Patient Reported Outcome Measures in Endodontics using a mixed methodology

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Endodontic Doctorate in Dental Sciences

by Robert Peter Jacobs September 2018
Abstract

Patient reported outcome measures in Endodontics

using a mixed methodology

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Introduction and Aims: Historically, endodontic treatment outcomes have been measured via clinical outcomes, rather than patients' perspectives. The aim of this thesis was to design a user-friendly and reliable tool for reporting patient reported outcomes in endodontics. This was achieved by piloting the tool, followed by a prospective longitudinal study on a sample of endodontic patients in secondary care treated by postgraduates. Thematic analysis of semi-structured interviews explored the concerns and the impact of endodontics on quality of life, on a sample of patients' who participated in the longitudinal study.

Methods: A PROMs tool was developed using Oral Health Impact Profile (OHIP-14), which consisted of 14 questions over 7 domains, answered on a Likert scale ranging from 0 (never) to 4 (very often) In addition, 4 visual analogue scales assessed patients' levels of pain, anxiety, concern and oral health state from 0 (no problem) to 100 (maximum problem). Ethical approval was granted, and data was collected from patients treated by postgraduates at LUDH. Eligibility criteria were adults (age ≥18) requiring: RCT, ReRCT or Surgery. Questionnaires were completed pre-treatment (T0), 2 months post-treatment (T1), and 6 months post-treatment (T2).
Twenty-one patients participated in a qualitative study, with telephone interviews recorded and transcribed, followed by coding and thematic analysis.

**Results:** 53 patients provided PROMs at T0 and T2, analysed with Paired Samples *t* Test. OHIP-14 mean values revealed a non-statistically significant reduction of 2.6±10.3 (*P*=0.067). The VAS scale means showed statistically significant reductions in anxiety 12.9±32.1 (*P*=0.005), and concerns 15.5±32.3 (*P*=0.001), and non-statistically significant reductions in mean levels of pain 3.0±21.1 (*P*=0.305) and oral health state -1.6±35.8 (*P*=0.752). Qualitative analysis highlighted patient awareness of treatment complexity and subsequent referral to specialist services. Patients were concerned about pain levels in relation to endodontics. Trust and resultant reduced anxiety were key themes in terms of expertise and equipment encountered at LUDH, as well as dentist qualifications and supervision by consultants. Patients valued endodontics to avoid the consequences of tooth loss and resultant functional and cosmetic concerns.

**Conclusions:** Patient reported outcomes indicated an improvement in oral health-related quality of life (OHRQoL) following endodontics, although OHIP-14 mean reduction was not statistically significant, and the OH-VAS scale did not adequately capture the OHRQoL improvement. Key points raised from the telephone interviews were as follows: the important and meaningful impact of tooth loss regarding function and aesthetics, the recognition that OHIP-14 was imperfect but still captured key issues regarding function for some participants, and the complexities surrounding referral to secondary care.
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<tbody>
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<td>RCT</td>
<td>Primary Root Canal Treatment</td>
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<tr>
<td>ReRCT</td>
<td>Secondary Root Canal Treatment</td>
</tr>
<tr>
<td>GDP</td>
<td>General Dental Practitioner</td>
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<tr>
<td>LUDH</td>
<td>Liverpool University Dental Hospital</td>
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<tr>
<td>PROM</td>
<td>Patient Reported Outcome Measure</td>
</tr>
<tr>
<td>OHIP</td>
<td>Oral Health Impact Profile</td>
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<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
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<tr>
<td>Pain VAS</td>
<td>Visual Analogue Scale - Pain</td>
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<td>VAS-A</td>
<td>Visual Analogue Scale - Anxiety</td>
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<td>VAS-C</td>
<td>Visual Analogue Scale - Concern</td>
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<td>OH-VAS</td>
<td>Oral Health Related - Visual Analogue Scale</td>
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<tr>
<td>CDAS</td>
<td>Corah’s Dental Anxiety Scale</td>
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<td>MPQ</td>
<td>McGill Pain Questionnaire</td>
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<tr>
<td>MDAS</td>
<td>Modified Dental Anxiety Score</td>
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<tr>
<td>EQ-5D</td>
<td>European Quality of Life – 5 Dimensions Questionnaire</td>
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<td>GHQ-12</td>
<td>General Health Questionnaire - 12</td>
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<tr>
<td>NHS</td>
<td>National Health Service</td>
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<tr>
<td>IRAS</td>
<td>Integrated Research Application System</td>
</tr>
<tr>
<td>SIDD</td>
<td>Social Impacts of Dental Disease</td>
</tr>
<tr>
<td>GOHAI</td>
<td>Geriatric Oral Health Assessment Index</td>
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<tr>
<td>DIP</td>
<td>Dental Impact Profile</td>
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<tr>
<td>OHQoL-UK</td>
<td>Oral Health-Related Quality of Life–UK</td>
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<tr>
<td>HADS</td>
<td>Hospital Anxiety and Depression scale</td>
</tr>
<tr>
<td>HRA</td>
<td>Health Research Authority</td>
</tr>
<tr>
<td>REC</td>
<td>Research Ethics Committee</td>
</tr>
<tr>
<td>IADR</td>
<td>International Association of Dental Research</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organisation</td>
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<tr>
<td>HRQL</td>
<td>Health-Related Quality of Life</td>
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<tr>
<td>OHRQoL</td>
<td>Oral Health-Related Quality of Life</td>
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<tr>
<td>IMD</td>
<td>Index of Multiple Deprivation</td>
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CHAPTER 1 INTRODUCTION

1.1 Overview of endodontics

Endodontics refers to the dental specialty concerned with diagnosis, management and treatment of the dental pulp. Endodontic treatment is required when a pulp undergoes necrosis, or becomes infected for a number of reasons; most commonly due to tooth decay or traumatic injuries to the tooth, leading to the ingress of microorganisms (Kakehashi et al., 1965). Microorganisms have long been identified as the key causative agent of root canal infection, toxin release into peri-radicular tissues (Kakehashi et al., 1965), and treatment-resistant chronic periapical periodontitis (Molander et al., 1998, Nair et al., 1990, Sundqvist et al., 1998). Their toxins and by-products can lead to the development of inflammation (Zehnder and Belibasakis, 2015, Zehnder et al., 2002).

Following diagnosis of an irreversibly inflamed or necrotic pulp, the following options are available to patients:

1. Primary root canal treatment (RCT) and definitive restoration
2. Extraction (XLA)
3. Monitor without active treatment

RCT involves chemomechanical debridement of the root canal system, followed by obturation of the canals, aiming to prevent reintroduction of bacteria into the canals (Sjögren et al., 1990). In addition to providing an
apical seal, treatment success is reliant on a sealing coronal restoration to prevent re-infection of the canal space, caused by microleakage from the oral cavity (Ray and Trope, 1995).

The other option available for patients with endodontically involved teeth is extraction, with/without replacement of the resultant space in the dentition. The option to root treat or extract teeth involves numerous factors, with patients valuing communication and trust, the importance of tooth retention, aesthetics, cost, longevity and pre-operative pain as their most important decision values (Azarpazhooh et al., 2016). On other occasions, the tooth may require extraction due to unrestorable caries, root fracture or extensive root resorption (McCaul et al., 2001).

Following extraction, options for the resultant space are as follows:

1. Leave the gap (no replacement)
2. Implant-supported restoration
3. Bridge (fixed or resin bonded)
4. Denture (acrylic or cobalt chrome)

If primary root canal treatment fails (continued signs or symptoms), further treatments available other than XLA are:

1. Endodontic Retreatment (ReRCT)
2. Apical surgery (root end surgery)
From a clinical perspective, ReRCT is advised when the primary root canal filling is suboptimal, or there has been a failure of the coronal restoration, leading to leakage from the oral cavity and re-infection of the canal space. In contrast, apical surgery is advised in cases where; the coronal seal is sound or where access from the crown is contraindicated (for example part of a long span bridge), an overextended previous root filling not amenable to orthograde ReRCT, or a canal blockage that prevents gaining canal patency.

1.2 What is a Patient Reported Outcome Measure?

A patient reported outcome measure (PROM) is any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else (Food and Drug Administration, 2006).

The main aim of health care is to improve patients’ health (defined in section 2.3.1), so using PROMs to measure clinical efforts will help improve the quality and effectiveness of health care. In addition, the King’s Fund (a body tasked with understanding how NHS healthcare can be improved) believed that PROMs may help shape how health care is funded, provided and managed (Devlin et al., 2010).

