed at any time by the patient, and they are lower cost, require less clinical time, provide good chewing efficiency, and a rapid positive effect on the quality of life (Paulino et al., 2015). In addition, in some cases, a removable prosthesis is a safer and more effective option than a fixed tooth replacement option. For some active periodontitis and cancer patients a removable denture provides more flexibility and adaptability (Friel et al., 2020). It allows for addition of teeth to the prosthesis and can be removed to check soft tissues for recurrent lesions (Avukat et al., 2020). However, dentures may not be the optimal option for all patients (Wostmann et al., 2006).

Some patients experience difficulty in adapting to removable dentures (Szentpétery et al., 2005). Psychologically it can be harder to adapt and accept removable prostheses as they feel less like natural teeth (Kudsi, 2019), and for those with reduced manual motor and oral motor ability there can be a permanent altered oral perception through denture wearing (Müller et al., 1995). Dentures have also been shown to modify the wearer's perception of taste especially for bitter tastes (da Silva et al., 2021). Difficulties in adapting to removable prostheses can affect OHRQoL and it has been shown that patient satisfaction was significantly higher and OHRQoL less impaired in those who had fixed tooth replacement as compared to those with removable dentures (Egido Moreno et al., 2020) (Lin et al., 2021 a). Significant positive correlation has been found between the OHRQoL scores and denture satisfaction scores (Hashem et al., 2013). In addition, as removable appliances rest on the soft tissues and the tooth spaces, the pressure on the gum and bone encourages resorption of the bone in these regions over time (Carlsson, 1998). This gradual bone resorption makes it harder to stabilise the denture and can reduce bone volume which limits implant options in the future (Misch, 2015). As the bone changes so does the fit of the dentures. Ill-fitting or poorly cleaned removable prostheses can cause oral mucosal lesions, ulcers, or superficial infections, complications that are common, with 78% of denture-wearing participants shown to have at least one denture-related lesion in a recent study (Brantes et al., 2019). These lesions require intervention which may be either an adjustment or topical treatments to the gum. Most patients prefer the idea of a fixed tooth replacement as it better replicates a natural tooth, and many people see removable prosthesis options as a temporary or a suboptimal replacement (Jayasinghe et al., 2017).

Although there are drawbacks to removable dentures advances in technology such as Computer aided design/computer added manufacture (CAD/CAM) has profoundly changed the construction of removable partial dentures, bringing new possibilities in many aspects such as denture design, material selection, and restoration procedures (Ma et al., 2021).

1.3.3 Fixed tooth replacement

Advances in CAD/CAM, impression materials, adhesive dentistry and implants have made it more possible to reliably replace missing teeth using fixed options, but has made treatment planning increasingly difficult due to the increase in treatment options (Rich et al., 2002).

1.3.3.1 Conventional bridges

A conventional bridge is a fixed dental restoration in which an artificial tooth is joined to an adjacent tooth/teeth to replace one or more missing teeth and used to be the main option for replacement of missing teeth. Conventional bridges show high survival rates with 5 year survival rates for cantilever and fixed-fixed bridges of 81.1% and 89.1%, respectively (Tan et al., 2004), and it has recently been reported that the proportion of adults with one or more crowns was 46.5% and that those with a crown had an average of 3.2 crowned teeth (National Dental Public Health Team, 2020). OHRQoL changes in patients treated with conventional bridges is limited due to the vast range and variability of treatments within this category. Studies looking at comparisons between different types of fixed tooth replacement show significant improvement in OHRQoL with use of conventional bridges but that this treatment can have different impacts on the OHRQoL depending on the location and number of missing teeth (Gurevich et al., 2014).

However, any conventional bridgework requires preparation of the adjacent teeth/tooth by shaping (Edelhoff et al., 2002). The reduction of the tooth tissue of the surrounding/abutment teeth shortens the lifespan of those teeth, with 32.6% of prepared bridge abutment teeth losing vitality over a 5-year period (Pjetursson et al., 2004) which is a major disadvantage of this tooth replacement technique. However, these restorations can be very time efficient as no delay for healing is required and in 2 visits a new conventional bridge could be fitted. In terms of cost initially the cost of a conventional bridge is lower than that of a dental implant and cost effectiveness overtime is comparable (Zitzmann et al., 2013).

Less aggressive treatments are more favourable for patients as they avoid local anaesthesia and destruction of tooth structure. Therefore, there is a preference for more conservative techniques and the use implants which avoid tooth preparation (Walsh, 2007).

1.3.3.2 Implant supported prosthesis

Dental implant therapy is now an accepted and reliable tooth replacement technique (Howe et al., 2019). The implants themselves are made from biocompatible materials such as titanium or ceramic screws that replace a tooth root and undergo osseointegration enabling considerable survival rates with estimates for 10-year survival at the implant level of 96.4% (Bonfante et al., 2019; Howe et al., 2019). Different types of prosthesis (artificial teeth and soft tissues) are used to replace missing teeth and are fixed by screws or cement to the implant. Implant prostheses can also be removable and the implants are used for stabilisation and retention (Sadowsky, 1997). The main benefit of implants is that their success is not linked to surrounding teeth and they can independently support a prosthesis. In addition, they help with the maintenance of bone after tooth loss, maintain facial aesthetics, and can improve retention, function, and performance of a removable prosthesis. Evidence-based reports indicate implant restorations last longer and the remaining teeth are at less risk of loss or complications than when bridgework is used to replace the same teeth (Misch, 2001). The use of dental implants has grown across the UK and according to data taken from the 2009 Adult Dental Health Survey, half a million adults have at least one dental implant (Hill et al., 2013). Similarly there has been an increase in dental implant prevalence in the US since 1999, and it is projected that there will be a further increase of between 5.7-23% by 2026 (Dovigi et al., 2016). The function and aesthetics of patient dentition restored with fixed implant-supported restorations show a very high patient satisfaction 10-year after implant placement (Wang et al., 2021).

Although there are many advantages of implants, there are also disadvantages. Complications including frequent technical/mechanical complications such as: abutment screw loosening, fracture of the overdenture prostheses, activation of retentive clips, ceramic chipping, and abutment fractures are common (Gupta et al., 2015). In addition, implants need adequate bone volume and good gum health to survive predictably in the long term (Adler et al., 2020). Biological complications that arise, generally from poor oral health, include peri-implantitis, peri-implant mucositis, mucosal enlargement, resulting in bone loss, pain, and implant loss/failure (Hanif et al., 2017).

There is also added complexity with the use of dental implants for tooth replacement due to the surgery that is involved. Implant surgery requires; cone beam computerised tomography (CBCT) scans for implant placement planning (Benavides et al., 2012), local anaesthetic, anxious patients may need further anaesthesia, possible bone augmentation or muso-gingival surgery procedures (Wright et al., 2016). The total number of appointments needed for dental implant crowns/bridges is greater and appointments more frequent than needed for conventional crowns/bridges. Also, the

initial cost of dental implant crowns/bridges is greater than conventional alternatives (Vogel et al., 2013) due to the need for specialist equipment, equipment maintenance and training of dental care professionals (DCPs) (Bouchard et al., 2009). Furthermore, the national health service (NHS) does not support the costs of dental implant treatment unless patients fall into a specific priority group such as: having developmental conditions resulting in deformed and/or missing teeth; having lost teeth due to trauma with a dento-alveolar component; having had ablative surgery for head and neck cancer causing tooth loss; having extra-oral defects, the orthodontic anchorage requiring an implant; and in exception circumstances with special funding support having aggressive periodontitis requiring dentures or edentulous in one or both jaws but suffering with severe denture intolerance (Alani et al., 2014). Finally, the ongoing maintenance of dental implants is a more involved lifelong commitment than that required for other tooth replacement options and comes with time, cost and complexity implications above those of conventional restorations (Beddis et al., 2017).

Therefore, while patient satisfaction with the aesthetics of implants has been shown to be good (Adler et al., 2016), they are certainly not a quick or cheap fix, requiring a life time of maintenance and effective patient home care if they are to be successful and survive as a long term restoration (Silverstein et al., 2006).

1.3.3.3 Resin Retained Bridges

Resin Retained Bridges (RRBs) are a minimally invasive option for the replacement of missing teeth in which the replacement tooth is held in position by a metal strip stuck to an adjacent (abutment) tooth (Durey et al., 2011). The glue used to stick the metal to the tooth is a resin cement, hence their designation as resin retained. The resin adhesive sticks well to tooth enamel and metal, and can also adhere to resin composite fillings but does not bond well to other fillings, more microleakage has been demonstrated following bonding to amalgam than to resin composite restorations in vitro (Saunders, 1990).

The first style of RRB was the Rochette bridge that relied on countersunk holes that perforated the metal abutment wing and were filled with composite cement on seating the restoration, providing macro-mechanical retention for the prosthesis (Rochette, 1973). More modern cements (described below) have enabled better retention of the prosthesis without the need for holes in the retainer wing and subsequent loss of strength, however, Rochette bridges remain in service today and can be used as provisional restorations with good outcomes (Poyser et al., 2004). The Maryland bridge was developed from the Rochette bridge by removing the holes in the abutment wing and instead using minimal tooth preparation to aid macro-mechanical retention of the abutment wing to the enamel

(Meyer et al., 1985). These bridges also show good survival rates, 77% after 10 years of service, but the requirement for some tooth destruction is a disadvantage (Aggstaller et al., 2008).

The modern RRB design (also known as resin-bonded-bridge) was first developed due to the advances in dental materials and their ability to chemically bond to both metal and enamel. This was achieved by the use of adhesive cements, porous metal coatings, tribochemical coating and silicoating (Hansson, 1989). In parallel, progress in micro-mechanical retention through the use of sand blasting of the metal surface with aluminium oxide to increase the surface energy of the metal and enhance wettability, had been made, resulting in improvements of the adhesion of materials to the metals (Minford, 1995). Alternative techniques for micro-mechanical retention which have been developed and can be used are electrochemical or chemical etching (Adept Institute, 1991). The combination of these developments in bonding allowed the metal abutment wing to adhere to enamel without any additional macro-mechanical retention (tooth or wing preparations)(Hansson, Ola, 1996). Thus, no tooth preparation is required for the abutment and treatment is totally reversible (Durey et al 2011).

RRBs are relatively easy to install and are therefore appropriate for patients who may have increased anxiety in dental chair, as they rarely need local anaesthesia and do not require multiple dental appointments. RRBs tend to remove pressure from mucosae and unlike partial dentures which take support from the alveolar ridge, RRBs are supported by teeth therefore reducing the risk of alveolar bone resorption (Van Waas et al., 1993). Irrespective of the tooth replacement options patients should be properly educated and motivated in the importance of adequate oral health and hygiene, as poor maintenance of resin bonded bridge can lead to gingivitis, periodontal issues and failure of the restorations (Vulićević et al., 2017).

The modern RRB design has shown good survival rates with five-year at 80.8% and ten-year survival at 80.4%, and when RRBs with incisal coverage were compared against those with no incisal coverage survival was 89.6% and 73.2% respectively at 5 years (King et al., 2015). This study also showed that RRBs made with minimal tooth preparation were superior in terms of longevity than other types of RRBs which used tooth preparation (King et al., 2015). RRBs also have good patient related outcomes in terms of aesthetics and function with 88% of patients rating their appearance as good and 94.9% reporting their function as good (Djemal et al., 1999). Thus the main advantages of RRBs are their preservation of healthy tooth substance, reduced costs due to fewer customised components, the need for fewer clinical sessions and generally good patient acceptance (Vallittu et al., 2000).

Materials play an important role in the success of RRB. Metal wings are the gold standard for modern RRBs, however other materials such as fibre-reinforced bridges and all-ceramic bridges have been tested in an attempt to make the wing material white and potentially more aesthetically pleasing. A study that compared the failure rates/year of the metal wing, fibre-reinforced and all-ceramic resin bonded bridges demonstrated they were 4.6%, 4.1% and 11.7%, respectively showing metal and fibre had similar outcomes but ceramic wings had twice the rate of failure (Miettinen et al., 2013). However, a review of studies reporting 5-year survival rates of fibre-reinforced bridges demonstrated that the success rate was 45% and survival rate was only 64% at this time point (van Heumen et al., 2009). The most common complications with metal wing RRB are debonding of the wing from the abutment, caries and tooth discolouration (Goodacre et al., 2003). Other white materials had different complications such as delamination of the composite veneering material for the fibre-reinforced bridges (41% of all failures) and fracture of the framework for the all-ceramic bridges (57% of all failures) (Miettinen et al., 2013). The delamination of a metal wing is the simplest of these failures and therefore is the easiest to manage and correct. By contrast, trying to remove white material wings from teeth is difficult as the colour matched wing material and cement lute increase the chance of accidental tooth destruction. As metal wings are clearly a different colour and contrast well against the tooth enamel, and the luting cements used is opaque and also contrasts with the tooth enamel, it is easy to identify and remove them conservatively from the tooth if required. When considering aesthetics RRBs show good outcomes (Tredwin et al., 2007). This compares well with other fixed tooth replacement options such as conventional bridges and implants (Meyenberg et al., 1997).

Fixed tooth replacement in children and young adolescents is challenging due to changes in tooth shape, colour, and position during growth, however fixed tooth replacement is important for young patient groups to maintain space and keep aesthetics (Kopel, 1950). A hypodontia patient study showed that following fixed tooth replacement, 87% of patients who received implant-supported restorations and 84% of patients who received adhesive bridges restorations were very satisfied or satisfied with the treatment outcome (Dueled et al., 2009). However, implants are ideally avoided in growing patients as if implants are placed while jaws are still growing then complications such as infra-occlusion and rotation are common (Bohner et al., 2019).

For replacement of a single tooth in children and young adolescents a RRB is usually the option of choice. There is no age limit on their use, they do not place pressure on the residual alveolar ridge and therefore do not encourage bone resorption (Van Waas et al., 1993). RRBs do not damage tooth

structure, they can be removed and replaced, they are simple for patients to clean around, and their placement does not require 3D scans, surgery, or bone augmentations. They are quick and easy to place, requiring no anaesthetic and are cheaper than most alternative tooth replacements. Their only true drawback is debonding, but the 15-year failure rates are low and complication rates are lower than other fixed tooth replacement alternatives (implants/conventional bridges). If they do fail by debonding the wing can be removed, thereby removing the RRB, without having to damage the tooth this then allows replacement of the missing tooth by any restoration including another RRB.

When considering replacement strategies for tooth loss any of the above discussed strategies could theoretically work but it is very dependent on individual patient circumstances. In the anterior dentition it could be argued that any form of tooth replacement is important for functionality and aesthetics. It is a personal choice as to which tooth replacement option would satisfy an individual patient. Therefore, case circumstance and patient dependant factors designate what is the right choice.

1.4 Justification and aims

Patients attending Bristol Dental Hospital (BDH) for tooth replacement for reasons such as hypodontia (missing teeth) or trauma are regularly treated using a RRB. The current design (original) RRB used in Bristol is a metal frame RRB in which 1-2 pontic (false teeth) fill the spaces lying beside the abutment (supporting) teeth and are linked by the metal frame across the back (palatal/lingual surface) of the adjacent teeth (Figure 1.1). In some patients, only one tooth requires replacement (one pontic needed) this can be supported by either one or two abutment teeth (Figure 1.1A). More commonly in hypodontia symmetrical teeth can be missing and therefore two teeth require replacement (two pontic teeth on 2 abutments) (Figure 1.1B). The metal not only covers the back of the natural tooth abutment tooth but also wraps around its incisal edge(s) to increase RRB survival (Djemalet al., 1999). While most of the metal is hidden from the vision of the observer behind the pontic and abutment tooth, if the bridge is on the anterior (front) tooth/teeth the portion of metal at the incisal edge of the abutment tooth/teeth may be visible or cause changes to the translucency of the incisal edge resulting in a small grey flash appearance when the patient speaks or smiles (Figure 1.1A). At review appointments some patients say that this change in their appearance is upsetting, and in previous studies the metal of the retainer was reported to be the most common reason for patient dissatisfaction with their RRB (Djemalet al., 1999; Durey et al., 2011).

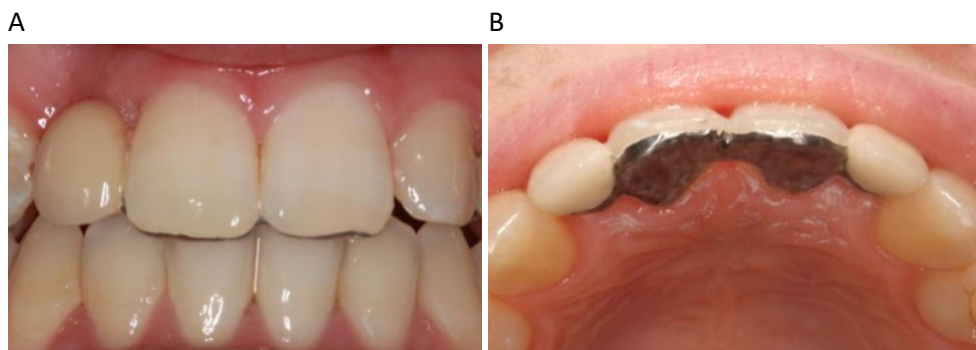


Figure 1.1. Resin retained Bridges: A: the extension of the bridge restoration is visible at the upper incisal edge of the abutment teeth and is visible in this example even after the maximum adjustment that is possible had been made, this bridge replaces one tooth the Upper Right 2 (UR2).

B: image showing a palatal wing design RRB with incisal edge coverage, this bridge has two pontics and is replacing two teeth upper right 2 (UR2) and upper left 2 (UL2).

When RRBs were originally designed it was deemed necessary for the metal to extend over the incisal edge of the abutment tooth/teeth to improve its retention and hence longevity as covering as much of the enamel of the abutment surface as possible was shown to be a powerful factor tending to enhance survival (Djemalet al., 1999).

Since the survival of the original design was assessed, in Djemal et al (1999) and then re-assessed by King et al (2015), over 28 years and 21 years ago, respectively, research and development have improved bonding materials, impression materials and fit of bridges due to the use Computer Aided Design and Computer Aided Manufacturing (CAD/CAM) technology. Considering all the improvements it has now been possible to redesign the original RRB with a reduced incisal extension (Adjusted RRB), such that aesthetics are improved without seemingly affecting the survival of the RRB. This design has been used in general dental practice for some time however, there has been no standardisation of the adjusted design or randomised controlled trial to confirm that survival is not compromised. The aesthetic improvements of the adjusted RRB are noticeable and patients appear to be more satisfied with this design, but similar to survival, no study to directly compare aesthetic outcomes of the adjusted and original RRB, or to determine relative OHRQoL outcomes, has been undertaken.

1.4.1 Aim of study:

To determine if adjustments to the current anterior RRB design (original RRB), so that no metal wraps around the abutment tooth incisal edge (adjusted bridge), improves aesthetic outcomes. Survival rates of both bridge design was also measured of 18 months. The null hypothesis was that there would be no differences between aesthetic preferences of participants assessing the RRBs with the original or adjusted RRB design.

1.4.2 Specific Objectives:

- To compare the aesthetic outcomes of anteriorly placed original and adjusted design RRBs after bridge fit as assessed by three independent groups, hypodontia patients who had not yet received a RRB, the public and dental care professionals (DCPs).
- To determine if the three groups assessing the aesthetic outcomes, DCPs, patients with hypodontia and The Public preferred the same RRB and compare the similarity of their views.
- To assess and compare OHRQoL from participants receiving placement of either an adjusted design RRB or original design RRB.
- To assess and compare RRB failure rate after 18 months from participants receiving placement of either an adjusted design or original design RRB.

2 Method

2.1 Study overview:

This was a two-part study. The clinical phase was a single centre, randomised, two treatment regimen, parallel study in dental patients presenting with a missing tooth in maxillary anterior sextant (front teeth in the upper jaw) requiring tooth replacement. The study protocol and associated documents and subsequent amendments (Appendix 1 and Protocol appendices 1-8) were given a favourable opinion by the North of Scotland Research Ethics Committee (REC REF 19/NS/0050, IRAS ID: 257107), and HRA and University Hospitals Bristol and West NHS Foundation Trust approval was additionally gained and the study was conducted in accordance with Good Clinical Practice. Clinical assessments for study outcomes were limited to recording failure of bridges such as debonding which has been documented as 93% of all RRB failures. Following standard care procedures for this type of treatment the study participants returned to their general dental practitioner (GDP) for their routine care after receiving their bridge. If failures occurred GDPs would report this to the study clinician/clinician's team beyond the end of this study. In line with normal procedures for patients receiving an RRB, study participants will be referred back to the BDH team for confirmation and corrective treatment, and the failure will be recorded.

Approximately 40 patients aged 11 or over who required a RRB on an anterior (front) tooth as part of their routine dental treatment were approached to take part in the clinical study and 40 were recruited. Initial screening took place at BDH on general, trauma or hypodontia (missing tooth) assessment clinics. Patients who fulfilled the eligibility criteria and consented to take part in the study (with parental consent in place where required) were randomised to receive one of two bridge designs (20 patients for each group). This randomisation schedule was created using a free online resource random.org (Neuhaus et al., 2006).

Participants were asked to complete a quality-of-life questionnaire (OHIP 14 – Protocol Appendix 1) or a version adjusted for younger people (Protocol Appendix 2) before treatment began, and at one month post treatment. The adjustments made for the younger persons OHIP-14 where small changes to the language used for the questions, these changes where then appropriately age tested by young adolescents to check the new questions for readability and understanding.

Assessment of aesthetics in the non-clinical part of the study was conducted using a panel of photographs taken during the clinical phase of the study. These photos were fully anonymised and standardised showing just teeth and gingivae (gums) and were taken by the study dentist immediately

after study participants had received their RRB, using the same camera and standardised settings. These anonymised photos were assessed by participants who were not recruited to the treatment part of the study and were a hypodontia patient group, members of the public and dental care professionals who were all blinded to the treatment received by participants in the clinical study (Protocol Appendix 3). Reported bridge failures in each clinical participant group were monitored throughout the study and are continuing to be monitored, the findings will be summarised at 18 months after placement after the end of the MSc.

2.2 Clinical study

2.2.1 Study recruitment

Patients attending BDH for consultation appointments who required tooth replacement were approached to take part in the study. Potential participants who needed treatment for anterior sextant maxillary tooth loss were identified, the majority were identified when they attended 'new patient clinics' for treatment planning.

Clinicians at BDH were informed about the study and given a letter that contained brief information about the study and contact details for study staff, to give to any of their patients who might be eligible (had missing teeth), and who expressed an interest in taking part (Protocol Appendix 4). The clinicians provided a brief overview to potential participants, advised them to read the letter and then to contact the study team for more information if they were still interested in participating. Participants who contacted the study team were sent the participant information sheet (Protocol Appendix 5a, 5b, 5c), provided with any further information that they requested and booked in for a screening appointment. If a participant wanted more time before committing to a screening appointment this was given.

2.2.2 Screening appointment (participants requiring a bridge)

At the start of the screening appointment, the patient was asked if they had received the participant information sheet and had sufficient time to read it. The main study dentist or a member of their team (dentally qualified clinician who was supporting the study) went through the participant information sheet (Protocol Appendix 5a, 5b, 5c) with the participant and answered any questions. Those participants who agreed to take part in the study, were asked to sign a consent form (Protocol Appendix 8a, 8b, 8c) prior to any study procedures beginning. The participants were provided with a copy of their signed and dated consent form. Those participants consenting to take part in the study were then screened.

The main study dentist recorded demographics, current and concomitant medications, undertook a full Oral Soft Tissue (OST) examination including taking appropriate radiograph(s) as is standard for any treatment to replace a missing tooth, and confirmed whether the participant fulfilled the inclusion/exclusion criteria as outlined in table 2.1.

Any concomitant medication or other dental treatments needed by the participants during the study period were recorded in the participant's notes/CRF.

