A TWO CENTRE SINGLE BLIND RANDOMISED CONTROLLED TRIAL TO
ASSESS THE EFFECT OF A PATIENT INFORMATION WEBSITE ON PATIENTS
UNDERSTANDING OF ORTHOGNATHIC SURGERY.

By

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A thesis submitted to the University of Birmingham for the degree of

MASTER OF SCIENCE

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July 2016
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Abstract

Aim: To evaluate the effectiveness of a bespoke patient information website on patients understanding of orthognathic surgery and the treatment care pathway.

Method: A two-centre, single blinded prospective, randomised controlled trial was conducted. A total of 51 adult patients (26 male, 25 female) aged between 15 and 45 years were recruited and enrolled in the study from the orthodontic department at the Birmingham Dental Hospital, and Solihull Hospital, United Kingdom. Patients were randomly allocated to either receive access to a bespoke patient information website or the standard British Orthodontic Society patient information leaflet on orthognathic surgery. The primary outcome measure: patients knowledge regarding orthodontic–orthognathic treatment and their attitude towards their care, was assessed using a questionnaire completed at their subsequent orthodontic appointment. Age, gender and stage of orthodontic treatment were also recorded.

Results: All patients who entered the study completed the questionnaire. There was no influence on the total questionnaire score for age, gender or stage of orthodontic treatment which patients were at. No significant difference was found between the two groups with regards to their level of knowledge (p=0.06). When a per protocol analysis was carried out, the compliers in the website group scored 5.7 points higher than participants in the leaflet group for the total score. This was statistically significant (p=0.01)

Conclusion: A bespoke patient information website has the potential to provide patients with more information of the orthognathic surgery care pathway when compared to the BOS patient information leaflet, however some patients may chose not to access the website. Information should be made available using both modes of delivery.
Acknowledgements

I would like to express my sincere gratitude to the following people:

Ms Sheena Kotecha for her endless guidance, supervision and time.

Mr John Turner for his ongoing support.

Professor Thomas Dietrich for his statistical support.

Mr. Rhodri Williams for his guidance and direction.

The patients at the Birmingham Dental Hospital and Solihull Hospital for kindly taking part in the study.
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Chapter 1

LITERATURE REVIEW
1. Literature review

1.1 Introduction

The term ‘orthognathic’ originates from the Greek ‘ortho’ (straight, upright, correct) and gnathic (jaw). Orthognathic surgery is defined by the American Academy of Oral and Maxillofacial surgery as ‘the surgical correction of abnormalities of the mandible, maxilla, or both. The underlying abnormality may be present at birth or become evident as the patient grows and develops. It may also be as the result of traumatic injuries. The severity of these deformities precludes adequate treatment through dental treatment alone’ (American Association of Oral & Maxillofacial Surgery, 2015).

Orthognathic treatment is the combined surgical treatment provided by a maxillofacial surgeon and an orthodontist in an effort to correct the dentofacial disproportions that exist which are beyond the scope of conventional orthodontics alone. Treatment may also involve the restorative dentist when hypodontia complicates the skeletal discrepancy.

1.2 History of orthognathic surgery

‘Beauty consists of due proportion, because the senses delight in well portioned things.’

This quote from Thomas Aquinas dating back to c.1225 demonstrates how human kind has always been concerned with facial aesthetics and the apparent appearance of ‘what is normal’ (Aquinas, 2006).

This theme was also evident in Ancient Egyptian civilisation, which focused heavily on aesthetic harmony and balance. Those they idolised were depicted to have perfect facial proportions and symmetry, such as the famous painted limestone figure of Queen
Nefertiti. Unfortunately, for those living with any facial disharmony or asymmetry at that time, altering the facial proportions was not possible. It was not until the development of general anaesthesia in the 19th century that the concept of changing the structure of the face and correcting facial disharmony became possible (Naini, 2011).

The first orthognathic surgery operation was carried out in the United States in 1849 where a surgeon, Simon Hullihen attempted to reconstruct the face of a patient who had suffered extensive burns as a child and was left with extensive scarring from previous attempts to repair the defects. He completed a procedure known as a mandibular subapical osteotomy, termed ‘Hullihen’s procedure’, in an attempt to correct an anterior open bite, which was then followed by soft tissue reconstruction to facilitate lip closure, restoring function and improving the overall appearance (Moos and Ayoub, 2010).

Hullihen, like many others of his time, was trained as a general surgeon that also had dental training. Others such as von Langenbeck, Cheever, Billroth and Dufourmentel followed suit, experimenting with a variety of different techniques to treat a dento-facial discrepancy (Steinhauser, 1996). It was however the work of Edward Angle and his surgeon, Vilray Blair in St Louis that marked the beginning of orthognathic surgical procedures as we know today when they treated a patient with mandibular prognathism with an ostectomy, held together with a splint and subsequently replaced by orthodontic fixation using orthodontic bands by Angle (Steinhauser, 1996).

It was not until the 1920s that maxillary surgery to treat a severely retruded maxilla was first carried out. It subsequently became a common procedure to treat maxillary hypoplasia in cleft patients. After the First World War, the Le Fort 1 osteotomies were widely used to correct mid-face injuries. It was at this point that the technique became
widely accepted as the treatment of choice to treat low-level mid-face deformities, often in conjunction with mandibular osteotomies. (Moos and Ayoob, 2010) In order to allow healing to occur post operatively, external fixators were often used as well as intra oral fixation. The development of endotracheal intubation in the 20th century enabled further development of orthognathic surgery as a whole.

Over time, it became evident that orthodontics was necessary both before and after orthognathic surgery to achieve an optimal result. Orthodontic treatment became a key part of the orthognathic care pathway in order to prepare the dentition for surgery and ensure a more predictable and stable result following the surgical procedure. In contemporary orthognathic treatment, patients usually undergo a course of fixed appliance treatment prior to surgery and the appliance remains in situ during and after the operation until a satisfactory occlusal relationship has been achieved. With advances in technology, it is now possible to accurately plan the proposed surgical movements digitally using computer software, simulating the potential effect they will have on the facial profile and dental relationship. The soft tissue profile however has shown to be difficult to accurately predict in surgical planning with simulating software (Kaipatur and Flore-Mir, 2009).

1.3 Treatment care pathway of orthognathic surgery

Although orthognathic surgery itself has become an established and routine procedure, it is the management of the patient undergoing such treatment that has developed in recent years. In the UK today, it is thought that there are a quarter of a million people who would benefit form orthognathic surgery (Cunningham and Johal, 2015).
Currently, it best practice to adopt a multidisciplinary approach for every patient considering orthognathic surgery under the National Health Service in the United Kingdom. This is to ensure consistent, reliable and seamless care and to maximise patient satisfaction (Gill and Naini, 2011).

Members of the multidisciplinary team involved in orthognathic care include a consultant orthodontist, a maxillofacial surgeon, a dietician and a dental technician. On occasions, other members of the dental or medical team may be required such as a restorative dentist, a plastic surgeon or a psychiatrist.

Patients are usually referred first to an orthodontist who decides whether orthognathic surgery is an appropriate and a feasible treatment option. The Index of Orthognathic Functional Treatment Need (IOFTN) may be used to categorise treatment need (Ireland et al., 2014). Patients are subsequently reviewed on a multidisciplinary orthodontic and orthognathic surgery clinic with a consultant orthodontist and maxillofacial surgeon. At this appointment, the patients main concerns are identified, possible treatment options discussed and a treatment plan agreed, following a discussion regarding the potential risks and benefits. Following this, the patient is consented to begin treatment, which usually involves a pre-surgical course of orthodontic treatment typically lasting 18 to 24 months (Gill and Naini, 2011). As the patient approaches the end of this phase of orthodontic treatment, they are reviewed again on the joint clinic with the surgeon and orthodontist, where the final surgical movements are confirmed. The patient is also seen in the hospital unit where the surgery is to take place for a number of pre-operative appointments where they will meet members of the nursing team, the dental technicians, anesthetists and psychiatry team as necessary.
Following the surgical procedure, the patient will continue to see the surgeon at regular intervals as well as the orthodontist for routine visits until treatment is complete. The post-surgical orthodontic phase usually takes 6-9 months.

1.4 Reasons why patients seek treatment for jaw deformity

The overall orthodontic and surgical aims of treatment are to improve occlusal function and to produce a more harmonious facial skeletal relationship (Hunt et al., 2001). From a patient perspective, this is not necessarily the reason why they will seek treatment. A recent article by Cunningham and Johal (2015) reported the main reasons for patients seeking correction of their dentofacial discrepancy to be aesthetics, function, psychosocial well-being or to improve their quality of life (Cunningham and Johal, 2015). Ryan et al. (2012) also reported that patients who seek treatment feel ‘that life was more difficult and might have turned out differently if they had not been affected in this way,’ and that they ‘had an additional hurdle to jump or a “millstone” around their neck’ (Ryan et al., 2012). This highlights how facial disharmony may affect patients who seek orthognathic surgery, negatively impacting on their quality of life as well as compromising normal function and esthetics.

A cross sectional survey study by Stirling et al. (2007) which employed both questionnaire and interview methods, explored the reasons why patients sought referral to an orthognathic unit. Thematic content analysis revealed the most commonly cited reasons for referral included, dissatisfaction with the appearance of their teeth, bite problems and general appearance problems respectively. Issues around self-esteem were also expressed as well as problems with speech and socialising (Stirling et al., 2007).
1.4.1 Aesthetics

It is well documented that the majority of patients wish to improve their facial appearance when they seek orthognathic surgery (William et al., 2005, Kiyak 1981, Flanary et al., 1985, Stirling et al., 2007). With an ever-increasing emphasis on facial aesthetics and appearance in today’s society, it is not surprising that this remains a key driver for patients seeking treatment. However, Williams et al. (2005) found that it was the appearance of their teeth rather than their ‘looks’ they wanted to change most. Stirling et al. (2007) reported similar findings with 44% of patients most concerned with the appearance of their teeth.

1.4.2 Function

Biting, chewing, speech and potential risk of future dental problems are another motivator for patients. A systematic review in 2001 found that 33-60% of patients seek treatment for functional concerns (Hunt et al., 2001). Stirling et al. (2007) supports the above findings with biting problems being the second most common reason patients requested referral for an orthognathic surgery opinion.

1.4.3 Psychosocial well being and quality of life

Patients often report a negative association between their appearance and their self-esteem and confidence. Numerous studies have highlighted this and the subsequent improvement following surgery in the patient’s self-esteem, self-confidence, body image, facial-attractiveness image, personality, social functioning, emotional stability, overall mood, ability to mix socially, and positive life changes including better personal

1.5 Patient involvement

Since the Darzi Report (2008), quality in healthcare was redefined to include patient experience, patient safety and clinical effectiveness. Greater emphasis is placed on adopting a patient centered approach to health care and patient related outcome measures.