In 2015, the National Health Service (NHS) England’s Chief Dental Officer wrote a manual titled the Guide for Commissioning Specialty Dental Services. This document aimed to help NHS England Dental Commissioners provide, “a consistent and coherent approach… to commission dental
specialist services.” In this document, forecasts regarding future care commissioning hypothesised that PROMs will play a key role in future assessment of quality of patient care, and in benchmarking levels of care (NHS England Chief Dental Officer Team, 2015). It also allows for comparison between service providers to ensure consistent quality of care. There was an expectation that PROMs would be used by clinicians to analyse treatment, helping future patients’ decision making (Brooks, 1996).

As well as providing treatment outcomes, PROMs allow patients to have more control of where, and from whom, they undergo treatment. PROMs will also provide an effective measure of individual professionals’ outcomes, although this will also need to assessed alongside clinical treatment quality. This is a key strategy in the changes to health policy in the UK, with the NHS keen to be more empathetic and reactive to patients’ wishes and preferences (Devlin et al., 2010).

From an economic standpoint, spending on healthcare amounted to 18% of UK government spending in 2007/08 (Hawe, 2009), but it can be challenging to measure the output and productivity of this expenditure. Following the financial crisis and recession of 2008/09, NHS spending was scrutinised in terms of output, and the use of resources to maximise value to patients and society (Devlin et al., 2010). PROMs have the potential to dictate funding and payments to treatment providers, based on performance in improving patient health.
1.2.1 Why are PROMs useful in Dentistry?

PROMs measure the psychosocial wellbeing of patients, shifting from the management of disease, to a concern with quality of life (QoL), and represents a paradigm shift towards health promotion and prevention. In addition, patients’ are being valued as individuals, with more appreciation of self-reported outcomes to interpret their own health or ‘disability.’ Healthcare professionals value treatment outcomes in a very different way to patients’. This can lead to services being planned and commissioned without managing the patients’ health impacts, worries and concerns (Slevin et al., 1988).

1.3 Dental fear pathways

Patients have traditionally feared endodontic treatment of all types. A study in the International Endodontic Journal in 2015 investigated pathways of fear for endodontic patients (Carter et al., 2015), finding five main pathways leading to dental fear and anxiety shown in Figure 1.1.

1. Cognitive – learn by personal experience
2. Informative – children learning phobia from other adults or media outlets
3. Parental – patients learning from the thoughts/experiences of parents
4. Verbal threat – other peoples’ negative stories of dental visits
5. Vicarious – people see friends/family in pain as onlookers at the dentist

Figure 1.1 Five pathways leading to dental fear and anxiety (Carter et al., 2015)
A questionnaire focusing on phobias was re-worded to make it specific to endodontic phobias, and related to each of the five themes above. This was completed by 594 patients prior to root canal treatment in Australia (Carter et al., 2015). Conclusions were that the cognitive (personal experiences) and parental (learning from parents) pathways were the main cause of patients’ fears and anxieties of treatment. This highlights the depth of patients’ fears regarding endodontics, and the value of accurate self-reported outcomes.

1.4 Why is this research original?

Endodontic studies have primarily focused on clinical outcomes. However, these differ from PROMs as they depend on dentists’ clinical and radiographic findings, whilst PROMs focus on patient-reported outcomes of treatment. There has been a lack of research helping understand treatment effectiveness from the patients’ perspectives, and the correlation between specific oral conditions and general QoL (Sischo and Broder, 2011). The use of OHRQoL as an evaluative outcome measure is in harmony with patient-oriented care.

Previous studies have assessed PROMs in endodontics, but no comparable study has been conducted in the UK. Existing studies in the literature have primarily used the oral health impact profile (OHIP-14) as the primary outcome measure, plus a targeted treatment-specific tool. OHIP-14 has the benefits of being generalisable and comparable between different fields of
dentistry, but is not specific to individual treatments. A key aim was to develop a targeted endodontic-specific tool.

The use of qualitative data recognised and investigated patients’ self-reported outcomes in greater depth, whilst assessing the questionnaire’s relevance and quality. Using mixed methods to conduct this project will increase validity of the project findings, giving a broader and deeper understanding of the research topic (Hurmerinta-Peltonäki and Nummela, 2006). Specifically, the qualitative interviews provided data that ultimately led to amendments of the questionnaire tool suggested for future quantitative studies of endodontic PROMs.
1.4.1 Research aims and objectives

Aims

The aim of this thesis was to design a user-friendly and reliable tool for reporting patient reported outcomes, specifically in endodontics.

Objectives

- Review the available literature regarding endodontic PROMs
- Design and pilot a patient-reported outcome tool.
- Conduct a prospective longitudinal study to evaluate PROMs on a sample of endodonic patients treated at LUDH by postgraduates.
- Use thematic analysis of semi-structured interviews to explore the concerns and impact of endodontics on the QoL of a sample of patients’ from the longitudinal study population.
- Synthesise the information from the literature review, pilot study, longitudinal study and qualitative study to formulate a strategy for collecting patient-reported outcomes.
CHAPTER 2 LITERATURE REVIEW

2.1 Traditional measures of endodontic success

2.1.1 Non-surgical endodontic outcome studies

Common measures of endodontic treatment outcome have historically centred around clinical and radiographic findings, such as Strindberg’s criteria (Strindberg, 1956). Strindberg’s criteria define strict postoperative criteria, specifically a clinically symptom free tooth and radiographically normal periapical tissues. Similarly, the European Society of Endodontology (2006) has defined success of non-surgical endodontics as:

- Absence of pain, swelling and symptoms
- No sinus tract
- No loss of function
- Radiological evidence of absence of periradicular pathology

The difficulty in utilising treatment success rates is degree of variance depending on study design. A systematic review assessing endodontic success rates found that success of primary RCT varied from 31-96% using strict criteria (Ng et al., 2007). This systematic review focused on the pre and post-operative periapical status radiographically, without investigating how various treatment techniques affected outcomes. Subsequently, a prospective study assessed non-surgical endodontic success rates and prognostic factors affecting outcomes in a secondary-care setting (Ng et al.,
Teeth were excluded if they had preoperative periodontal disease, historical endodontic surgery or the apices were not detected radiographically. Postgraduates provided treatment following consistent but not strict protocols. Teeth were excluded from the study if; post-treatment review was less than 2 years, the tooth was extracted for non-endodontic reasons, or data collection regarding treatment was incomplete. 702 primary cases and 750 retreatments were included, analysed by number of roots (1170 and 1314 roots respectively). Successful healing at the root apex according to strict criteria occurred in 80.5% of primary RCTs, and 77.9% of retreatments.

A retrospective study of 2000 cases performed by endodontic specialists reported 96% success rates of primary endodontics and 86% of retreatments (Imura et al., 2007) at >18 months recall. All teeth with traumatic dental injuries were excluded from the study. Preoperative analysis assessed vitality, previous endodontics, and presence of periapical pathology. Treatment protocols attempted to remain standardised (with regards cleaning/shaping, irrigation, temporisation, obturation and restoration). All apical preparations were minimum size 30, and obturation involved lateral condensation of GP and sealer. Clinical recall assessed signs and symptoms, presence of periapical pathology, and restoration provided.

The studies by Ng et al and Imura provide important information about clinical outcomes of endodontics, but also raise a number of questions for both operators and patients’, as many variables were present even in
carefully designed studies, which may affect result validity. In addition, the success outcome figures quoted are significantly different.

Radiographic assessment of obturation quality have been used to assess outcomes, with key prognostic factors of root filling within 0-2mm of the radiographic apex, no overextension or voids and a satisfactory coronal restoration (Ng et al., 2008). The relevance of coronal restoration to outcome was analysed by evaluating the relationship between the quality of the coronal restoration and the root canal obturation. Endodontically treated teeth (n=1010) were assessed radiographically regarding: quality of obturation, quality of restoration, and presence of periapical pathology. When both the endodontic filling and coronal restoration were of a good quality, 91.4% of teeth had no lesion. A poor restoration caused a greater decrease in outcomes than poor endodontics, although this study was limited by the variables involved and the methodology used (Ray and Trope, 1995).

Cone beam computed tomography (CBCT) has been utilised in endodontic outcome studies. A study of 123 teeth that had undergone primary RCT found an absence of periapical pathology in 87% of teeth viewed on a periapical radiograph, but only 63% when viewed using CBCT (Patel et al., 2012). CBCT’s sensitivity and specificity has shown assessing periapical radiographs causes overestimation of endodontic success rates, when using periapical pathology as the measure of success.
2.1.2 The use of survival as an outcome measure

In recent times, the survival of teeth in the mouth following endodontic treatment has been suggested as an alternative outcome measure. The increased use of survival in endodontics relates to its popularity in measuring implant outcomes, allowing comparison between the two treatment options (Iqbal and Kim, 2008).