2.2.2.1 Inclusion/Exclusion Criteria. Table 2.1

Inclusion	Exclusion
Consent	
Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent	Unable or unwilling to consent or take part voluntarily. Is a family member or clinical trials unit employee.
Compliance	
Understands and is willing, able and likely to comply with all study procedures.	Is unable to understand or cannot comply with study protocol.
General Health	
Good general health with (in the opinion of the investigator) no clinically significant and relevant abnormalities of medical history on examination.	Current or relevant previous history of serious, severe or unstable physical or psychiatric illness, or any medical disorder that may require treatment or make the participant unlikely to fully complete the study, or any condition that presents undue risk from the study products or procedures.
	Have any bleeding disorders.
	The patient is immuno-compromised ⁴ .
	Known or suspected allergy or intolerance or sensitivity to the study materials (or closely related compounds) or any of their stated ingredients.
	Participation in another clinical study or receipt of an investigational drug within 10 days of the screening visit.
Medication	
No medications which will interfere with the study.	Any medication ⁵ which in the Investigators opinion may interfere with the study.
Substance abuse	
No recent history or active substance abuse.	Active or recent history of alcohol or other substance abuse ⁶ .
Oral Cavity	
Has at least one missing tooth, bounded by teeth, which is a single unit in the front of the mouth, being either an incisor or canine.	Current or recurrent disease/dental pathology that could affect bridge treatment.
Has teeth that can be used as abutments (for attachment of the RRB) that are unrestored and without pathology	Possible abutment teeth (for attachment of the RRB) are restored and/or have pathology
The tooth space is able to accommodate a pontic tooth replacement restoration	There is insufficient space for a pontic tooth.
Teeth have no more than mild toothwear with Basic Erosive Wear Examination (BEWE) ¹ score of 1 or less with no history of parafunctional habits.	The teeth have a toothwear index of >1 on BEWE ¹ and/or have a history of parafunctional habits ⁷ .
Oral Hygiene Status	
The teeth exhibit a good oral hygiene routine with a full mouth Turesky plaque index ² score <1	The teeth have plaque deposits with a full mouth Turesky plaque index ² score >1
The Basic Periodontal Exam (BPE) ³ scores of 0, 1, 2. With a maximum of one sextant with a score of 3	The Basic Periodontal Exam (BPE) ³ scores of 3, 4. With a minimum of two sextants with a score of 3.
Age	
Aged 11 plus	Younger than 11 years old
	Any patient who, in the judgement of the investigator, should not participate in the study.

¹(Bartlett et al., 2008),²(Turesky et al., 1970), ³(Ower, 2016), ⁴(Gingival inflammation and periodontal diseases are seen due to primary deficiencies in the immune system and can become acute quickly due to increased gingival sensitivity (Peacock et al., 2017)). ⁵(Ciancio, 2004). ⁶(Baghaie et al., 2017). ⁷(Saker et al., 2019).

2.2.2.2 Study enrolment

Participants who successfully fulfilled all the necessary entrance criteria were enrolled in the study and given a paper copy of the questionnaire on quality of life with regards to oral health (Protocol Appendix 1: OHIP-14. Protocol Appendix 2: Adjusted OHIP-14) which they were asked to complete pre-treatment. Study participants were then randomized to receive either bridge original or adjusted design (table 2.2) according to a predetermined randomization schedule. A photograph of the treatment site was taken together with an impression for working models (table 2). The bridge designs are shown in figures 2.1 and 2.2.

Table 2.2. Randomization:

Treatment Regimen	Design
Original (green)	Standard incisal edge overlap metal wing design using CAD/CAM (to reduce technician variation)
Adjusted (blue)	No incisal edge overlap lap wing design using CAD/CAM

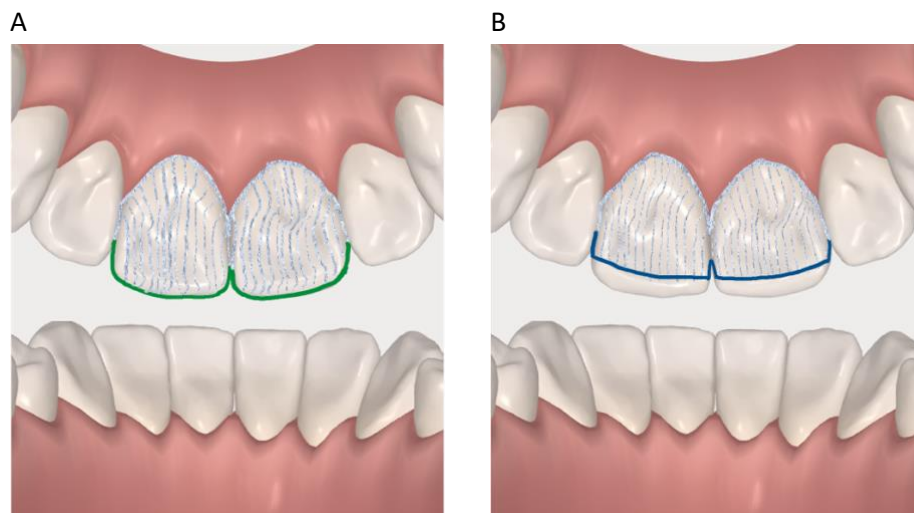


Figure 2.1 A diagrammatic representation of the metal wing of the palatal tooth surface (as would be utilised for two abutments).

A: The metal wing finishes at coloured height; original bridge (green lines – over incisal edge).

B: The metal wing finished at coloured height; adjusted bridge (blue lines- short if incisal edge).

A



B



Figure 2.2. Examples of the metal wing coverage of the palatal tooth surface (as would be seen when using two abutments and two pontics).

A: The metal wing finishes over the incisal edge, original bridge.

B: The metal wing finishes short of the incisal edge, adjusted bridge.

For all participants:

Photographs of the dental arch in the area of the missing tooth/teeth were taken using standard cheek retractors (UnoDent, HM Logistics Limited, Manchester, UK) at roughly 30cm from dentition. The camera was a Cannon SLR D500 (Ota City, Tokyo, Japan) and the settings used were taken from those suggested in the British Dental Journal (Ahmad, 2009) as follows: auto-focus with aperture set at f22, electronic cannon ring flash with shutter speed synchronised automatically by the camera (ranging from 1/125 to 1/250 s), ISO 100. The image colour space used was Adobe RGB, white balancing was automatic, and files saved as JPEG.s. The same dentist took all study photographs.

Colour selection of the pontic for the RRB was made by the dentist and participant with the assistance of the dental nurse. To help select the correct colour a cotton wool roll was placed behind the teeth that were to be used as abutments where the metal wing would sit to replicate the effect of the opaque cement on tooth colour and the colour chosen for the pontic matched. The VITA classical A1-D4® shade guide (VITA Zahnfabrik, Bad Säckingen, Germany) was used for colour selection.

Impressions of the dental arches and bite registration were then taken. Upper working impressions were taken using light body A-Silicone wash and heavy body Affinis (Coltene, Altstätten, Switzerland)(Tolidis et al., 2013), patient bite registration was taken using Futar D (Kettenbach GmbH & Co. KG, Eschenburg, Germany), and lower impressions were taken using alginate. Using the impressions, dye cast models were made and scanned using Medit DS20 (Renishaw Dental, Wotton under Edge, UK) this machine is accurate up to a distortion of 85.8 nanometers on all axis (Revilla-León et al., 2018).

The metal used for the wing of the RRB was Renishaw DMLS Cobalt Chrome alloy CoCr DG1 which complies with ISO 22674 and ISO 9693-1. Standard analysis by percentage weight of the elements were as follows: Co 63.9, Cr 24.7, Mo 5.0, W 5.4, Si 1.0. The CAD/CAM metal wing frameworks were laser sintered by Renishaw Dental (Renishaw Dental, Wotton under Edge, UK). A 12µm space between the metal wing and the abutment tooth surface was factored in to allow for optimal physical properties and minimal film thickness of the luting cement used for adhesion (Daud et al., 2018). The metal wing was designed with a minimum thickness of 0.5-0.6mm for CAD, the final thickness was between 0.3-0.25mm once finished and polished. The metal thickness at the connector was made to 9mm³ and polished by hand to accommodate the small pontic and occluding dentition.

For participants allocated to treatment regimen, original RRB (Fig 2.1A)

The wing extended to cover the maximum available palatal space of the abutment tooth, with coverage of 50% of incisal edge depth if an incisal shelf was present or coverage of the whole incisal edge if it was a knife point edge.

For participants allocated to treatment regimen, adjusted RRB (Fig 2.1B)

The wing extended to cover maximum available palatal space of the abutment tooth up to 0.5mm under the palatal-incisal bevel.

For all participants:

The metal wing frameworks were sand blasted using 50-micron sized Aluminum Oxide (approx. 2 bar pressure, approx. 40mm distance), prior to delivery to the dental clinic. At the junction to soft tissue, where the metal wing approaches the gum line, 0.5mm space was left to allow for cleaning at the gingival margin. The pontics were handmade using feldspathic porcelain (Vita, Bad Säckingen, Germany).

A letter was sent to the participants GDP to explain that their patient was taking part in this clinical study (Protocol Appendix 6).

2.2.3 Further treatment appointments

At the second appointment the RRB (original or adjusted bridge design) was placed, and clinical photographs taken. Clinical photographs were taken using the set standards as outlined above in 2.2.2. Participants were assessed to confirm that they still met the inclusion criteria throughout the duration of the study, and those who continued to be eligible (those who still met all the inclusion criteria) were fitted with their RRB using the stages as described below.

Initially a fit check was carried out to make sure there was no interference on placement of the wing onto the abutment tooth and the pontic into the tooth space (passive fit). Colour check was then carried out using opaquer on the fitting surface of the metal wing. Any adjustments were made to the fit and the colour on the same day. The fit surface wing was then sand blasted using 50-micron sized Aluminum Oxide (approx. 2 bar pressure, approx. 40mm distance).

The abutment tooth was isolated with Cotton Wool Rolls No.1 (UnoDent, HM Logistics Limited, Manchester, UK), dry tips (Microbrush, Wisconsin, USA) cheek isolation and aspiration. The abutment tooth fit surface was cleaned with prophylactic paste (TOC Dental, Bristol, UK). The fit surface was then etched with 37% phosphoric acid etchant Super Etch (SDI, Bayswater, Australia). The luting cement used was Panavia F 2.0 (Kuraray Tokyo, Japan) opaque shade. Equal amounts of ED PRIMER II A&B were mixed and applied to the abutment tooth, and after 30 seconds gently air dried. Equal amounts of paste A & B (opaque) were dispensed, the luting cement was loaded onto the abutment wing using a microbrush (Microbrush, Wisconsin, USA) and the wing was seated onto the abutment tooth. Excess cement was removed using a Benda Brush (Centrix, Connecticut, USA) and the surface was light cured for 20sec per surface using Smartlight Focus Dentsply (Pennsylvania, USA) LED light. Then a final self-cure material Oxyguard II was applied to the margins of the restoration. While waiting for the 3 min required for the Oxyguard II to work the excess cement was removed with sickle scaler and floss.

The two treatment procedures, including those outlined in ‘screening appointment’ above are summarised in table 2.3.

Table 2.3 Clinical treatment procedures and assessments

Treatment procedure Original RRB	Treatment procedure Adjusted RRB
Impression for working models, clinic photos, screening clinical assessments and OHIP-14 questionnaire.	Impression for working models, clinic photos, screening clinical assessments and OHIP-14 questionnaire.
Plain radiograph of pontic site and surrounding teeth. If required, many patients will have these radiographs already.	Plain radiograph of pontic site and surrounding teeth. If required, many patients will have these radiographs already.
Fit of RRB. Original design. Using Panavia F and clinical photos	Fit of RRB. Adjusted design. Using Panavia F and clinical photos

Patient groups and GDP assessment of aesthetics of RRB cases.	Patient groups and GDP assessment of aesthetics of RRB cases.
OHIP-14 questionnaire.	OHIP-14 questionnaire.
18 months after bridge placement, review the number of failures reported	18 months after bridge placement, review the number of failures reported

One month after resin bridge fit the patient was sent a link to an electronic version of the questionnaire on quality of life and a paper copy of the questionnaire with a stamped addressed return envelope (as an alternative to the electronic version), with regards to oral health (Protocol Appendix 1: OHIP-14. Protocol Appendix 2: Adjusted OHIP-14). One reminder letter to complete the OHIP-14 questionnaire with the link to the on-line version as well as a paper copy and a stamped addressed return envelope was sent to participants. After bridge fit the participant was referred by to their general dentist with whom a standard review was scheduled every 6 months as is routine with this type of treatment.

2.2.4 Outcome measures

One of the most important outcomes for tooth replacement is the survival of the RRB. This study was not powered to determine differences in RRB failure rates as this was not the main outcome measure, however it is important to know the failure and complication rates for the participants in this study group. A 1999 paper that tested the same design of RRB used as the control in this study considered the coverage of metal on the abutment tooth as an indicator for length of survival. It showed the design/extent of the metal wing on the abutment affected the survival of RRB and suggested that the increased coverage had the best survival and had less failures for the first 35months compared with other designs (Djermal et al., 1999). Further analysis of the original RRB over a longer period showed that most failures happened within the first 18 months post RRB placement, then flatlined at 35 months (King et al., 2015) this information can be taken from the graphs within the paper and has been confirmed by the author. As a result of these findings, even though improvements in bonding materials and metal fit should ensure that the reduced metal coverage on the adjusted wing would not result in poorer survival, the failure rates of this participant cohort are being reviewed at 18 months post RRB placement.

The participants GDPs were asked to contact the study dentist if there were any RRB failures or

complications as is standard procedure for any patient who has a RRB fitted on the study clinician's clinic. Complications/failures would be managed by normal local Bristol Dental Hospital protocol for any failures as follows, the participant would be seen again within BDH and a senior clinician would reassess them and treat appropriately according to the clinical findings. Only standard practice treatment (not the use of adjusted design bridge) would be used to manage any failures and treatment would be carried out at BDH.

2.3 Aesthetics assessments

2.3.1 Recruitment of participants assessing aesthetic outcomes

Three groups of participants were identified and recruited into the study. The three groups were Group 1: Dental Care Professionals, (DCPs adults aged 18+) Group 2: Hypodontia patients and Group (aged 11+) 3: The public (adults aged 18+).

DCPs at Bristol Dental Hospital and School were sent an email giving an overview of the study and the participant information sheet (Protocol Appendix 7e) using the two global addresses that together reach all DCPS working at BDH. The email contained a link to the anonymised images and assessment hosted on an on-line surveys platform (<https://www.onlinesurveys.ac.uk>).

Adults and young adults with hypodontia (from age 11 years and older) were recruited from those patients who were scheduled to attend a Hypodontia clinic at BDH. The patients were contacted by the dental administrator who manages the appointments for this clinic with information about the study, a participant information sheet (Protocol Appendix 7a-c) and a link to the images and assessment hosted on an online survey platform (<https://www.onlinesurveys.ac.uk>). Information sheets about the study were also handed out at the hypodontia clinic and had a Quick Response code (QR code) generated from (<https://www.the-qr-code-generator.com>) to the online survey platform (<https://www.onlinesurveys.ac.uk>).

The Public were recruited via the charity 'Health Watch' (<https://www.healthwatch-uk.org>) who posted the study with links to the participant information sheet (Protocol Appendix 7d) and anonymised images and assessment on their social media pages that can be accessed by their members.

Participation in this part of the study was anonymous. Due to the pandemic all participants were asked to complete the aesthetics assessment using the online survey platform to reduce contact. Those

completing the assessment online were asked to confirm that they consented to participation before opening the assessment. Responses from the on-line assessment were returned in fully anonymised form.

2.3.2 Aesthetic image assessment

Due to the delays imposed by the COVID-19 pandemic on the clinical study there were only 27 images available to generate the aesthetics questionnaire. The decision to generate the questionnaire at this time was taken due to the uncertainty surrounding study re-start and the timelines of this research. The images showed the anterior maxillary sextant with cheek retraction (dental view) as previously lay persons have perceived the aesthetic impact of the visible anterior occlusion was greater in a dental view than full facial view (Flores-Mir et al., 2004). The 27 images were divided into “original” and “adjusted” groups and 5 images from each group (Stenvik et al., 1997; Kokich et al., 1999) were randomly selected to use for comparison. The selection of the 5 images from each group and their randomisation of the images into the questionnaire format was done using a free online resource “random.org”.

The anonymised images of the RRB cases, 5 from group A and 5 from group B were assessed by the 3 participant groups (Hypodontia patients, The Public and Dental Care Professionals (DCPs)) (Rosa et al., 2013)(Kuncio et al., 2007)(Tedesco et al., 1983). The decision to use three groups was made as this would allow the assessment of possible variation in opinion of dental aesthetics between the groups as well as the determination of whether one RRB was preferred over the other.

For each image participants were asked to respond to the following question:

‘Please rate 1-5 overall attractiveness. (1-Very unattractive, 2-Unattractive, 3-Neither attractive nor unattractive, 4-Attractive, 5-Very attractive) (Ong et al., 2006). The questionnaire was created on an on-line platform (<https://www.onlinesurveys.ac.uk>). Participant gender was also recorded, but no additional information, each group had a link to the questionnaire that was unique to their group. An example page from the electronic questionnaire can be found in Protocol Appendix 3.

2.3.3 Statistical Methods

2.3.3.1 *Sample size*

Clinical study:

In the clinical part of the study, differences in bridge failure rates between groups at 18 months is anticipated to be very low, and data will be collected simply to monitor this in case there are any differences. If available by the time the thesis is submitted this data will also be described using descriptive statistics.

Aesthetic study:

Aesthetic outcome samples sizes were calculated separately for groups of assessors as described below.

Previous evaluations of service provision on hypodontia patients at Bristol Dental Hospital had indicated that approximately 40% of patients receiving the original bridge design voiced concerns about the visible metal incisal edge of the bridge on their front teeth. Therefore, we felt it likely that when looking at clinical images of the dentition some would see the metal incisal edge of bridge and therefore would see a difference between bridge designs original and adjusted. The adjusted design of bridge is used in general dental practice (without standardised design but leaving the metal short of the incisal edge) due to patient dissatisfaction with the visible metal edge.

Hypodontia patients: The sample size was based on the primary outcome measure of the proportion of hypodontia patients preferring the adjusted bridge design over the original bridge design. As described above, on patient review approximately 40% of patients receiving the original bridge had voiced concerns about the visible metal incisal edge of the bridge (false tooth) after it has been fitted. It was anticipated therefore that 40% of hypodontia patients assessing the images would prefer the adjusted design to the original design and the remaining hypodontia patients would be split equally between adjusted and original designs. Based on this assumption, a sample size of 47 hypodontia patients provided 80% power of detecting a difference between the bridge designs at the 5% level.

The Public participants: The sample size was based on the primary outcome measure of the proportion of public preferring the adjusted bridge design over the original bridge design. It was anticipated that public would be slightly less likely to see things that could compromise the aesthetics of a replaced tooth, being more focussed on the general overall appearance of the teeth. As these

adults were not dentists, may not have had much exposure to dentistry and therefore would be less likely to be dentally aware it was anticipated that 30% of this group would see a difference between bridge designs overall preferring the adjusted design, the remaining individuals being split equally between adjusted and original design. Based on this assumption, a sample size of 89 members of the public would provide 80% power of detecting a difference between the bridge designs at the 5% level.

Dental Care Professionals: The sample size was based on the primary outcome measure of the proportion of dental professionals (those with GDC registration) preferring the adjusted bridge design over the original bridge design. It was anticipated that dental care professionals would be more likely to detect differences in the aesthetic outcomes of the two bridge designs as they are dental professionals, but as they were only reviewing images rather than patients in a dental chair a conservative estimate was that 50% would prefer the adjusted design over the original design, the remaining DCPs being split equally between adjusted and original design. Based on this assumption, a sample size of 29 DCPs provided 80% power of detecting a difference between the bridge designs at the 5% level.

It was not possible to power for a difference between the groups of assessors (dental care professionals as compared to The Public, as compared to dentally aware patients).

2.3.3.2 Statistical Analysis

Clinical Study OHIP-14 responses to each item were scored on a 5-point scale from 0 (never), to 4 (very often), and the total OHIP-14 score before and after bridge fit for each participant was calculated. As OHIP-14 scores did not follow a normal distribution (tested for by Shapiro-Wilk), the non-parametric Wilcoxon signed Rank test was used to determine if there were improvements in OHRQoL following bridge fit within each group, and the Mann Whitney U test was used to determine whether there was a difference in OHRQoL between patients receiving the original as compared to the adjusted bridge.

Aesthetic data analysis: To see if there was any difference in the preference of participants for the adjusted or original bridge design, an overall score per participant for each set of 5 images (original and adjusted RRB) was calculated using ascending numerical values assigned to the 5-point aesthetic scale (1 = very unattractive, 5 = very attractive). Comparison of the total score for each bridge design indicated if the participant had no overall preference (scores equal for each design of RRB), or if there was an overall preference for the original or adjusted RRB. Data were cross tabulated by group

including row percentages and analysed using Pearson χ^2 analysis using the three-category outcome of no preference, preference for the original bridge or preference for the adjusted bridge. As the percentage who had no preference was very similar in each of the three participant groups, this analysis was repeated with a two-category outcome. The two categories were those with no preference added to those who preferred the original bridge (i.e. all those who did not actively prefer the adjusted bridge design were grouped together), and this merged group was compared to those who preferred the adjusted bridge. This was done to determine if there was statistical evidence for an overall preference for the adjusted bridge when all participants scores were pooled, and for each individual participant group. One sample χ^2 tests of proportions were carried out using the two-category outcome. Analysis to determine whether there was a difference between males and females in preference for the original or adjusted bridge was carried out on the combined participant data grouped by gender and analysed using χ^2 for both three and two category outcomes.

3 Results

3.1 Clinical study

During the clinical aspect of this research the global pandemic COVID-19 halted clinical trials and other on-site research projects which put anyone at unnecessary risk on 23rd March 2020 due to routine procedures prohibited with closure of Bristol Dental Hospital. Routine dentistry within general dental practice was also suspended until 8th June 2020. Emergencies dental services were operational in the Dental Hospital during this time.

While participant enrolment had already been completed by the by 16th March 2020, not all RRBs could be fitted before the official restrictions were imposed on routine care. These outstanding RRB fits could not take place until after permission to re-start the study was granted (22nd October 2020) and routine dental care could be resumed. When the study was restarted, it was imperative that the final 12 participants received their RRB as soon as possible. The fitting of a RRB is deemed an aerosol generating procedure (AGP) and AGP sessions were equally divided between staff, therefore it was not practical to restrict bridge fit to only one clinician as if the participants had had to wait to see one specific clinician for RRB fit, some would have an additional wait of up to 6 months. The recall of patients, including study participants, back to the Bristol Dental Hospital (BDH) for treatment was done in the order in which they were originally booked, excepting priority for any emergencies or complications. All staff who fitted the bridges were suitably senior and experienced to manage the complexity of fitting the RRBs who worked regularly on the clinic. They had been trained by the main study clinician in the fitting of RRBs which forms part of their normal role on this clinic, and the fitting stages for the original and adjusted RRB were the same with the exception that the original RRB also required final adjustment and polishing to the incisal edge overlap for which these staff has also been trained and is undertaken as standard practice. The final study bridge was fitted on 17th Nov 2020.

Demographic information

The percentage of males to females within clinical element of the study was 43% to 58% respectively which is a ratio of 1:1.34

A large proportion of the clinical trial group were under 18 years old (73%). The adults in the group accounted for 30% of the study group.

The reasons for tooth loss amongst participants was hypodontia 85% and trauma 15%. The patient flow through the study is shown in Figure 3.1

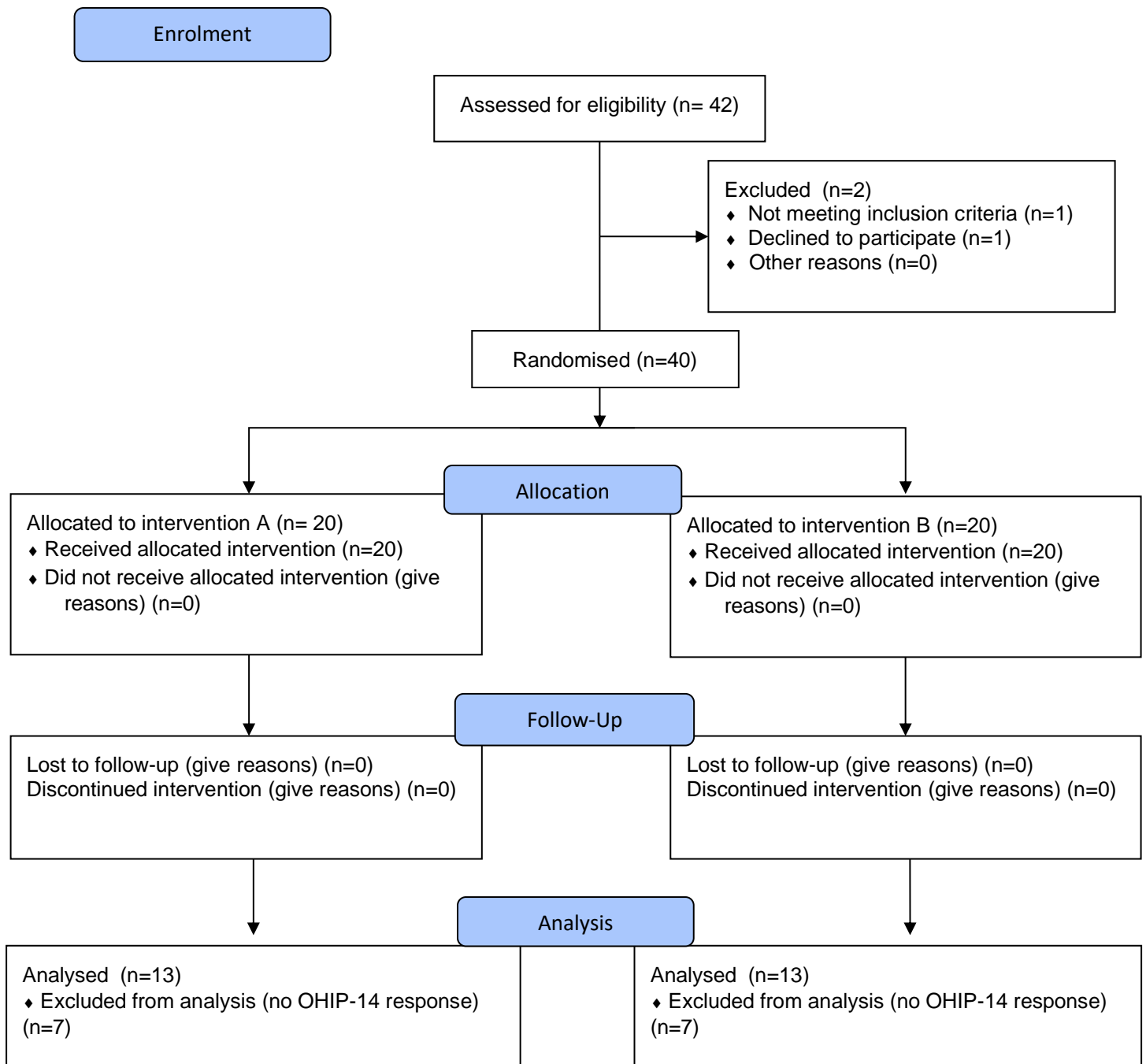


Figure 3.1. Participant flow through the study

Oral Health Quality of Life

All 40 participants completed the OHIP-14 (Protocol Appendix 1: OHIP-14. Protocol Appendix 2: Adjusted OHIP-14) survey before any treatment commenced, 28 participants were young adults (age 11-18 years) and 12 were adults (18 years +). Post treatment, 26 participants completed the post-treatment survey (65%), 21 were young adults and 5 were adults. Figure 3.2 shows pre-treatment results.