It has also been identified that what health care workers may define as success of treatment may differ from the patient (Williams et al., 2004). Patient satisfaction with treatment will be influenced by their initial concerns and reasons for seeking treatment.

The National Institute of Clinical Excellence provided guidance (2012), detailing the type of care a patient should experience in the NHS today. They recommend that ‘patients have opportunities to discuss their health beliefs, concerns and preferences to inform their individualized care’ (National Institute of Clinical Excellence, 2012). Therefore, in an attempt to address this, a patient’s motivation for seeking treatment should be explored and addressed. In particular in orthognathic surgery, the reason why a patient seeks treatment has been shown to be an important factor in predicting their satisfaction with the outcomes (Ryan et al., 2012).

1.6 Consent

Consent is defined in the Oxford English Dictionary as ‘permission granted in the knowledge of the possible consequences; (spec. in Med.) consent to clinical treatment given after all the relevant information (esp. regarding the potential risk and benefits)
has been disclosed to the patient or his or her guardian’ (Oxford Dictionary of English, 2015).

We are required by our regulatory bodies and by law to obtain valid and informed consent for every patient. Valid consent is when consent is ‘given voluntarily by an appropriately informed person who has the capacity to consent to the intervention in question’ (Department of Health, 2009). It must be given freely and without any pressure or coercion. Adults are assumed to have capacity to consent unless demonstrated otherwise.

In order for a person to give valid consent, they must understand the reason for, and the nature of the procedure they are to undergo. Consent will avoid the claim of battery however there is a further legal duty of care to the patient to provide them with additional relevant information about the treatment including the benefits and risks of treatment as well as the alternative options available to them. This in turn is ‘informed consent’.

Failure to supply this information may be construed as negligence if the patient is subsequently harmed as a result of the treatment performed. The Department of Health states that ‘if the patient is not offered as much information as they reasonably need to make their decision, and in a form they can understand, their consent may not be valid.’ (Department of Health, 2001). The General Dental Council guidance suggests that the patient should be provided with the information they want and need, in a way they can use, so that they are able to make informed decisions about their care’ (General Dental Council, 2009).
1.6.1 Legality of informed consent and information provision

Currently, there are no definitive regulations stating how much information patients should be given regarding their treatment, but the Law surrounding this is ever evolving.

Originally, the depth of information to be provided to patients regarding the risks of a particular procedure was governed by the House of Lords decision in Sidway (Sidway v Board of Governors of the Bethlem Royal Hospital, 1985). It states that the test of liability in relation to the clinician’s duty to warn patients with regards to the potential side effects was governed by the same test applicable to diagnosis and treatment, the Bolam test (Chate, 2008). Clinicians were therefore expected to provide the level of information, which would be accepted by a responsible body of medical opinion. However, the landmark case of Bolitho v City, 1998, resulted in an addition to the previous statement that not only should it be accepted by a responsible body but also to a reasonable body and the opinion should be logical (Bolitho v City and Hackney Health Authority, 1998).

In subsequent cases the courts have ruled that it is the responsibility of the treating clinician to inform the patient of any risk that could affect the judgement of a reasonable patient. In the seminal case of Chester v Afshar, 2004, Lord Steyn stipulated that every patient be informed of ‘a small, but well established, risk of serious injury as a result of surgery’ (Chester v Afshar 2004). Clinicians should therefore inform patients of any severe complications to treatment, even when the risk is small (Montgomery v Lanarkshire Health Board, 1999). It is the duty of each clinician to be meticulous in their consent process, to ensure that patients provide valid, informed consent. Above all,
health care professionals have a legal and ethical duty of care to patients to ensure they are as informed as possible about the treatment they are consenting to enabling them to make a valid and informed decision.

Chate (2008), examined the knowledge and understanding of informed consent amongst orthodontic consultants in England, Wales and Northern Ireland with a questionnaire based study. A high response rate was achieved of 78.5%. However of the questionnaires returned, only 57% of questions were answered correctly. A lack of knowledge was identified in relation to the consent needed for orthognathic surgery; specifically ‘explanations needed from clinicians in order for them to give consent, how to fully judge if a patient is capable of giving consent, whether consent forms have to be re-signed if the start of treatment is delayed by six months or more, and that dentists referring patients for treatment requiring general anaesthetic have the same duty to receive consent for the anaesthesia as do the clinicians who will be performing the surgical procedure’ (Chate, 2008). This may imply that there is a lack of understanding amongst consultant orthodontists of the consent process in order to comply with legal and ethical obligations as health care providers.

It is also important to highlight that litigation against the medical and dental profession has risen over the past two decades. In 1990/91, the cost of clinical negligence claims to the National Health Service in the United Kingdom was estimated at around £52 million (Fenn et al., 2000). In 2009/10, twenty years later, the NHS Litigation Authority (NHSLA) reported a marked increase in negligence claims with 6,652 reported cases, representing a 10% increase on the previous year, and were subsequently required to pay almost £800 million in damages (NHS Litigation Authority, 2010).
1.6.2 Consent in orthognathic surgery

The multidisciplinary approach to orthognathic surgery is particularly important in relation to the consent process. As all potential orthognathic surgery patients having treatment under the NHS are seen on multidisciplinary clinic with a maxillofacial surgeon and an orthodontist, the patient should receive all the necessary information from the orthodontist and surgeon to allow them to make an informed decision. (Cunningham et al., 2015)

Consent is not a single event; it is an on-going process that gives the patient the ability to withdraw consent at any stage. Informed consent for orthognathic surgery begins at the initial joint clinic appointment and continues until the patient undergoes surgery and even after when they continue their orthodontic treatment. The General Dental Council recommends that a written treatment plan be provided for all patients undergoing any dental treatment. This is supported by studies, which have shown that the provision of written information significantly improves a patient’s retention and recall (Ibrahim et al., 2004, Layton et al., 1994.)

1.7 Information for patients undergoing orthognathic surgery

The Department of Health in the United Kingdom states that ‘quality information empowers people to make choices that are right for them’ (Department of Health, 2010). Current UK government policy advocates that patients are provided with information that is of high quality and accessible (Department of Health, 2010).

There are several sources of information for patients regarding orthognathic surgery.
These include their orthodontist, surgeon, friends or family members who have had surgery, patient information leaflets (PILs) (Appendix 1) (British Orthodontics Society (BOS) and the British Association of Oral and Maxillofacial Surgery), DVDs (BOS) and the Internet (information websites, blogs).

At present in the UK, there are two recognised forms of information delivery for orthognathic surgery patients, to support the information given verbally by the clinicians, both of which have been created and provided by the BOS. These include the BOS information leaflet entitled ‘Orthognathic Surgery’ (Appendix 1) and the BOS orthognathic surgery DVD.

1.7.1 Leaflets

Verbal information should be supported by a written format to reinforce information retention and improve recall rates (Thomson et al., 2001). Leaflets are a method of information delivery which when compared with other formats, are relatively low in cost. Ormrod and Robinson (1994) found that patients sometimes felt embarrassed asking particular questions in a clinical environment and that in this respect information leaflets are a useful resource. They can also reinforce what has been discussed with the patient and clinician and act as a reference for the patient to refer back to as required (Moll, 1986, Bishop et al., 1996) However, in order for PILs to be effective they must be well designed, easy to read and written using language that can be easily understood.

Harwood and Harrison (2004) assessed the readability of orthodontic PILs created by the American Association of Orthodontics and the BOS. In total 26 orthodontic leaflets
were assessed, including the ‘Orthognathic Surgery’ leaflet from the BOS. Forty two per cent of the leaflets evaluated were recorded as being ‘difficult’ or ‘fairly difficult’ to read. All but one of the BOS leaflets were reportedly ‘standard’ or ‘fairly easy’ to read. The ‘Orthognathic Surgery’ PIL was found to have a reading difficulty of a ‘standard’ level, which indicates that 70% of the UK population would be able to understand it, but 30% would not. The quality of information in the leaflets was not assessed.

The BOS orthognathic surgery leaflet is in a format that answers a series of commonly asked questions that a typical prospective orthognathic patient may have. It covers topics such as why a patient would benefit from surgery, the type of brace required and the risks of surgery. There are a number of images illustrating the text. Most orthodontic departments in the UK provide this leaflet for patients when they are considering surgery even though there is a paucity of evidence in the literature regarding the efficacy of this leaflet or the knowledge gained by the patients as a result of reading it. Furthermore, it has been advocated that it is now time to move away from the traditional information leaflets in healthcare as they rely on patients having a certain degree of literacy and reading ability which is not always the case (Colledge et al., 2008).

1.7.2 DVD

The BOS produced a DVD in 2007 to aid patient’s understanding of orthognathic surgery (Flett et al., 2014). It was developed by a group of clinicians including an orthodontist who had previously undergone orthognathic surgery. The BOS states that the DVD was produced in an effort to facilitate an understanding of orthognathic
surgery for patients, providing explanations of the different surgical procedures, the planning involved, the brace work required before and after surgery and incorporating interviews with patients who have undergone orthognathic surgery. Providing this in DVD format offers patients the opportunity to watch the DVD at home away from the clinical environment. They may also choose to watch it with family or friends.

To date, there has been one study that examined the value of the BOS DVD for patients considering surgery. A qualitative cross sectional study using interviews to determine whether the DVD influences a patients decision whether to proceed or not with surgery was undertaken. A total of 10 patients were interviewed after having watched the DVD. Overall, it was felt that the DVD provided a useful resource for patients, however it did not necessarily influence their decision-making. Patients reported that the most useful aspect of the DVD were the accounts of surgery by patients who had previously undergone treatment. Patients also found the images on the DVD a useful aid to explaining the process of surgery and the outcomes. Similarly, they felt reassured that a reputable association had created the DVD. Conversely, they expressed concern regarding the reliability of information on general Internet search engines such as Google and Wikipedia.

The age range of those in the DVD does not reflect the group of patients who undergo orthognathic surgery: most orthognathic surgery patients are in their late teens to early twenties however those in the DVD are middle aged (Cunningham and Moles, 2009). Further, it has been suggested that the format and content of the before and after treatment images needs to be improved.
A number of participants raised the possibility of creating a website as a resource that patients could trust. They would be able to logon to the site, which would hold all the necessary information about OS and also incorporate clips from the DVD. Flett et al. (2014) remarks that this would allow regular updating of information and allow patient access to be monitored.

1.7.3 Information retention of patients

The detail of information given to patients and the mode through which we deliver this information, impacts both on the patients understanding of treatment and ultimately on their decision-making. Improving the level of understanding of patients may lead to increased satisfaction and improved compliance (Brattstrom et al., 1991).