A systematic review of tooth survival following endodontics (Ng et al., 2010), found that the majority of survival studies were retrospective cohort studies. The largest of these involved 1,462,936 teeth (Salehrabi and Rotstein, 2004), using insurance records to assess treatment provided over an 8 year period. Survival rates of 97% were reported, but failed to provide detailed clinical data due to the nature of the study. An investigation of tooth survival post-endodontics by general dental practitioners (GDP) in the UK, analysed 30,843 teeth finding 10 year survival rates of 74% (Lumley et al., 2008). Survival was strongly correlated to patient age and the tooth treated. However, the possibility of the patient seeking dental care from a non-NHS provider was not considered in the study analysis.

A systematic review assessed survival of root treated teeth, comparing extracted teeth with no replacement, and those with implant or bridge replacement (Torabinejad et al., 2007). Analysis led to the inclusion of 143 studies assessing success and survival. Implant-retained restorations had the highest success rate, but the success criteria differed greatly between the different treatment types, rendering the comparison futile. Long-term survival of implant-retained restorations and endodontically treated teeth were similar, and higher than bridge restorations.
A prospective study assessed tooth survival rates following endodontics by postgraduates, and highlighted the main prognostic factors affecting outcome (Ng et al., 2011a). Follow-up was 2-4 years, with estimated survival rates of 95.4% for RCT and 95.3% for ReRCT.

Setzer analysed long-term survival of implants and Endodontically treated tooth, discussing the complexities of choosing the correct treatment based on specific tooth prognosis (Setzer and Kim, 2014).

### 2.1.3 Traditional measures of surgical endodontic outcomes

Traditional apical surgery has been extensively researched, such as the evaluation of amalgam root end fillings that showed 10 year success in terms of periapical healing on PA radiographs of 57% (Frank et al., 1992). Endodontic microsurgery has adapted the technique to improve healing and success rates due to:

- Flap designs for improved healing and less scarring
- Smaller osteotomy sizes to improve post-operative healing
- Root resection ideally 0° bevel to decreasing open dentinal tubules
- Inspection of the root surface under magnification for cracks/isthmuses
- Canal preparation with ultrasonics rather than burs, decreasing damage to the root
- Root end filling with bioceramics rather than amalgam
- Earlier suture removal for improved soft tissue healing
Success criteria for surgical endodontics are defined by the European Society of Endodontology (2006) as:

- Absence of pain, swelling and other symptoms
- Satisfactory healing of soft tissue
- No sinus tract
- No loss of function
- Radiological evidence of absence of periradicular pathology

A systematic review exploring outcomes of non-surgical endodontic retreatment to apical surgery, showed higher success in terms of periapical healing on PA radiographs of apical surgery at 2-4 years (78% surgery compared to 71% retreatment). However, 4-6 year outcomes revealed higher success rates of retreatment (83% non-surgical compared to 72% surgery) (Torabinejad et al., 2009). A prospective, consecutive outcome study of 322 teeth requiring microsurgical endodontics using mineral trioxide aggregate as the root end filling material reported a success rate of 89% (healing and healed lesions included) (Saunders, 2008).

Patient-centred approaches to surgical flap design have been utilised in studies to help guide clinicians, by assessing clinical parameters (soft tissue healing following apical surgery) alongside patient factors (pain levels post-surgery and effect on chewing, eating, sleeping and work interruption) (Del Fabbro et al., 2009, von Arx et al., 2011).
A Meta-analysis to explore the prognostic factors in apical surgery found higher healing rates were associated with: no preoperative signs and symptoms, good density of root filling, absence of periapical radiolucency (or less than 5mm in size), and use of the microscope (von Arx et al., 2010).

### 2.1.4 Relevance to this project

The review of traditional measures of endodontics success outcomes reveals that the vast majority of research fails to include patient reported outcomes, instead focusing on clinical outcome measures. This provides valuable information on success rates of endodontics within the terms of success used by dental researchers, and the technical aspects of treatment that encourage successful outcome. However, although patients can be given these figures prior to treatment to support decision making, the majority of the research assess treatment protocols relevant to clinicians, rather than outcomes from the patients’ perspective. It is uncertain whether success/survival figures from historical studies performed on different cohorts in different settings, help individual patients make treatment decisions relevant to them. Would they find other patients’ self-reported outcomes more helpful to their decision making?
2.2 The significance of measuring Oral Health-Related Quality of Life (OHRQoL)

There has been a shift in health care towards investigating patient reported outcomes to evaluate effect of treatment on OHRQoL. A study assessing the value and use of QoL studies in primary dental care outlined the benefits to patients, dentists and commissioners (McGrath and Bedi, 1999). Patients noted improved communication and understanding, as QoL tools provided methods to describe and quantify their own dental problems. The authors recognised that QoL indicators were a valuable measure of treatment quality as it demonstrated the quality of dental treatment to, ‘restore function, prevent disability and attain the goal of oral health.’ In terms of commissioning dental services, traditionally DMFT (decayed, missing filled teeth), community periodontal index of treatment needs (CPITN) or basic periodontal exam (BPE) measures have been used, but these only assess disease, whilst QoL indicators also assess the social and psychological impact of oral health.

A systematic review analysed responses to the research question: is tooth loss associated with impairment of people's OHRQoL, and what is the role of both the location and distribution of tooth loss in this relationship? (Gerritsen et al., 2010). Thirty-five studies were included in the study, including two studies that reported OHIP data as mean total scores from three different samples containing 12,965 subjects. The subjects were split into groups with regards number of teeth remaining and it was shown that, the fewer teeth
present, the higher the impact on OHRQoL, with a marked deterioration once the number of remaining teeth drops below seventeen teeth. This outlines the importance of maintaining teeth via endodontic treatment, which has a positive effect on patients’ OHRQoL.

2.3 A brief history of the development of PROMs

2.3.1 Defining health and Health-Related Quality of Life

The definition of health by the World Health Organisation (WHO) is, “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”

Health includes both physical and mental well-being, but health is often seen in purely the illness model. Health-related quality of life (HRQL) is a way to ensure that physical, mental and social well-being are valued, and was described as follows; “it moves beyond the direct manifestations of illness to study the patient’s personal morbidity – that is, the various effects that illnesses and treatments have on daily life and life satisfaction” (Muldoon et al., 1998). This definition of HRQL states the direct link between illnesses and their treatment, and the area that HRQL captures.

There have been numerous definitions of oral health. A definition was outlined stating that oral health was concerned with “the functioning of the
oral cavity and the person as a whole… and with subjectively perceived symptoms, such as pain and discomfort,” (Locker, 1989). The definition was later extended to be more specific and comprehensive by declaring, “when talking about oral health, our focus is not on the oral cavity itself, but on the individual and the way in which oral disorders, diseases and conditions threaten health, well-being and quality of life” (Slade et al., 1996).

There is general agreement that disease, health and quality of life are distinct concepts. However, “whether the measures developed for use in oral research and practice should be considered to be indicators of health status, or indicators of health-related quality of life is somewhat uncertain” (Locker et al., 2002).

### 2.3.2 The first use of PROMs

PROMs were first utilised to examine patients’ perceptions of their own health in the 1970s. Cohen and Jago recognised that indices of oral health status were via clinical assessment such as caries, periodontal disease, malocclusion. They recognised the need to develop social indicators in the form of a global social health index (Cohen and Jago, 1976). Five years later, Sheiham and Croog acknowledged that although dental disease was highly prevalent, its impact on individuals had not been adequately examined (Sheiham and Croog, 1981). In addition to this, the study recognised that measurements of dental impairment and their effects were very limited. The authors felt dentistry had advanced with regards technology and treatment
innovation, but had not improved its knowledge of the social, psychological and economic effects of dental disease and oral impairment. An example of this was shown when a national survey in New Zealand uncovered for the first time that the lower a patient’s socio-economic status, the greater the degree of edentulousness, something now taken for granted as a social phenomenon (Davis, 1981).

A scale for measuring general health perception was made, featuring 36 questions surveying, ‘people’s perceptions concerning their own health.’ relating to current health, prior health, health outlooks, concerns and attitudes towards going to the doctor (Ware, 1976). Subsequently, a plethora of different tools has been developed in healthcare to try and capture PROMs.

In 1988, a paper detailed a conceptual framework of measuring oral health (Locker, 1988). This was used during the formulation of sections of the OHIP-14, as illustrated in Figure 2.1 (Slade, 1997). It was based on the WHO classification of impairment, disability and handicap, and aimed to encapsulate all possible functional and psycho-social outcomes of oral disorders (W.H.O., 1980).