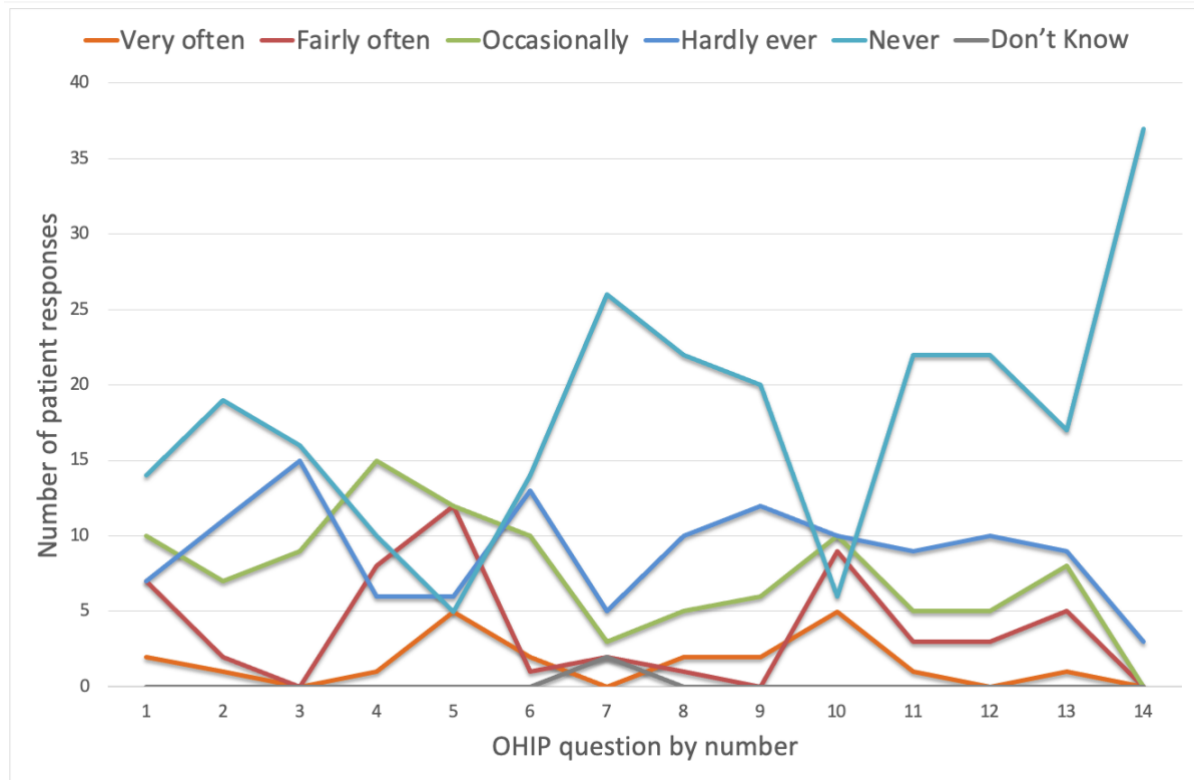


Figure 3.2: The effect of problems with study participants teeth or mouths on daily activities before treatment intervention as measured by OHIP14. Effect on: Q1 pronouncing words, Q2 taste, Q3 pain (aching), Q4 eating (discomfort), Q5 self-consciousness, Q6 stress, Q7 diet, Q8 mealtimes, Q9 ability to relax, Q10 embarrassment, Q11 irritability, Q12 general daily activities, Q13 happiness, Q14 ability to function. The blue lines show the number of participants with more positive (never, hardly ever) OHIP-14 responses and red lines the more negative (very or fairly often) OHIP-14 responses for each question. (Protocol Appendix 1: OHIP-14. Protocol Appendix 2: Adjusted OHIP-14).

The factors that were of most concern to participants very or fairly often before treatment were as follows: 42.5% were feeling self-conscious (Q5), about their mouth/teeth (17/40), 35% were embarrassed (Q10) about their mouth/teeth (14/40), 22.5% were finding it uncomfortable to eat some foods (Q4) (9/40), 22.5% had trouble pronouncing words (Q1) (9/40) and 15% were feeling unhappy about their mouth/teeth (Q13) (6/40).

Figure 3.3 shows the data for the 26 of the 40 patients completed the post treatment OHIP-14 survey after treatment.

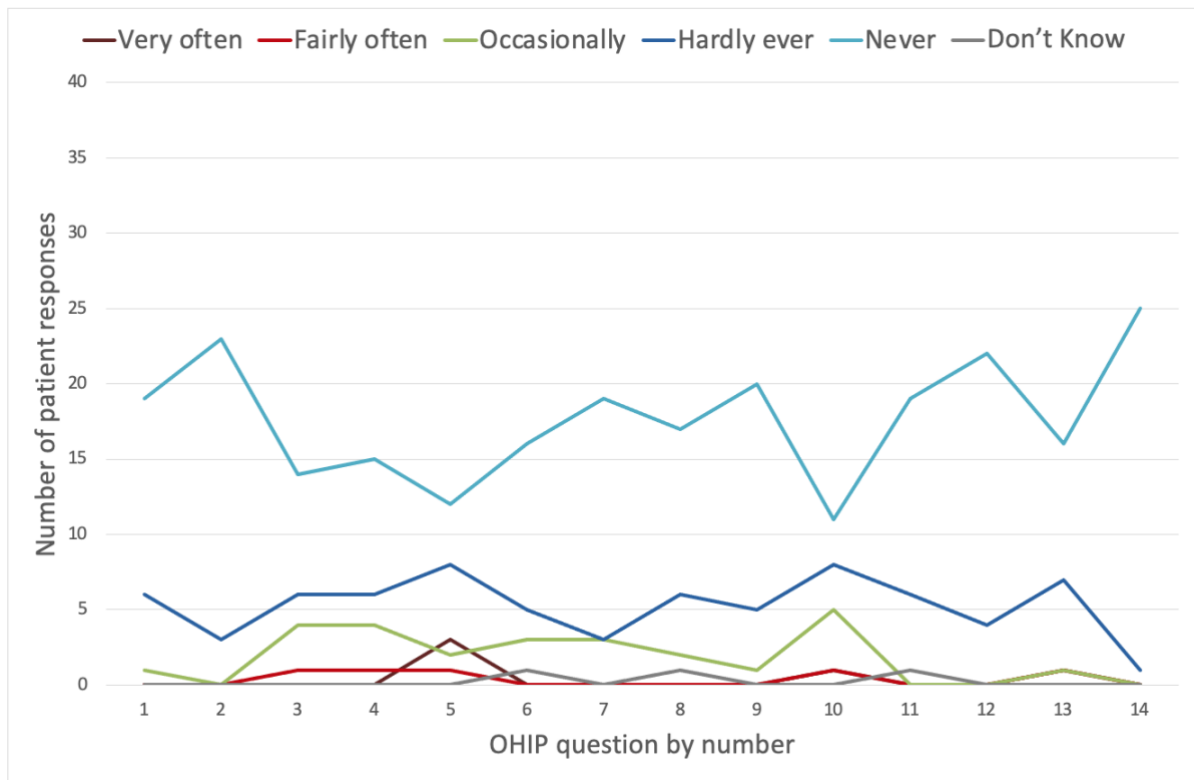


Figure 3.3: The effect of problems with study participants teeth or mouths on daily activities after treatment intervention as measured by OHIP14. Effect on: Q1 pronouncing words, Q2 taste, Q3 pain (aching), Q4 eating (discomfort), Q5 self-consciousness, Q6 stress, Q7 diet, Q8 mealtimes, Q9 ability to relax, Q10 embarrassment, Q11 irritability, Q12 general daily activities, Q13 happiness, Q14 ability to function. The blue lines show the number of participants with more positive (never, hardly ever) OHIP-14 responses, and red lines the more negative (very or fairly often) OHIP-14 responses for each question. (Protocol Appendix 1: OHIP-14. Protocol Appendix 2: Adjusted OHIP-14).

While the number of responses post treatment were moderate (n=26, 65%), the data demonstrated that the only item on the OHIP-14 scale that continued to cause any concern was self-confidence (Q5), with 15.3% finding they were still self-conscious about their teeth very often (3/26) and fairly often (1/26), although this number was far less than 42.5% (17/40) pre-treatment.

All total OHIP-14 (OHRQoL scores) pre and post treatment are shown in **Figure 3.4**. Prior to treatment there was no statistical difference in total OHRQoL scores between groups. When total OHRQoL scores were compared before and after treatment for those participants who completed both questionnaires, statistical evidence for an improvement in OHRQoL was demonstrated both when all participants were considered together (p<0.001) and when the groups receiving the original and the adjusted bridge were considered separately (Original p = 0.002 and Adjusted p = 0.001

respectively). However, there was no statistical evidence for a difference in improvement in OHRQoL between the two groups.

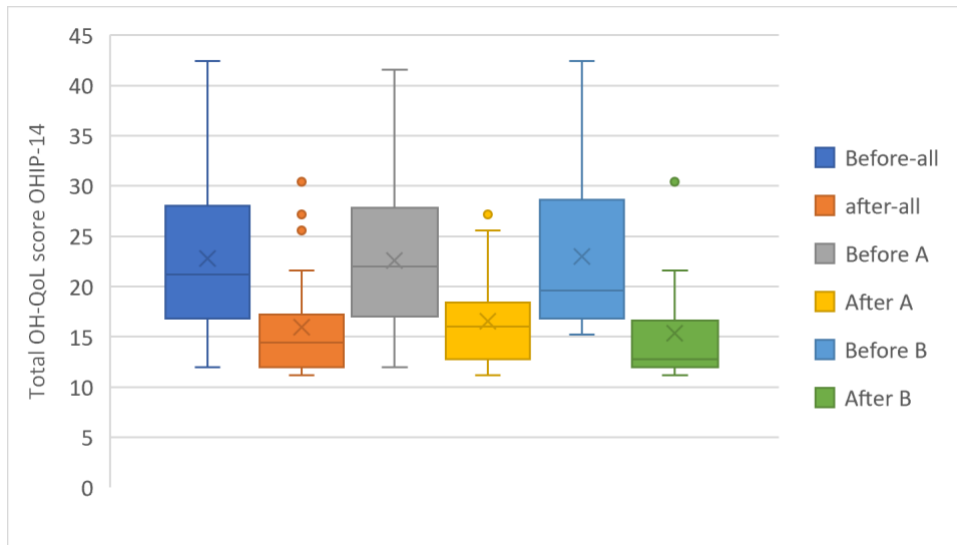


Figure 3.4. Box and Whisker plot of the total quality of life scores for each participant who completed the OHIP-14 questionnaire before (40) and after (26) receiving their RRB. A: original RRB. B: adjusted RRB. Horizontal lines indicate the median value of each box, and X the mean value.

To date there have been no reported failures or complications of any of the RRBs fitted with design original or adjusted RRB.

3.2 Aesthetics data

In total, 222 individuals completed the aesthetics questionnaire, 109 members of The Public, 76 hypodontia patients and 37 DCPs.

Data for the hypodontia patient responses are shown in figure 3.5.

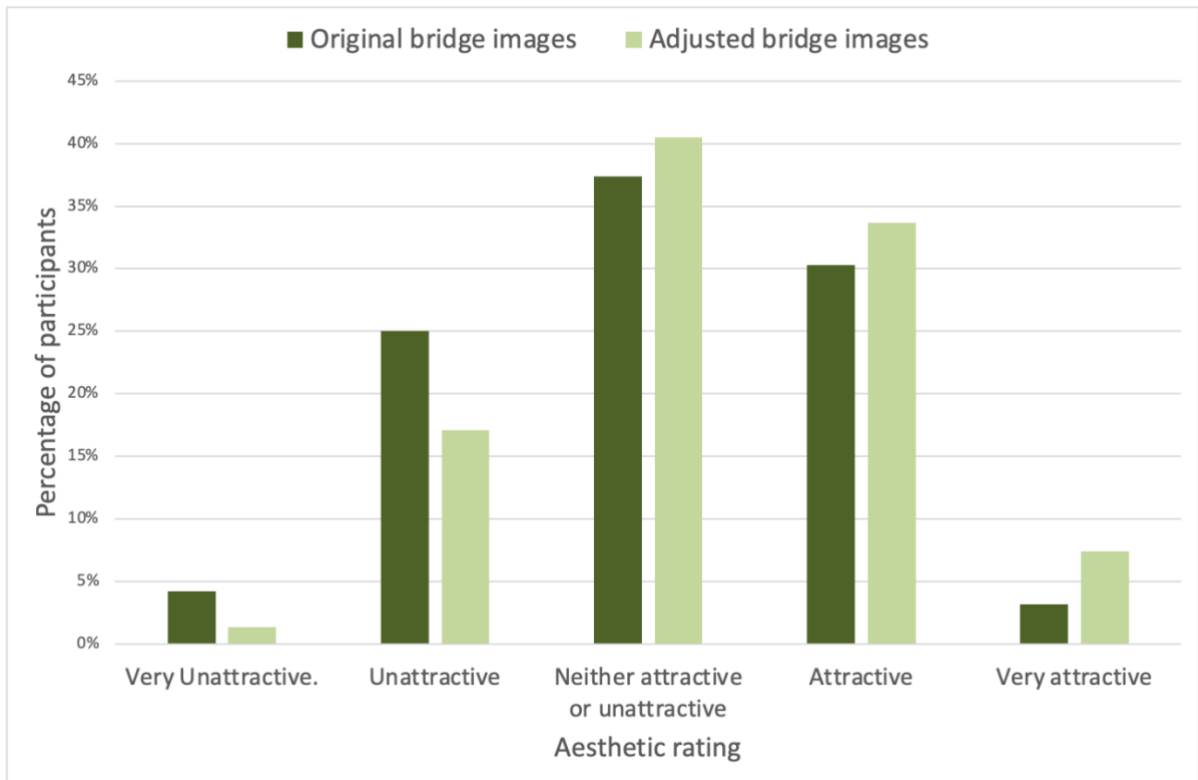


Figure 3.5: Hypodontia patient’s opinion of the aesthetics of the original as compared to the adjusted RRB design (n=76). Each participant chose an attractiveness rating for each of 10 images, 5 original RRB and 5 adjusted RRB. The total scores obtained for original RRB or adjusted RRB for each aesthetic rating were calculated and the percentage of participants giving this rating displayed.

While participants felt that the attractiveness of the 2 bridge designs was very similar, 4% thought the original design bridge was very unattractive while only 1% indicated the adjusted design was very unattractive. Similarly, 7% indicated the adjusted design bridge was very attractive as compared to 3% who thought the original design bridge was very attractive.

Figure 3.6 shows the data obtained from The Public.

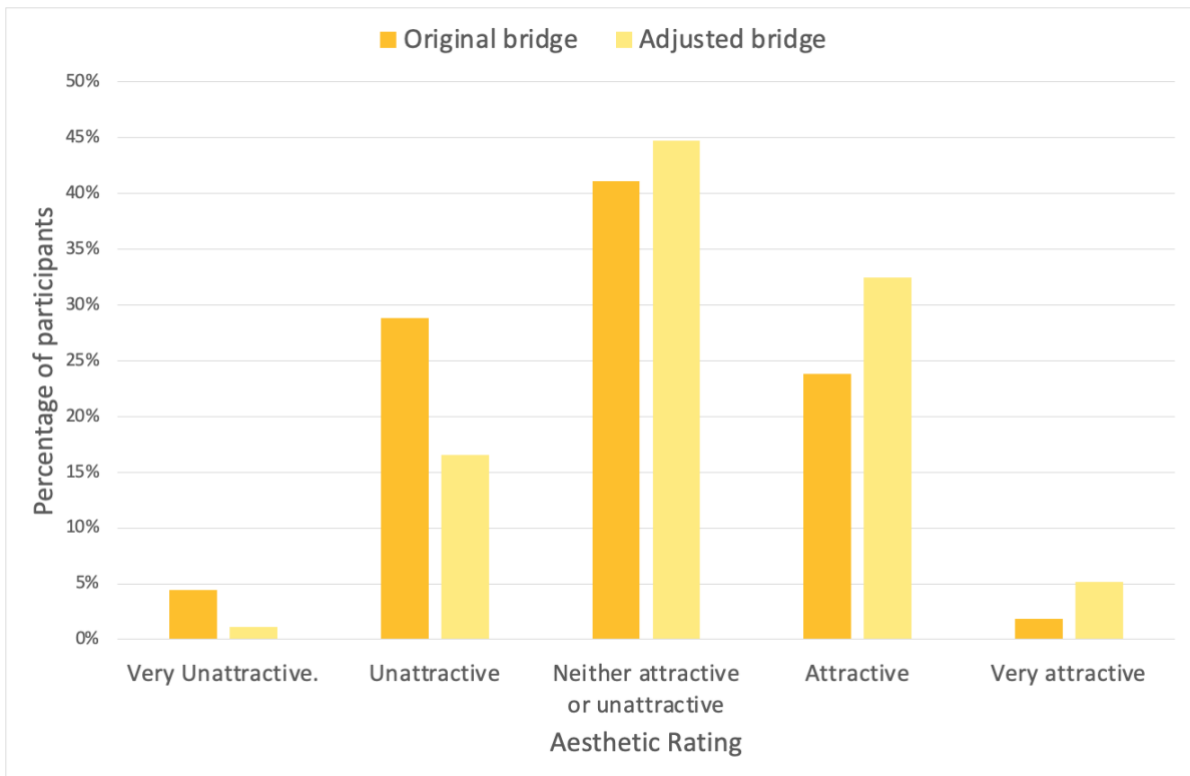


Figure 3.6: The Public’s opinion of the aesthetics of the original as compared to the adjusted RRB design (n=109). Each participant chose an attractiveness rating for each of 10 images, 5 original RRB and 5 adjusted RRB. The total scores obtained for original RRB or adjusted RRB for each aesthetic rating were calculated and the percentage of participants giving this rating is displayed.

Similar to the hypodontia patient responses, the profile of assessments for each bridge design is similar, however the original bridge design was reported as being very unattractive or unattractive by 33% of participants, whereas the adjusted bridge designs was reported as being very unattractive or unattractive by only 18%. In line with this, 32% vs 24% of participants thought that the adjusted bridge design was attractive, and 5% vs 2% of participants thought that the adjusted bridge design was very attractive.

Responses of Dental Care Professionals to the images of the 2 bridge designs are shown in Figure 3.7

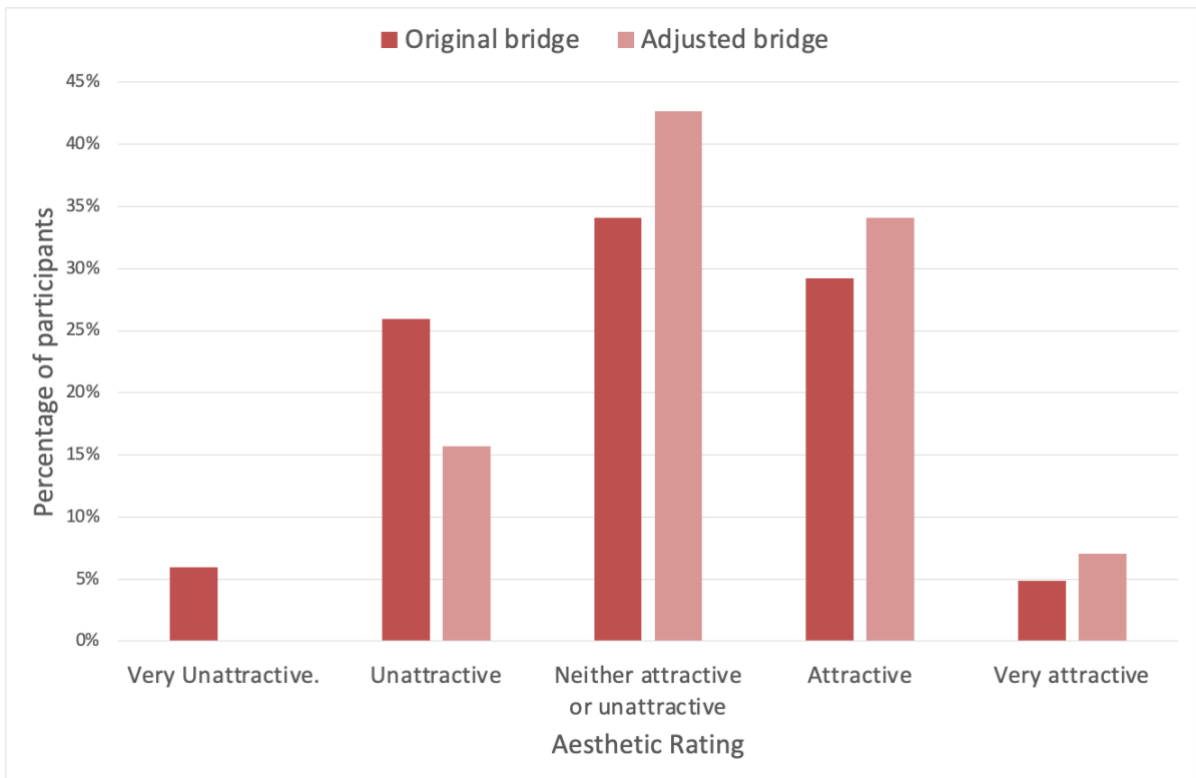


Figure 3.7: The dental care professional’s opinion of the aesthetics of the original as compared to the adjusted RRB design (n=37). Each participant chose an attractiveness rating for 10 images, 5 original RRB and 5 adjusted RRB. The total scores obtained for original RRB or adjusted RRB for each aesthetic rating were calculated and the percentage of participants giving this rating displayed.

While the overall pattern of responses in the DCP group is similar for the original and adjusted bridge, a clearer polarisation can be seen in these participants Figure 3.7. There is a clear difference in scoring with very unattractive only being the original bridge and a clear preference can be seen in every other assessment score for the adjusted bridge.

Total aesthetic scores calculated per participant for each bridge type are shown in **Figure 3.8**.