There is a paucity of research in this area of dentistry, in particular in orthodontics. A small number of studies have examined the factors that affect information retention in patients including the mode through which the information provided (Lees and Rock., 2000, Patel et al., 2008, Thickett and Newton, 2006, Thomson et al., 2001)

Patel et al. (2008), in a prospective questionnaire-based study examined the factors that affect the retention of information in orthodontic patients. Participants were randomly divided into one of two groups: one given an information leaflet and the other a visual computer program (including the same information as the leaflet but in picture form) with the same information about orthodontic treatment. The mode of information delivery as well as the age, gender, ethnicity, index of relative deprivation of area of residence and the time taken to view or read the information were recorded. They found
that the mode of information delivery was the only factor that affected retention of information in patients. The group who viewed the visual computer program achieved higher scores in the questionnaire. The study concluded that computer based visual information was shown to be a superior form of information delivery in orthodontics (Patel et al., 2008).

Lees and Rock (2000) assessed whether a difference existed in a patients level of oral hygiene, relative to the mode through which oral hygiene instruction was given to them. Sixty-five subjects wearing a lower fixed appliance were divided into one of three groups for oral hygiene instruction: a written information sheet, a video cassette containing a film made specifically for the study and a verbal instruction visit delivered by a hygienist. Patients were then asked to complete a questionnaire. On comparison of the three modes of information delivery, they found that video and verbal instruction scored higher than the written group, however the difference was not statistically significant (Lees and Rock, 2000). A similar questionnaire based study was carried out comparing the effectiveness of three modalities of information delivery in orthodontics, these included a written leaflet, a pictorial PowerPoint presentation and a verbal explanation with each modality providing identical information. Although a number of questions produced significant findings, overall the study concluded that there was little difference between the three modes of information delivery (Thomson et al., 2001).

In other areas of healthcare, modalities similar to those in this study have been examined. Heeney and Irvine (2014) carried out a randomised controlled trial to compare the efficiency of a website and a written patient information leaflet to inform
patients about functional endoscopic sinus surgery. They carried out a prospective, randomised controlled trial aiming to assess the readability, usability and the recall of complications of the procedure. These were tested using a questionnaire. They found the readability and usability was acceptable in both groups and no difference in the recall of information was reported.

The above studies demonstrate that there are a number of different modalities available to aid in the recall of information for patients and that there is little difference in the efficacy of one method over another. It is well recognised that no one instructional method will suit all learners and therefore information should be provided in as many formats as possible (Lees and Rock, 2000, Yoder, 1994).

1.7.4 The Internet
The Internet first became publicly available on the 6th August 1991. It has since grown and evolved into what we now know it as the World Wide Web or the ‘web’ (Coleman and Mc Dowell, 2012).

The Internet is a powerful search engine, information tool and online resource for patients to access information via websites, blogs, discussion groups and now social media. In 2015, between January and March, the office for National Statistics reported 39.3 million (78%) adults in the U.K accessed the Internet every day or almost everyday. This is a 24.3 million increase from 2006. In 2015, 96% of adults aged 16-24 years accessed the Internet ‘on the go’ using a phone (Office for National Statistics, 2015). In particular, more and more patients are using the Internet to obtain health
information about a particular condition or procedure. In 2013, 43% of adults used the Internet to obtain health information.

### 1.7.5 Reliability of information on the Internet

Nowadays, patients have access to more medical and dental information than ever before. But how do patients know if the information is accurate and reliable? The difficulty with this question lies in the fact that there is a vast quantity of information now available to patients regarding orthognathic surgery and a lack of online regulation, which makes it virtually impossible to guarantee the quality of this information. Of concern, is that patients may be using this information to make decisions regarding whether to proceed with orthognathic surgery. In an article by Clyne and Haynes (2001), they highlighted that 47% of patients who sought health information on the Internet reported that this information influenced their decisions regarding their treatment (Cline and Haynes, 2001).

Aldairy et al. (2012) recognized this and as a result sought to investigate the accuracy of information on the Internet regarding orthognathic surgery. Discussion groups, news and video feeds were excluded, but 25 relevant sites were examined in detail using the DISCERN tool which has previously been shown to have good internal consistency (Ademiluyi et al., 2003). Of the 25 websites that were assessed, all scored well below the maximum score of 80 points based on 16 questions (each scored 1 – 5 point) using the DISCERN tool. The most reliable website was found to be Wikipedia which scored 64 out of 80 (Aldairy et al., 2012). The paucity of reliable websites on orthognathic surgery strengthens the need to develop a reliable and informative website to which
patients can be directed prior to orthognathic surgery to improve their understanding of the treatment pathway

Stephens et al. (2013) explored how patients seek information in relation to orthodontic treatment, the reasons for which they search the information and how they prefer the information to be delivered. A qualitative study using structured interviews was undertaken to explore the above questions using a sample of 15 patients. Patients reported that the majority of the information they obtained was through talking to their orthodontist or dentist (84%), their peers (66%) and through reading PILs (64%). Surprisingly only 8% of patients searched the Internet for information. Similarly, when asked how they would like to obtain information, only 4% of patients said via the Internet. Participants cited that the reason for which they did not access the internet for information was due to concerns over the reliability of information, supporting the need to create a resource for patients on orthognathic surgery created by healthcare professionals providing accurate, valid and reliable information in a patient friendly manner (Stephens et al., 2013).

In contrast, a survey of 300 British adults carried out in the UK demonstrated that 80 per cent of patients were likely to source information not only from their healthcare professional but also online. When asked their preferred source of information the results showed that their healthcare professional was first, followed by the internet/online and then leaflets or books (Coulter and Ellins, 2007).

1.7.6 Inadequacy of information provided for patients

Despite the resources discussed above, numerous studies in the literature have
highlighted the lack of information given to patients prior to orthognathic surgery which as discussed previously may in turn have an impact on the patient’s overall satisfaction following surgery (AlKharafi et al., 2014; Stirling et al., 2007; Williams et al., 2004; Cunningham et al., 1996).

Flanary et al. (1983) found that dissatisfaction with orthognathic surgery stems from the occurrence of unexpected side effects of surgery about which the patient was not previously aware. Cunningham et al. (1996) assessed patient satisfaction with joint orthodontic and orthognathic surgery treatment, which revealed that patient’s dissatisfaction could be minimized by a clear and accurate explanation of the treatment and the risks involved. AlKharafi et al. (2014) found parallels with this study, in that although patients generally felt well informed regarding orthognathic surgery, they were more likely to be satisfied with the outcomes of treatment when provided with more information about post-operative discomfort and surgical risks. Others have reported that a lack of information may also increase periprocedural anxiety (Mulsow et al., 2012).

Stirling et al. (2007), in a cross sectional study of 61 orthognathic surgery patients found that almost half of the participants felt their knowledge of orthognathic surgery was poor, and that this subsequently resulted in them having a negative outlook towards their experience after treatment. Often the anticipated symptoms are also underemphasised and therefore underestimated by the patient, which can subsequently increase initial post-operative satisfaction. Zhou et al. (2001) found that patients experienced more pain (44%), numbness (57%) and swelling (73%) than expected. Interestingly the level of patient satisfaction increased with time, with 92% of patients
reporting satisfaction with treatment at 24 months post operatively compared to 87% at 6 months post operatively (Zhou et al., 2001).

The evidence suggests that, there is a need to disseminate accurate, reliable and valid information for patients via a web based approach, in keeping with technological advances in society.
1.8 Aims

The aim of the present study was to evaluate the effectiveness of a bespoke patient information website on the patients understanding of orthognathic surgery and a combined treatment pathway compared to a widely used information leaflet and to explore the effect of the information provided on patient attitudes towards orthognathic surgery.

The null hypothesis was:

There is no difference in the level of understanding of orthognathic surgery and the treatment pathway between patients who receive the BOS ‘Orthognathic Surgery’ information leaflet and those given access to a bespoke orthognathic surgery patient information website.
Chapter 2

METHOD
2. METHOD

2.1 Ethical approval

Ethical approval was granted by the National Research and Ethics Committee on the 27th January 2015 for this project (REC reference number 15/WA/0028). Research and development approval was obtained from the Birmingham Community Healthcare NHS Trust and Heart of England Healthcare NHS Trust.

2.2 Study Participants

This was a single-blind randomised controlled trial of adults undergoing pre-surgical orthodontic treatment at two centres, a teaching hospital: Birmingham Dental Hospital and a local district hospital: Solihull Hospital.

Potential participants, who satisfied the inclusion criteria for the trial were identified by senior orthodontic registrars and consultant orthodontists in the departments. These clinicians were treating the participants on a regular basis as part of their routine pre-surgical orthodontic treatment. All consecutive patients who satisfied the inclusion criteria were invited to participate in the study.

The inclusion criteria for this study were:

- Patients, 16 years of age and above,
- Subjects who had been seen by a consultant orthodontist and maxillofacial surgeon and were undergoing pre-surgical orthodontics in preparation for orthognathic surgery
- Subjects who provided consent to participate
Exclusion criteria for this study were:

- Subjects who had previously received orthognathic treatment
- Subjects who were younger than 16 years of age
- Subjects with congenital craniofacial anomalies or acquired defects
- Non-English speaking subjects
- Subjects who did not have access to the internet either via a mobile device or a computer
- Subjects who did not consent to participate

2.3 Sample size calculation

Based on previous research (Patel et al. 2008), a difference of 10% in the total possible score in the questionnaire (3.4 marks) between the two groups was deemed to be clinically significant. Assuming a common standard deviation of 3.3, it was calculated that 20 participants were required in each group for the study to have 90% power to detect a difference in mean scores of 3.4 at the 5% significance level. Assuming a 20% noncompliance with completion of the questionnaire, a minimum of 24 participants were recruited in each group. A pilot study was conducted with 5 patients per group in order to assess the readability of the questionnaire.

2.4 Pilot study

In order to test the readability of the patient information website and questionnaire, a pilot study was undertaken. Ten patients in total were included, 5 in the website
intervention group and 5 in the leaflet control group. The same method as described below was used to carry out the pilot study.

The data obtained was analysed and using the standard deviation an accurate sample size calculation was determined. There were no issues raised with the questionnaire readability during the pilot study. One participant in the website group highlighted that the website was not supported by Internet Explorer 8 therefore this information was added to the website patient information sheet for the main study information patients that they must use Internet Explorer 9 or higher, or alternatively Google Chrome or Safari Internet browsers. Other than this, there were no other issues highlighted by patients during or after the pilot study.