People who lose teeth are impaired (they lose a body part) but this also causes disability (such as difficulty speaking or chewing) and handicap (for example, reduced social contact and interaction due to embarrassment with dentures). Locker’s publication of the conceptual model of oral health helped develop research in this area of dentistry. Until that time, oral health and
psychosocial well-being had not been researched, because oral conditions are rarely life threatening and the oral cavity is dissociated from the rest of the body when considering overall health (Allen, 2003).

Figure 2.1 Locker's conceptual model of oral health (Locker, 1988).

It has since been demonstrated that oral disorders do cause significant psycho-social and emotional consequences, with an estimation made in a 1984 study of 160 million work hours a year lost in the USA due to oral disorders (Reisine, 1984). A study comparing baseline quality of life scores of patients with temporomandibular disorders (TMD) and cardiac disorders highlighted a greater disability with regards sleep, rest, social interaction and communication in the TMD group (Reisine et al., 1989).

### 2.4 Use of PROMs in NHS medical services

The use of PROMs has taken a more prominent role in the NHS since April 2009. Since this time, PROMs have been recorded before and after four
different surgeries (data collection for varicose vein and groin hernia surgery ceased on 1st October 2017):

1. Hip replacements
2. Knee replacements
3. Varicose vein surgery
4. Groin hernia surgery

Around 250,000 patients undergo these surgeries and an estimated 80% response rate was achieved. The procedures themselves cost £800 million per year to perform. The UK department of health is also considering implementing PROMs in mental health and cancer care patients, as well as those with chronic conditions (asthma, COPD, diabetes, epilepsy, heart failure and stroke) (Devlin et al., 2010).
2.4.1 EQ-5D tool

The European Quality of Life – 5 dimension questionnaire (EQ-5D-3L) measures anxiety/depression, mobility, self-care, usual activities and pain/discomfort. Each question is graded 1-3 (no problems, some problems or extreme problems) giving an overall score between 5 and 15. The EQ-5D-5L was later developed giving a wider variation of answers to the five dimensions. The EQ-5D-3L was chosen as the generic tool to measure PROMs in hip and knee replacements, varicose vein and groin hernia surgery (see section 2.4). This is the most widely used instrument of its kind in the UK and Europe (Brooks, 1996). Following this, patients provide an assessment of their health state on a visual analogue scale (VAS) from 0-100. A disease-specific tool alongside EQ-5D highlighted specific PROMs to that procedure, such as the Oxford Knees Score PROM following knee replacements.

2.5 Historical oral health-related quality of life measures

A conference titled Measuring Oral Health and Quality of Life took place in June 1996, where a number of presentations were made discussing methods of measuring oral health related quality of life, aiming to educate and align professionals who had been using different tools to measure oral health outcome research (Slade et al., 1996). The conference was organised to
unite two groups of researchers who had previously been working independently of each other:

1. Psychometric and social survey researchers

2. Clinical / health service researchers

The social survey researchers had spent time developing instruments to measure OHRQoL, whilst the clinical researchers had focused on clinical services and trials, thereby utilising these instruments.

It was identified that key terms to OHRQoL and patient focused research had not been clearly defined. A key term requiring definition was oral health, described as, “a comfortable and functional dentition which allows individuals to continue in their desired social role” (Dolan, 1993). This definition is more patient centred, whilst traditional definitions of oral health are more clinically focused describing oral health, using terms such as caries free or healthy gums. The second key term is quality of life, defined as, “the degree to which a person enjoys the important possibilities of life” (Raphael et al., 1996), or in other words, how much do you enjoy your life?

In conclusion, quality of life is more than simply health, and poor health does not necessarily mean poor quality of life (consider patients with chronic illness/disability who still rate their quality of life highly).

2.5.1 Choosing a PROMs tool

Within oral health research, the tools used to measure OHRQoL have been widely discussed with a vast amount of tools created and trialled. Both generic and disease-specific tools have been generated, and utilised. The
benefits of generic measures are that the psychometric properties of the measure are better understood, validated, and comparisons can be made between populations (for example OHIP-14). However, generic scales may lack sensitivity to specific oral health disorders, as demonstrated by (Allen et al., 2001). This paper aimed to assess the responsiveness of the sensitivity to change of the Oral Health Impact Profile using different scoring methods. The study involved three groups:

1) Edentulous patients with history wearing conventional dentures, who requested and received implant retained dentures.

2) Edentulous patients with history wearing conventional dentures, who requested implant retained dentures, but received conventional dentures.

3) Edentulous patients who requested replacement of their conventional dentures.

Prior to beginning treatment, patients completed the OHIP-49 and a denture satisfaction questionnaire. The denture satisfaction questionnaire involved rating denture satisfaction on a Likert scale from 1 (totally satisfied), to 5 (not at all satisfied). Following treatment, the questionnaires were repeated and the mean change in score was analysed using Paired samples t Test.

The study showed that OHIP was able to detect changes between patients’ in the three treatment groups, highlighting those that would most benefit from implant-retained dentures. The aim of the study was to detect how well the test detected changes following treatment, and results showed the greatest satisfaction occurred in patients who received the treatment they requested.
At baseline, denture satisfaction questionnaire scores were similar across the three groups, which is unsurprising as they all requested new dentures. This test did not capture effect on quality of life as effectively as the OHIP. This suggests using solely the denture satisfaction questionnaire may fail to highlight the true effect of the clinical intervention.

A medical publication produced a catalogue assessing the psychometric properties of tools designed for disease-specific measurement of QoL (Bowling, 1995). This document proposed that both a disease-specific and generic measurement were required in evaluating QoL. The main benefit of a disease-specific measure is to improve knowledge surrounding the impact of therapeutic interventions on health-related quality of life.

### 2.5.2 Sickness Impact Profile

The Sickness Impact Profile (SIP) attempted to develop a measure of health status that had multiple dimensions and was based on patient behaviours (Gilson et al., 1975, Bergner et al., 1976). The questionnaire was made by analysing reports from patients’ with behaviour dysfunction, as well as health care workers and healthy individuals. However, the SIP’s main limitation was the length of time it took to complete (30 minutes). It was also a generic measure of health status, but was lacking sensitivity to all oral health problems (Locker, 1988). Locker indicated that the measure highlighted the impact of acute and chronic pain conditions, but did not measure specific effects such as tooth loss.
2.5.3 Social Impacts of Dental Disease

The Social Impacts of Dental Disease (SIDD) was developed in the 1980s, focusing on physical, social and psychological health status, with solely the psychological aspect being measured by the patient (Cushing et al., 1986). Qualitative interviews were used to develop the psychosocial impact of dental disease based on five categories: eating restrictions, communication restrictions, pain, discomfort and aesthetic dissatisfaction (as shown in Figure 2.2). Questions were asked within each group with a score of 1 for a positive answer, with the total value of the 5 groups giving a score of 0-5. This formed the basis of the later development of the OHIP questionnaire (see section 2.4.5).

<table>
<thead>
<tr>
<th>Impact Category</th>
<th>Items†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Functional</strong></td>
<td></td>
</tr>
<tr>
<td>Eating</td>
<td>• difficulty chewing&lt;br&gt;• difficulty biting hard&lt;br&gt;• difficulty taking a big bite&lt;br&gt;• having to change types of food eaten</td>
</tr>
<tr>
<td><strong>Social Interaction</strong></td>
<td></td>
</tr>
<tr>
<td>Communication</td>
<td>• difficulty or restriction talking&lt;br&gt;• difficulty or restriction smiling&lt;br&gt;• difficulty or restriction laughing&lt;br&gt;• difficulty or restriction kissing</td>
</tr>
<tr>
<td><strong>Comfort and Well-being</strong></td>
<td></td>
</tr>
<tr>
<td>1. Pain</td>
<td>• toothache or pain currently or in previous 12 months</td>
</tr>
<tr>
<td>2. Discomfort</td>
<td>• sensitivity to cold&lt;br&gt;• food packing&lt;br&gt;• denture discomfort currently or in previous 12 months</td>
</tr>
<tr>
<td><strong>Self Image</strong></td>
<td></td>
</tr>
<tr>
<td>Aesthetics</td>
<td>• dissatisfaction with teeth in relation to other features of appearance&lt;br&gt;• dissatisfaction with appearance of dentures</td>
</tr>
</tbody>
</table>

* A score of 1 is given to the impact category if a positive response has been given to any of the items in the category.

Total Impact Score (0-4) = Sum of categories eating, communication, pain and aesthetics

Total Impact Score (0-5, including discomfort) = Sum of categories eating, communication, pain, discomfort and aesthetics.

† Examples of questions used are:

Are there any types of food you have difficulties chewing? If yes, what food?

Have you had to change the kinds of food you eat because of your teeth or dentures?