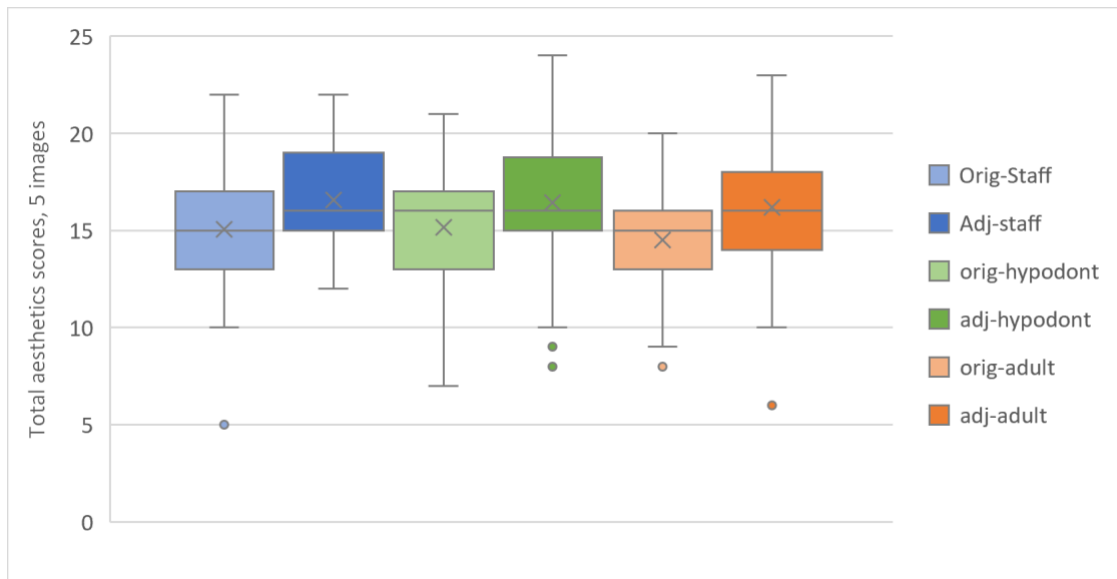


Figure 3.8. Box and Whisker plot of the total aesthetic score (where very unattractive =1, and very attractive = 5), for each bridge type as assessed by each group. Orig: original RRB. Adj: adjusted RRB. Horizontal lines indicate the median value of each box, and X the mean value.

The number of participants who, when considering their scores for each bridge type (5 images) together, had an overall preference for the original bridge, adjusted bridge, or no preference is shown in Table 3.1 and, the number who had a preference for the adjusted bridge as compared to either no preference or preference for the original bridge (combined) is shown in Table 3.2.

Table 3.1 Three category outcome for aesthetics outcomes for all groups

Group	No preference n (%)	Preference original n (%)	Preference adjusted n (%)	Total n (%)
Hypodontia patient	12 (17.11)	20 (26.32)	43 (56.58)	76 (100)
The Public	19 (17.43)	19 (17.43)	71 (65.14)	109 (100)
DCPs	6 (16.22)	9 (24.32)	22 (59.46)	37 (100)
Total	38 (17.12)	48 (21.62)	136 (61.26)	222(100)

Table 3.2 Two category outcome for aesthetics outcomes for all groups

Group	No Preference and preference original n (%)	Preference adjusted n (%)	Total n (%)
Hypodontia patient	33 (43.42)	43 (56.58)	76 (100)
The Public	38 (34.86)	71 (65.14)	109 (100)
DCPs	15 (40.54)	22 (59.46)	37 (100)
Total	86 (38.74)	136 (61.26)	222(100)

There was no statistical evidence for a difference in the percentage of participants in each of the groups that preferred the adjusted bridge either when percentages for the 3 outcomes (prefer original, prefer adjusted, no preference) were compared, or when the percentages for the 2

outcomes (in which the no preference outcome was combined with prefer original) were compared giving **Table 3.1:** Chi² 2.3675, p=0.668 **Table 3.2:** Chi² 1.4429 p= 0.486.

When data from all three participant groups were combined, the two-outcome analysis demonstrated that there was statistical evidence for a preference for the adjusted bridge (p < 0.001). Similarly, when considering each of the groups separately a two-outcome analysis showed there was statistical evidence for a preference for the adjusted bridge by The Public (p= 0.003). However, although the DCPs and hypodontia groups indicated a preference for the adjusted bridge the statistical evidence to support this preference was not sufficient to confirm this (p = 0.251 and p = 0.250, respectively).

Considering the influence of gender on bridge type preference across all participant groups. The number of participants from each gender who, when considering their scores for each bridge type (5 images) together, had an overall preference for the original bridge, adjusted bridge, or no preference for either is shown in Table 3.3 and the number who had a preference for the adjusted bridge as compared to either no preference or preference for the original bridge (combined) is shown in Table 3.4.

Table 3.3 Three category outcome for aesthetics outcomes for gender

Group	No preference n (%)	Preference original n (%)	Preference adjusted n (%)	Total n (%)
Male	16 (20.00)	23 (28.75)	41 (51.25)	80 (100)
Female	21 (15.00)	25 (17.86)	94 (67.14)	140 (100)
Total	37 (16.82)	48 (21.82)	135 (61.36)	220(100)

Table 3.4 Two category outcome for aesthetics outcomes for gender

Group	No Preference & Preference original n (%)	Preference adjusted n (%)	Total n (%)
Male	39 (48.75)	41 (51.25)	80 (100)
Female	46 (32.860)	94 (67.14)	140 (100)
Total	85 (38.64)	135 (61.36)	220(100)

Statistical evidence for a gender difference in the percentage, who preferred the adjusted bridge, was borderline (p = 0.06), when data were analysed with three outcome categories and marginally stronger when analysed with two outcome categories (p=0.02), and indicated that more females than males preferred the adjusted bridge

4 Discussion

This study was undertaken in 2 parts, in the clinical phase study participants with hypodontia or missing teeth due to trauma were randomised to receive either the original or adjusted RRB, then in phase 2, anonymised photographs of the two RRBs post placement were assessed by three independent groups to determine if the adjusted bridge improved aesthetic outcomes. The null hypothesis, there were no differences between preferences of participants for the RRBs was disproved, with sufficient statistical evidence to support a preference for the adjusted RRB.

4.1 Participants in the clinical study

In the clinical part of the study the 40 planned participants received their RRBs despite the interruption of the study due to the COVID-19 pandemic. More females than males received the RRB (M:F 1:1.34). When considering only the hypodontia patients (85%), the male to female ratio was (M:F 1:1.61) which is slightly higher than that described internationally as reported by a systemic review and meta-analysis (male: female, 1:1.16) (Rakhshan et al., 2016). Thus, gender does appear to affect the prevalence of congenital missing teeth. In the UK, a large seminal orthodontic study of 6000 patients showed a 1:1.46 male: female ratio for congenitally missing teeth (Rose, 1966), and more recently, Polder et al (2004) found that females had a prevalence value 1.37 times higher than males, a difference that was statistically significant (RR 51.37; 95% CI for RR 51.28–1.45). The ratio of female to male hypodontia participants in the UK study reported here, therefore, is in line with the literature. There may be a genetic basis for the difference in prevalence of hypodontia between females and males, however the cause of the most common forms of hypodontia remain unknown (Shimizu et al., 2009). The higher number of female hypodontia sufferers seen in this study could also reflect the greater presentation of treatment need amongst females (Doyal et al., 2010) (Aasheim et al., 1993).

As predicted a large proportion of the clinical trial participants in the present study were under 18 years old (73%). This is likely to be because patients with hypodontia are frequently diagnosed at young age, and then seen on hypodontia multidisciplinary team (MDT) clinics at age 12-14 years old (Harrison, 2019). Many then undertake multidisciplinary treatment that can span several years (Bharmal et al., 2018), generally finishing their orthodontic treatment within 21 months (Stevenson et al., 2013). If these patients require tooth replacement, they are referred to specialist services post orthodontic treatment. The reasons for tooth loss amongst study participants were hypodontia 85%

and trauma 15%. These percentages are in line with what would be expected as a recent service evaluation of the reasons for referral of patients to the Restorative Dentistry MDT clinic for tooth loss reported that of the total referrals, 75% were for hypodontia and 18% for trauma (Lin et al., 2021 b), the remainder being for a broad range of other reasons. Overall, the study data indicates that the study population appeared representative of the population normally seen at BDH for RRBs.

4.2 RRB survival and complications

The last RRB was fitted on 17th November 2020, normal reporting systems and review appointments for emergencies were possible throughout the pandemic, and to date (1st August 2022) there have been no recorded survival or complication issues with either bridge design, all are still in situ 21 months later. By contrast, while data from a previous study of the original RRB used here indicated 5-year and 10-year survival rates of 80.8% and 80.4%, respectively, it also demonstrated roughly that 10% failed within the first year (King et al., 2015). It likely that there is less failure within the cohort fitted with the original RRB in the present study as the clinician placing the RRBs was highly qualified and materials are better now than they were 22+ years ago when the RRBs were assessed original studies (Djemal et al., 1999; King et al., 2015). The 3 most common complications associated with resin-bonded prostheses are: prosthesis debonding (21%), tooth discoloration (18%), and caries (7%) (Goodacre et al., 2003). The 5-year survival rates for RRBs reported by King et al (2015) are in line with the findings of a recent systematic review that demonstrated 83.6% survived to 5-years, with anterior RRBs more retentive than those placed on posterior teeth, the review recommending that when possible, RRBs should be included as a treatment option (Balasubramaniam, 2017). The long-term follow up for all participants in the present study will be monitored by their GDP who will carry out 6 monthly patient reviews for 2 years following bridge placement as is standard for this treatment. Any complications or failures will be sent back to BDH for management and recorded for study purposes and the participant will then be treatment planned to offer alternative tooth replacement if appropriate.

4.3 OHRQoL in participants who received a RRB

Patients who require fixed tooth replacement, in most circumstances, initially have an immediate removable denture to replace the teeth while waiting for their fixed replacement. Patients who have required orthodontics to create an appropriate space for a fixed tooth replacement also have a form of immediate removable denture known as a retainer (either Hawley or Essix with teeth) immediately after debond of their orthodontic appliance, which remains in place until their fixed tooth replacement can be fitted. These retainers maintain the space where a tooth is missing until

the fixed tooth replacement is fitted, thus all study participants waiting for RRBs to be placed wore removable partial dentures at the study start.

The OHRQoL scores pre-treatment reported here are what would be expected for individuals wearing a removable prosthesis (denture/retainer) and are in line with other studies which have yielded relatively similar results (Shaghaghian et al., 2015). Removable partial dentures (RPDs) address some of the impacts that missing anterior teeth have on OHRQoL, with a significant improvement (a decrease of 9 points in OHIP-20 scores) seen following tooth replacement (Ali et al., 2017). However, using OHIP-14 to determine OHRQoL for RPDs it has previously been shown that improvements in OHRQoL in study participants are strongly associated with good oral health and hygiene practices which will not be common to all wearers, and furthermore, that the OHRQoL of the RPD wearers was generally not optimal (Shaghaghian et al., 2015).

The OHIP-14 questionnaire covers a range of different OHRQoL issues: Function limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and social handicap (Slade, 1997 a). As RPDs cover the palate and/or the teeth this results in potential functional limitations, at least in the short term. RPD coverage affects speech as it alters the tongue position, it also changes the way the teeth meet which can allow for air to escape through the teeth making lisping more common (De Siqueira et al., 2013). A common reason for RPD wearers to experience difficulty with eating is the coverage of the removable prosthesis over the palate/teeth which causes food packing around and under the removable prosthetic, and can cause ulceration due to rocking (Theenathayalan et al., 2019). In addition, RPD coverage over the teeth and change in bite make chewing more difficult, thus even though a removable prosthesis can help, it does not re-establish the masticatory function fully (Bessadet et al., 2013). For many of the issues described here, patients are able to adapt to wearing their RPD over time, and although some adapt more easily than others it has been shown that most adapt within 3 months (Luraschi et al., 2013). However, it should be noted that the participants in the current study had opted for a fixed tooth replacement, suggesting that they had not adapted well to wearing their RPD.

In the present study, the parameters of OHRQoL which were impacted the most prior to the placement of RRBs fell into 4 main areas, feelings of self-consciousness/embarrassment, feeling unhappy, finding it uncomfortable to eat and experiencing trouble pronouncing words. Difficulty in eating was a key finding in a previous study carried out in Iranian adults where 27 and 24% reported meal disruption and discomfort when eating, however for the remaining OHIP-14 items, participant

responses varied a great deal with no consistent pattern (Shaghaghian et al., 2015). While the percentage of individuals in the present study that found difficulty in eating very/fairly often was similar (22.5%), the most common items affecting OHRQoL were those associated with being self-conscious or embarrassed, issues which were not consistently found in the Iranian study (Shaghaghian et al., 2015). This may reflect the age of study participants, those in the present study were all young adults whereas in the Iranian study 55% were aged 50 or over. It has been shown previously that there are significant differences in oral aesthetic scores reported by individuals of different ages, with different aspects important to different age groups (Larsson, 2010; Larsson et al., 2021). Furthermore, it has also been shown previously that as well as functional disturbances of wearing an RPD, wearers report psychological and social impacts (Roumanas, 2009), which often centre around the anxiety of the prosthesis falling out/moving or others knowing they are missing teeth (Shaha et al., 2021). However, in another study no significant difference in denture satisfaction among different age groups or gender was identified, suggesting that when considered overall, issues affecting denture wearers are likely to be prevalent in adults and young people (Aljabri et al., 2017), although the relative importance of individual issues to different age groups may vary.

In the present study there were no differences between OHRQoL scores between groups randomised to the original and adjusted RRBs after the replacement bridges had been fitted. However, there was good statistical evidence that OHRQoL was improved as compared to pre-treatment in all participants fitted with a RRB, which indicates the importance of fixed tooth replacement. In another study of hypodontia patients a poorer OHRQoL score was seen in patients who were still undergoing orthodontic treatment as compared to those who had completed this and been fitted with their RRBs (Anweigi et al., 2013 b). Further, in a smaller study that compared patient reported outcomes of 2 unit cantilevered as compared to 3 unit fixed-fixed RRBs, OHRQoL scores for both groups were similar and indicative of good OHRQoL after treatment, but no pre-treatment assessment was undertaken (Botelho et al., 2016). Before and after OHRQoL scores were recorded in a longer term 5 year study of the rehabilitation of a partially dentate patients, and similar to the present study, OHRQoL improvements were shown for both fixed prostheses tested (implant single crowns or RRBs) with no difference between them (Lam et al., 2014). These three studies were also assessed in a systematic review to determine the effectiveness of a RRB to replace one missing tooth, and it was concluded that together they demonstrated that following RRB placement there was a large improvement in OHRQoL, regardless of the reason for teeth being absent (Hoyle et al 2019). However, the quality of evidence provided by the studies was deemed to

be only moderate or low, and the impact of factors such as bridge design of RRBs and comparison of RRBs to other treatment modalities, were not considered in Hoyle analysis.

The improvement seen in the present study in OHRQoL when participants moved away from a removable prosthesis to a fixed prosthesis is also supported by other studies which compared outcomes for different fixed prostheses with those obtained from removable prostheses. When comparing dentures to fixed bridgework satisfaction scores suggested improved satisfaction and larger clinical effect for bridges over dentures (Jepson et al., 2003). Further in a study that evaluated the use of RRBs to replace removable prosthesis to recreate at least a shortened denture arch, significantly better OHRQoL scores were obtained from participants fitted with RRBs compared to removable prostheses (McKenna et al., 2015). Furthermore, Tan et al (2005) demonstrated that 95% of patients with bridges were satisfied with the aesthetic appearance, 96% with chewing comfort, and 100% with the ability to speak normally. This suggests that compared to removable prostheses, patient satisfaction with the functional aspects of bridges is generally very high.

Although it is perhaps likely that the reason that there no differences in OHRQoL seen between the groups who received the original or adjusted bridge is because evidence indicates that scores improve when moving from a removable to fixed prosthesis, it is possible that the lack of difference was in part influenced by other factors. All the participants in our study had planned tooth replacement and had actively sought treatment to get a fixed tooth replacement. The participants therefore knew they wanted a change in treatment strategy and may therefore have been prone to exhibit a positive response when treatment was implemented. Individuals participating in a clinical trial can also be subject to the Hawthorne effect, meaning that they might have a positive response, only because they are being studied (McCarney et al., 2007). Further, it has been demonstrated that the Hawthorne effect can worsen OHRQoL dimensions Bouchet et al (1996). The positive psychological effect of being on a study might also have improved patients' perception of OHRQoL, by a simple placebo effect, because having a fixed tooth replacement does not automatically improve OHRQoL outcomes (Rosenthal et al., 1956). The lack of difference between treatment groups could also be due to the fact that OHIP-14 is not as sensitive as aesthetic scales at measuring aesthetics differences, and that these are important to this patient group. When looking at malocclusion the sensitivity of OHIP-14 to changes is was low when compared to the Dental Aesthetic Index (Ashari et al., 2016). In addition, there was no payment required by the patients for any appointments, treatments or the RRBs as all patients fell within treatment guidelines for care within a hospital setting. Not requiring remuneration for treatment does effect patient choice as

Willingness to accept (WTA) vs Willingness to pay (WTP) disparity results in patients choosing dental interventions of both lower cost and health outcomes (Sendi et al., 2020). It has been suggested that most patients are not willing to trade the increase in quality of life for fixed tooth replacement, due to higher costs, suggesting that WTA, exceeds by the WTP (Sendi et al., 2017). Feeling that the treatment provided in the present study was free may have influenced satisfaction, participants being overall more satisfied than if they had had to pay for the tooth replacement.

The largest improvements in participant OHIP-14 items post bridge fit in the current study were seen in reduced self-conscious or embarrassment about the participant's mouth/teeth and being unhappy about their mouth/teeth. In addition, fewer individuals reported finding it uncomfortable to eat some foods and it difficult to pronounce some words, while other concerns that were moderate at baseline disappeared completely following tooth replacement. The literature supports the improvements seen in self-confidence following fit of RRBs which can be highly effective in restoring oral function, aesthetics and resulting in high levels of patient satisfaction (Durey et al., 2011). It has been shown that fixed prosthesis for the replacement of anterior teeth are the most significant predictors of increased satisfaction allowing patients to reach a level which matches that of patients who have not required any dental treatment (Elias et al., 1999). The improvements in eating and embarrassment observed in the present study have also been reported in other studies. In a study of Spanish adults participants perceived benefits in chewing ability, aesthetics and satisfaction with their mouth after placement of bridges (Montero et al., 2013), and in a study of Middle Eastern children with Ectodermal-Dysplasia the replacement of missing teeth with fixed prosthesis restored masticatory function, aesthetics, speech and boosted the patient's self-esteem in turn improving the overall quality of life (Alnuaimi et al., 2019).

In the current study one domain, pain was slightly worse post bridge fit than pre-bridge fit, with one participant reporting painful aching and total inability to function "fairly often". Similar to the present study, Montero et al (2013) also found worsening of oral wellbeing after prosthetic treatment in the pain and discomfort dimensions. This finding could be related to participant recollection of the initial change in bite that is experienced post bridge fit, due to the tooth contact with the metal bridge wing on the palatal aspect of the tooth. This metal wing causes an increase in the vertical dimension, which pulls apart the other teeth, after which the contact is allowed to re-establish over time through a combination of intrusion and over-eruption of the teeth, this is called the Dahl effect (Dahl et al., 1975). Some negative signs and symptoms from patients have been identified when using Dahl, but they were shown to be self-limiting (Abduo, 2012), and it has been

shown that the Dahl effect is well tolerated and patients adapt to the altered position of their teeth (Saha et al., 2004). The current evidence indicates that the Dahl technique is safe, avoids performing destructive restorative procedures, can be confidently and successfully used in a variety of clinical situations, the development of adverse events are rare, and if any occur they are minor in nature and transient with no long-term adverse sequelae (Poyser et al., 2005).

In addition to the finding that the OHIP-14 pain score increased in one participant, small numbers of participants still felt self-conscious (Q5) often and very often 15.3% and/or were a bit embarrassed (Q10) 7.69% after treatment. This could be in relation to their perceived aesthetics concerns as minor differences in dental aesthetics may have a significant effect on perceived OHRQoL (Klages et al., 2004). It appears this persistent concern can be greater in adolescence as differences exist between the impacts of self-perceived and normatively assessed dental aesthetics on the OHRQoL of young adults (Isiekwe et al., 2016). The finding of the present study is in line with other studies which have shown that even though the majority of OHRQoL components improved post RRB placement, some patients may still have some OHRQoL concerns. The most common concerns which relate to a poorer OHRQoL are; ease of cleaning and firmness of the prosthesis (Botelho et al., 2016), and the experience of complications with their RRBs OHRQoL (Lam et al., 2014). Major complications related to RRBs have been shown to worsen OHRQoL (Hoyle et al., 2019). The impact of complications on OHRQoL in our study could not be considered as the currently the survival rate is 100% and complication rate is 0%.

Taken together, the results of the present study support the current literature that indicates that patient OHRQoL is improved when tooth loss is treated using a fixed prosthesis. In the current study the improvements in OHRQoL were seen irrespective of the design of RRB the participant received, demonstrating that the adjusted design bridge did not negatively impact the OHRQoL and is a suitable alternative bridge design with respect to quality of life.

4.4 Aesthetic assessment of the RRBs by other participant groups

In the present study although participants with hypodontia who received RRBs reported similar improvements in OHRQoL irrespective of bridge design, there was statistical evidence that individuals who had not received the RRBs and assessed images of the RRB outcomes on aesthetics alone preferred the adjusted bridge. This significance was achieved when the preferences of the three independent groups studied; members of The Public, DCPs and hypodontia patients were considered together.

The finding that independent assessors indicated a preference for the adjusted bridge, whereas no differences in OHRQoL scores were identified in those receiving the different bridge designs, is likely due to the different assessment tools used (aesthetics rating vs OHRQoL). Participants asked to rate tooth replacement outcomes could show an aesthetic preference for one bridge but show no difference in OHRQoL as OHIP questionnaires have limited discriminating ability with respect to self-perceptions of dental aesthetics, partly due to the limited questions which focus on this (Wong et al., 2007). There may also be reduced sensitivity of OHIP questionnaires to the quality of life aspects of adolescents, as both the long and short forms of OHIP were validated using data from an epidemiologic study of people aged 60+ years in South Australia (Slade, 1997 a). However, OHIP-14 has been shown to reliably reflect self-reported OHRQoL including the impact of dental aesthetics in adolescents (De Paula et al., 2009; Silveira et al., 2019). As in the present study it was important to gain an insight into both OHRQoL and aesthetic perceptions of those receiving the RRBs without overburdening them with questionnaires, the OHIP-14 was selected as a tool that could capture both aspects in those receiving RRBs, although it is recognised that an aesthetic questionnaire to the clinical participants might have been valuable.

In contrast to the present study, the majority of the limited number of previous RRB clinical studies that have been undertaken have had the primary aim of testing changes in RRB materials or designs to identify those with best survival outcomes and fewest complications for the patient. For example, a comparison of RRBs made with two different restorative materials, all ceramic vs metal-ceramic, demonstrated that the metal-ceramic bridge can be used more predictively (Eraslan et al 2005); while a comparison of two designs of RRB that used the same materials, but compared a single vs two-retainer design, showed reduced complications in the single-retainer design thus improving clinical performance (Ries et al., 2006). In these studies, no assessment of patient related outcome measures such as satisfaction was undertaken and there was no assessment of aesthetic outcomes using aesthetic scales or VAS assessment of images before and after treatment by either the individual receiving the treatment or by an independent third party. As indicated above, to date in the present study, no differences in survival rate between the two RRBs tested have been identified.

However, as also referenced above, participant satisfaction following bridge fit has been included in some RRB studies as a secondary outcome. In the study by Botelho et al (2016) comparing two-unit cantilevered and three-unit fixed-fixed RRBs for the replacement of a maxillary permanent incisors, in addition to survival score and OHRQoL measured by OHIP-49, participant satisfaction with the RRB

was assessed using visual analogue scale (VAS), from 0 (totally unsatisfied) to 100 (totally satisfied). Of the 15 questions assessed by VAS, two related to aesthetics, one asked about appearance of the RRB and the second about appearance of the RRB as compared to the appearance of the participants natural teeth. Good participant-reported outcomes in these aesthetics outcomes were found for both groups who received the RRBs, with no difference between them. However, aesthetic outcomes were participant reported outcome measures rather than being independently assessed by individuals blinded to the bridge type as was undertaken in the study described in this thesis. By contrast to the study by Botelho et al (2016), in a more recent study by Klaus et al (2021) that compared 2 and 3-unit fixed metal-ceramic as compared to all composite RRBs, although there was no difference between them for the study primary study outcome of survival, a secondary aesthetic outcome as measured by VAS from 0 (poor aesthetics) to 100 (optimal aesthetics) yielded differences. It was demonstrated that the individuals fitted with the ceramic pontics were happier with the aesthetic outcome than those who received the composite pontics, it was suggested this was due to the superior aesthetics of the ceramic over composite with better colour matching of ceramic. Interestingly, the metal wing compared to the composite wing was not seen to be an aesthetic concern (Klaus et al 2021). However, in contrast to the present study, and similar to the study by Botelho et al (2016), the aesthetic assessment was a participant reported outcome, only undertaken by the participants who received RRBs. In addition, the bridge design changes were two-fold, both the number of abutments used, and the materials used were altered, creating 4 variables for comparison by study participants as compared to the single variable in the bridge design used in the present study. In a previous study of the original bridge design tested in this MSc, patient satisfaction data was collected, and 88% of study participants felt the appearance of their RRB was good, however there was no comparison with alternative bridge designs (Djemaal et al., 1999).