2.5 Method

Potential participants were identified by their treating clinician and informed of the nature of the trial at one of their pre-surgical orthodontic appointments. Patients were given a cover letter (Appendix 2) and a participant information sheet (Appendix 2), which provided details about the study. At their next appointment, 6-8 weeks later, patients were invited to participate and if they were willing to do so, the treating clinician obtained valid, informed consent using the consent form developed for the trial (Appendix 4).

2.5.1 Randomization

Randomization was carried out by a statistician in advance of the trial and was achieved by permuted block randomisation. Blocks varied in size. Following block randomization, tamper-proof sequentially numbered, opaque sealed envelopes were
constructed for allocation concealment. A senior nurse at both units who was independent of the trial controlled the allocation concealment.

Once consent had been obtained, the clinician approached the senior nurse who provided the clinician with a pre-prepared sealed envelope which randomly allocated the patient to one of two groups (the intervention or the control group) by stating ‘WEBSITE’ to receive the intervention or ‘LEAFLET’ to be allocated to the control group. Once the group had been determined, each participant received an information pack appropriate for the group they were assigned to and a unique identifier number that included a letter (e.g. ‘A1’ or ‘B1’) to denote the study arm.

2.5.2 Trial Interventions:

Intervention: Webpage

A bespoke patient information website (Appendix 5) on orthognathic surgery was developed by the principal researcher using information obtained from a patient focus group, as well as the allied specialties of dietetics and nursing team. A focus group, led by the principal researcher and an oral and maxillofacial surgery senior house officer, was held at the Queen Elizabeth Hospital on the 4th January, 2014 with seven participants who had undergone orthognathic surgery more than one year previously. Participants discussed aspects of the orthognathic surgery treatment care pathway where they felt information for patients was lacking. They provided information from a patient perspective of important points they would have liked to have been told. The information obtained from this focus group in combination with the views of the multidisciplinary team were used to design and develop the website.
The website aimed to ensure that patients have all the necessary information to prepare them during orthodontic treatment, leading up to their surgery and thereafter. The website was created by the principal researcher using an online website development tool ‘Wix’. It was accessible on personal computers and also optimized for mobile phone access. The readability was assessed both with an online readability assessment tool (Fleisch Kincaid Reading Ease) and also during the pilot study.

All participants in the website intervention group were given an information leaflet (Appendix 6) detailing how to find and access the website and what the website contained.

Access to the website was enabled for each participant in the intervention group. Participants had to create an account and sign in with an anonymous username and password, provided on the information leaflet. This allowed the research team to monitor which participants in the intervention group logged onto and accessed the website and those that did not.

The website was hidden from all Internet search engines to ensure participants in the control group did not find the website should they search for further information on the Internet.

Participants assigned to this group were asked to access this website before their next orthodontic appointment.

**Control: Orthognathic surgery leaflet**

Participants randomised to the control arm of the study were provided with the standard BOS patient information leaflet on orthognathic surgery as per current department
protocol (Appendix 6). They were encouraged to read the leaflet as often as needed before their next appointment.

Participants were also given the opportunity during the pilot study to highlight any aspects of the patient information leaflet and the website which they did not understand or had difficulty reading. There were no issues raised with regards to the readability or understanding of the content.

2.5.3 Questionnaire

Both groups of participants completed a questionnaire (Appendix 7) at their next orthodontic appointment (6-8 weeks later). The questionnaire consisted of two sections. Part A, assessed the knowledge participants had regarding the orthodontic-orthognathic surgery treatment care pathway. The questions were devised in conjunction with members of the orthodontic and orthognathic surgery team, based on information that they felt patients should know before undergoing orthognathic surgery. The questions were devised prior to any member of either team viewing the website. The information obtained during the focus group at the Queen Elizabeth Hospital was also used to create Part A of the questionnaire. Two types of questions were employed, those requiring a single response and another, which asked participants to select all correct answers where more than one answer was correct. Five questions in Part A could be answered by participants from either group as the information to answer could be found on both the website and the leaflet. In addition this would allow us to compare the mode of information delivery and its effect on the patients understanding.

Part B assessed patient attitudes to their care. This second part required the participants to score six questions on a 4-point Likert scale from ‘extremely’ to ‘not at
The treating clinicians requested the participants to complete the questionnaire anonymously. Each participant completed the questionnaire on the clinic without help from any external source. Participants were asked not to use their mobile phones for the duration of time spent completing the questionnaire to avoid those in the website group accessing the website. All questionnaires were returned to a file for the principal researcher (Susan O’Connell). The age, gender and the stage of each participant’s orthodontic treatment were also recorded on the questionnaire.

2.5.4 Blinding

Patients were given a unique patient number when they were recruited into the study with their information pack corresponding to either intervention or control group for example A1 or B1. This identifier was used for each participant throughout the study and on the completed questionnaires. The questionnaires were analysed by the principal researcher, who was blind to the study arm of the participant and also which group was represented by ‘A’ or ‘B’. Once data analysis was completed, the senior nurse was able to reveal to the principal researcher, which group was intervention and which was the control.

2.5.5 Data Protection

This study adhered to Data Protection Principles and maintained patient confidentiality at all times. Questionnaires only had patient identifier numbers. Participant details were kept on an encrypted memory stick, to which only the chief investigator had access. A study file was created and held in the Chief Investigator’s office in a locked filling cabinet to which only the Chief Investigator (Sheena Kotecha) had access. Participant
consent forms and completed questionnaires were scanned onto an encrypted memory stick to which only the chief investigator and principal researcher had access. The paper copies were destroyed as confidential waste immediately after scanning.

2.6 Statistical Analysis

All participants were allocated a unique identified number and the coded data was subsequently entered onto a unique database (Microsoft Access x.x, 2014, Microsoft Corp., Seattle, USA) for analysis. Overall questionnaire scores were calculated for each participant by summing the total number of correct answers. Every correct answer for which the patient scored was awarded one point. For questions where more than one option was correct, patients received one point for every correct option they selected. The total maximum score achievable was 34 points. Subscale scores were also calculated by summing the question responses that related to pre-operative treatment, the surgical procedure and post-surgical orthodontics. Analysis of the data was conducted using Stata Statistical Software (Stata 14, Statacorp LP., College Station, TX, USA). The data was initially analysed using descriptive statistics. Normality of the distribution of overall and subscale scores was tested using QQ plots and the Shapiro-Wilk test. Parametric statistical methods were used as the questionnaire scores were normally distributed. Unpaired t-tests were used to determine differences in the overall and subscales scores between the leaflet and website group. Unpaired t-tests were also used to test for differences in scores according to gender and duration in treatment. Participants in the website group were divided into those that had accessed the website (compliers) and those that had not. A per protocol analysis was carried out comparing
compliers to the leaflet group using unpaired t-tests. All statistical tests were two-sided at a significance level of $\alpha=0.05$.

The data in Part B of the questionnaire was ordinal in nature. Non-parametric statistical methods were used to analyse the data. Mann-Whitney U tests were used to determine the difference between the two groups.
Chapter 3

RESULTS
3. RESULTS

3.1 Characteristics of the sample

The recruitment of participants for this trial began in January 2015 and was completed by September 2015. All patients who were approached by orthodontic senior registrars or orthodontic consultants to participate in the trial agreed to take part. There was a 100% response rate for completion of the questionnaire. Initially 52 adults completed the questionnaire but subsequently, one questionnaire was excluded as two questions had been omitted.

Table 3.1: Characteristics of the sample

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Website group (n=27)</th>
<th>Leaflet group (n=24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender % (n)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>56 (15)</td>
<td>46 (11)</td>
</tr>
<tr>
<td>Female</td>
<td>44 (12)</td>
<td>54 (13)</td>
</tr>
<tr>
<td>Age, mean (SD)</td>
<td>23.3 (6.5)</td>
<td>23.1 (5.6)</td>
</tr>
<tr>
<td>Range</td>
<td>17-45</td>
<td>15-37</td>
</tr>
</tbody>
</table>

The demographics of the study sample are demonstrated in Table 3.1. In total, 51 adults who completed the trial, 26 males and 25 females. This included participants from the pilot study as no changes were made following the pilot study. In the leaflet (control) group, 46% of the subjects were male and 54% were female. In the website (intervention) group, 56% of subjects were male and 44% female. The average age in
the leaflet group was 23.1 years (S.D 6.51) and in the website group was 23.3 years (S.D. 5.61)

3.2 Duration of orthodontic treatment

The subjects were also asked to record their duration of orthodontic treatment at the time the questionnaire was completed. Table 3.2 shows the ranges of treatment duration. The majority of subjects in both groups were in the early stages of their orthodontic treatment (0-6 months). Forty eight per cent of subjects in the website group and 41% of the leaflet group reported to be 0-6 months into their orthodontic treatment. Only 3 participants in total were >18 - 24 months into orthodontic treatment.

Table 3.2: Participant reported duration of orthodontic treatment at the time of completing the questionnaire.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Website (n=27)</th>
<th>Leaflet (n=24)</th>
<th>Total (n=51)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 months</td>
<td>48 (13)</td>
<td>41 (10)</td>
<td>45 (23)</td>
</tr>
<tr>
<td>&gt;6 -12 months</td>
<td>15 (4)</td>
<td>21 (5)</td>
<td>18 (9)</td>
</tr>
<tr>
<td>&gt;12 -18 months</td>
<td>19 (5)</td>
<td>21 (5)</td>
<td>20 (10)</td>
</tr>
<tr>
<td>&gt;18 -24 months</td>
<td>4 (1)</td>
<td>8 (2)</td>
<td>6 (3)</td>
</tr>
<tr>
<td>&gt;24 months</td>
<td>15 (4)</td>
<td>8 (2)</td>
<td>12 (6)</td>
</tr>
</tbody>
</table>
3.3 Part A of the questionnaire

For the purpose of analyses, the questionnaire was divided into 3 subscales: questions related to pre-operative orthodontic and orthognathic care (pre-op), surgical procedure (operation) and post-surgical orthodontics (post-op).

Part A of the questionnaire consisted of a total of 20 questions. Both QQ plots and the Shapiro-Wilk test suggested that the total questionnaire scores were normally distributed (p=0.39). Similar results were obtained for the subscale scores (pre-op p= 0.15, operation p= 0.05, post-op p= 0.15). The data was analysed using unpaired t-tests and simple linear regression.