Have you any pain from your teeth or gums now or in the past 12 months? If yes, did this trouble interfer with anything you normally do like doing your work, eating normally, sleeping or going out?

Would you say you try to avoid showing too much of your teeth when talking, smiling or laughing?

Figure 2.2: Questions and subgroups SIDD questionnaire (Slade et al., 1996).
2.5.4 Geriatric Oral Health Assessment Index

A measurement of patient-reported oral functional problems was formed to test psychosocial impacts of oral diseases in patients aged over 65 (Atchison and Dolan, 1990). The Geriatric Oral Health Assessment Index (GOHAI) consisted of 12 questions (answered on a Likert scale), formed from previous questionnaires, reviews of the literature and consultations with health providers (see Figure 2.3). The test had good validity and reliability, and was later used for all ages rather than solely geriatric patients.

<table>
<thead>
<tr>
<th>GOHAI (mean, sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>How often did you limit the kinds or amounts of food you eat because of problems with your teeth or dentures?</em></td>
</tr>
<tr>
<td><em>How often did you have trouble biting or chewing any kinds of food, such as firm meat or apples? How often were you able to swallow comfortably?</em></td>
</tr>
<tr>
<td><em>How often have your teeth or dentures prevented you from speaking the way you wanted? How often were you able to eat anything without feeling discomfort?</em></td>
</tr>
<tr>
<td><em>How often did you limit contacts with people because of the condition of your teeth or dentures? How often were you pleased or happy with the looks of your teeth and gums, or dentures?</em></td>
</tr>
<tr>
<td><em>How often did you use medication to relieve pain or discomfort from around your mouth? How often were you worried or concerned about the problems with your teeth, gums or dentures?</em></td>
</tr>
<tr>
<td><em>How often did you feel nervous or self-conscious because of problems with your teeth, gums or dentures?</em></td>
</tr>
<tr>
<td><em>How often did you feel uncomfortable eating in front of people because of problems with your teeth or dentures?</em></td>
</tr>
<tr>
<td><em>How often were your teeth or gums sensitive to hot, cold or sweets?</em></td>
</tr>
</tbody>
</table>

Figure 2.3 GOHAI index questions (Slade et al., 1996).

The questions in GOHAI are similar to those subsequently used in OHIP-14. This is because new tools were being formulated by utilising and adjusting existing tools to suit the cohort of patients being treated, such as the GOHAI.
focusing on questions relevant to older patients. It is interesting that following early studies showing good validity and reliability of the tool, its use was then extended to an all age sample in Los Angeles (Atchison et al., 1998). The tool remained a useful and accurate indicator of self-reported oral functional problems.

2.5.5 Dental Impact Profile

The Dental Impact Profile (DIP) was developed to answer the question of “how much do teeth and the mouth matter in people’s lives?” DIP was developed following qualitative questioning and interviewing of dentists and the public (see Figure 2.4). Twenty-five questions were included, after being flagged as important by over 50% of the tested sample (Strauss and Hunt, 1993). Four subscales in this tool were:

1) Eating
2) Health / well-being
3) Social relations
4) Romance

Four scores were calculated based on responses to the 25 questions, providing an overall profile score based on the number of positive and negative responses. Previous measures had focused on life quality, whilst this highlighted impact on life, whether positive or negative.

This tool was simple and short, allowed for both positive and negative responses, and measured self-perceived health. However, it did not measure
dental disability/dysfunction and required an interviewer which was inconvenient (Slade et al., 1996).

Figure 2. 4 Questions from Dental Impact Profile (Strauss and Hunt, 1993).

<table>
<thead>
<tr>
<th>Question</th>
<th>Response codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. feeling comfortable</td>
<td>1. Good Effect</td>
</tr>
<tr>
<td>2. having confidence around others</td>
<td>2. Bad Effect</td>
</tr>
<tr>
<td>3. eating</td>
<td>3. No Effect</td>
</tr>
<tr>
<td>4. lasting</td>
<td></td>
</tr>
<tr>
<td>5. living a long life</td>
<td></td>
</tr>
<tr>
<td>6. chewing and biting</td>
<td></td>
</tr>
<tr>
<td>7. appearance to other people (how you look to others)</td>
<td></td>
</tr>
<tr>
<td>8. moods</td>
<td></td>
</tr>
<tr>
<td>9. kissing</td>
<td></td>
</tr>
<tr>
<td>10. general health</td>
<td></td>
</tr>
<tr>
<td>11. attendance at activities</td>
<td></td>
</tr>
<tr>
<td>12. success at work</td>
<td></td>
</tr>
<tr>
<td>13. appetite</td>
<td></td>
</tr>
<tr>
<td>14. smiling and laughing</td>
<td></td>
</tr>
<tr>
<td>15. having sex appeal</td>
<td></td>
</tr>
<tr>
<td>16. facial appearance (how your face looks to you)</td>
<td></td>
</tr>
<tr>
<td>17. social life</td>
<td></td>
</tr>
<tr>
<td>18. enjoyment of eating</td>
<td></td>
</tr>
<tr>
<td>19. speech</td>
<td></td>
</tr>
<tr>
<td>20. breath</td>
<td></td>
</tr>
<tr>
<td>21. foods you chose to eat</td>
<td></td>
</tr>
<tr>
<td>22. enjoyment of life</td>
<td></td>
</tr>
<tr>
<td>23. romantic relationships</td>
<td></td>
</tr>
<tr>
<td>24. general happiness</td>
<td></td>
</tr>
<tr>
<td>25. weight</td>
<td></td>
</tr>
</tbody>
</table>

2.5.6 The development of Oral Health-Related Quality of Life–UK (W)

Researchers in Hong Kong carried out evaluation of a measure aiming to assess both the ‘effect’ and ‘impact’ of oral health on life quality (McGrath and Bedi, 2001). This was carried out to provide a measure that was patient-centred, as previous tools had reflected the professions values of what health is, or only asked a small non-random sample of patients their opinion (often older, dentally ill patients). In addition to this, the existing oral health
measures focused on negative effects, which was potentially narrowing the conceptualisation of health, which should also include positive effects with regards ability, function and social adjustment. Finally, the authors of Oral Health-Related Quality of Life–UK (OHQoL-UK) wanted to measure the impact (weighting) of an effect, rather than just assess prevalence.

To test this new tool, a large random probability sample in the UK (n=1865) were questioned, and 16 key areas of oral health were identified. Five hundred adults were then interviewed and each of the 16 questions were scored both regarding effect (from bad to good) and impact (from none to extreme). The data were analysed and showed that 80% of participants 'perceived their oral health as impacting on their quality of life.' Interestingly, it was more common for respondents to report that their OHRQoL led to enhanced rather than reduced QoL. This positive dimension of OHRQoL had not previously incorporated this positive dimension.

![Example question from OHQoL-UK](W)

Figure 2. 5 Example question from OHQoL-UK (W)
2.5.7 Development of Oral Health Impact Profile

Questionnaire tools were developed in slightly different circumstances for different populations with regards age, ethnicity, socio economic status and type of dental disease. However, the similarities and shared themes between them provided a sound foundation to the development of the Oral Health Impact Profile (Slade and Spencer, 1994).

OHIP brings together many aspects and questions from the tools discussed, and has become the dominant tool in OHRQoL research, possibly because it found the right balance between previous tools, but being generic, functions in all fields of dentistry.

The OHIP aimed to provide a thorough measure of self-reported dysfunction, discomfort and disability attributed to oral conditions. The OHIP focuses on impairment, and three functional status dimensions (social, psychological and physical) which form four of the seven domains that comprise health-related quality of life (Patrick and Bergner, 1990).

The OHIP was developed by first deciding on a conceptual model (Locker’s model of oral health) (Locker, 1988) and then forming questions around each dimension. Seven dimensions of impact were defined as:

1) Functional limitation
2) Physical pain
3) Psychological discomfort
4) Physical disability
5) Psychological disability
6) Social disability
7) Handicap
The model was based on the World Health Organisation’s classification of disease, impairments and disabilities (W.H.O., 1980). The original tool had 49 questions, formed following interviewing of 64 volunteers in Australia with open-ended questions. Resulting from the interviews were 535 statements and following analysis, 46 of these unique statements were then categorised within the seven domains. Three additional statements were adapted for use to bring the total to 49. This was a major advantage of the tool, as the statements were patient-derived as opposed to being designed by researchers.