In the present study, although when the three groups of independent assessors were considered together as a whole, there was statistical evidence for a preference for the adjusted RRB, this was only true for The Public when the groups were analysed separately. The finding that in the hypodontia and DCPs groups, evidence was not strong enough to confirm a preference for the adjusted bridge was surprising. This could be due to study numbers in these groups being too small, as The Public, where a preference was observed, was the largest group. As the adjusted bridge design had not previously been the subject of any studies there was no data available to calculate statistical power. As a result, best estimates, based on in-house service evaluations of hypodontia patient tooth replacement, and the frequency with which these patients had indicated dissatisfaction with the metal rim of the original RRB design, were made to estimate the size of

difference in preference for each RRB design that might be seen in this group. From this initial estimate it was further predicted that the DCP group (due to their dental interest) would be the most sensitive to the aesthetic difference, and The Public the least likely to identify differences in outcomes between bridge designs, with the hypodontia group (due to their dental exposure) between these two predictions. The data obtained in the present study suggest that it is likely that the assumption of how readily the DCPs and hypodontia groups would identify aesthetic differences between the two RRBs was inaccurate, and that these groups were underpowered to detect difference between preferences. However, although there was insufficient evidence that assessors in the DCPs and hypodontia groups preferred the adjusted bridge, their responses did favour the adjusted bridge design.

Also, somewhat surprisingly, there was no difference between the three groups with respect to the percentage in each group that preferred the adjusted bridge in the current study. It might be expected that hypodontia patients who are directly affected by tooth replacement aesthetics and DCPs who are very familiar with assessing teeth and gums without the context of a full face for dental health and aesthetics, would more readily identify the metal rim and altered translucency of the original RRB in the images assessed. A lack of difference in the assessment of aesthetics between participant groups was also seen in an orthodontic study that compared how patients, parents, and dentists ranked 10 images of teeth by the aesthetic component of their perceived orthodontic need, from worst to best appearance, and showed that median rankings of dental aesthetics were similar for each group (Hamdan et al., 2007). By contrast, more commonly studies have shown that aesthetic opinions do vary according to the groups making the assessment (Al Moaleem et al., 2017). In the first of two seminal papers the opinions of patients (classed as lay people), general dentists and orthodontists, regarding a set of images of dentitions with various morphologies and orthodontic needs it was demonstrated that general dentists and orthodontists essentially agreed in their responses and as a combined group, and were much more critical than patients (Prahlandersen et al., 1979). In the second seminal paper, it was shown that patients, dental students and dentists all preferred teeth of a similar shape, however the dentists preferred longer/thinner teeth than the patients (Brisman 1980). In addition, in a more recent study comparing patients and orthodontists a difference in perception of smile aesthetics was reported between these groups (Shiyan et al., 2016). Interestingly, in contrast to the study by Prahlandersen et al., (1979), orthodontists were shown to be more critical than prosthodontists, oral surgeons and dental students in a study of implant aesthetics (Fürhauser et al., 2005). This perhaps is not surprising as

orthodontic specialists would be expected to be more critical of aesthetic outcomes, as their goal is to create both a more ideal bite and an aesthetically ideal tooth appearance for patients.

Dental education has been shown to influence the assessment of dental aesthetics, a study by Mehl et al (2015) demonstrating that students and dentists who had received formal dental education had similar aesthetic judgement, and that this was different than the self-evaluation assessment of dental appearance by patients. This confirms that there is an element of education around dental aesthetics which can play a part in perception of dental appearance and explains why studies suggest dentist and patient opinions vary. There could also be a greater sensitivity to tooth pontic aesthetics in those dentally trained. A study carried out by Alshiddi et al (2015) looked at a range of aesthetic outcomes of anterior fixed prosthetic treatment and showed that agreement between patient and clinician satisfaction varied depending on the parameter assessed with the highest agreement related to colour of the restoration margin and the lowest related to the natural look of the restoration. Due to the influence of social media, patients' awareness of dental aesthetics has been raised and it might be expected that lay people/the public now would be more critical of dental appearance than they would have been a generation ago. Aesthetic perception has been seen in children as young as 2 to 7 years, where children are conscious about their dental aesthetic appearance and that of the other children (Vale et al., 2009). It has been shown that the whiteness of patients natural teeth is important to patients and that patients perceive their own teeth to be darker than dental assessments by clinicians indicate, suggesting management of patients expectations and education around white aesthetics is important (Rodríguez-Martínez et al., 2019). This increasing awareness of the public of smile aesthetics might be responsible, at least in part for the lack of differences between this group and the other groups with regards their preference for the bridge designs in the present study.

It should be noted that many of the above studies that demonstrated differences between lay people and those with dental education considered orthodontic patients and cases in which DCPs might be influenced not only by the aesthetics but subconsciously by the functional requirements of the dentition. By contrast, in the study presented here DCPs, hypodontia patients and The Public were asked to rate images post tooth replacement treatment where there was no further treatment need which could influence preference, offering a possible explanation for the difference between our findings and those studies in which differences between groups of assessors were found. The results of the present study may also have been affected by the number of participants within each group as the study was powered to detect the preference of each group for the original or adjusted

RRB design, and it was not possible to also power for a difference between the groups. In addition, orthodontic aesthetic studies assess orthodontic tooth movements and there are a great many changes to the aesthetics and bite, whereas there were only small subtle changes between groups in the current study. Finally, within the DCPs group in the present study there was likely a wide variety of practitioners including orthodontists who are shown to be more aesthetically sensitive (Fürhauser et al., 2005), GDPs, hygienists, therapists and dental nurses, who are likely to have varying degrees of sensitivity to dental aesthetics, if this group had been sub-divided differences may have been uncovered.

The influence of gender on preference of adjusted or original RRB was examined in the current study and it was shown that there was statistical evidence that a greater percentage of females preferred the adjusted bridge as compared to males suggesting they were more sensitive to the aesthetic differences between the two bridge designs. Similar increased sensitivity in females for aesthetic outcomes has been demonstrated in the current literature. A higher percentage of female respondents were shown to be more critical of their dental appearance and aesthetics when compared with male respondents (Strajnić et al., 2016), and females have been shown to be more critical of tooth size and shape (Azodo et al., 2014). Similarly, in a study of 200 adolescents aged 12–15 evaluated for orthodontic treatment using the IOTN-AC and DAI, females showed greater sensitivity to the impact of malocclusion by both indices (Ilijazi-Shahiqi et al., 2020), and in a study of Columbian adolescents, when participants had poor dental aesthetics, more females than males reported a negative effect on their self-esteem (Mafla et al., 2011). Further, dental aesthetics concerns linked with social impact factors have been shown to be significantly different between the genders; while dental aesthetics were found to affect the psychological well-being of all participants, post treatment females were more disappointed with the aesthetic outcomes than males which was linked with adverse social impact (Chen et al., 2012; Zaidi et al., 2020). This suggests that expectations need to be managed before treatment to avoid disappointment and reduced self-esteem post treatment. Within the context of study design, gender variation needs to be considered when recruiting participants and ideally an even mix of gender could help avoid effects of gender bias on results.

Aesthetic data for tooth loss replacement options largely comes from implant studies. Interestingly a recent systematic review and meta-analysis that aimed to compare participant-reported aesthetics outcomes following different tooth replacement options was unable to include any tooth-supported prostheses studies in the primary outcome analysis, as there were too few studies that fit the review

criteria (Wittneben et al 2018). Focussing on the implant supported FDPs, the review demonstrated that the overall aesthetic evaluation by study participants as assessed by VAS was high for both the implant supported FDP and the surrounding mucosa (Wittneben et al., 2018). However, studies frequently used only post-treatment participant reported outcome measures which are not standardised, and participants who received treatment may not have been blinded to the treatment option received, as this is difficult to achieve. Our findings in which participants blinded to study treatments rated two RRB designs for attractiveness therefore add to the current literature and demonstrate that individuals are sensitive to small changes when they impact aesthetics. Similarly in the only other study published to date that has used an aesthetic score to assess two RRB designs it was shown that participants could see and preferred white materials to metal in RRB designs (Klaus et al., 2021). It is also important to consider that in the present study there was not only a preference for the aesthetics of the adjusted bridge but also a reduced need for adjustment of incisal edge metal of the restoration of the adjusted bridge during the bridge fit process. This made the fitting of this bridge easier, as a clinician, and has the potential to reduce variability in aesthetic outcomes of RRBs of this style between clinicians.

4.5 Study design and limitations

This study was designed to determine if there were differences in aesthetic outcomes following the placement of 2 different bridge designs, the original and the adjusted bridge. It was also important to formally assess survival outcomes (as outlined in section 4.2 and discussed in further detail below) and OHRQoL of the adjusted bridge as although this bridge design has been used for some time in private practice, survival and OHRQoL compared to the original RRB has not been determined. A parallel randomised control trial (RCT) design was used to assess OHQoL and survival outcomes as this is the gold standard for determining how effective an intervention is, allowing the testing of the safety and efficacy of new treatments and, as in this case, the comparison of treatments to establish superiority (Hariton et al., 2018). The randomisation of participants to either the original or adjusted bridge minimised allocation bias and selection bias.

One previous published RCT that had evaluated the use of cantilevered versus fixed–fixed RRBs for missing maxillary incisors, recruited 28 participants randomly assigned to either group and demonstrated differences in survival and complications (Botelho et al., 2016). Therefore, a minimum of 14 participants per group were considered necessary for the present study. However, the study was not powered to determine differences in RRB failure rates as this was not the main outcome

measure, but it was powered to see a 5% difference in survival rates between bridge designs. It was planned for 20 participants per group which exceeded the 14 per group used by Botelho et al (2016). This was also similar to numbers used in more recent Klaus et al (2021) study which had 50 participants in total split between 4 groups for comparison. The total of 40 images allowed 20 images of each bridge design from which 5 images from each group were randomly selected and used for the aesthetic questionnaire (primary objective of the study). Due to the pandemic, however, images from only 27 participants were available in time for the preparation of the aesthetic questionnaire (Protocol Appendix 3).

Survival outcomes were not expected to be able to be captured for this study during the period of the thesis. A previous study that tested the same original design of RRB (used here as the control RRB) determined survival rates over a longer period of time and showed that most failures happened within the first 18 months post RRB placement, and failures flat-lined at 35 months (King et al., 2015). As a result of these findings, the failure rates of this participant cohort will be reviewed up to 18 months post RRB placement. To date (a minimum of 1 year post bridge for all RRBs fitted to date) there have been no complications or failures of either the original or adjusted design groups. The follow up for RRBs placed in secondary care is usually carried out by the referring general dental practitioner. In addition, many of the patients who have previously also received orthodontic treatment at BDH as part of the MDT approach will see the secondary care orthodontic team roughly 12 months after brace removal (around 9 months post RRB fit). These visits will also pick up any issues with the patients RRB, thus failure and complication rates for the participants in this study group will be recorded beyond the period of this thesis.

Blinding was not possible in the clinical element of the study presented here as the clinician fitting the bridge was able to determine which RRB the participant had been assigned to, it is not possible to disguise this. This lack of blinding will not affect the survival data for the bridges. Survival data should also not be affected by the change in clinician towards the end of the study. Of the 40 bridges, 28 were fitted by the same clinician, while as a result of COVID delays, 12 were fitted by clinicians trained by the primary clinician using standardised methods, 6 from each design group, 6 original and 6 adjusted. It was also not possible to totally blind the participant to their treatment. Participants were not told which bridge they had been given however it cannot be ruled out they were able to tell which bridge design they had received. A lack of complete blinding of the participants could have affected the OHRQoL outcomes. If a patient believed they had been fitted with the adjusted bridge they could have reported improved OHRQoL according to the placebo

effect (Rosenthal et al., 1956). Alternatively, participants could also have reported reduced OHRQoL if they felt their bridge did not meet their expectations and had wrongly decided they received the bridge which was not as aesthetic (the original design). Unfortunately, there was no way of preventing participants from working out which RRB they had been given.

In the current study other measures of OHRQoL were initially considered including OHIP-49, Oral Impacts on Daily Performance (OIDP) and the Geriatric/General Oral Health Assessment Index (GOHAI) which have all stood the test of time and are still widely used. The Oral Impacts on Daily Performance (OIDP) has been shown to be effective for assessment of OHRQoL, but although the psychometric properties of OHIP-14 and OIDP were shown to be comparable, the use of OIDP has been shown to result in loss of data, particularly from people who were not White English (Robinson et al., 2001). By contrast, when comparing OHIP-14 and GOHAI both were equally good at predicting overall psychological well-being and life satisfaction and neither was markedly superior to the other (Locker et al., 2008), however GOHAI was developed specifically for older adults thus the OHIP-14 was favoured for the present study. The Short Form Health Survey (SF-36) is another OHRQoL measure regularly used within medicine, but it has been shown that the disease-specific OHIP-14 is more highly correlated to oral health conditions (Lee et al., 2007). OHIP has been applied to a considerable number of studies of children and adolescents within the literature and has been shown to be effective in measuring OHRQoL across these groups (Omara et al., 2021).

Consideration was also given as to whether for those receiving the RRBs an aesthetic assessment should be undertaken pre and post treatment rather than OHRQoL, however it was judged important to confirm whether or not the adjusted bridge design affected OHRQoL more adversely than the original design. While it was beneficial to capture some aesthetics data from participants receiving the RRBs via the two aesthetics questions on OHIP-14, as 100% blinding of these individuals could not be guaranteed it was deemed preferable to gain aesthetics judgments from those who were not involved in the clinical arm of the study to avoid possible bias. If the study had only wanted to judge aesthetics in those receiving RRBs, use of an adapted OHIP-49 questionnaire looking at aesthetics known as the OHIP-conceptual would have been considered (Wong et al., 2007). The short 14 question OHIP-conceptual has been shown to be comparable to OHIP-49 in terms of measurement properties, and to be more sensitive to measuring changes in dental tooth whitening when compared with OHIP-14 (Wong et al., 2007). However, there has been no further validation of OHIP-conceptual and it only considered tooth whitening as an element of dental aesthetics. Therefore, taking everything into consideration, and as the present study was designed to look assess bridge design and not directly tooth colour, it was felt that the OHIP-14 was most

appropriate OHRQoL measurement tool as it was suitable and is the most widely reported measure (Tsakos et al., 2013), allowing for easy comparison with data from other studies.

During the clinical phase of the present study photographs of the fitted RRBs were taken both for patient records but also to generate the images for the main part of the study. These images were standardised using settings taken from those suggested in the British Dental Journal (Ahmad, 2009): auto-focus with aperture set at f22, electronic cannon ring flash with shutter speed synchronised automatically by the camera (ranging from 1/125 to 1/250 s), ISO 100, image colour space Adobe RGB, white balancing was automatic. The same dentist took all study photographs. Assessment of aesthetics was conducted using a panel of photographs which were fully anonymised and standardised showing teeth and gingivae (gums) without facial features as these can impact the assessment of aesthetic outcomes (Anderson et al., 2005). It was recognised during the study that the images used for the aesthetics review could have been improved by taking them at least 24 hours after rather than immediately after bridge fit as due to the drying effect of the materials used to cement the bridge, the colour of the natural teeth is transiently changed (Gorucu-Coskuner et al., 2018). This makes the pontic tooth/teeth more obvious until the natural colour returns to the abutment teeth. Once recognised it was decided to accept this compromise to save the study participants additional hospital appointments as this affected both RRB designs equally, in addition the additional visits for this purpose during the pandemic lockdowns would not have been permitted. Clinical photographs have frequently been used for the assessment of aesthetics (Prasad et al., 2018; Zheng et al., 2018; Amirkhanov et al., 2020; Janu et al., 2020). However, photographs are prone to distortions resulting from different angles of view and are not always adequate for measurements (Signori et al., 2018; Kerner et al., 2020; Mackenzie et al., 2020). Therefore, methods for standardization of photographic measurements by means of reproducible exposure positions and calibration using reference structures have been proposed (Ahmad, 2009, 2020), and were used in the current study.

The 10 images of the aesthetic questionnaire (Protocol Appendix 3) used in the present study were assessed by a 5 point Likert scale, chosen because it has been used successfully in previous studies to determine the relative importance of various dental features that contribute to overall dental attractiveness, with good interrater reliability (Ong et al., 2006). The choice 10 images was also based on previous studies and has been widely used in orthodontic aesthetic assessments (Brook et al., 1989; Kokich et al., 1999). Randomisation of the anonymised images for selection and position in the questionnaire allowed an unbiased assessment of the two bridge designs to be made, and the

subsequent determination of overall preference. It is possible that the clinical images were difficult to rate for non-clinicians, as they do not represent the average smile, and some participants may have found them unattractive, however including facial details would have introduced bias. It was also reported that there were many images to judge and that some images looked the same, however there were only 10 images and it was felt that any fewer would not be sufficient to detect overall preferences. The differences in the RRBs tested by the study are relatively subtle and participants did overall indicate a preference for the adjusted RRB, suggesting that this was in fact a fair test. It is accepted that a pilot of the questionnaire could have been undertaken, and if undertaken participants could have been asked to repeat the questionnaire at a second time point to check reliability of the scale and reproducibility of their responses.

Other aesthetics scales were considered for use in the current study. The Smile Aesthetics Satisfaction Scale (SASS) uses a three-point Likert scale (Likert, 1932) and assesses five dimensions of tooth aesthetics (Lajnert et al., 2018) and in adults and the elderly it has been demonstrated that the SASS had good reliability and psychometric properties. However, the combination of the three-point Likert scale with five dimensions of tooth aesthetics that have to be assessed per image means this scale is complicated and time consuming. Similarly, the Oral Esthetic Scale (OES) developed for prosthodontic patients uses a 0-10 numerical scale and assesses both oral and facial aesthetics and thus is also time consuming and more complex than needed (Tedesco et al., 1983). The Aesthetic Component in the Index of Orthodontic Treatment (IOTN AC) which uses a 10-image scale (least to most attractive) was also discounted for the present study as it has not been used as a direct tool for aesthetic assessment in RCT (Shaw et al., 1991) and has an orthodontic aesthetic focus.

A simple assessment tool that has been used in many aesthetic studies is the Visual Analogue Scale (VAS) (Parrini et al., 2016), and VAS instead of the Likert 5 point scale was considered carefully for use in the present study. There are however inherent issues with using a VAS. Standard VAS scales use a horizontal line and participants mark on this line where they feel their aesthetics lies on a 100mm scale (Rosa et al., 2013). The problem associated with this is that there are no intermediate labels on scale, to guide the participants, as a result this scale can see systematic variation (Heft et al., 1984). Participants also vary in their perception of where they should place their mark on the scale, such that participants who have the same rating can record markedly different VAS scores (Scott et al., 1976). Furthermore, when VAS is used in situations where there will be multiple low to moderate answers, scoring becomes concentrated at the lower or higher end of the scale, the differences between scores are smaller and a significant differences is unlikely to be seen (Heaton et

al., 2013). As the aesthetics differences in the present study were likely to be relatively subtle it was felt that using a VAS would reduce the chances of identifying a preference.

The clinical element of this RRB study could have been badly affected by the pandemic due to the limitation in access to services. Fortunately, all the participants needed for the study had already been recruited prior to closure of any services. However, the hospital services were closed for a 2-week period, and following this period, services were open for emergencies which included management of any complications of restorations placed in the hospital but not procedures such as RRB bridge fit. After a further 6 weeks services resumed for patients' mid treatment, which caused a delay from recruitment to treatment for 12 study participants. However, although the length of time between recruitment and impression appointments was delayed, the length of time between impression and bridge fit did not change, which was important to avoid issues with the fit and ultimate survival of the RRBs. As bridge fit is an aerosol generating procedure, slots for appointments were limited, therefore, to ensure these 12 participants were seen in a timely manner their bridges were fitted by clinicians who were not the main study clinician. These clinicians had been trained previously by the main study clinician, and it was important to consider best practice and patient care for the participants and not prioritise the study protocol.

Initially in the present study the OHRQoL questionnaire was to be handed out as a paper questionnaire, and this was done for all patients prior to bridge fit as all were recruited prior to the first lock-down for the pandemic. Following the onset of the pandemic, limitations placed on face-to-face contact with patients and the passing of items between persons, resulted in the need to change the OHRQoL questionnaire to an electronic online format. This helped to avoid unnecessary participant contact, and QR codes were used, scanned by the participants onto their personal devices to access the questionnaires which could then be completed at home. This reduced the time participants spent in the Hospital but inadvertently could have reduced the response rate, participants no longer had a physical form to complete at a time when they were waiting for treatment sign off, and this may have reduced the number of post RRB fit OHRQoL responses. Reminders were sent by post and email, unfortunately this had little effect on response numbers. In a previous study it has been shown that response rates for on-line and paper questionnaires before and after reminders is 18% and 64% compared to 73% and 77% respectively, however while 98% participants completed the online questionnaire without missing data, only 63% completed the paper questionnaire with no missing responses (Kongsved et al., 2007). Despite the pandemic, overall response rates in the present study were similar to those achieved by (Kongsved et al., 2007).

Similar to the OHRQoL questionnaires, in the current study originally aesthetic questionnaires were planned to be in paper format. However, due to the same pandemic limitations, the aesthetic questionnaire was also converted to an electronic online format. To gain access to our local populations we were able to access the DCPs group through staff group mailing lists, the hypodontia group were accessible through a patient data base and for The Public group, we were able to use our regional health watch website. The response rate from the DCPs group was good from the start, perhaps reflecting the increased time that these clinicians had while treating a reduced patient number due to COVID restrictions. By contrast, initially responses from the hypodontia patient group and the health watch website were slow as people focussed on COVID-19 and not in other health issues, however, after a slow start the responses from these groups increased rapidly. Even with the slower response rate achieved with the online questionnaires the numbers of participants powered for in each group were achieved and slightly exceeded. This slightly increased number of responses occurred due to a lack of familiarity with the electronic online system used and being unable to close questionnaires down the moment that the target responses were achieved. The numbers were monitored, and the online survey questionnaire was closed when the required numbers were reached, but in each group a small number of additional responses were collected due to monitoring being daily and questionnaire closure manual, rather than real-time monitoring and automatic closure. Ethical approval for the switch from paper to online questionnaires and alteration in recruitment routes was obtained prior to any online questionnaires being distributed.

In a previous study it has been shown that there are differences in how paper and digital images are rated for smile aesthetics, equivalence cannot be assumed and paper-based photographs may lead to clinically relevant overestimations of perceived attractiveness, which was not seen with digital images (Agou, 2020), suggesting the conversion to a digital aesthetic format might have been beneficial. However, there are also likely to have been differences in the quality of images each respondent viewed dependant on the style of device used (phone, tablet or computer) and the quality of the screen (LCD, HD or OLED/AMOLED displays) along with display features (Retina, True-tone and IPS). Therefore, variation in the way participants saw the images was inevitable but the standardised online questionnaire platform used, and the fact that both image sets were viewed together ensured that the image quality was standardised for each participant for the two RRB designs. This was important as it has been shown that sharpness and contrast are the most important attributes for the majority of scene types and original image qualities (Park et al., 2014).

Reflecting on the results and conduct of the present study there are three aspects which if repeated could be altered to improve the quality of the data obtained. It would be sensible to have a standard and suitable delay before taking the final clinical intra-oral photos for use in any comparative

questionnaire, this would reduce any transient iatrogenic changes in tooth or soft tissues which could affect the intra-oral images. The use of intraoral scanning could also help stream line procedures and increase accuracy of RRB fit (Ting-shu et al., 2015). In addition, due to the lack of statistical evidence for the individual groups regarding preference for the adjusted bridge, even though the data indicated that this preference may exist, in future studies there should be an increase in participant numbers for the DCPs and hypodontia groups, so all groups have the same participant numbers. This may help to better show the sensitive to aesthetics which could be represented between the groups.

5 Conclusion

The aesthetic questionnaire was used successfully in our study and shows merit in use as a standardised aesthetic assessment tool for comparison of fixed prosthetic dental treatment. Views from DCPs, patients with hypodontia and The Public demonstrated that there was a preference for the aesthetic appearance of the adjusted bridge. OHRQoL scores showed a significant improvement for both bridge designs confirming the benefits of fixed as compared to removable prostheses. To date there have been no reported failures or complications for the original or adjusted bridge designs showing they have successful longevity in the time observed and that reducing the incisal extension of the metal wing has not adversely affected survival.

6 Future work

As discussed, aesthetics scales are varied and in contrast with orthodontics there has been little work done within the field of prosthodontics considering the patients perception of aesthetics. This may in part be due to the large variety of treatments within prosthodontics and the individual patient case complexities that makes variability between cases high. This can make methodology for RCTs difficult and more work is needed to improve this element of many prosthodontic studies (Jokstad et al., 2002). The quality of transparent reporting as suggested by CONSORT (Schulz et al., 2010) of RCTs in major dental journals are considered suboptimal and improving quality of RCTs is a fundamental prerequisite for improved dental outcomes (Pandis et al., 2010).