Table 3.3: Overall score for participants in both groups for Part A of questionnaire

<table>
<thead>
<tr>
<th>Score</th>
<th>Website mean (SD)</th>
<th>Leaflet mean (SD)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total score mean (SD)</td>
<td>27.7 (6.98)</td>
<td>24.2 (6.03)</td>
<td>0.06</td>
</tr>
<tr>
<td>95% CI</td>
<td>21.3-27.1</td>
<td>25.3 – 30.1</td>
<td></td>
</tr>
</tbody>
</table>

*2 tailed t-test

The total scores for Part A of the questionnaire were calculated for each participant in both groups. The total maximum score achievable was 34. The mean total overall score achieved by subjects in the leaflet group was 24.2 (Table 3.3). In the website group, the mean score achieved was 27.7, a points difference of 3.5. Two sided unpaired t-tests
showed that the difference in the total score between participants in the website group and the leaflet group was not statistically significant (p=0.06).

Table 3.4: Subscales and overall score according to gender

<table>
<thead>
<tr>
<th>Stage</th>
<th>Male</th>
<th>Female</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative score mean (SD)</td>
<td>8.6 (2.3)</td>
<td>8.8 (3.2)</td>
<td>0.73</td>
</tr>
<tr>
<td>95% CI</td>
<td>7.6-9.5</td>
<td>7.5-10.1</td>
<td></td>
</tr>
<tr>
<td>Operative score mean (SD)</td>
<td>5.1 (1.3)</td>
<td>5.5 (1.6)</td>
<td>0.27</td>
</tr>
<tr>
<td>95% CI</td>
<td>4.6-5.6</td>
<td>4.9-6.2</td>
<td></td>
</tr>
<tr>
<td>Post-operative score mean (SD)</td>
<td>12.3 (3.4)</td>
<td>11.8 (3.8)</td>
<td>0.61</td>
</tr>
<tr>
<td>95% CI</td>
<td>11.0-14.0</td>
<td>10.2-13.3</td>
<td></td>
</tr>
<tr>
<td>Overall score mean (SD)</td>
<td>25.9 (5.8)</td>
<td>26.2 (7.6)</td>
<td>0.91</td>
</tr>
<tr>
<td>95% CI</td>
<td>23.6-28.3</td>
<td>23.1-29.3</td>
<td></td>
</tr>
</tbody>
</table>

*2 tailed t-test

Table 3.4 compares the combined control and intervention overall scores and the subscale scores according to gender. Females scored higher in the pre-operative and operative sections and also obtained an overall higher score when compared to males. Statistical analysis using the two-sample t-test found that there were no significant differences between males and females for either the overall scores or the subscale scores.
Table 3.5: Subscales and overall score according to treatment duration

<table>
<thead>
<tr>
<th>Stage</th>
<th>0-6months</th>
<th>&gt;6months</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>9.3 (2.3)</td>
<td>8.3 (3.0)</td>
<td>0.19</td>
</tr>
<tr>
<td>95% CI</td>
<td>8.3-10.2</td>
<td>7.1-9.4</td>
<td></td>
</tr>
<tr>
<td>Operative score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>5.4 (1.4)</td>
<td>5.2 (1.5)</td>
<td>0.53</td>
</tr>
<tr>
<td>95% CI</td>
<td>4.8-6</td>
<td>4.6-5.8</td>
<td></td>
</tr>
<tr>
<td>Post-operative score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>12.1 (3.4)</td>
<td>12.0 (3.7)</td>
<td>0.95</td>
</tr>
<tr>
<td>95% CI</td>
<td>10.6-13.6</td>
<td>10.5-13.5</td>
<td></td>
</tr>
<tr>
<td>Overall score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>26.8 (5.9)</td>
<td>25.5 (7.3)</td>
<td>0.49</td>
</tr>
<tr>
<td>95% CI</td>
<td>24.2-29.3</td>
<td>22.6-29.3</td>
<td></td>
</tr>
</tbody>
</table>

*2 tailed t-test

The duration of orthodontic treatment and its relationship to the subscale and overall scores was also assessed (Table 3.5). Subjects undergoing orthodontic treatment for 6 months or less demonstrated higher scores in all subscales and the overall score when compared to those in treatment longer than 6 months. These differences were not statistically significant.
Table 3.6 Subscale scores according to study group

<table>
<thead>
<tr>
<th>Stage</th>
<th>Website</th>
<th>Leaflet</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-operative score mean (SD)</td>
<td>9.6 (2.5)</td>
<td>7.7 (2.5)</td>
<td>0.01</td>
</tr>
<tr>
<td>95% CI</td>
<td>8.6-10.6</td>
<td>6.5-8.7</td>
<td></td>
</tr>
<tr>
<td>Operative score mean (SD)</td>
<td>5.3 (1.48)</td>
<td>5.3 (1.4)</td>
<td>0.86</td>
</tr>
<tr>
<td>95% CI</td>
<td>4.7-5.8</td>
<td>4.7-5.9</td>
<td></td>
</tr>
<tr>
<td>Post-operative score mean (SD)</td>
<td>12.8 (2.8)</td>
<td>11.2 (4.1)</td>
<td>0.11</td>
</tr>
<tr>
<td>95% CI</td>
<td>11.7-13.9</td>
<td>9.5-13.0</td>
<td></td>
</tr>
<tr>
<td>Overall score mean (SD)</td>
<td>27.7 (6.03)</td>
<td>24.2 (6.98)</td>
<td>0.06</td>
</tr>
<tr>
<td>95% CI</td>
<td>25.3-30.1</td>
<td>21.3-27.2</td>
<td></td>
</tr>
</tbody>
</table>

*2 tailed t-test

The total scores according to subscale for each study group were then analysed. The maximum points achievable by participants for the questions relating to the pre-operative stage of orthognathic surgery was 11 points (Table 3.6). The mean score for patients in the leaflet group was 7.7 and those in the website group scored 1.9 points higher. These findings were significant (p = 0.01).

The maximum number of points achievable by participants for the operative subscale was 6. Both groups achieved a mean score of 5.3 (Table 3.6).

The maximum score achievable for the post-operative subscale of the questionnaire was 17 points (Table 3.6). The website group scored higher with a mean of 12.8 points.
compared to 11.2 points in the leaflet group, although this was not statistically significant (p = 0.10).

Linear regression analysis was carried to evaluate differences between the two groups adjusted for sex, age and duration. This resulted in an adjusted mean of 27.9 for the website group and 24.0 for the leaflet group. Therefore on average, subjects in the leaflet group scored 3.8 less points compared to the website group independent of age, sex and duration in treatment. These results were statistically significant (p = 0.01).

The website allowed us to monitor when participants, who were assigned to this group, accessed it. The intervention group was further divided into subjects who had accessed the website prior to completing the questionnaire (compliers) and those that had not (non-compliers) (Table 3.7).
Table 3.7 Comparison of overall and subscale scores between compliers and non compliers in the website group

<table>
<thead>
<tr>
<th>Website Group</th>
<th>Compliers (n=15)</th>
<th>Non compliers (n=12)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre operative score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>10.5 (2.3)</td>
<td>8.6 (2.6)</td>
<td>0.06</td>
</tr>
<tr>
<td>95% CI</td>
<td>9.2-11.8</td>
<td>6.9-10.2</td>
<td></td>
</tr>
<tr>
<td>Operative score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>5.7 (1.5)</td>
<td>4.7 (1.3)</td>
<td>0.06</td>
</tr>
<tr>
<td>95% CI</td>
<td>4.9-6.6</td>
<td>3.8-5.5</td>
<td></td>
</tr>
<tr>
<td>Post operative score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>13.4 (2.3)</td>
<td>12.1 (3.3)</td>
<td>0.2</td>
</tr>
<tr>
<td>95% CI</td>
<td>12.1-14.7</td>
<td>10-14.2</td>
<td></td>
</tr>
<tr>
<td>Overall score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>mean (SD)</td>
<td>29.9 (5.3)</td>
<td>25.3 (6.3)</td>
<td>0.06</td>
</tr>
<tr>
<td>95% CI</td>
<td>26.7-32.5</td>
<td>21.3-29.3</td>
<td></td>
</tr>
</tbody>
</table>

*2 tailed t-test

In total, 15 out of 27 participants accessed the website before completing the questionnaire. Twelve participants who were assigned to the website group and given logon details did not access the website before completing the questionnaire.

Those patients who had accessed the website had a higher total scores and subscale scores when compared to those who had not accessed the website. However, statistical analysis revealed that this was not significant (p=0.06)
Table 3.8 Comparison of overall scores for compliers in the website group versus the leaflet group

<table>
<thead>
<tr>
<th>Score</th>
<th>Compliers Website group (n=15)</th>
<th>Leaflet group (n=24)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total score mean (SD)</td>
<td>29.6 (5.3)</td>
<td>24.2 (7.0)</td>
<td>p=0.01</td>
</tr>
<tr>
<td>95% CI</td>
<td>26.7-32.5</td>
<td>21.2-27.2</td>
<td></td>
</tr>
</tbody>
</table>

*2 tailed t-test

A per protocol analysis was carried out in order to compare the compliers in the website group against subjects in the leaflet group. The compliers in the website group scored 5.7 points higher than participants in the leaflet group for the total score (Table 3.8). This was statistically significant (p=0.01). When subscales for the same groups were compared, the difference in pre-operative scores were highly significant (p=0.001) whereas the operative and postoperative scores were not significant (p=0.4 and p=0.06 respectively).

In order to test the mode of information delivery and its effect on the patients understanding of joint orthodontic orthognathic treatment, the questions which were applicable to both the website and the leaflet were compared. Questions 2, 3, 5, 7 and 14 asked the participants information that could be found on both leaflet and the website. As a result, the total scores for these 5 questions were compared according to group (Table 3.9). Both groups had an overall total mean score of 8.6 points however statistical analysis revealed this was not statistically significant.
Table 3.9: Overall score for participants in both groups for Part A of questionnaire comparing question 2, 3, 5, 7, 14 (to test mode of information delivery).

<table>
<thead>
<tr>
<th>Score</th>
<th>Website</th>
<th>Leaflet</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total score</td>
<td>8.6 (2.53)</td>
<td>8.6 (2.82)</td>
<td>0.97</td>
</tr>
<tr>
<td>mean (SD)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>7.55-9.56</td>
<td>7.39-9.78</td>
<td></td>
</tr>
<tr>
<td>95% CI</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*2 tailed t-test
3.4 Part B of Questionnaire

Part B of the questionnaire was a qualitative assessment of the patient’s attitude towards their care. It was compromised of six questions with possible response options scale ranging from ‘extremely’ to ‘not at all’ on a 4-point Likert scale.

Table 3.10: Scores for Question 1 Part B

<table>
<thead>
<tr>
<th></th>
<th>Leaflet</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Fairly</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Very</td>
<td>11</td>
<td>13</td>
</tr>
<tr>
<td>Extremely</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>27</td>
</tr>
</tbody>
</table>

Two-sample Wilcoxon rank-sum, p=0.39

Question one asked the participants ‘How prepared do you feel for your surgery?’ In both groups, the highest response was ‘very’ prepared (Table 3.9). Only 3 out of the total 51 subjects felt they were ‘not at all’ prepared.