Volunteers who were members of community groups or university students in Adelaide carried out weighting of statements. This weighting procedure was also performed in Ontario and Quebec with broadly similar results. The 49 statements were rephrased as questions, and patients asked to respond via a 5-point Likert scale ranging from: 0 (never), to 4 (very often). Three of the questions referred to dentures, with non-wearers omitting those questions. Data collected in South Australia was reanalysed to form and validate the short form OHIP-14 questionnaire (Slade, 1997). A sample of 1650 people aged over 60 years old took part in face-to-face interviews, with a calculated mean score per question. Statistical analysis identified 14 key questions, and testing of the shortened tool’s validity was investigated, by assessing whether its associations with sociodemographic and clinical variables were similar to the associations between the full OHIP-49 with the same variables.

Although this tool is regarded as being highly calibrated, reliable and specific, 3 of the 49 questions were actually added by the author to round up the total
to 49 (7 per domain) with no scientific research supporting this. Additionally, the shorter OHIP-14 validation was on a sample of people over 60, but is now used throughout all age groups routinely. Following the reduction of the OHIP to OHIP-14, the new tool was tested for responsiveness, validity and reliability in edentulous patients (Awad et al., 2008). The study found that although the responsiveness (namely the ability of the tool to detect change) of the tool was unchanged, it led to a reduction in reliability and validity of the tool.

Despite these limitations, OHIP-14 has become the most commonly used general measure of OHRQoL, and has been translated and validated into many different languages around the world (Xin and Ling, 2006).

### 2.5.8 Pain measures

The measurement of pain has been carried out using a VAS since it was first introduced in the Lancet journal in 1975 (Huskisson, 1974). Visual analogue scales are considered the ‘gold standard’ technique of pain measurement, used particularly in pain-related research. The commonest form consists of a 100mm unmarked line with standardised wording: on the left of the line ‘no pain’, and on the right ‘worst pain imaginable.’ The patient then places a mark on the line representing their level of pain.

Another measure of pain is the McGill pain questionnaire (MPQ) which is a self-reported questionnaire that provides description of the intensity and degree of pain a patient is experiencing. The questionnaire involves a list of
78 words in 20 sections that are all pain related. The users highlight the words that best define their pain, covering sensory, affective, evaluative and miscellaneous components of pain. Each of the words in the groups has a ranking, used to give an overall score. For example, if thermal properties of pain are being assessed, ‘searing’ carries a higher score than ‘hot’ (Melzack, 1975).

A study compared patients with pulpitis and pericorinitis using the MPQ and the VAS, testing whether they could be used in general dental populations (Seymour et al., 1983). Fifty participants in each group filled in three pain VAS measuring level of pain historically, presently, and at its most intense. The MPQ focused on choosing words to describe pain, ascertaining the degree of pain patients were experiencing. The findings of this study were that women reported higher levels of pain, and the MPQ was more sensitive at recording pain than the pain VAS. However, VAS scales are still the predominant pain measure in dentistry.

Pain VAS validity testing revealed a 13mm change in pain severity (that is to say a change in score of at least 13) is the minimum difference in VAS scores that can reflect clinically significant change in patient pain severity (Gallagher et al., 2001, Todd et al., 1996). Participants were those seen on an emergency ward who were asked to complete the VAS scales every 20 minutes and asked to indicate whether they had, “much less,” “a little less,” “about the same,” “a little more,” or “much more” pain.
In general health care, the Hospital Anxiety and Depression Scale (HADS) is a highly validated scale across a number of healthcare settings, which assesses risk of anxiety and depression in hospital or community. The HADS scale consists of 14 items—seven for anxiety and seven for depression. Each item scores from 0-3 points. A total score of more than eight out of 21 for anxiety and/or depression represents clinically significant risk in these entities, with score-related ranking of severity as mild (8–10), moderate (11–15), and severe (16–21). (Bendinger and Plunkett, 2016).

2.5.9 Anxiety measures

Anxiety in dentistry has been measured by a number of tools, the most common being the Modified Dental Anxiety Score (MDAS), which consists of 5 questions with 5 ratings ranging from “not anxious” to “extremely anxious.” It was based on an earlier system called Corah’s Dental Anxiety Scale (CDAS) (Corah, 1969). An anxiety VAS was tested to compare 45 patients undergoing extraction, who completed both the MDAS scale and VAS scale. The study reported that both scales provided similar outcome measures, but that patients found VAS scales easier to use and complete. This study found that the VAS scale was accurate at detecting changes in anxiety, with comparable sensitivity and specificity to MDAS (Luyk et al., 1988).

In conclusion, there are a large number of dental measures of PROM, but none of these measures is ideally suited to measure OHRQoL of patients’ undergoing endodontic treatment, as none of the measures discussed cover all topics of importance when capturing endodontic PROMs.
2.6 Literature on endodontic fear, anxiety and pain

2.6.1 Measuring endodontic fear and anxiety

An endodontic fear survey was created in 1988 in USA measuring patients’ pre-treatment anxiety level, which then asked a series of questions directly related to aspects of the treatment, to ascertain if the patients anxiety dropped (LeClaire et al., 1988). Anxiety levels of patients were reported to have dropped by 44%, but the most unpleasant experiences related to injections, the sensation of files in the canal and tapping on a sore tooth. The results of this study should be viewed cautiously as the research question was adapted following treatment and seems to have been judged subjectively by the author.

Endodontic patients undergoing non-surgical and surgical treatment were compared for their levels of treatment-induced stress by measuring heart rate and blood pressure (Georgelin-Gurgel et al., 2009). There were no statistically significant associations found between patient-reported levels of pain, stress and discomfort. This highlights that the type of treatment should not affect the results reported by the participants, although patients may be more anxious before undergoing surgical treatment, as this is an unknown entity to many.

Anxiety before endodontic treatment was analysed using CDAS in a sample of 200 patients in Pakistan, with 45% showing high or severe levels of anxiety pre-treatment (score of ≥13 on CDAS) (Wali et al., 2016). However, the study did not assess levels of anxiety post-treatment stating that there was no current tool to measure post-treatment anxiety.
A systematic review of anxiety related to non-surgical root canal treatment was carried out in 2016. Meta-analysis of 18 articles containing 1989 subjects gave a pre-treatment anxiety score of 39±9 on a 100-point scale. A meta-analysis of 4 articles containing 232 subjects gave a post-treatment anxiety rating of 27±5, representing a 30% reduction in anxiety (Khan et al., 2016).

### 2.6.2 Measuring endodontic pain

The incidence of pre-operative and post-operative pain in 1204 teeth, of 803 patients was investigated (Genet et al., 1986). Pain was measured on a three-point scale of no pain, moderate pain or severe pain. Moderate post-operative pain was experienced by 23% of patients following the initiation of endodontic therapy, with 7% experiencing severe pain. A key finding was the strong positive correlation between pre-operative and post-operative pain. This paper summarised that pre-operative pain scores are a prerequisite for studies observing pain levels.

Measurements and/or prevalence of pain were used to assess various different sections of endodontic treatment. Pain has been used as a measure for the efficacy of endodontic file systems, as discussed in a systematic review (Sun et al., 2018), and a randomised clinical trial assessing post-operative QoL following single visit RCT using either rotary or reciprocating instrumentation (Pasqualini et al., 2016). Post-operative pain in relation to
single and multiple visit endodontics formed a systematic review, indicating evidence is lacking in this area (Sathorn et al., 2008).

A systematic review was carried out to investigate pain prevalence and severity before, during and after non-surgical RCT (Pak and White, 2011). Pain 1 week post-treatment had dropped from a pre-treatment value of 28% to 14%. Severity decreased from 54/100 to 5/100 1 week post-treatment. However, being a systematic review, each study included had slightly different parameters and designs. Rather than measuring pain before and after treatment, Watkins et al compared anticipated to experienced pain following RCT (Watkins et al., 2002). Pain VAS measure determined that pain experienced was less than expected, although women anticipated more pain and younger patients both experienced and anticipated more pain. This highlights the perceptions of patients’ regarding endodontics, which is borne out of longstanding beliefs surrounding treatment discomfort.

A common observation from recent endodontic publications is the use of patient-reported post-operative pain measures to assess the success of a treatment. This method has analysed responses to two different treatment regimes, such as the reported pain from management of grossly carious teeth with mineral trioxide aggregate (MTA) pulpotomy vs RCT (Galani et al., 2017), or pain reported comparing manual vs mechanical glide path performed during RCT (Pasqualini et al., 2012). Patients with irreversible pulpitis, or pulpal necrosis with/out apical periodontitis were included leading to a sample size of 280. Patients were randomly allocated to the two
treatment arms, with treatment provided by twenty-one endodontic postgraduates. A five level pain scale was then used to evaluate pain severity, ranging from 0 (no pain) to 5 (extremely severe pain). Glide path preparation with mechanical instruments was reported to be less painful, but there were a number of other variables that must be accounted for, such as high number of operators which may decrease standardisation, and individual anatomy, host response, bacterial load and so on.