The present study demonstrated an overall preference for the adjusted RRB but did not find statistical evidence for a preference for this design for patients with hypodontia or DCP. It is

important that groups judging the aesthetic comparisons are suitably large and a further aesthetic study using the same questionnaire with larger numbers in these groups would be beneficial and could be powered based on the findings of the present study.

It also appears from the results of this thesis that the opinions between groups (The Public, DCPs and Hypodontia patients) were not as varied as expected. A further study to investigate this could be carried out with more individuals in each group and specifying which DCPs should respond as previous studies have indicated that orthodontists may be more critical when judging aesthetic appearance than other DCPs. The methods of recruitment for the aesthetics questionnaire could be adjusted to help target populations via specific websites or patient group sites to gain more tailored results. When designing the study response rates of patient satisfaction surveys should be considered as these can be as low as 67% for mail and 76% for face-to-face surveys (Sitzia et al., 1998). Internet participation has been shown to be as good as, in some cases better than mailed questionnaires and has been shown to be reliable and answered similarly to traditional mailed paper questionnaires (Ritter et al., 2004).

The aesthetic scale piloted in the present study needs further development through validation, focusing on its use as an aesthetics scale for prosthodontic work. This validation study could be undertaken using various different methods. The questionnaire could be designed to compare mirrored images so there is no difference in the aesthetics being judged, to see if respondents will show preference when there is in reality no difference in the images they are rating. Alternatively, the same prosthodontic images for aesthetics could be used but assessed using already validated aesthetics scales (such as a VAS scale or The Orofacial Esthetic Scale (OES)) and comparing the results of these scales on comparison images to results using the aesthetic scale described in this thesis.

Once validated this thesis's prosthodontic aesthetics scale could be used as a stand-alone scale, for aesthetics comparison of prosthodontic dental work of any type by inserting the appropriate images. For example, it could be used to look at the use of digital colour matching compared to clinician colour matching of replacement tooth prosthodontics or to compare alterations which can improve the tooth replacement (pontic) design. The questionnaire could be used to carrying out a study looking at tooth loss in different regions of the mouth, maxilla/mandible, front sextant vs posterior sextants, to see if a preference can be seen which may help to identify the regions of the mouth that patients feel are the most aesthetics.

It would also now be possible with the data collected to determine the number of participants that would be required to power a RCT study looking at OHRQoL or aesthetics outcomes.

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7 Appendix

7.1 Appendix 1 Protocol 10th July 2020, Version 4.0 IRAS 257107



A randomised clinical trial to determine the aesthetic outcomes of two designs of resin-retained bridge

Version 4.0

Summary Information

Title:	A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge
Protocol Number:	2018-4679
Sponsor:	Dr Rachel Davies Acting Co-Head of Research Governance and Research and Human Tissue Manager Research Governance Team Research & Enterprise Development University of Bristol Trinity Street, College Green, One Cathedral Square Bristol BS1 5DD Tel: (0)117 4284021 Email : research-governance@bristol.ac.uk
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Background

Patients attending Bristol Dental Hospital (BDH) for tooth replacement for reasons such as hypodontia (missing teeth) or trauma are currently treated using a Bristol bridge. The Bristol bridge is a type of metal framed resin retained bridge (RRB) in which the pontic ('false tooth') is bonded to an adjacent tooth/teeth via a metal frame by composite resin. The metal frame (retainer) acts as a connector between the adjacent tooth and the false tooth and extends behind the false tooth and wraps around the incisal edge (tip of the tooth). While the majority of the metal is invisible, as it is hidden behind the false tooth and supporting tooth, when the patient smiles, if the bridge is on the anterior (front) teeth the portion of metal at the incisal edge may be visible or cause changes to the translucency of the incisal edge resulting in a small grey flash appearance (Figure 1). At review appointments some patients say that this change in their appearance is upsetting, and in a previous study the metal of the retainer was reported to be the most common reason for patient dissatisfaction with their RRB (Durey et al 2011).

The Bristol bridge can be adjusted to reduce the visibility of the metal edge of the bridge, but it will always be apparent. When the Bristol bridge was designed it was deemed necessary for the metal to extend right to the tip of the bridge to improve its longevity, however with improved bonding materials and better fit of bridges due to the use Computer Aided Design and Computer Aided Manufacturing (CAD/CAM) technology it should now be possible to redesign the bridge with a reduced extension such that aesthetics are not compromised (Figure 2). Current Longevity studies on the standard Bristol bridge design have a 5-year survival rate of 80.8% (95% confidence interval 78.0–83.6%), and a 10-year survival rate 80.4% (95% confidence interval 77.6–83.2%), with the majority failing within the first year (King et al 2015).



Figure 1. Bristol Bridge with rim of restoration visible at the upper incisal edge even after adjustment

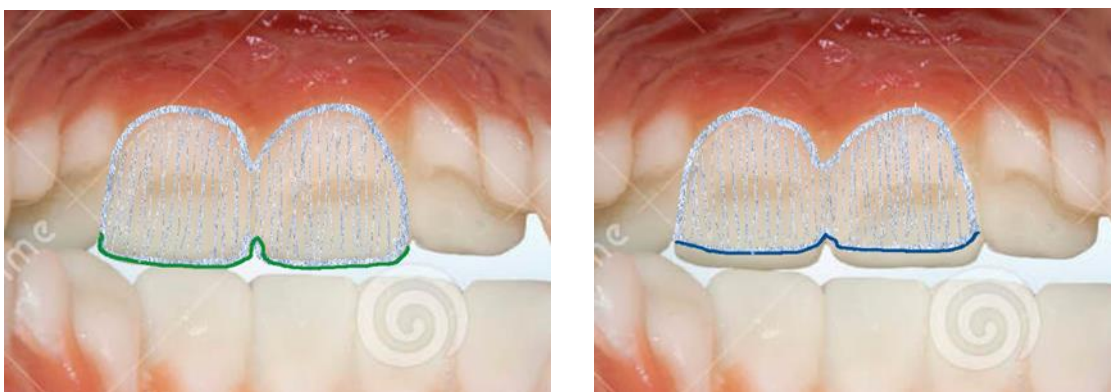


Figure 2. Design of the metal wing of bridges on palatal tooth surface, of the supporting teeth. The metal wing finishes at coloured height; current bridge (green line) and the adjusted bridge (blue line)

Aim of study:

To determine if changes to the current resin-retained bridge design can improve aesthetic outcomes without adversely affecting failure rates.

Specific Objectives:

- To compare the aesthetic outcomes of the current and adjusted design resin-retained bridge after bridge fit.
- To determine if dentists, patients with hypodontia and patients attending BDH for other routine treatment have similar views about the aesthetics of the 2 different bridge types.
- To assess the failure of the adjusted design of resin-retained bridge after 18 months.

METHOD**1. Study overview:**

This is a single centre, randomised, two treatment regimen, parallel study in dental patients presenting with a missing tooth in the front teeth (upper or lower) requiring tooth replacement. Aesthetic outcomes following treatment will be assessed by two patient groups and dental clinicians who are blinded to the treatment received by study participants. Clinical assessments for study outcomes are limited to recording failure of bridges. Following standard care procedures for this type of treatment the study participants will return to their general dental practitioner (GDP) for their routine care after receiving their bridge. The GDP will report any bridge failure in line with normal procedures and refer the participant back to the study clinician for confirmation and corrective treatment, at this time the failure will be recorded.

Approximately 40 patients aged 11 or over who require a resin retained bridge on an anterior (front) tooth as part of their routine dental treatment will be recruited to the study. Initial screening will take place at BDH on general, trauma or hypodontia (missing tooth) assessment clinics. Patients who do not fulfil the entry criteria or decline to take part in the study will be treated for their tooth loss following the standard protocol at the Bristol Dental Hospital (BDH) and not enrolled in the study. Patients who fulfil the eligibility criteria and have consented to take part in the study (with parental consent in place where required) will be randomized to receive one of two bridge designs (20 patients for each group).

Participants will be asked to complete a quality of life questionnaire (OHIP 14 – Appendix 1) or a version adjusted for younger people (Appendix 2) before treatment begins, and at one month post treatment. OHIP 14 is a short form of the Oral Health Impact Profile which provides a generic measure of oral health related quality of life and is the most commonly used oral health quality of life measure in the world. Despite being generic, OHIP is sensitive to the impacts of tooth loss and has shown itself to be responsive to the effects of different treatments for the condition (Anweigi et al 2013).

Assessment of aesthetics will be conducted using a panel of photographs. These photos will be fully anonymised and standardised showing just teeth and gingivae (gums). These will have been taken by the study dentist immediately after treatment of study participants using the same camera and standardised settings. These will be assessed by dentists and individuals who are not recruited to the treatment part of the study. Reported bridge failures in each group will be monitored throughout the study and the findings summarised at 18 months after placement.

2. Study recruitment

Patients requiring a bridge

Patients attending BDH for consultation appointments will be approached to take part in the study. Potential participants who need treatment for tooth loss will be identified by their clinical team, the majority will be identified when they attend 'new patient clinics' for treatment planning. Other patients may be identified by their direct clinical team when attending for routine appointments where on-going treatment is also being planned.

Clinicians at BDH will have been informed about the study and given a letter to give to participants who express an interest in taking part. The clinicians will provide a brief overview and advise the potential participant to read the letter and contact the study team using the contact details included in the letter for more information about the study and to book a screening appointment if they are interested in taking part. Participants who contact the study team will be sent the participant information sheet, provided with any further information that they request and booked in for a screening appointment. If a participant wants more time before committing to a screening appointment this will be given.

Participants assessing aesthetic outcomes

- Group 1: Dentists: To recruit dentists to rate the aesthetic outcomes of the two types of bridges following treatment, an email giving an overview of the study and the participant information sheet will be sent using the two global addresses that together reach all dentists working at BDH. The email will contain a link to the anonymised images hosted on the on-line surveys platform to which University students can be granted access.

:

- Group 2: Hypodontia patients:
 - patients who are scheduled to attend this clinic will be contacted by email by the dental administrator who manages the appointments for this clinic with information about the study, an information sheet and a link to the images hosted on the online survey platform.
 - Information sheets about the study will be handed out in the hypodontia clinic together with the sheet of anonymised images and space for answers.
- Group 3: Individuals who are not dentists and not attending for hypodontia treatment
 - Non-hypodontia BDH patients:
Information sheets about the study will be handed out on the adult dental health clinic together with the sheet of anonymised images and space for answers
 - Individuals who are not attending BDH for treatment
These individuals will also be recruited to rate the images for objective 2. The charity 'Health Watch' will email their members with information about the study, an information sheet and a link to the images hosted on the online survey platform.

Participation in this part of the study will be anonymous, and consent will be deemed as having been given if the photo sheet is completed and returned to a drop box placed in the waiting room (patients – paper copies). Those completing the assessment online will be asked to confirm that they consent

to participation before opening the assessment. Responses from the on-line assessment will be returned in fully anonymised form.

3. Screening appointment (participants requiring a bridge)

At the start of the screening appointment the main study dentist or a member of their team will go through the participant information sheet with the participant and answer any questions they may have. If the participant agrees to take part in the study, they will be asked to sign a consent form prior to any study procedures beginning. The participant will be provided with a copy of their signed and dated consent form. Those participants consenting to take part in the study will then be screened.

The main study dentist will record demographics, current and concomitant medications, undertake a full Oral Soft Tissue (OST) examination including taking appropriate radiograph(s) as is standard for any treatment to replace a missing tooth, and confirm whether the participant fulfils the inclusion/exclusion criteria as outlined below.

Inclusion criteria

1. Consent: Demonstrates understanding of the study and willingness to participate as evidenced by voluntary written informed consent and has received a signed and dated copy of the informed consent form.
2. Compliance: Understands and is willing, able and likely to comply with all study procedures.
3. General Health: Good general health with (in the opinion of the investigator) no clinically significant and relevant abnormalities of medical history on oral examination.
4. Oral Cavity, participants must:
 - a. have at least one missing tooth, bounded by teeth, which is a single unit in the front of the mouth, being either an incisor or canine (UR123 UL123 LR123 LL123).
 - b. have teeth that can be used as abutments (for attachment of the RRB) that are unrestored and without pathology
 - c. be able to accommodate a pontic tooth replacement restoration
 - d. have no more than mild toothwear with Basic Erosive Wear Examination (BEWE) score of 1 or less (Bartlett et al 2008) with no history of parafunctional habits
5. Oral Hygiene Status:
 - a. have good oral hygiene with
 - i. a full mouth Turesky plaque index score <1 (Turesky et al 1970)
 - ii. Basic Periodontal Exam (BPE) scores of 0, 1, 2. With a maximum of one sextant with a score of 3.
6. Aged 11 plus

Exclusion criteria

1. Disease, participants will be excluded if they have:
 - a) Current or recurrent disease/dental pathology that could affect bridge treatment.
 - b) Bleeding disorders.
 - c) Are immuno-compromised.
 - d) Current or relevant previous history of serious, severe or unstable physical or psychiatric illness, or any medical disorder that may require treatment or make

the participant unlikely to fully complete the study, or any condition that presents undue risk from the study products or procedures.

2. Allergy/Intolerance: Known or suspected intolerance or sensitivity to the study materials (or closely related compounds) or any of their stated ingredients.
3. Medication: Any medication which in the Investigators opinion may interfere with the study.
4. Clinical Study/Experimental Medication: Participation in another clinical study or receipt of an investigational drug within 10 days of the screening visit.
5. Substance abuse: Recent history of alcohol or other substance abuse.
6. Any patient who, in the judgement of the investigator, should not participate in the study.

Participants who successfully fulfill all the necessary entrance criteria will be enrolled in the study and sent a link to an electronic copy of the questionnaire on quality of life with regards to oral health (OHIP 14; Appendix 1/ adjusted OHIP14 Appendix 2) which they will be asked to complete pre-treatment. A paper copy can be provided if required. Study participants will then be randomised to receive either bridge design A or B (table 1) according to a predetermined randomization schedule. A photograph of the treatment site will be taken together with an impression for working models (table 2).

Table 1. Randomisation:

Treatment Regimen	Design
A (Blue and green)	Standard incisal edge overlap metal wing design using CAD/CAM (to reduce technician variation)
B (blue only)	No incisal edge overlap lap wing design using CAD/CAM

4. Further treatment appointments

At the second appointment the resin retained bridge (A or B) will be placed and clinical photographs taken. Clinical photos will be taken using the same camera with standardised settings. The two treatment procedures in full, including those outlined in 'screening appointment' above, are shown in table 2.

Table 2. Clinical treatment procedures and assessments

<u>Treatment procedure A</u>	<u>Treatment procedure B</u>
Impression for working models, clinic photos, screening clinical assessments and QoL	Impression for working models, clinic photos, screening clinical assessments and QoL
Plain radiograph of pontic site and surrounding teeth. If required, many patients will have these radiographs already.	Plain radiograph of pontic site and surrounding teeth. If required, many patients will have these radiographs already.
Fit of resin retained bridge. Current design. Using Panavia F and clinical photos	Fit of resin retained bridge. Adjusted design. Using Panavia F and clinical photos
Patient groups and GDP assessment of aesthetics of RRB cases.	Patient groups and GDP assessment of aesthetics of RRB cases.
QoL and aesthetic questionnaires.	QoL and aesthetic questionnaires.

18 months after bridge placement, review the number of failures reported	18 months after bridge placement, review the number of failures reported
--	--

One month after resin bridge fit the patient will be sent a link to an electronic version of the questionnaire on quality of life and a paper copy of the questionnaire with a stamped addressed return envelope (as an alternative to the electronic version), with regards to oral health (OHIP 14; Appendix 1/ adjusted OHIP14 Appendix 2). One reminder letter to complete the OHIP14 questionnaire with a stamped addressed return envelope will be sent to participants who have not returned it. After bridge fit the participant will have standard review with their general dentist every 6 months as is routine with this type of treatment.

Data on failure rates is reported by GDPs – treatment of failures will follow normal procedures. If any treatment fails, a clinician will reassess the patient, and treat appropriately according to the clinical findings, following standard practice for treatment failure at BDH.

Aesthetic image assessment

Randomly selected participants will be used for completion of the questionnaire, consisting of three different groups;

1. Patients (General Public) visiting the dental hospital for routine treatments other than tooth replacement, or General Public recruited who are members of the ‘Health Watch’ charity.
2. Dental Patients from the hypodontia clinic
3. Dental Professionals at Bristol Dental Hospital

Will be asked to complete the aesthetic questionnaire. This will consist of anonymised images of the RRB cases, 5 from group A and 5 from group B (Kokich et al 1999).

For each image participants will be asked to respond to the following question:

Please rate 1-5 overall attractiveness. (1-Very unattractive, 2-Unattractive, 3-Neither attractive nor unattractive, 4-Attractive, 5-Very attractive) (Stenvik et al 1997). A template for this can be found in Appendix 3.

Participant restrictions

- **Lifestyle**

Following the treatment, the participants will be advised how to look after their mouth. This is the routine post-operative care plan for all patients undergoing this type of treatment.

- **Medications and treatments**

Any concomitant medication taken by participants during the study period will be recorded in the participant’s notes/CRF.

- **New information**

If, during a patient’s participation in the trial, any new information becomes available that may affect the participants willingness to participate in the study, each ongoing participant will receive a copy of this new information and be re-consented into the study. Participants will be provided with a copy of the signed and dated amended consent form.

Statistical Methods

Sample size

Aesthetic outcome samples sizes are calculated separately for patient groups and staff assessors as follows:

Hypodontia patients: The sample size is based on the primary outcome measure of the proportion of hypodontia patients preferring the adjusted bridge design over the current bridge design. Approximately 40% of patients receiving the current bridge design voice concerns about the visible metal rim of the bridge (false tooth) after it has been fitted. It is anticipated therefore that 40% of hypodontia patients assessing the images will prefer the adjusted design to the current design and the remaining hypodontia patients will be split equally between adjusted and current. Based on this assumption, a sample size of 47 hypodontia patients will provide 80% power of detecting a difference between the bridge designs at a 5% level.

Non-hypodontia patients: The sample size is based on the primary outcome measure of the proportion of non-hypodontia patients preferring the adjusted bridge design over the current bridge design. It is anticipated that non-hypodontia patients will be slightly less likely to see things that could compromise the aesthetics of a replaced tooth being more focussed on the general overall appearance of the teeth. As these non-hypodontia patients are still dental attenders and thus likely to be dentally aware it is anticipated that 30% of patients assessing the images will see a difference between teeth as a result of the difference in bridge designs overall preferring the adjusted design, the remaining patients being split equally between adjusted and current. Based on this assumption, a sample size of 89 non-hypodontia patients will provide 80% power of detecting a difference between the bridge designs at a 5% level.

Staff: The sample size is based on the primary outcome measure of the proportion of staff preferring the adjusted bridge design over the current bridge design. It is anticipated that staff will be more likely to detect differences in the aesthetic outcomes of the two bridge designs as they are dental professionals, but as they will only be reviewing images rather than patients in a dental chair a conservative estimate is that 50% will prefer the adjusted design over the current design, the remaining staff being split equally between adjusted and current. Based on this assumption, a sample size of 29 staff will provide 80% power of detecting a difference between the bridge designs at a 5% level.

It is not possible to power for a difference between assessors, differences will be described using descriptive statistics.

Patient samples sizes for the two groups of RRB design are calculated as follows:

Differences in bridge failure rates between groups at 18 months is anticipated to be very low, and data will be collected simply to monitor this in case there are any differences. This data will also be described using descriptive statistics.

Statistical Analysis

One samples proportion tests will be used to determine whether patient groups or staff prefer the adjusted or current bridge.

Reporting adverse events and serious adverse events

AEs will be reported from the time a signed and dated informed consent form is obtained until the participant completes the last study-related procedure. Those occurrences meeting the definition of SAEs will be reported using the UH Bristol Serious Adverse Event Form, including SAEs spontaneously reported to the Investigator within 30 days after the participant has completed the study (including post study follow-up). UH Bristol, on behalf of the Sponsor, will evaluate any safety information that is spontaneously reported by a Principal Investigator (PI) beyond the time frame specified in the protocol.

All AEs, regardless of seriousness, severity, or presumed relationship to study treatments, will be recorded in the source document and the CRF, together with any measures taken. The PI will record in the CRF their opinion concerning the relationship of the adverse event to study therapy. UH Bristol, on behalf of the Sponsor, assumes responsibility for appropriate reporting of adverse events to the regulatory authorities.

Reporting Adverse events

AEs will be recorded in the AE section of the CRF.

Reporting serious adverse events

All SAEs will be reported to the UH Bristol contact (0117 3420233) by investigational staff within 24 hours of their knowledge of the event. All SAEs that have not resolved by the end of the study, or that have not resolved upon discontinuation of the participant's participation in the study, will be followed until any of the following occurs:

- the event resolves
- the event stabilizes
- the event returns to baseline, if a baseline value is available
- the event can be attributed to agents other than the study drug or to factors unrelated to study conduct
- when it becomes unlikely that any additional information can be obtained (participant or health care practitioner refusal to provide additional information, lost to follow-up after demonstration of due diligence with follow-up efforts)

The death of a participant is considered an SAE, as is any event requiring hospitalization (or prolongation of hospitalization) that occurs during the course of a participant's participation. Exceptions to this are hospitalizations for:

- social reasons in absence of an adverse event
- the in-clinic protocol procedures
- surgery or procedure planned before entry into the study (must be documented in the CRF)

Follow-up of adverse events and serious adverse events

After the initial report, the investigator will be required to proactively follow up with each participant and provide further information on the participant's condition. All AEs/SAEs will be followed until

resolution, until the condition stabilizes, until the event is otherwise explained, or until the participant is lost to follow-up. The investigator may be required to obtain additional laboratory tests or investigations, and/or provide the University of Bristol with additional documentation, including autopsy reports.

Ethical and Regulatory Aspects

Local Regulations/Declaration of Helsinki

The Principal Investigator will ensure that this study is conducted in full conformance with the laws and regulations of the country in which the research is conducted and the Declaration of Helsinki.

Informed Consent

It is the responsibility of the investigator, or designee, to obtain written (signed and dated by the participant) informed consent from each individual receiving treatment for hypodontia in this study. Data from those participants who simply assess aesthetic outcomes will be collected in fully anonymised format, these participants will be provided with an information sheet about the study, but consent will be deemed if they complete the sheet assessing aesthetic outcomes and deposit it in the drop box. Major/substantial amendments to the protocol that affect the scope of the study at the participant level and/or updates to the safety profile of the investigational product will be reflected in the consent form and active participants re-consented.

Independent Ethics Committee

This study has been reviewed and given a favourable opinion by an independent UK NHS Research Ethics Committee. Any amendments will be reviewed by the Sponsor prior to submission for approval by the NHS Research Ethics Committee.

Monitoring of the Study

The University of Bristol has a policy for monitoring 10% of studies. Monitoring of studies is conducted in accordance with UH Bristol monitoring policy in relation to the service level agreement with the University of Bristol.

Insurance

The University of Bristol has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management or design of the research by the University, and the policy provides an indemnity for their employees for their potential liability for harm to participants during the conduct of the research.

In addition, Professor Nicola West holds an honorary appointment and Miss Claire Forbes-Haley an appointment with University Hospitals Bristol NHS Foundation Trust giving them the protection of the NHS indemnity scheme.

Conflict of Interest and publication

The investigators have no conflict of interest with regards to this study. Data from this study will be published in a peer reviewed journal.

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10th July 2020, Version 4.0, IRAS 257107

7.2 Protocol Appendix 1 OHIP-14

OHIP14

Participant number _____

Date _____

How often have you had the problem in the past 6 months (circle your answer)

DROP BOX IN RECEPTION.

1. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
2. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
3. Have you had painful aching in your mouth?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
4. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
5. Have you been self conscious because of your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
6. Have you felt tense because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
7. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
8. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
9. Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
10. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
11. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
12. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
13. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
14. Have you been totally unable to function because of problems with your teeth, mouth or dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know

7.3 Protocol Appendix 2 OHIP-14 Young Adult

OHIP14 adjusted for young adults

Participant number _____

Date _____

How often have you had the problem in the past 6 months (circle your answer)

1. Do you have trouble saying any words because of problems with your teeth, mouth or retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
2. Do you think that the taste of foods or drinks has changed because of problems with your teeth, mouth or retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
3. Have you had painful aching in your mouth other than that caused by braces?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
4. Do you find it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures other than retainers/dentures	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
5. Have you been self conscious because of your teeth, mouth or retainers/dentures ?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
6. Have you felt stressed because of problems with your teeth, mouth or retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
7. Has your diet been adjusted in a way that you aren't happy with because of problems with your teeth, mouth o retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
8. Have you had to interrupt meals because of problems with your teeth, mouth or retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
9. Have you found it difficult to relax because of problems with your teeth, mouth or retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
10. Have you been a bit embarrassed because of problems with your teeth, mouth or retainers/dentures	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
11. Have you been a bit irritable with other people because of problems with your teeth, mouth or retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
12. Have you had difficulty doing the things you normally do in the day because of problems with your teeth, mouth or retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
13. Have you felt unhappy because of problems with your teeth, mouth or retainers/dentures ?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know
14. Have you been totally unable to function because of problems with your teeth, mouth or retainers/dentures?	Very often	Fairly often	Occasionally	Hardly ever	Never	Don't know



A randomised clinical trial to determine the aesthetic outcomes of two designs of resin-retained bridge

I would like to invite you to participate in this survey, which forms part of my MSc research. The study has received full ethical approval from the NRES Committee SE Coast-Brighton and Sussex [19 LO 0618]

Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please contact me if anything is not clear or if you would like more information using the contact details below.