Table 3.11: Scores for Question 2 Part B

<table>
<thead>
<tr>
<th></th>
<th>Leaflet</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Fairly</td>
<td>10</td>
<td>8</td>
</tr>
<tr>
<td>Very</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Extremely</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>27</td>
</tr>
</tbody>
</table>

Two-sample Wilcoxon rank-sum, p=0.08
Question 2 asked patients to decide how informed they felt about surgery. In the leaflet group, subjects chose the option ‘fairly’ most often whereas in the website group, ‘very’ and ‘extremely’ informed were selected above the other options (Table 3.10).

Table 3.12: Scores for Question 3 Part B

<table>
<thead>
<tr>
<th></th>
<th>Leaflet</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Fairly</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Very</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Extremely</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>27</td>
</tr>
</tbody>
</table>

Two-sample Wilcoxon rank-sum, p=0.89

Question 3 aimed to assess the level of anxiety experienced by both groups in relation to orthognathic surgery. 13 out of the 27 subjects in the website group admitted they felt ‘fairly’ anxious in comparison to only 7 subjects in the leaflet group for the same option (Table 3.11). However, more subjects felt ‘extremely’ anxious in the leaflet group than in the website group.

Table 3.13: Scores for Question 4 Part B

<table>
<thead>
<tr>
<th></th>
<th>Leaflet</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Fairly</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Very</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>Extremely</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>27</td>
</tr>
</tbody>
</table>

Two-sample Wilcoxon rank-sum, p=0.24
Subjects were asked ‘How aware of the risks of surgery are you?’ in Question 4. The majority of the website group were either ‘very’ or ‘extremely’ aware of the risks with the results more variable in the leaflet group (Table 3.12).

Table 3.14: Scores for Question 5 Part B

<table>
<thead>
<tr>
<th></th>
<th>Leaflet</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Fairly</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Very</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td>Extremely</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>27</td>
</tr>
</tbody>
</table>

Two-sample Wilcoxon rank-sum, p=0.80

Question 5 asked participants ‘How aware are you about what to expect after your surgery?’ The most commonly selected answer in both groups was ‘very’ aware (Table 3.13).

Table 3.15: Scores for Question 6 Part B

<table>
<thead>
<tr>
<th></th>
<th>Leaflet</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Fairly</td>
<td>8</td>
<td>6</td>
</tr>
<tr>
<td>Very</td>
<td>11</td>
<td>9</td>
</tr>
<tr>
<td>Extremely</td>
<td>5</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td>27</td>
</tr>
</tbody>
</table>

Two-sample Wilcoxon rank-sum, p=0.11
The final question sought to assess how satisfied subjects were with the information they had been provided with regards to orthognathic surgery. No subject was ‘not at all’ satisfied with the level of information provided (Table 3.14). The majority of subjects in the website group were ‘extremely’ happy whereas in the leaflet group the most selected option was ‘very’ satisfied.

The data in part B of the questionnaire was ordinal in nature. Mann-Whitney U-tests were used to evaluate differences between the two groups. No significant differences between the two groups were found for any of the six questions in part B of the questionnaire.
Chapter 4

DISCUSSION
4. DISCUSSION

4.1 Discussion

A randomised controlled trial was conducted to assess the effect of a patient information website on a patient’s understanding of orthognathic surgery and the treatment pathway. This study is unique in evaluating how informative a patient information leaflet was in comparison to a bespoke website. We also sought to compare the mode of delivery of information and determine whether it had an effect on the patients understanding. The study was carried out at the Birmingham Dental Hospital and Solihull Hospital. Fifty-one patients were recruited for the trial, twenty-six male and twenty-one female. No differences were found in overall score according to age or gender. This is in accordance with a similar study by Patel et al. (2008).

The age range in this study was 15 – 45 years. This range is larger than in previous reports from the U.K, which suggest that most orthognathic surgery patients are in their late teens to early twenties with an average age of 22.6 years (O’Brien et al., 2009, Cunningham and Moles, 2008, Flett et al., 2014). Only 5 subjects were aged above 30 years with the rest of the subjects within the expected age range for orthognathic surgery.

The majority of subjects were at the early stage of their pre-surgical orthodontics, with 48% of the website group and 41% of the leaflet group self-reporting to be within 0-6 months into their orthodontic treatment. This demographic may be due to the fact that data collection commenced within 6 months of several new Post CCSTs starting their posts, during which they were allocated orthognathic surgery patients to begin
treatment. In addition these figures were self-reported by the participants and may not be fully accurate.

All patients in the present study were randomised using block randomisation to achieve equal numbers in both groups. Randomisation ensured that patients with prior knowledge on orthognathic surgery would be evenly split between both groups. Allocation concealment was carried out using sealed envelopes to ensure unbiased allocation of subjects. There are no studies in the published literature with the exact study design as the present study, however a number of studies were very similar in methodology (Patel et al., 2008, Henney and Irving, 2014). The sample size was determined based on one of these similar studies (Patel et al., 2008). The present study had adequate power to identify whether a difference existed between the interventions. Assuring a 90% power, a sample size of 40 subjects was required. A total sample size of 51 participants, were recruited in the event that incomplete questionnaires were returned or that patients did not wish to participate after randomisation.

Orthognathic surgery is a lengthy treatment process. It begins with combined orthodontic treatment followed by assessment and identification of patients who may benefit from combined orthodontic-orthognathic treatment. Potential patients who would benefit from surgery should be given all necessary information to decide whether this is an appropriate option for them to support. The information given must be accurate, easily understood and retained by the patient when they consent to treatment. Numerous studies in the literature highlight the paucity of information given to patients undergoing orthognathic surgery and how this ultimately has an effect on the patients
overall satisfaction (AlKharafi et al., 2014; Stirling et al., 2007; Williams et al., 2004; Cunningham et al., 1996). In particular, the lack of accurate information on the Internet regarding orthognathic surgery has been well documented (Cobb and Scotton, 2013, Aldairy et al., 2012).

Although the patient information leaflet used in the present study (British Orthodontic Society, 2003) is available online via the British Orthodontic Society website, we did not find any evidence in the orthodontic or orthognathic surgery literature, where a bespoke patient information website was created to inform patients about their treatment. A number of studies have provided patients with visual computer programs or information in multimedia format (Patel et al., 2008, Lees and Rock, 2000), however none where a website was developed to provide information. The authors feel that with advances in technology and increasing use of online resources, particularly in younger generations justifies the need to provide patients with health information in an online format as well as in a written leaflet (Cline and Haynes, 2001). This ensures full time access to accurate and verified information about their treatment, provided by qualified health care professionals. It also provides the option for immediate feedback and interactivity, both of which would be useful for orthognathic surgery patients (Griffiths et al., 2006). A survey of 300 British adults carried out in the UK demonstrated that 80 per cent of patients were likely to source information not only from their healthcare professional but also online. When asked their preferred source of information the results showed that their healthcare professional was first, followed by the internet/online and then leaflets or books (Ellins and Coulter, 2007). Providing the website in a format optimised also for mobile phone use allows patients to access the
information at any stage, even whilst in hospital before and after their surgery (Office for National Statistics, 2015). It could also be argued that a website would be more cost effective reaching a wider audience than that of a printed leaflet (Oenema et al., 2001). However, this requires patients to have access to the Internet and the necessary skills to navigate an information-based webpage.

Patients understanding of the orthodontic orthognathic care pathway was evaluated by a patient completed questionnaire. The results demonstrate no statistically significant differences in the overall score between the website group and the leaflet group. This is in agreement to previous studies with similar methodology (Henney and Irving, 2014). When further analysed by subscales (operative and post-operative) there were no statistically significant differences according to study group, gender and treatment duration. This is contrary to what the authors suspected. It was anticipated that there would be a significant difference in relation to treatment duration and level of knowledge participants had regarding the three stages of surgery. We suspected that patients in the earlier stages of orthodontic treatment (0-6 months) would have been able to recall more information about the treatment pathway as they would have completed the consent process more recently, during which they would have been informed of the treatment pathway in detail. Similarly, patients that are close to surgery (>18 -24 months) would also be expected to know more about the surgical aspects, as they would have attended a recent orthognathic multidisciplinary clinic where the details of the operation and surgical pathway are explained.
In the pre operative subscale, a highly significant difference was found between the website and leaflet group, with the website group scoring 1.9 points higher. On closer examination, answers for the questions in this section are not provided in the BOS leaflet. This also occurs in the other subsections of the questionnaire. The current BOS orthognathic surgery patient information leaflet does not cover the information deemed to be important, by the multidisciplinary team, which should be provided to orthodontic-orthognathic patients prior to start treatment. In our opinion, this highlights then need to revise the leaflet or supplement it with further resources that provide more detailed information.

It is important to recognise also, that patients were given a limited time period of 6-8 weeks to utilise the resources given to them. This is in keeping with other studies of similar design (Lees and Rock, 2000). However, outside a trial based environment, patients would have the option to read either the leaflet or the website in their own time and most importantly, when it was appropriate to the stage of their treatment. Patients who are early in their orthodontic treatment may be less likely to read information about the surgical aspects of treatment compared to those closer to surgery. Patients will find different aspects of each resource more relevant to them, depending on their stage of treatment, and may choose only to read the information that is relevant to them.

In research, participants do not always adhere to the planned protocol. In the present study, participants who did not adhere to the protocol set out for the website group were identified. The website platform used, enabled monitoring of the activity of the subjects assigned to the website group. Analysis revealed a total of 12 out of 27 subjects,
assigned to the website group, did not access the website before completing the questionnaire. This is perhaps reflective how in a routine clinical environment, not all patients will read information material provided to them or will follow advice given to them.

Although the use of per protocol analysis is at risk of introducing attrition bias, it allowed us to compare the ‘per protocol population’ in the website group versus the leaflet group. When the compliers in the website group were isolated and compared to all patients in the leaflet group, the difference in overall score in the questionnaire was 5.7 points. This was shown to be highly significant (p=0.01). Although the effect may be exaggerated by adapting a per protocol analysis, a significant difference highlights that subjects who read the content of the website, may be better informed compared to those who just read the leaflet. It was not possible to do a per protocol analysis in the leaflet group as we did not ask whether the patients in this group had actually read the leaflet or not. It would not have been possible to monitor during the present study. In retrospect, a possible way to overcome this would be to have the participants read the leaflet or access the website in the clinic in a supervised manner, following which they would complete the questionnaire. A similar design has been used in a previous study by Patel et al., 2008.