2.7 Overview of quantitative endodontic PROMs

Endodontics is a commonly required treatment, with the sequelae of root canal infection (pain, swelling or suppuration) convincing patients to visit the dentist. It is clear that toothache and endodontic treatment effects patients’ QoL with regards their oral health. A study investigated two groups of patients for satisfaction and quality of life following endodontic treatment (provided by either a generalist or an endodontist) (Dugas et al., 2002). Questionnaires were completed by patients aged between 25 and 40 treated at dental facilities in Toronto or Saskatoon. Data was gathered in the form of 17 questions chosen from the OHIP-49 and a semantic differential scale questionnaire measuring treatment satisfaction (see Figures 2.6 and 2.7). If OHIP responses improved post-treatment, a score of 1 was given so that a maximum score of 17 could be scored. Significant improvements in pain and quality of life were seen, more so when endodontists provided the treatment. However, the methodology limited the studies value, as the change in QoL may be stated as improved, with no improvement felt by the patient. For
example, in answering the question, ‘Have you had any trouble pronouncing words because of your teeth and mouth?’ the patient could choose the following answers; 4 = very often; 3 = fairly often; 2 = occasionally; 1 = hardly ever; and 0 = never. If the patients’ pre-treatment response was ‘very often’ and post-treatment response was ‘fairly often,’ this was recorded as an improvement in quality of life. Nevertheless, the patient may have viewed this ‘improvement’ insignificant to them. (Dugas et al., 2002).

<table>
<thead>
<tr>
<th>Conceptual Dimension</th>
<th>Item</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional limitation</td>
<td>Have you had trouble pronouncing words because of your teeth and mouth?</td>
</tr>
<tr>
<td>Physical pain</td>
<td>Have you felt that your sense of taste has worsened because of your teeth or mouth?</td>
</tr>
<tr>
<td></td>
<td>Have you had painful aching in your mouth?</td>
</tr>
<tr>
<td></td>
<td>Have you found it uncomfortable to eat any foods because of your teeth or mouth?</td>
</tr>
<tr>
<td>Psychological discomfort</td>
<td>Have you had to alter the temperature of the foods that you eat because of your teeth or mouth?</td>
</tr>
<tr>
<td>Physical disability</td>
<td>Have you felt tense because of your teeth or mouth?</td>
</tr>
<tr>
<td></td>
<td>Has your diet been unsatisfactory because of your teeth or mouth?</td>
</tr>
<tr>
<td>Psychological disability</td>
<td>Have you had to interrupt meals because of your teeth or mouth?</td>
</tr>
<tr>
<td>Social disability</td>
<td>Have you been self-conscious because of your teeth or mouth?</td>
</tr>
<tr>
<td></td>
<td>Have you felt tense because of your teeth or mouth?</td>
</tr>
<tr>
<td>Handicap</td>
<td>Have you been embarrassed because of your teeth or mouth?</td>
</tr>
<tr>
<td></td>
<td>Have you been unable to fall asleep because of your teeth or mouth?</td>
</tr>
<tr>
<td></td>
<td>Have you ever been awakened by problems with your teeth or mouth?</td>
</tr>
<tr>
<td></td>
<td>Have you had difficulty doing your usual jobs because of problems with your teeth or mouth?</td>
</tr>
</tbody>
</table>

Figure 2. 6 Seventeen questions used from OHIP-49 (Dugas et al., 2002).

My endodontic treatment was...

- 1 = very expensive, 10 = very inexpensive
- 1 = very time-consuming, 10 = very quick
- 1 = very painful, 10 = very pain free
- 1 = very poor aesthetics, 10 = very good aesthetics
- 1 = very poor chewing ability, 10 = very good chewing ability
- 1 = very unpleasant, 10 = very pleasant

I was...

- 1 = very very dissatisfied, 10 = very very satisfied

Figure 2. 7 Questionnaire assessing QoL post endodontics (Dugas et al., 2002).
A number of studies were published regarding OHRQoL on a population treated at Hong Kong University, beginning with a case control study in 2012 comparing endodontic and routine periodontal patients (control) (Liu et al., 2012). OHIP-14 assessed OHRQoL, and the General Health Questionnaire 12 (GHQ-12) tested psychological well-being. OHRQoL was shown to be impaired in those attending for endodontic treatment, to a greater magnitude than patients in periodontal maintenance.

A prospective longitudinal study of patients’ undergoing endodontic treatment measured PROMs by completing OHIP-14 at baseline, 1 month post-treatment, and 6 months post-treatment. Radiographs at baseline and 6 months were compared to the OHIP scores, with an association found between reduced OHIP-14 scores and radiographic healing. The domains that showed improvement, physical pain, physical disability and handicap also correlated with the changes in the periapical (PA) radiographs (rated by PAI score) (Liu et al., 2014b). However, it is questionable whether the use of the generic OHIP-14 measure is the best measure to capture endodontic PROMs.

A third study investigated the key endodontic factors with relation to OHRQoL (Liu et al., 2014a), finding that participants’ age, multiple teeth requiring RCT and pain VAS rating were significant factors leading to worsened OHRQoL.
Quality of life studies are being utilised in endodontic microsurgery to assess healing and post-operative pain. A randomised clinical study compared two different incision techniques for effect on quality of life (Del Fabbro et al., 2009). This topic was investigated as endodontic surgery has evolved from purely being concerned with surgical management of pathology, to also aiming to preserve and maintain periodontal support and aesthetics. Forty patients were enrolled in the study with randomisation allocating twenty to have a sulcular-base incision and twenty to have a papilla-base incision. Patients then recorded pain levels on a VAS, and answered questions about impairment of common activities (effect on sleeping, chewing, phonetics, daily routine and missed work) on a five-point scale. Questionnaires were completed daily for one week.

Patients preferred the papilla-based incision as PROMs reported significantly reduced pain levels and analgesic use from day 3 post-surgery. This is an interesting and important use of PROMs to guide clinical management, as this area of endodontic microsurgery has been studied extensively, aiming to find the optimal technique to minimise periodontal recession post-surgery (Velvart et al., 2003, Velvart et al., 2004, von Arx et al., 2011). This study utilised patient reported outcomes to guide clinical management, whilst simultaneously measuring the clinical outcomes of periodontal recession, aiming to lessen the impact of dental surgery for the patient.
2.8 Overview of qualitative endodontic PROMs

OHRQoL studies rely on patients’ perceptions, thoughts and desires, and qualitative research is a helpful technique to detect these views. Focus groups were used to compare patients QoL following endodontic treatment of a single tooth, or replacement with an implant-supported restoration (Gatten et al., 2011). Thirty-seven patients were recruited, with treatment completed at least 1 year earlier. Patients completed the OHIP-14 before the 90-minute semi-structured discussion group. The interview schedule is shown in Figure 2.8. The main themes that endodontic patients reported (see Figure 2.9), were a desire to maintain their teeth, learning from experiences of other family members who have lost teeth, and a desire to look after their teeth more diligently since having treatment. Patients reported being surprised at the lack of pain during root canal treatment, and others reported sensations but not pain during the procedure. Endodontic patients complained about how long they had to keep their mouth open, and complained of jaw soreness following the procedure. With regards function, some endodontic patients reported that they could now use the tooth in function. They did not report a large effect on aesthetics, especially when posterior teeth were treated.

OHIP-14 measures were only recorded post-treatment limiting their usefulness, as they could not be compared to pre-treatment values. Results of OHIP-14 were presented as percentages responding, “occasionally, fairly often or very often,” but “never and hardly ever” were not included.
1. Before you received your endodontic treatment or implant, how did you feel about the importance of keeping your own teeth?
2. Before your treatment, how often did you visit the dentist? What was your main reason for visiting the dentist?
3. After your treatment, how often have you visited the dentist? What has been your main reason for visiting?
5. How does your endodontically treated tooth or implant feel compared with your other teeth?
6. How does your endodontically treated tooth or implant affect your eating? Drinking? Does it feel different to eat or drink now?
7. How does your endodontically treated tooth or implant affect your appearance? How has it affected your appearance and smile?
8. Thinking back to the procedure when you had your endodontic treatment or implant, how would you rate the pain? What was your level of pain after the procedure? Currently?
9. Can you describe any issues or concerns with maintaining your implant or endodontically treated tooth?
10. If you had to go back for maintenance, how many times and what type of procedures were done?
11. Are you satisfied with the result of your root canal–treated tooth or implant?

Figure 2. 8 Interview schedule investigating endodontics vs implants (Gatten et al., 2011).