Click [HERE](#) to view the participants' information sheet. Please note that as participation is anonymous, it will not be possible for us to withdraw your data once you have submitted your responses.

If you have any concerns or questions, please contact Claire Forbes-Haley:

Email: c.forbes-haley@bristol.ac.uk

I confirm I have read and understood the information sheet dated 10.07.20 for the above study *
Required

Please select

I confirm I have had the opportunity to ask questions which have been answered to my satisfaction *
Required

Please select

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and that this will have no negative impact on me * *Required*

Please select

I understand that the anonymous data collected will be used to support other research in the future, and may be shared anonymously with other researchers * *Required*

Please select

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 1



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 2



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Picture 3



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 4



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 5



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 6



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 7



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 8



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 9



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

This part of the survey uses a table of questions, [view as separate questions instead?](#)

Picture 10



Please don't select more than 1 answer(s) per row.

	1 - Very unattractive	2 - Unattractive	3 - Neither attractive nor unattractive	4 - Attractive	5 - Very attractive
Picture 10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



< Previous

Finish ✓



University of
BRISTOL

Bristol Dental School

Clinical Trials Unit (Periodontology)

University of Bristol

Lower Maudlin Street, BRISTOL BS1 2LY

Professor N West BDS FDS RCS PhD FDS (Rest Dent)

Professor/Honorary Consultant in Restorative Dentistry

Dear

INVITATION TO TAKE PART IN A RESEARCH STUDY

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

We are looking for volunteers who have missing teeth to take part in a study which will compare two designs of adhesive bridges. You have been given this letter by your treating dentist as you or your child have a missing tooth, or teeth, and could be eligible to take part in the study.

Adhesive bridges are used frequently to replace missing teeth, especially at the front of the mouth. The most commonly used type of bridge is a false tooth which is stuck to the adjacent teeth using a metal wing. In the current bridge design this metal wing can be seen as a rim above the false tooth. However, with improvements in bonding materials, the bridge has now been re-designed so that the metal cannot be seen. We would like to compare these two adhesive bridge designs to see if one is preferred over the other.

If you or your child would like to take part in this study, you will have to attend 3 appointments at the Bristol Dental Hospital over 4 months. This is the same number of appointments that you would have to attend to have a bridge fitted, even if you did not want to take part in the study. If you do decide to take part, there will be a 50% chance of you having either one of two bridge designs fitted: the standard bridge design (currently used at the Bristol Dental Hospital) or the adjusted bridge design. We will also take photographs of your mouth (your face will not be seen) and you will be asked to complete a questionnaire, before and after the bridge has been fitted, about how much the missing tooth affects your/your child's quality of life.

Contact details

If you would be interested in learning more about the study please email your contact details (email, mobile number, full name) to the address below and a member of the clinical trials team will contact you with more information.

dental-clinical-trials@bristol.ac.uk

Subject in email: RRB Trial

Letter of Invitation, Version 2.0 9th May 2019

IRAS 257107



RESEARCH PARTICIPANT INFORMATION SHEET - Parent Guardian

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

We would like to invite your child to take part in a research study which is being undertaken as part of an MSc project.

Before you decide if you are happy for your child to take part, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with your child, family, friends or your dentist, if you wish. Ask us if there is anything that is not clear or if you would like more information (contact details can be found at the end of the sheet). Take time to decide whether or not you wish your child to take part. Thank you for your interest in this research study.

What is the purpose of the study? Why is this study being carried out?

Missing teeth is a common problem which can make it more difficult to chew and make people self-conscious of their appearance and less confident. Adhesive bridges where a false tooth is attached to the teeth either side of the gap are used frequently to replace missing teeth especially at the front of the mouth. They have been shown to last a long time in the mouth without needing further treatment.

There are different materials and designs of bridge that can be chosen. The most successful type currently used has its supporting wing made of metal. The metal must cover the whole of the back of the supporting tooth and in the current design this extends over the front edge of the tooth. This bridge design has a thin flash of metal which can be seen on the tip or edge of the tooth. With improvements in bonding materials it is now possible to re-design the bridge so that the metal cannot be seen. Although it isn't much, this bit of metal can bother some people who receive this type of replacement tooth. The aim of our study is to compare the two designs of adhesive bridge to see if either one looks and/or performs better.

Why has my child been invited to take part?

Your child has been invited to take part in this study because they have a tooth missing at the front of their mouth which can be replaced using an adhesive bridge. Altogether, 40 participants will be invited to take part in this study, which will last approximately 18 months. All potential participants will be patients attending for dental treatment of tooth loss.

Does my child have to take part in this study?

No, your child is entirely free to choose, and they may stop taking part in the study at any time without giving a reason. The study dentist can stop their participation in the study in the event of illness or other reasons. We will keep you informed of any new information that may become available during the study that may affect your willingness for your child to continue participating. Not agreeing to take part or withdrawal from the study will not affect your child's treatment.

What will happen to my child if they take part in this study / what will they have to do?

To complete this study, your child will need to attend 3 times in approximately 4 months as follows (if your child decided not to take part in the study, they would still receive an adhesive bridge and have the same number of appointments to fit their bridge):

- **Screening visit:** 15 minutes
- **Impression visit:** 30 minutes
- **Bridge fit visit:** 2 x 30 minutes with an hour between on same day

We will also ask your child to complete two questionnaires (one after screening and one after the bridge fit) about how their missing tooth affects everyday things, like eating.

If your child is interested in taking part in the study, they will be given their own an information sheet about the study to read and invited to a **Screening visit**. At this screening visit:

- A research staff member will go through this information sheet and answer any questions you both may have.
- You and your child will both be asked to sign a form to say that you agree to take part in the study (you will both have copies of these forms to take home with you).
- The study dentist will then record your child's age, gender and the first three digits of postcode.
- The study dentist will also take a medical history and ask about any medicines that your child may be taking.
- Next, the study dentist will examine your child's mouth and make sure they are missing a tooth in the right area. They may also take X-rays of your child's mouth, if required.
- If your child is suitable and willing to take part in the study, the dentist will then identify which type of bridge they will receive, the standard (current) design or the alternative design. The decision over which bridge your child receives will be made at random (like tossing a coin), neither you nor the dentist will be able to choose which bridge your child receives. Half the participants on the study will be given the currently used, standard bridge design and the other half will have the alternative design.
- The dentist will then take a photograph of your child's mouth. These photographs will not include your child's face.
- Your child will be asked to complete a short questionnaire about how much their missing tooth affects everyday things like eating. This questionnaire will be sent to you electronically, just after screening.
- The screening visit will take around 15 minutes in total.

Your child will then be invited to attend an **Impression visit**. At this Impression visit:

- The study dentist will make moulds of your child's teeth, both the top and bottom set.
- The study dentist will also look at the colour of the teeth and make a record of this so that the colour of the false tooth (bridge) will match.
- This visit will take approximately 30 minutes.

Your child's final visit will be the **Bridge fit visit**. At the bridge fit visit:

- Your child's bridge will be tried in their mouth to see how well it fits and how well the colour matches their other teeth. If any changes to the colour are required these will be made on the day.

- The bridge will then be stuck to the teeth using dental cement and once the cement is dry, and any extra bits have been cleaned off, your child will be shown how best to clean around the area.
- The dentist will also take a photograph of your child's mouth after the bridge has been fitted. These photographs will not include your child's face.
- The bridge fit visit will consist of 2 x 30-minute appointments on the same day with at least an hour between them. The second appointment is only used if a colour change of the teeth is needed.
- Approximately a month after the Bridge fit visit, you will be sent a link to an electronic form that asks questions about how easy your child finds it to eat or do other daily activities, as we want to know if the bridge has helped them.

What will you do with the photographs that you have taken of my child's mouth?

The photographs that were taken of your child's mouth will be added to photographs from our other study participants. We will not be able to identify your child from the photographs. Patients and staff will then look at the photographs to see which bridge they think looks better.

Is there anything my child should or should not do?

Following treatment, your child will be advised how to brush their teeth. If you subscribe to a private dental healthcare plan, then you are advised to inform the providers of the plan about your participation in the study in case it voids the cover.

Are there any expenses or payments for taking part?

You or your child will not be reimbursed for taking part in this study as the bridge treatment your child will receive forms part of the standard treatment at a dental hospital for people with missing teeth.

What are the possible risks/ side effects of taking part?

With any bridge there is a risk it may come loose. Approximately, 20% of bridges can come loose or have other problems (such as: being knocked out, chipping of the ceramic false tooth, or poor teeth cleaning at home) within 5 years. We do not anticipate this to be different in the adjusted bridge design to the standard one currently used. If there are any problems with the bridge, you should tell your child's dentist who will let us know so that we can fix it. All procedures will be carried out by experienced and appropriately qualified personnel using standard techniques.

Are there any benefits to my child if they take part?

We cannot say whether the adjusted adhesive bridge design will look better than the standard bridge currently used or last as long, but the results of this study will help determine whether the adjusted adhesive bridge design could be of benefit to patients in the future.

Are there any reasons why my child's participation in this study could be ended?

Your child's participation in this study can be ended for several reasons such as: their safety (such as an adverse reaction to one of the study materials), if your child decides that they do not want to continue in the study (if this happens your child will receive their treatment as normal at the dental hospital), or at the study dentist's request.

What happens when the research study ends?

All patients will be reviewed and followed up in accordance with guidelines for all patients undergoing adhesive bridge treatment. This is usually standard follow up with your child's normal dentist. Your child

will keep the bridge that they were allocated in the study. Your child's anonymised data will be held within the Clinical Trials Unit at Bristol Dental Hospital and with your permission may be released in anonymised form to support other researchers in the future.

What if relevant new information becomes available?

Sometimes during a research project, new information becomes available about the treatment that is being studied. If this happens, your research dentist will tell you about it and discuss whether you and your child want to or should continue the study. If your child decides to continue in the study you will both be asked to sign an updated consent form. On receiving new information your research dentist might consider it to be in your child's best interests to withdraw them from the study, if this happens, he/she will explain the reasons why. If the study is stopped for any other reason, you will be informed why.

What will happen to the results of the research study?

It is possible that the results of the study will be published in an internationally refereed scientific journal. Should this be the case any information about you will be anonymised.

Who is organising this research?

The Clinical Trials Unit at the Bristol Dental School at the University of Bristol are organising the research. Claire Forbes-Haley, the study dentist, is conducting this research as part of a Research Master's degree.

What if there is a problem?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, please contact Professor Nicola West (details below) or the Patient Support and Complaints Team (at UHBristol) on 0117 342 3604.

Who has reviewed the study?

This study has been reviewed and given favourable ethical approval by the London-Brighton & Sussex Research Ethics Committee (REC number 19/NS/0050).

Will my child's participation in this study be kept confidential?

All information about your child will be made anonymous and only the study dentist, your child's dentist and members of the study team will know you have taken part in the study. We will not write your name or address on any questionnaires or study paperwork. Written data will be kept in a secure location (a locked filing cabinet at the University of Bristol). No identifying information will be accompanying the data; instead each person will be allocated a number, to protect their identity.

Bristol University will oversee this research to ensure it is carried out correctly and that you and your child are treated properly. When the study is finished all information collected from questionnaires and your child's study appointments will be kept in a locked filing cabinet by the Clinical Trials Unit at Bristol University for up to 15 years. It will then be destroyed.

Your rights to look at or change your information, or your child's information, are limited, as we need to manage information in specific ways for the research to be reliable and accurate. If you and your child withdraw from the study, we will keep the information about your child that we have already obtained. To safeguard your rights, we will use as little information that could identify your child as possible. You can find out more about how we use your information at <https://www.hra.nhs.uk/information-about-patients>.

Further information and contact details

If you have any further questions concerning the study, or in case of any difficulty during the study, please contact: Miss Claire Forbes-Haley (0117 342 9638) – Study Dentist, Prof. Nicola West - Principal Investigator (0117 342 4145) or Dr. Emma Macdonald – Study Co-ordinator (0117 342 9638) at the Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY. **Emergency 24-hour contact number: 07827 956855**

**Thank you for reading this document.
If you have any further questions, please do not hesitate to ask.**

Research Participant Information Sheet – Parent/Guardian
Version 3.0, 4th June 2019, 1RAS 257107



RESEARCH PARTICIPANT INFORMATION SHEET-ADULT

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

We would like to invite you to take part in a research study which is being undertaken as part of an MSc project.

Before you decide to take part, it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully and discuss it with your family, friends or your dentist, if you wish. Ask us if there is anything that is not clear or if you would like more information (contact details can be found at the end of the sheet). Take time to decide whether you wish to take part. Thank you for your interest in this research study.

What is the purpose of the study? Why is this study being carried out?

Missing teeth is a common problem which can make it more difficult to chew and make people self-conscious of their appearance and less confident. Adhesive bridges where a false tooth is attached to the teeth either side of the gap are used frequently to replace missing teeth especially at the front of the mouth. They have been shown to last a long time without needing further treatment.

There are different materials and designs of bridge that can be chosen. The most successful type currently used has its supporting wing made of metal. The metal must cover the whole of the back of the supporting tooth and in the current design this extends over the over the front edge of the tooth. This bridge design has a thin flash of metal which can be seen on the tip or edge of the tooth. With improvements in bonding materials it is now possible to re-design the bridge so that the metal cannot be seen. Although it isn't much, this bit of metal can bother some people who receive this type of replacement tooth. The aim of our study is to compare the two designs of adhesive bridge to see if either one looks and/or performs better.

Why have I been invited to take part?

You have been invited to take part in this study because you have a tooth missing at the front of your mouth which can be replaced using an adhesive bridge. Altogether, 40 participants will be invited to take part in this study, which will last approximately 18 months. All potential participants will be patients attending the Bristol Dental School and Hospital for treatment of tooth loss.

Do I have to take part in this study?

No, you are entirely free to choose and you may stop taking part in the study at any time without giving a reason. The study dentist can stop your participation in the study in the event of illness or other reasons. We will keep you informed of any new information that may become available during the study that may affect your willingness to continue participating. Not agreeing to take part or withdrawal from the study will not affect your treatment.

What will happen to me if I take part in this study / what will I have to do?

To complete this study, you will need to attend 3 times in approximately 4 months as follows (if you decided not to take part in the study you would still receive an adhesive bridge and have the same number of appointments to fit your bridge):

- **Screening visit:** 15 minutes.
- **Impression visit:** 30 minutes
- **Bridge fit visit:** 2 x 30 minutes with an hour between on same day

We will also ask you to complete two questionnaires (one after screening and one after the bridge fit) about how your missing tooth affects everyday things, like eating.

If you are interested in taking part in the study you will be invited to a **Screening visit**. At this screening visit:

- A research staff member will go through this information sheet with you and answer any questions that you might have.
- You will be asked to sign a consent form to say that you agree to take part in the study. You will be given a copy of this form to take home with you.
- The study dentist will then record your age, gender and the first three digits of your postcode.
- The study dentist will also take your medical history and ask about any medicines that you are currently taking.
- Next, the study dentist will examine your mouth and make sure you are missing a tooth in the right area. They may also take X-rays of your mouth, if required.
- If you are suitable and willing to take part in the study, the dentist will then identify which type of bridge you will receive, the standard (current) design or the alternative design. The decision over which bridge you receive will be made at random (like tossing a coin), neither you nor the dentist will be able to choose which bridge you receive. Half the participants on the study will be given the currently used, standard bridge design and the other half will have the alternative design.
- The dentist will then take a photograph of your mouth. These photographs will not include your face.
- You will also be asked to complete a short questionnaire about how your missing tooth affects everyday things like eating. This questionnaire will be sent to you electronically, just after screening.
- The screening visit will take around 15 minutes in total.

You will then be invited to attend an **Impression visit**. At this Impression visit:

- The study dentist will make moulds of your teeth, both the top and bottom set.
- The study dentist will also look at the colour of your teeth and make a record of this so that the colour of the false tooth (bridge) will match them.
- This visit will take approximately 30 minutes.

Your final visit will be the **Bridge fit visit**. At the bridge fit visit:

- Your bridge will be tried in your mouth to see how well it fits and how well the colour matches your other teeth. If any changes to the colour are required these will be made on the day.
- The bridge will then be stuck to the teeth using dental cement and once the cement is dry, and any extra bits have been cleaned off, you will be shown how best to clean around the area.

- The dentist will also take a photograph of your mouth after the bridge has been fitted. These photographs will not include your face.
- The bridge fit visit will consist of 2 x 30-minute appointments on the same day with at least an hour between them. The second appointment is only used if a colour change of the teeth is needed.
- Approximately a month after the Bridge fit visit, you will be sent a link to an electronic form that asks questions about how easy you find it to eat or do other daily activities, as we want to know if the bridge has helped you.

What will you do with the photographs that you have taken of my mouth?

The photographs that were taken from after your bridge was fitted will be added to photographs from our other study participants. We will not be able to identify you from the photographs. Patients and staff at will then look at the photographs to see which bridge they think looks better.

Is there anything I should or should not do?

Following treatment, you will be advised how to brush your teeth. If you subscribe to a private dental healthcare plan, then you are advised to inform the providers of the plan about your participation in the study in case it voids your cover.

Are there any expenses or payments for taking part?

You will not be reimbursed for taking part in this study as the bridge treatment you receive forms part of the standard treatment at a dental hospital for people with missing teeth.

What are the possible risks / side effects of taking part?

With any bridge there is a risk it may come loose. Approximately, 20% of bridges can come loose or have other problems (such as being knocked out, chipping of the ceramic false tooth, or poor teeth cleaning at home) within 5 years. We do not anticipate this to be different in the adjusted bridge design to the one currently used. If the bridge does have any problems then you should tell your dentist who will let us know so that we can fix it. All procedures will be carried out by experienced and appropriately qualified personnel using standard techniques.

Are there any benefits in taking part?

We cannot say whether the adjusted adhesive bridge design will look better than the standard bridge design currently used or last as long, but the results of this study will help determine whether the new adhesive bridge design could be of benefit to patients in the future.

Are there any reasons why my participation in this study could be ended?

Your participation in this study can be ended for several reasons such as: your safety (such as an adverse reaction to one of the study materials, if you decide you do not want to continue in the study (if this happens you will receive your treatment as normal at the dental hospital), or at the study dentist's request.

What happens when the research study ends?

All patients will be reviewed and followed up in accordance with guidelines for all patients undergoing adhesive bridge treatment. This is usually standard follow up with your local dentist. You will keep the same bridge that you were allocated in the study. Your anonymised data will be held within the Clinical Trials Unit at Bristol Dental Hospital and with your permission may be released in anonymised form to support other researchers in the future.

What if relevant new information becomes available?

Sometimes during a research project, new information becomes available about the treatment that is being studied. If this happens, your research dentist will tell you about it and discuss whether you want to or

should continue the study. If you decide to continue in the study you will be asked to sign an updated consent form. On receiving new information your research dentist might consider it to be in your best interests to withdraw you from the study, if this happens, he/she will explain the reasons why. If the study is stopped for any other reason, you will be informed why.

What will happen to the results of the research study?

It is possible that the results of the study will be published in an internationally refereed scientific journal. Should this be the case any information about you will be anonymised.

Who is organising this research?

The Clinical Trials Unit at the Bristol Dental School at the University of Bristol are organising the research. Claire Forbes-Haley, the study dentist, is conducting this research as part of a Research Master's degree.

What if there is a problem?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, please contact Professor Nicola West (details below) or the Patient Support and Complaints Team (at UHBristol) on 0117 342 3604.

Who has reviewed the study?

This study has been reviewed and given favourable ethical approval by the London-Brighton & Sussex Research Ethics Committee (REC number 19/NS/0050).

Will my participation in this study be kept confidential?

All information about you will be made anonymous and only the study dentist, your dentist and members of the study team will know you have taken part in the study. We will not write your name or address on any questionnaires or study paperwork. Written data will be kept in a secure location (a locked filing cabinet at the University of Bristol). No identifying information will be accompanying the data; instead each person will be allocated a number, to protect their identity.

Bristol University will oversee this research to ensure it is carried out correctly and that you are treated properly. When the study is finished all information collected from questionnaires and your study appointments will be kept in a locked filing cabinet by the Clinical Trials Unit at Bristol University for up to 15 years. It will then be destroyed.

Your rights to look at or change your information are limited, as we need to manage your information in specific ways for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use as little information that could identify you as possible. You can find out more about how we use your information at <https://www.hra.nhs.uk/information-about-patients>.

Further information and contact details

If you have any further questions concerning the study, or in case of any difficulty during the study, please contact: Miss Claire Forbes-Haley (0117 342 9638) – Study Dentist, Prof. Nicola West - Principal Investigator (0117 342 4145) or Dr. Emma Macdonald – Study Co-ordinator (0117 342 9638) at the Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY. **Emergency 24-hour contact number: 07827 956855**

Thank you for reading this document.

If you have any further questions, please do not hesitate to ask.

Research Participant Information Sheet - Adult
Version 3.0, 4th June 2019, 1RAS 257107

RESEARCH PARTICIPANT INFORMATION SHEET- YOUNG PERSON (11-18yrs)

A study looking at the appearance of 2 different types of dental bridges

We would like to invite you to take part in a research study which is being undertaken as part of a higher education degree (a Master in Science). This sheet contains information about the study and what you would need to do if you wanted to take part. You will need to read this before you can start the study. If you are interested in taking part, please take time and read this sheet as it is important for you to understand why the research is being carried out and what you would have to do if you took part.

If you wish to discuss taking part with your family, friends or your normal dentist, please do so. Also, feel free to ask us if there is anything you do not understand or would like more information on. We have put our contact details at the end of this information sheet. You do not have to decide straight away if you would like to take part in this research.

What is this study about?

Missing teeth is a common problem which can make it difficult to eat and make people concerned about how they look when they open their mouth or smile. A missing tooth is often replaced by a false tooth which is held in place by sticking it to the teeth on either side of it. This is called a bridge and once in place it will last a long time with no further treatment. As part of this bridge, a bit of metal can be seen at the tip of the false tooth and this can bother some people. The purpose of our study is to compare this bridge with an adjusted design of bridge, which has been changed a little, and see which one people prefer the look of and how well they both last.

Why do you want me to take part?

You have been invited to take part as you have a tooth missing at the front of your mouth which can be replaced using a bridge. We would like 40 people who have come for treatment for lost teeth to take part.

Do I have to take part in this study?

No, it is entirely up to you and you parent/guardian if you wish to take part or not. Don't worry, if you do not want to take part, you will still receive the normal treatment for your missing tooth. If you decide to take part in the study, you are free to change your mind and stop taking part at any time without telling us why.

The dentist who sees you at the hospital (your study dentist) may need to stop you taking part if they feel it is in your interest, for example in the event of you experiencing any illness. If this does happen, the study dentist will explain why they need to stop you taking part. If any new information about the

research becomes available during the study, we will let you know and check that you are still happy to take part.

What will happen to me if I do take part in this study?

To be included in the study you will need to sign a form to say you agree to take part - this is called an 'Assent Form'. We will also need your parent/guardian to sign a 'Consent Form' for you to take part.

To complete the study, you will need to visit 3 times in approximately 4 months. This is the same number of visits you would have to have a bridge fitted, even if you didn't want to take part in the study. To help you prepare, below is a list of what will happen at each visit and how long each visit will be:

Visit 1 (Screening Visit) – approximately 15 minutes

- A member of the research team will ask you if you have understood what the study is about and what will happen to you. They will also answer any questions that you might have.
- If you are happy to take part, both you and your parent/guardian will be asked to sign forms to say that you agree to take part.
- The study dentist will then record some information about you, for example, how old you are, whether you are male or female, the start of your postcode and some questions about your health and any medicines that you are currently taking.
- Next, the study dentist will check your mouth and make sure you are missing a tooth in the right area for the study and take X-rays of your mouth, if needed.
- If the study dentist confirms you have a missing tooth in the right place for the study, the type of bridge you will have fitted will be allocated to you. The bridge will be either the standard type normally used or the adjusted design. The decision over which bridge you receive will be made at random (like tossing a coin), neither you nor the dentist will be able to choose which bridge you receive. Half the people on the study will be given the normal bridge and the other half will have the alternative design.
- The dentist will then take a photograph of your mouth, but this will not include your face.
- After your appointment, you will be sent a short electronic questionnaire about how your missing tooth affects everyday things like eating. Please can you to complete this and return to us via email. If you would prefer a paper copy, we can provide this for you.