The authors agree that the patients in the website group who chose to use the website, may not be a true representation of all patients as they are likely to be more eager to inform themselves than the average patient, often described as the ‘per protocol population’ or the ‘ideal’ patient. If there are patients who wish to obtain more
information regarding their treatment that is provided by health care professionals, this option should be available. Informed consent is an essential part of a patient’s care and is linked to patient satisfaction: improving the provision of information and enhancing the knowledge of patients regarding their treatment where possible is paramount (AlKharafi et al., 2014; Stirling et al., 2007; Williams et al., 2004; Cunningham et al., 1996).

Also of relevance is that patients have different learning styles depending on their personality (Barbe et al., 1979). Patients who are visual learners may prefer information in a leaflet and therefore the BOS leaflet may be appropriate for them. Whereas those that are kinaesthetic learners may require more interactive forms of information delivery such as the website. So for example, if a visual learner was assigned to the website group, they may have found the format of information delivery too complex and perhaps unsuitable for them and hence would not utilise the resource. Likewise with kinaesthetic learners in the leaflet group, they may have found the leaflet too simple and less interactive then they required to understand and retain the information. Essentially, patients will choose the format of information delivery that suits them best with regards to the type of learner they are. We must therefore aim to provide information in as many different formats as possible to ensure at least one will suit each individual (NHS Institute for Innovation and Improvement, 2008). Furthermore, this study showed that mode of information delivery had no significant effect on the participants’ level of understanding of combined orthodontic orthognathic treatment. This is in line with findings from previous studies (Lees and Rock, 2000, Patel et al., 2008, Heeney and Irvine, 2014, Marshall et al., 2003, Thomson et al., 2001.) As a result patient
preferences should be considered when providing information so that the provision of information can be optimised.

It is important to consider the potential bias that may exist owing to the fact that patients may have sourced information elsewhere during the time that they were enrolled in the study. Although the website in this study was hidden from search engines meaning that only the patients in the website group would know the website address, both groups had the ability to find additional information on the Internet if they wished. This would increase their knowledge and influence how well they completed the questionnaire and therefore the number of correct answers. If further research was to be carried out it could perhaps be emphasized to the patients to avoid reading or searching any additional information other than the information provided by the research team for the duration of the study, although this would not be reflective of what is likely to happen outside of a study.

Part B of the questionnaire assessed patient’s attitudes to their care and their feelings towards surgery. It is well documented that patients who are ill informed about their treatment are more likely to be dissatisfied with their care (Williams et al., 2004, Williams et al., 2005, Flanary et al., 1985, Kiyak et al., 1982, Olson and Laskin, 1980). Statistical analysis of our results revealed no difference between the two groups with regarding to their attitudes towards their treatment and care. However, questions 4-6 ask the patients about aspects of treatment following surgery, or of their overall treatment experience, for example, ‘how aware of the risks are you?’ or ‘how aware are you of what to expect following surgery?’ It could be argued that, although patients may feel
prepared prior to surgery of what to expect after surgery, it is difficult for them to judge the appropriateness of the information they were given until they have the surgery. The patient may believe they have been given all the necessary information and are content with this but following surgery discover that information they would have considered to be important for them was omitted. Therefore, if the patients were asked questions 4-6 again after surgery the outcome may be quite different.

The majority of studies in the literature that examine a patients satisfaction with treatment and the information received, have been carried out following orthognathic surgery which may provide a more accurate representation of the patients satisfaction with the information they had been given (Williams et al., 2005, Williams et al., 2004, Rittersma, J., 1989, Cunningham et al., 1996, Alkharafi et al., 2014, Olson and Laskin, 1980, Flanary et al., 1985, Kiyak et al., 1982). To further evaluate the effectiveness of the different methods of informing patients about treatment, a questionnaire should also be given to patients post-surgery to analyse patient satisfaction with the information they received prior to surgery. This would be an interesting progression to the current project.

Limitations

It could be considered that one limitation of the study is the stage at which patients were at when recruited into the trial. We recognise that patients may have had a certain level of knowledge regarding orthognathic surgery prior to entering the trial. However, even if we were to include patients who were at the beginning of treatment before they had even consented, it is impossible to guarantee that some patients will not have researched
the treatment prior to this. We therefore felt it was more appropriate to include patients at all stages of treatment prior to surgery and to record at what stage of orthodontic treatment they were at. This allowed the effect of treatment stage to be analysed. The results showed that there was no difference in how well informed patients were according to their treatment duration to date.

Patients without access to the Internet were excluded from this study and it could be argued that this therefore reduces the generalisability of the study results.

It may also have been beneficial to ask patients whether they were satisfied with the format in which the information was given to identify whether patients preferred a written or online format. Future research could be directed at transferring the information contained in the website to a leaflet, thereby ensuring both the website and leaflet contained the same information. This would allow the effect of the mode of delivery to be investigated.

This study took place in an area where there is large ethnic diversity and where English is not every patient’s first language. If the provision of information for patients is to be in an online format as well as printed, consideration should be given to ensuring its availability in a variety of languages.

Recording of time spent online in participants who logged onto the website could also have been recorded to allow comparison within the website group to assess whether the time spent reading the information impacted how informed the patient was.
Further research is required to investigate and develop upon these points.

4.2 Conclusions

Combined orthodontic-orthognathic surgery is a complex treatment pathway. It is essential that patients are fully informed to obtain valid consent.

The present study did not demonstrate a significant difference between the website and leaflet with regards to patient knowledge on the orthodontic-orthognathic pathway. However on comparing patients who had accessed the website to those given the leaflet, patients in the website group were better informed.

The authors recognise that the website is a useful information tool, and is equally as effective at informing patients as the leaflet that is currently in use. It is felt that the website should be made available to all patients as either an alternative or additional form of information delivery, but also understand that its uptake will depend on several factors including the personality and learning style of the patient and access to the Internet. Consideration should be given to revising the current BOS orthognathic surgery leaflet.
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Sidaway v Board of Governors of the Bethlem Royal Hospital. 1985 1 AC 871


Appendix 1: British orthodontic society orthognathic surgery patient information leaflet

Will I look very different after the operation?
You will almost certainly look different to some degree. How different, usually depends on how much movement of the jaws is required. You should discuss this with your orthodontist/ oral and maxillofacial surgeon.

How long will the overall treatment take?
It usually takes 12 - 36 months but will vary according to how severe your case is. Failed and cancelled appointments or repeated breakages of the brace will add to the overall treatment time.

How often will I need an appointment?
You will need frequent and regular appointments with the orthodontist during treatment for the brace to be adjusted.

Do I still need to see my regular dentist?
Yes. It will be important you still have check-ups with your regular dentist throughout orthodontic treatment. Your orthodontist will not be checking your teeth for decay.

If you have any further questions that you feel you would like to ask, then please write them down and bring them with you to your next appointment. It is important you fully understand what is involved in having orthodontic treatment before you decide to go ahead.
If you are considering having orthodontics and jaw surgery you may have a number of questions you would like answered.

**Why might I need surgery?**
In order to correct the position of the teeth and provide a functioning bite, the supporting bones of the jaws must be in the correct position. If this is not the case, orthodontics alone will not correct the bite. Surgery will be required to move the jaws into the proper position so the teeth will then meet correctly.

**If I need jaw surgery, why do I also require orthodontics?**
If the jaws are to be moved into the correct position, it is important your teeth are moved so that they will meet properly after surgery.

**What type of brace will I need to wear?**
Fixed braces are used prior to jaw surgery because they permit the most accurate positioning of the teeth prior to the operation.

**The bite before surgery**

**The bite after surgery**

Are the braces removed just before the operation?
No, the braces remain in position during and after the operation for a number of months. During the operation they help the surgeon to position the jaws correctly. After the operation they help the orthodontist fine tune the bite with the aid of elastic bands.

**How will the operation be done?**
The majority of the operation will be done from inside your mouth.

**Will my jaws be wired together?**
Patients having jaw surgery used to have their teeth wired together for 6 - 8 weeks afterwards. However, this is now fairly unusual, as small metal plates are used to hold the fracture sites together. These plates are on the surface of the bone but beneath the skin, and generally remain in place forever. Very occasionally they are removed at a later date.

**How long will I be in hospital?**
This varies, but in general between 3 - 5 days.

**Can I eat normally?**
Yes, up until the operation you should be able to eat normally. For your orthodontic treatment to work well and in the shortest possible time it is important you take care of your teeth and braces. In order to prevent damage to both, you should avoid the following:
- Toffees, boiled sweets, sugared chewing gum, chocolate bars, etc.
- Fizzy drinks including diet drinks, excessive amounts of fruit juice.
- Hard foods which might damage the brace such as crunchy apples, crusty bread rolls, etc.

Hard foods can be eaten with care if you cut them up first. After the operation you will have a more liquid diet for the first few weeks. However, the dietician at the hospital will advise you about this nearer the time.

**Are there any after effects?**
You will have some swelling and bruising after the operation. This will rapidly begin to subside over the first 2 - 3 weeks. For operations on the lower jaw it is fairly common to have some numbness of the lower lip for some weeks or months afterwards. In a very small number of cases a residual area of numbness will remain. This numbness will not affect movement of your lip, only the feeling in it, in a similar way to an injection at the dentist. As with any operation, you will have to take it easy for the first week or two afterwards. You should therefore expect to be off college/ work for at least this length of time.
Appendix 2: Participant Cover Letter

Dear Participant,

Invitation to take part in research to assess the effect of information sources on a patient’s understanding of jaw surgery.

My name is Susan O’Connell and I am an orthodontic trainee at the Birmingham Dental Hospital. I am part of a team working with the University of Birmingham who are undertaking research into a patient’s understanding of jaw surgery.

We are asking you to take part as we feel you fit the criteria for our research. If you agree to take part, then we will give you access to either an information leaflet or an information website which we will ask you to use before your jaw surgery. When you return to see your orthodontist for your next appointment, we will ask you to do a short questionnaire that will take approximately 10 minutes to complete.

All the information you should require is enclosed with this letter. You do not have to take part if you do not wish to and this will not affect your care at the Birmingham Dental Hospital/Solihull Hospital. However, we hope that you will take part and help us learn more about how we should be informing patients about jaw surgery.

Yours Sincerely,

Susan O’Connell

Specialist Registrar in Orthodontics
Appendix 3: Participant information sheet

INFORMATION SHEET

A SINGLE BLINDED RANDOMISED CONTROLLED TRIAL TO ASSESS TO EFFECT OF A PATIENT INFORMATION WEBSITE ON PATIENT ON PATIENTS UNDERSTANDING OF ORTHOGNATHIC SURGERY.