Visit 2 (Impression Visit) - approximately 30 minutes

- The study dentist will make moulds of your upper and lower teeth.
- The colour of your teeth where the bridge will be fitted will be checked by the dentist. This is to make sure the colour of the false tooth in your bridge will match your own teeth.

Visit 3 (Bridge fitting, final visit) – either one, or two 30-minute appointments on the same day.

- The dentist will place the bridge in your mouth to see how well it fits and how well the colour matches your other teeth. If any changes to the colour are required these will be made on the day.
- The bridge will then be stuck to the teeth either side using dental cement and once the cement is dry, and any extra bits have been cleaned off, you will be shown how best to clean around the area.

- A photograph of your mouth will be taken after the bridge has been fitted but will not include your face.
- This visit will consist of either one, or two 30-minute appointments on the same day. If the bridge is the right colour you will only have the first appointment. If the colour of the bridge is not quite right, you will need to wait an hour for the second appointment while the colour is fixed.
- Approximately a month after the Bridge fit visit, you will be sent a link to an electronic form that asks questions about how easy you find it to eat or do other daily activities, as we want to know if the bridge has helped you. Please can you to complete this and return to us via email. If you would prefer a paper copy, we can provide this for you.

What will you do with the photographs that you have taken of my mouth?

The photographs taken after the bridge has been fitted for each person in the study will be looked at by patients and staff, and they will be asked to rate the look of the bridges in the pictures. You will not be able to be identified from the pictures taken.

Are there any risks to me if I take part?

With any bridge there is a risk it may come loose. Normally, approximately 20% come loose or have other problems such as being knocked out. We do not think that there this will be different in the adjusted bridge design. If you have any problems with your bridge after it has been fitted, then you should tell your normal dentist who will then let us know so that we can fix it.

What are the potential benefits in taking part?

We cannot say whether the different bridge design will look better or last longer than the current one normally used one, but the results of this study will help determine whether this different bridge design could be of benefit to patients in the future.

What happens when the research study ends?

At the end of the study, you will go back to your normal dentist for your ongoing dental treatment.

It is possible that the results of the study will be published in a scientific journal, but this will be done anonymously; no one will know you were involved in the study. If you would like to find out the results of the study, please contact the Study Co-ordinator using the contact details below.

Who is organising this research?

The Clinical Trials Unit at the Bristol Dental School at the University of Bristol are organising the research. Claire Forbes-Haley, the study dentist, is conducting this research as part of a Research Master's degree.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee. Research Ethics Committees look after the rights of people who are involved in research and check that studies that patients are involved in are fair. This study has been reviewed and approved by the London-Brighton & Sussex Research Ethics Committee.

What if there is a problem?

If you wish to complain or have any concerns about any aspect of the way you have been approached or treated during this study, please contact Professor Nicola West (details below) or the Patient Support and Complaints Team (at UHBristol) on 0117 342 3604.

Who will know what I have said?

Only the study dentist, your dentist and members of the study team will know you have taken part in the study. We will not write your name or address on any questionnaires or study paperwork. Instead, to protect your identity, you will be given a unique study number. Written data will be kept in a secure location (a locked filing cabinet at the University of Bristol).

Bristol University will oversee this research to make sure it is carried out correctly and that you are treated properly. When the study is finished all information collected from questionnaires and your study appointments will be sent for secure filing by the Dental Clinical Trials Unit at Bristol University for up to 15 years. It will then be destroyed.

Further information and contact details

If you have any further questions concerning the study, or in case of any difficulty during the study, please contact:

Miss Claire Forbes-Haley (0117 342 9638) – Study Dentist,

Prof. Nicola West - Principal Investigator (0117 342 4145) or

Dr. Emma Macdonald – Study Co-ordinator (0117 342 9638) at the Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY.

Emergency 24-hour contact number: 07827 956855

Thank you for reading this document.

If you have any further questions, please do not hesitate to ask.



University of
BRISTOL

Bristol Dental School

Clinical Trials Unit (Periodontology)

University of Bristol

Lower Maudlin Street, BRISTOL BS1 2LY

Professor N West BDS FDS RCS PhD FDS (Rest Dent)

Professor/Honorary Consultant in Restorative Dentistry

Tel: 0117 342 9638

Date

Dear Dr.

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

Re: Name and Address of Individual (date of birth)

We understand that the above-named individual is under your care, but currently referred to Bristol Dental Hospital for tooth replacement. He/she has volunteered to take part in the above oral healthcare research study to compare two different adhesive bridge designs. I have included a patient information sheet which fully explains the study.

There are different materials and design of bridge that can be chosen. The most successful type of bridge has its supporting wing made of metal. It has been said that this metal must cover the whole of the back of the replacement tooth and over the front edge for the tooth for the adhesive bond to be successful. The disadvantage of this bridge design is that a thin flash of metal can be seen on the tip or edge of the tooth. With improvements in bonding materials it is now possible to re-design the bridge so that the metal cannot be seen. In this study, we aim to compare two adhesive bridge designs to see if the aesthetics and /or performance is different between the designs.

After the bridges have been fitted the patient will be discharged back to your care, as is normal protocol for treatment such as this. If any of the bridges suffers de-bond or failure, please inform us using the details above and addressing the letter to myself. If you have any questions regarding the study, please do not hesitate to contact me. All information will be treated in the strictest confidence.

The study has been reviewed and approved by the London – Brighton & Sussex Research Ethics Committee (19/NS/0050) and will be performed to comply with ICH GCP guidelines. Written informed consent has been obtained from the research participant.

Yours sincerely

Professor Nicola West

GDP Letter, Version 2.0, 9th May 2019, IRAS 257107



RESEARCH PARTICIPANT INFORMATION SHEET PATIENTS –ADULT

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

You are being invited to take part in this research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others, such as family and friends, if you wish. Ask us if there is anything that is not clear or if you would like more information. The results of this study will be used as part of an MSc research project. Thank you for your interest in this research study.

What is the purpose of the study? Why is this study being carried out?

Missing teeth are a common problem which can make it more difficult to chew and make people self-conscious of their appearance and less confident. Adhesive bridges are used frequently to replace missing teeth especially at the front of the mouth. The bridge is a ‘false tooth’ held in place by a wing that is attached to the adjacent tooth/teeth. Although these bridges are very successful and can last for a long time without needing further treatment, the metal wing that supports them can affect how they appear in the mouth. We have conducted a study in which patients who have missing teeth received either the standard, current adhesive bridge or a different adjusted bridge design. We now want to see what people who are having treatment for missing teeth think of the two bridge designs.

Why have I been invited to take part?

You have been invited to take part because you have missing teeth and are a patient at the Bristol Dental Hospital.

What will happen to me if I take part in this study / what will I have to do?

To take part in this study you will need to complete the short questionnaire accessed by the link in the email. This should take around **5 minutes**. The questionnaire is voluntary and anonymous. The questionnaire will ask you to rate 10 photographic images for overall attractiveness (1-Very unattractive, 2-Unattractive, 3-Neither attractive nor unattractive, 4-Attractive, 5-Very attractive).

When you click on the link you will be asked to consent to take part in the study and complete the questionnaire, if you agree you will be asked to complete and submit the questionnaire. You will not be asked to do anything else.

Do I have to take part in this study?

No, you do not have to take part in the study and can withdraw at any time up until you have submitted your questionnaire. However, as the questionnaires are anonymous, once it has been submitted, we will not be able to identify your questionnaire and therefore will not be able to remove your answers from the study.

Is there anything I should or should not do?

Once you have completed the questionnaire, please do not discuss your answers with anyone else.

What are the possible risks/ side effects of taking part?

The questionnaire is anonymous and whether you complete it or not will not affect your treatment at Bristol Dental Hospital.

Are there any benefits in taking part?

There is no personal benefit from taking part in this study, but we hope that the results of this study will help us to improve the look of replacement teeth in the future.

What will happen to the results of the research study?

The results of the study will be published in an internationally refereed scientific journal. Should this be the case any information about you will be anonymous, no one will know you have taken part in the study. If you would like to find out the results of the study, please contact the Study Co-ordinator using the contact details below.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee. This study has been reviewed and approved by the London-Brighton & Sussex Research Ethics Committee (19/LO/0618).

Further information and contact details

If you have any further questions concerning the study, or in case of any difficulty during the study, please contact: Miss Claire Forbes-Haley (0117 342 9638) – Study Dentist, Prof. Nicola West - Principal Investigator (0117 342 4145) or Dr. Emma Macdonald – Study Co-ordinator (0117 342 9638) at the Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY.
Emergency 24-hour contact number: 07827 956855

Thank you for reading this document.

If you have any further questions, please do not hesitate to ask.



RESEARCH PARTICIPANT INFORMATION SHEET PATIENTS – PARENT/GUARDIAN

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

Your child has been invited to take part in this research study. Before you decide whether your child should take part, it is important for you to understand why the research is being done and what it would involve for them. Please take time to read the following information carefully and discuss it with others, such as family and friends, if you wish. Ask us if there is anything that is not clear or if you would like more information. The results of this study will be used as part of an MSc research project. Thank you for your interest in this research study.

What is the purpose of the study? Why is this study being carried out?

Missing teeth are a common problem which can make it more difficult to chew and make people self-conscious of their appearance and less confident. Adhesive bridges are used frequently to replace missing teeth especially at the front of the mouth. The bridge is a 'false tooth' held in place by a wing that is attached to the adjacent tooth/teeth. Although these bridges are very successful and can last for a long time without needing further treatment, the metal wing that supports them can affect how they appear in the mouth. We have conducted a study in which patients who have missing teeth received either the standard, current adhesive bridge or a different adjusted bridge design. We now want to see what people who are having dental treatment for missing teeth think of the two bridge designs.

Why has my child been invited to take part?

Your child has been invited to take part because they have missing teeth and are a patient at the Bristol Dental Hospital.

What will happen to my child if they take part in this study / what will they have to do?

To take part in this study your child will need to complete the short questionnaire accessed by the link in the email. This should take around **5 minutes**. The questionnaire is voluntary and anonymous. The questionnaire will ask your child to rate 10 photographic images for overall attractiveness (1-Very unattractive, 2-Unattractive, 3-Neither attractive nor unattractive, 4-Attractive, 5-Very attractive).

When your child clicks on the link to access the questionnaire they will be asked if they are happy to take part in the study and complete it, if they confirm they are (give their consent), once your child has completed the questionnaire, and submitted it they will have consented to take part in the study.

Does my child have to take part in this study?

No, your child does not have to take part in the study and can withdraw at any time up until they have submitted questionnaire online. However, as the questionnaires are anonymous, once has been submitted, we will not be able to identify their questionnaire and therefore will not be able to remove their answers from the study.

Is there anything they or I should or should not do?

Following completion of the questionnaire, you and your child should not discuss their answers with anyone else.

What are the possible risks/ side effects of taking part?

The questionnaire is anonymous and whether your child completes it or not will not affect any aspect of their ongoing treatment at the Bristol Dental Hospital.

Are there any benefits in taking part?

There is no personal benefit from taking part in the study, but we hope that the results from the study will help to improve the look of replacement teeth in the future.

What will happen to the results of the research study?

The results of the study will be published in an internationally refereed scientific journal. Should this be the case any information about your child will be anonymous. If you or your child would like to find out the results of the study, please contact the Study Co-ordinator using the contact details below.

Who has reviewed the study?

This study has been reviewed and given a favourable ethical approval by the London-Brighton & Sussex Research Ethics Committee. (19/NS/0050).

Further information and contact details

If you have any further questions concerning the study, or in case of any difficulty during the study, please contact: Miss Claire Forbes-Haley (0117 342 9638) – Study Dentist, Prof. Nicola West - Principal Investigator (0117 342 4145) or Dr. Emma Macdonald – Study Co-ordinator (0117 342 9638) at the Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY. **Emergency 24-hour contact number: 07827 956855**

Thank you for reading this document.

If you have any further questions, please do not hesitate to ask.



RESEARCH PARTICIPANT INFORMATION SHEET – YOUNG ADULT (11-18yrs)

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

You are being invited to take part in this research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others, such as family and friends, if you wish. Ask us if there is anything that is not clear or if you would like more information. The results of this study will be used as part of an educational qualification (MSc). Thank you for your interest in this research study.

What is this study about?

Missing teeth is a common problem which can make it more difficult to chew and make people self-conscious of their appearance and less confident. Missing teeth, especially when they are at the front of the mouth, are often replaced with a false tooth that is stuck to the teeth either side of the gap, this is called a bridge. These bridges last for a long time without needing further treatment, but a bit of metal can be seen at the tip of the false tooth and this can bother some people. We have conducted a study in which some patients with missing teeth have been treated with two different bridge designs. We now want to see what patients such as you, who have a missing tooth think of the two bridge designs.

Why do you want me to take part?

You have been invited to take part because you have been born with a missing tooth and are a patient at Bristol Dental Hospital.

What will I have to do?

To take part in this study we would like you to complete the short questionnaire accessed by the link in the email. This should take around 5 minutes. The questionnaire is voluntary and anonymous. The questionnaire will ask you to rate 10 photographs for overall attractiveness from 1-Very unattractive, 2-Unattractive, 3-Neither attractive nor unattractive, 4-Attractive, 5-Very attractive).

When you click on the link you will be asked if you are happy to take part in the study and complete the questionnaire, if you click 'yes' and submit your answers you will have given your agreement to take part in the study.

Do I have to take part in this study?

No, you do not have to take part in the study and can withdraw at any time up until submit your questionnaire. However, as we won't be able to tell which questionnaire yours is after you have submitted it, once you have pressed submit, we will not be able to remove your answers from the study.

Is there anything I should or should not do?

Once you have completed the questionnaire, please do not discuss your answers with anyone else.

What are the possible risks/ side effects of taking part?

We will not be able to tell if you have completed a questionnaire and whether you complete it or not, your treatment at Bristol Dental Hospital will be the same.

Are there any benefits in taking part?

There is no personal benefit in taking part in the study, but we hope that the results of this study will help us to improve the look of replacement teeth in the future.

What will happen to the results of the research study?

The results of the study will be published in scientific journals. Should this be the case any information about you will be anonymous, no one will know you have taken part in the study. If you would like to find out the results of the study please contact the Study Co-ordinator using the contact details below.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee. Research Ethics Committees look after the rights of people who are involved in research. They check that studies that patients are involved in are fair. This study has been reviewed and approved by the London-Brighton & Sussex Research Ethics Committee.

Further information and contact details

If you have any further questions concerning the study, or in case of any difficulty during the study, please contact: Miss Claire Forbes-Haley (0117 342 9638) – Study Dentist, Prof. Nicola West - Principal Investigator (0117 342 4145) or Dr. Emma Macdonald – Study Co-ordinator (0117 342 9638) at the Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY. **Emergency 24-hour contact number: 07827 956855**

**Thank you for reading this document.
If you have any further questions, please do not hesitate to ask.**

RESEARCH PARTICIPANT INFORMATION SHEET PATIENTS – ADULT PATIENT

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

You are being invited to take part in this research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with others, such as family and friends, if you wish. Ask us if there is anything that is not clear or if you would like more information. The results of this study will be used as part of an MSc research project. Thank you for your interest in this research study.

What is the purpose of the study? Why is this study being carried out?

Missing teeth are a common problem which can make it more difficult to chew and make people self-conscious of their appearance and less confident. Adhesive bridges are used frequently to replace missing teeth especially at the front of the mouth. The bridge is a ‘false tooth’ held in place by a wing that is attached to the adjacent tooth/teeth. Although these bridges are very successful and can last for a long time without needing further treatment, the metal wing that supports them can affect how they appear in the mouth. We have conducted a study in which patients who have missing teeth received either the standard, current adhesive bridge or a different adjusted bridge design. We now want to see what members of the public think of the two bridge designs.

Why have I been invited to take part?

You have been invited to take part because you are 18 or over and have expressed an interest in this study.

What will happen to me if I take part in this study / what will I have to do?

To take part in this study you will need to complete the short questionnaire accessed by the link in the email. This should take around 5 minutes. The questionnaire is voluntary and anonymous. The questionnaire will ask you to rate 10 photographic images for overall attractiveness (1-Very unattractive, 2-Unattractive, 3-Neither attractive nor unattractive, 4-Attractive, 5-Very attractive).

When you click on the link you will be asked to consent to the questionnaire and inclusion in the study, if you confirm this you will be taken to the questionnaire. Once you have completed the questionnaire you will be asked to submit it, you will not be asked to do anything else..

Do I have to take part in this study?

No, you do not have to take part in the study and can withdraw at any time up until you submitted your questionnaire. However, as the questionnaires are anonymous, once it submitted, we will not

be able to identify your questionnaire and therefore will not be able to remove your answers from the study.

Is there anything I should or should not do?

Once you have completed the questionnaire, please do not discuss your answers with anyone else.

What are the possible risks/ side effects of taking part?

The questionnaire is anonymous and whether you complete it or not will not affect your treatment at the Bristol Dental Hospital.

Are there any benefits in taking part?

There is no personal benefit from taking part in this study, but we hope that the results of this study will help us to improve the look of replacement teeth in the future.

What will happen to the results of the research study?

The results of the study will be published in an internationally refereed scientific journal. Should this be the case any information about you will be anonymous, no one will know you have taken part in the study. If you would like to find out the results of the study please contact the Study Co-ordinator using the contact details below.

Who has reviewed the study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee. This study has been reviewed and approved by the London-Brighton & Sussex Research Ethics Committee (19/LO/0618).

Further information and contact details

If you have any further questions concerning the study, or in case of any difficulty during the study, please contact: Miss Claire Forbes-Haley (0117 342 9638) – Study Dentist, Prof. Nicola West - Principal Investigator (0117 342 4145) or Dr. Emma Macdonald – Study Co-ordinator (0117 342 9638) at the Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY.
Emergency 24-hour contact number: 07827 956855

**Thank you for reading this document.
If you have any further questions, please do not hesitate to ask.**



RESEARCH PARTICIPANT INFORMATION SHEET- STAFF

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

You are being invited to take part in this research study. Before you decide whether to take part, it is important for you to understand why the research is being done and what it would involve for you. Ask us if there is anything that is not clear or if you would like more information. The results of this study will be used as part of an MSc research project. Thank you for your interest in this research study.

What is the purpose of the study? Why is this study being carried out?

Adhesive bridges are used frequently to replace missing teeth especially at the front of the mouth. The current design bridge is held in place by a metal wing which can affect how they appear in the mouth, the metal being visible at the incisal edge or causing changes in tooth translucency. With new materials it is possible to reduce the metal at the incisal edge which should improve aesthetics.

We have conducted a study in which patients who have missing teeth either received the current bridge or an adjusted design bridge. We now want to see what dental professionals working at the Bristol Dental Hospital think about the aesthetics of the two bridge designs.

Why have I been invited to take part?

You have been invited to take part because you are a dental professional working at the Bristol Dental Hospital and have experience of dental aesthetics.

What will happen to me if I take part in this study / what will I have to do?

To take part in this study you will need to complete the short questionnaire accessed by the link in the email. This should take around 5 minutes. The questionnaire is voluntary and anonymous. The questionnaire will ask you to rate 10 photographic images for overall attractiveness (1-Very unattractive, 2-Unattractive, 3-Neither attractive nor unattractive, 4-Attractive, 5-Very attractive).

When you access the questionnaire on the on-line platform you will be asked to confirm your consent to participate in the study, once you have completed the questionnaire you will be asked to submit questionnaire. You will not be asked to do anything else..

Do I have to take part in this study?

No, you do not have to take part in the study and can withdraw at any time up until you have submitted your questionnaire. However, as the questionnaires are anonymous, once it has been

submitted we will not be able to identify your questionnaire and therefore will not be able to remove your responses from the study.

Is there anything I should or should not do?

Following completion of the questionnaire, you should not discuss your answers with any other else.

What are the possible risks/ side effects of taking part?

The questionnaire is anonymous and completing it will not affect any aspect of your work at the Bristol Dental Hospital.

Are there any benefits in taking part?

There is no personal benefit from taking part in the study, but we hope that the results of this study will help us to improve patient outcomes and bridge aesthetics.

What will happen to the results of the research study?

The results of the study will be published in an internationally refereed scientific journal. Should this be the case any information about you will be anonymous. If you would like to find out the results of the study please contact the Study Co-ordinator using the contact details below.

Who has reviewed the study?

This study has been reviewed and given favourable ethical approval by the London-Brighton & Sussex Research Ethics Committee (19/LO/0618).

Further information and contact details

If you have any further questions concerning the study, or in case of any difficulty during the study, please contact: Miss Claire Forbes-Haley (0117 342 9638) – Study Dentist, Prof. Nicola West - Principal Investigator (0117 342 4145) or Dr. Emma Macdonald – Study Co-ordinator (0117 342 9638) at the Bristol Dental School, University of Bristol, Lower Maudlin Street, Bristol, BS1 2LY. **Emergency 24-hour contact number: 07827 956855**

Thank you for reading this document.

If you have any further questions, please do not hesitate to ask.

7.15 Protocol Appendix 8a Study Consent form Adult



Miss Claire Forbes-Haley (Study Dentist)
Professor N West (Principal Investigator)

RESEARCH PARTICIPANT CONSENT FORM - ADULT

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

	Please initial boxes
1. I confirm that I have read and understood the information sheet dated 9 th May 2019 Version 2.0, for the above study and have had the opportunity to ask questions which have been answered to my satisfaction.	
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/dental care or legal rights being affected.	
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor, University of Bristol, from regulatory authorities or from the NHS Trust, 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 understand that radiographs may be taken, if required, to ensure suitability for treatment.	
5. I give permission for photographs to be taken of the area being treated before and after treatment.	
6. I give permission for the anonymised photographs to be assessed with those of other study participants by patients and staff at BDH as part of the study.	
7. I give permission for my General Dental Practitioner 'Dentist' to be notified of my participation in the study.	
8. I give my permission for my anonymised data to be made available to other researchers in the future.	
9. I agree to take part in the above study.	

Participant Screening Number _____

Signature of Participant

Full name of Participant (print)

Date

Signature of Person Taking Consent

Full name of Person Taking Consent (print)

Date

Adult Consent Form
Version 2.0, 9th May 2019, IRAS 257107

7.16 Protocol Appendix 8b Study Assent form Young Adult



Miss Claire Forbes-Haley (Study Dentist)
Professor N West (Principal Investigator)

RESEARCH PARTICIPANT ASSENT

to be completed by the child with their parent/guardian

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

Child/young person - please circle Y to all those you agree with:

1. Have you read (or had read to you) the information about taking part in this research study? Y / N
2. Do you understand the study and what it means to take part? Y / N
3. Do you understand that you will not be able to decide which bridge to have? Y / N
4. Do you understand that if you take part we will let your normal dentist know? Y / N
5. Are you happy for other researchers to use your study data in the future providing they cannot identify you? Y / N
6. Have you asked all the questions you want? Y / N
7. Have you had your questions answered in a way you understand? Y / N
8. Do you understand it's OK to stop taking part up at any time? Y / N
9. Are you happy to take part? Y / N

If you **don't** want to take part, please don't sign your name!

If you **do** want to take part, please write your name below

Your name _____ Date _____

The dentist who explained this project to you needs to sign too:

Dentist's name _____

Dentist's Signature _____ Date _____

Thank you for your help!

Assent Form
Version 2.0, 9th May 2019, IRAS 257107

7.17 Protocol Appendix 8c Study Consent form Guardian



Miss Claire Forbes-Haley (Study Dentist)
Professor N West (Principal Investigator)

RESEARCH PARTICIPANT CONSENT FORM – PARENT/GUARDIAN

A randomised clinical trial to determine the aesthetics outcomes of two designs of resin-retained bridge

	Please initial boxes
1. I confirm that I have read and understood the information sheet dated 9 th May 2019 Version 2.0, for my child to take part in the above study and have had the opportunity to ask questions which have been answered to my satisfaction.	
2. I understand that my child's participation is voluntary and that they are free to withdraw, without giving any reason, without their medical/dental care or legal rights being affected.	
3. I understand that relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the Sponsor, University of Bristol, from regulatory authorities or from the NHS Trust, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's records.	
4. I understand that radiographs may be taken, if required, to ensure suitability for treatment.	
5. I give permission for photographs of my child to be taken limited to the area being treated, before and after treatment.	
6. I give permission for the anonymized photographs of my child's mouth to be assessed with those of other study participants by patients and staff at BDH for the study.	
7. I give permission for my child's General Dental Practitioner 'Dentist' to be notified of my child's participation in the study.	
8. I give my permission for my child's anonymised data to be made available to other researchers in the future.	
9. I agree to my child taking part in the above study.	

Participant Screening Number _____

Signature of Parent/Guardian Full name of Parent/Guardian (print) Date

Signature of Person Taking Consent Full name of Person Taking Consent (print) Date

Parent/Guardian Consent Form
Version 2.0, 9th May 2019, IRAS 257107