Why have I been invited to complete a questionnaire?
We are asking you to take part in a research project to assess how well informed patients are before they have jaw surgery, in particular we want to see if how we provide the information has an effect on how well informed patients are. You have been asked to take part because you are having orthodontic treatment at the Birmingham Dental Hospital/Solihull Hospital before you have jaw surgery.

What will happen to me if I take part?
If you agree to take part, you will be randomly assigned to one of two groups which means your orthodontist will give you either an information leaflet or access to an information website in order to prepare you for your jaw surgery at your next appointment. We would encourage you to utilise leaflet or the website to ensure you are fully prepared. At the following orthodontic appointment six-eight weeks later, you will need to complete a short questionnaire when you return to see your orthodontist at the Birmingham Dental Hospital/Solihull Hospital for a check up. That will complete your participation in the research project.
Can anyone take part?

You are able to partake in this research project if:

• You are over 16 years of age and you are shortly to undergo jaw surgery.
• You are able to speak, read and write in English.
• You have access to the internet either via a mobile device or computer.
• You do not have any congenital craniofacial anomalies or acquired defects.
• You have not had jaw treatment already.

Do I have to take part?

No, if you don’t want to participate then you do not need to however your participation would be appreciated to contribute to this important research subject.

What happens to me after I take part?

If you want to receive information on the results of the trial we will send them to you by email. This will be available approximately 6 months after the results of the participants have been tested with statistical analyses. The questionnaire data will be stored on an NHS encrypted memory stick for 6 months after the project is written up and then destroyed.

Other information and contact details

This research is governed and supported by the University of Birmingham, will take place at Birmingham Dental Hospital and Solihull Hospital. It is being supervised by Ms Sheena Kotecha (Consultant Orthodontist).
This research has been reviewed by the NRES Committee as well as the local Research and Development departments for Solihull Hospital and the Birmingham Dental Hospital.

If you have any queries/question before or during the research project you can contact me:

Susan O’Connell (Orthodontic Specialty Registrar)

If you want to complain you can contact:

Derrick de Faye (Patient experience officer)

Thank you for reading and taking part.
Appendix 4: Participant consent form

Title of Study: A single blinded randomised controlled trial to assess the effect of a patient information website on patients understanding of orthognathic surgery.

Name of CI: Ms Sheena Kotecha

<table>
<thead>
<tr>
<th>1. I confirm that I have read and understand the information sheet v 1.7 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered these satisfactorily.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my treatment or legal rights being affected.</td>
</tr>
<tr>
<td>3. I understand that data collected during the study where it is relevant to taking part in this research, may be looked at by individuals carrying out the research who are part of the University of Birmingham. I understand this consent form is the only identifiable data that will be stored securely at the Birmingham Dental Hospital.</td>
</tr>
<tr>
<td>3. I understand that I will be randomly placed into one of two groups as part of the research project to inform me about jaw surgery.</td>
</tr>
<tr>
<td>4. I understand that the group into which I have been placed will not affect the treatment I receive by my orthodontist or my surgeon in any way.</td>
</tr>
<tr>
<td>5. I understand that the answers I give in the questionnaire will be used anonymously as part of this research.</td>
</tr>
<tr>
<td>6. I agree to take part in the research.</td>
</tr>
</tbody>
</table>

Name of Participant: ..................................................
Signed: .......................................... Date: .........................

Name of person taking consent: ..........................................
Signed: .......................................... Date: .........................

Version 1.7 26.1.15
Appendix 5: Screenshots of the patient information website

The website screenshot is redacted from the e-thesis in order to avoid copyright infringement.
Contact

If you have any questions or need advice please contact your surgeon’s secretary on the telephone numbers below. They are available Monday – Friday, 9am-5pm.

- Mr Williams & Mr Sharp’s secretary: Barbara Singh 0121 371 5026.
- Mr Dover, Mr Monaghan & Mr Evans’ secretary: Sharon Dillon 0121 371 5029.
- Mr Green & Mr Speculand’s secretary: Lyn Whitehead 0121 371 5024.

If you wish to contact your orthodontist, please do so between the hours of 9am -5pm on the following numbers.

- Birmingham Dental Hospital Orthodontics: 0121 466 5038.
  - Request to be put through to the orthodontic department.
- Solihull Hospital Orthodontics: 0121 424 5307.

A member of the orthodontic team will take a message and speak to your orthodontist for you.

If you need advice out of hours, please contact the Queen Elizabeth hospital. Ask to speak to the Maxillofacial on-call Senior House Officer who will be happy to help you:
Hospitals

**Address:**
New Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham, B15 2TH
Contact no.: (Hospital Switch Board): 0121 627 2000

**Address:**
Birmingham Dental Hospital, St Chad's Queensway, Birmingham, B6 4NN
Contact no.: 0121 406 5000

**Address:**
Solihull Hospital, Lode Lane, Solihull, B91 2JL
Contact no. (Orthodontic Department): 0121 424 5307
Appendix 6: Participant website information leaflet

Patient information website

jawsurgerysite.wix.com/birmingham

The information on this website has been creating using information provided by patients who have undergone jaw surgery, as well as information from you surgeon, your orthodontist and your medical team.

When should I use the website?

As soon as you receive your information pack, please sign up to the website and use it as often as possible before your surgery to prepare yourself.

Website address:

jawsurgerysite.wix.com/birmingham

How do I access the website?

In order to access the website, enter the website listed above into your internet browser. This will bring you to the website. You will then be asked to sign up/login. The first time you visit the
website you must sign up by entering the email address provided at the top of this page. Then create a password. Once you have entered these details, you will have access to the website.

**What sections should I look at?**

The following topics are covered on the website in detail:

- Introduction to your jaw surgery: Your appointment schedule, before your operation.

- At Hospital: After your operation (what to expect), Medication after your operation, Before you leave hospital (who you will see from the medical team).

- At Home - how to prepare in advance: Diet & Oral hygiene.

- Follow up schedule & Important Contact numbers It is important that you use all sections of the website.

We would encourage you to read all sections of the website before your surgery to ensure you are as prepared and informed as possible before you go into hospital.

If anything is unclear or you have any additional questions regarding the website please feel free to contact Susan O’Connell (Sue.o’connell@nhs.net).
Appendix 7: Participant Questionnaire

To assess if a jaw surgery patient information website is effective.

A SINGLE BLINDED RANDOMISED CONTROLLED TRIAL TO ASSESS THE EFFECT OF A PATIENT INFORMATION WEBSITE ON PATIENTS UNDERSTANDING OF ORTHOGNATHIC SURGERY.

Participant number: ______________________
Age: ______________________
Gender: Male ☐ Female ☐

How long have you had your braces on for? (Please circle the correct time - if you do not know please ask your orthodontist)
0-6 months ☐ >6-12 months ☐ >12-18 months ☐ >18-24 months ☐ >24 months ☐

1. Who will do my jaw surgery?
☐ My Orthodontist
☐ My Dentist
☐ Maxillofacial Surgeon (1mark)
☐ Don’t know

4. How long will I wear a brace for after my surgery?
☐ About 2 years
☐ My braces will be taken off straight after my surgery
☐ About 6-9 months (1mark)
☐ Don’t know

2. How long will I be in hospital?
☐ About 1-3 nights (1mark)
☐ About 4 weeks
☐ 1 week
☐ Don’t know

5. How long will I need off work/university?
☐ About 1 week
☐ About 1 day
☐ About 2-6 weeks (1mark)
☐ Don’t know

3. Will my braces stay on during the operation?
☐ Yes (1mark)
☐ No
☐ Don’t know

6. What medication will you be given after you operation? Tick all correct answers.
☐ Antibiotics (1mark)
☐ Painkillers (1mark)
☐ Steroids (1mark)
☐ All of the above (3 mark)
☐ Don’t know

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Please turn over...
7. Which of the following is/are a risk of jaw surgery? Tick all correct answers.
○ Numbness of lip
○ Infection
○ Swelling
○ Cold sore
○ Don’t know

8. Can you eat and drink before your surgery?
○ Yes, general anaesthetic is not affected.
○ No, it is dangerous if I do not following the pre anaesthetic instructions.
○ Don’t know

9. Which of the following appointments do I need to attend at the Queen Elizabeth Hospital before my surgery? Tick all correct answers.
○ Speech assessment
○ Pre general anaesthetic appointment
○ Planning appointment
○ Don’t know

10. What will be done at my planning appointment at the Queen Elizabeth Hospital? Tick all correct answers.
○ Moulds of my teeth will be taken
○ Bloods will be taken
○ X-rays will be taken
○ My brace will be adjusted
○ Don’t know

11. Why do I need to see my orthodontist the week/two weeks before my operation?
○ To clean my teeth
○ To tighten my brace
○ To put hooks on my brace for elastics
○ To remove my brace
○ Don’t know

12. What should I bring to hospital with me? Tick all correct answers
○ Loose clothes
○ Books to read/Ipad/Tablet
○ Ear plugs
○ Pen and paper
○ Food
○ Don’t know

13. Could my operation be cancelled on the day?
○ Yes, if something more life threatening needed a hospital bed.
○ No
○ Don’t know

14. What symptoms will I feel after the operation?
○ Pain
○ Swelling
○ Blocked nose
○ Sickness
○ Bruising
○ All of the above
○ Don’t know

15. Can I care for myself after the operation?
○ No, I need a friend or family member to help me at home.
○ My children can take care of me
○ Yes
○ Don’t know

16. How long do I need someone to be at home with me to help after my operation?
○ 1 day
○ 1 week
○ 5 weeks
○ I will not need someone to help me
○ Don’t know

Please turn over....
17. How must I get home from the hospital?
- By bus
- Walk home
- By car
- By train
- Don’t know

19. Who can tell me when to remove the elastics after surgery? Tick all correct answers.
- The nurse at hospital
- My surgeon
- My orthodontist
- The secretaries
- Don’t know

18. How many times a day should I do salt water mouth rinses?
- Every second day
- I do not need to do mouth rinses
- Three times
- 10 times
- Don’t know

20. Who do I contact if I have a problem outside normal working hours (after 5pm and before 9am)?
- My surgeon
- The secretaries
- The on call Senior House Officer at the Queen Elizabeth Hospital
- My orthodontist
- Don’t know

**Part 2**

Please tick the appropriate answer to the following questions:

<table>
<thead>
<tr>
<th></th>
<th>Extremely</th>
<th>Very</th>
<th>Fairly</th>
<th>Not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>How prepared do you feel for your surgery?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>How informed do you feel for your surgery?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>How anxious do you feel about your surgery?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>How aware of the risks of surgery are you?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>How aware are you about what to expect after your surgery?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
<tr>
<td>How satisfied are you with the information you have been given?</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

Thank you for completing this questionnaire - Please return to your orthodontist.