<table>
<thead>
<tr>
<th>RCT groups</th>
<th>Implant and RCT groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient with preoperative pain are happy with little or no pain during and after treatment</td>
<td>Both groups feel it is important to keep their teeth</td>
</tr>
<tr>
<td>Complain of having to open mouth a long time</td>
<td>Part of their overall health</td>
</tr>
<tr>
<td>Surprised of less pain with procedure than what they had heard from other people</td>
<td>Surprised of cost of crown on top of the treatment</td>
</tr>
<tr>
<td>The worst pain during treatment was from the anesthetic injection</td>
<td>Trouble flossing because of tight contact of new crown</td>
</tr>
<tr>
<td>Follow-ups are short appointments</td>
<td>Those with treatment in the anterior feel better esthetically</td>
</tr>
<tr>
<td>Peace of mind that infection is gone</td>
<td>Peer influence of getting respective treatment done</td>
</tr>
<tr>
<td>Tooth feels “numb”; no sensitivity to hot or cold</td>
<td>Minimal pain during treatment</td>
</tr>
<tr>
<td>No change in maintenance compared with the other teeth</td>
<td>Patients go to the dentist more regularly after treatment</td>
</tr>
<tr>
<td>Satisfied overall with treatment</td>
<td></td>
</tr>
</tbody>
</table>

Figure 2. 9 Themes highlighted during interviews (Gatten et al., 2011).
An example of the structural barriers patients face was deliberated in a Brazilian public health services study using semi-structured interviews and a field diary (Melgaco-Costa et al., 2016). The study was conducted in three Brazilian cities with similar socioeconomic indicators, which all had Dental Specialty Centres (DSC). The semi-structured interview schedule is shown in Figure 2.10.

<table>
<thead>
<tr>
<th>How many times did you come to the DSC to treat this tooth?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What was done during each session?</td>
</tr>
<tr>
<td>What is your opinion of the treatment received?</td>
</tr>
<tr>
<td>Approximately how long did you wait for endodontic treatment?</td>
</tr>
<tr>
<td>Would you recommend the treatment?</td>
</tr>
<tr>
<td>Did you finish the endodontic treatment of this tooth?</td>
</tr>
</tbody>
</table>

Figure 2.10 Interview schedule (Melgaco-Costa et al., 2016)

Ten interviews were completed until data reached saturation, and all were recorded and transcribed by the first author. The data were analysed using content analysis, where expressions and words led to the formation of central themes. Access to service and quality of service were identified as the themes of the interviews and discussed in detail.

Dentists have also been involved as participants in endodontic PROMs research. Twelve dentists participated in in-depth interviews investigating the behaviour of GDPs in their practice of endodontics (McColl et al., 1999). The interviews found that a key barrier to endodontic treatment quality was the NHS remuneration scheme, due to constraints on choice of techniques and materials, and effect on time available for treatment. Lack of endodontic
training (both undergraduate and postgraduate) was highlighted, with anxieties present in those with a lack of expertise, inexperience or inappropriate equipment or materials.

Fifty-two Australian endodontists were interviewed either face-to-face or by telephone to give their perceptions of single and multiple visit endodontic treatment (Sathorn et al., 2009). Semi-structured interviews lasting 15-20 minutes were completed. Patient, operator and biological factors were considered relevant to the decision between single and multiple visit treatment. The interview data were analysed using taxonomy (classification), a formal system for clarifying multifaceted complex phenomena, according to a set of conceptual domains and dimensions (Patton, 1999). The study concluded that multi visit treatment was preferred due to biological considerations (importance of calcium hydroxide interim measure), and endodontist preference due to treatment length.

### 2.8.1 Examples of qualitative data in implant dentistry

Telephone interviews were carried out for nine patients who had attended consultations with a restorative dental specialist regarding implant treatment in the UK (Grey et al., 2013). A semi-structured interview technique was used with calls ranging from 26-53 minutes. Call were recorded, transcribed and analysed using NVivo 9. Seven of the patients interviewed had completed implant treatment. One patient was midway through treatment,
and one had opted against treatment. The main themes centred on appearance and functioning, which the author termed ‘normality’. The study analysed expectations relating to implant treatment, and its effect on social and psychological domains, rather than changes in QoL following implant provision.

A systematic review of ‘qualitative interviews involving implant treatment,’ analysed ten studies of various methodologies (Kashbour et al., 2015). This project highlighted the depth of qualitative assessment of implant treatment, in contrast to endodontics, which has not been explored in detail by qualitative researchers.
CHAPTER 3 DEVELOPMENT OF PROMs TOOL FOR ENDODONTICS

3.1 Introduction

PROMs have seldom been utilised to measure outcomes in endodontics. Liu and McGrath investigated patient reported outcomes following endodontics in a prospective longitudinal study involving a sample of patients treated in a university in Hong Kong (Liu et al., 2014b), using OHIP-14 as the primary outcome to assess the change in PROMs following endodontic treatment.

The tool developed for piloting used OHIP-14, due to its previous validation for use in dentistry (Slade, 1997), and allowing assessment of the specificity and responsiveness of the VAS scales in relation to OHIP-14. Pain and anxiety are key measures with regards endodontic PROMs, and were measured using a pain VAS and anxiety VAS, which are validated measures that patients can quickly and easily complete (Huskinson, 1974, Luyk et al., 1988). The addition of the oral health state VAS was replicated from the EQ-5D tool which measures general health, adapted in this tool to capture the effect of endodontics on oral health state, in a more simple and user-friendly fashion than the OHIP-14.

To investigate PROMs in endodontics, a valid, specific and reliable tool is required. OHIP-14 is a generic tool that allows generalisable comparison across all fields of dentistry making it an excellent research tool. However, it
is not specific to endodontics and takes a long time to complete. Disease-specific tools are advantageous to generic tools as they are likely to be more responsive to change than a generic tool when focusing on a single disease entity (Sischo and Broder, 2011). The aim of this tool was to develop an endodontic-specific tool, allowing patients to accurately record self-reported outcomes using a disease-specific questionnaire tool.

### 3.2 Aims

- Design and test a PROMs tool for use in a prospective longitudinal study of patients requiring endodontic treatment.
- Facilitate power calculations for a prospective longitudinal study.

### 3.3 Method

An audit was designed using the form of a questionnaire and a series of Visual Analogue Scales (VAS). The audit was resisted and then approved, by the Royal Liverpool and Broadgreen University Hospitals NHS Trust (RLBUHT) clinical effectiveness team (see appendix 1). The audit focused on patient reported outcome measures following endodontics. The patients’ answered questions in paper format before and following endodontic treatment (RCT, ReRCT, apical surgery). The tool was designed following a review of the literature, and an assessment of the various PROMs measures in dentistry presented in Chapter 2.
Responses to the OHIP-14 questions were graded from 0-4 on a Likert scale, ranging from: 0-(never), 1-(hardly ever), 2-(occasionally), 3-(fairly often) to 4-(very often), giving a maximum score of 56 for the 14 questions combined.

As a more targeted endodontic tool, VAS scales were chosen because they are easy to interpret and do not take long to complete. Visual analogue scale for anxiety (VAS-A) had been validated against the MDAS measure in the past. Visual analogue scale for oral health state (OH-VAS) was a new measure adapted from the assessment of health state VAS used in the EQ-5D. Table 3.1 highlights the inclusion and exclusion criteria.

<table>
<thead>
<tr>
<th>INCLUSION CRITERIA</th>
<th>EXCLUSION CRITERIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Over 16</td>
<td>No vulnerable adults</td>
</tr>
<tr>
<td>Single RCT required</td>
<td>Routinely taking pain management medication</td>
</tr>
<tr>
<td>1-2 visits</td>
<td>Ongoing medical condition for example cancer</td>
</tr>
<tr>
<td>Male or female</td>
<td>Multiple teeth requiring RCT</td>
</tr>
<tr>
<td></td>
<td>Pts referred as difficult / challenging individuals</td>
</tr>
</tbody>
</table>

Table 3.1 Inclusion and exclusion criteria for Pilot study
The audit was active from February 2016 - May 2016, with thirty-five patients completing a pre-treatment questionnaire. Ten patients provided post-treatment data within one month of completing treatment. Forms were completed at the dental hospital on a paper OMR sheet (see Figure 3.1).

Figure 3. 1 Copy of pilot questionnaire on paper OMR sheet
3.4 Results

OHIP-14 mean pre-treatment value was 19 (±11), and decreased to 13 (±11) post-treatment, as shown in figure 3.2. Pain-VAS mean value was 21 (±21) pre-treatment, and 15 (±23) post-treatment. VAS-A mean value fell from 47 (±21) pre-treatment, to a post-treatment mean of 21 (±22). OH-VAS mean value indicated worsened oral health state with pre-treatment mean of 67 (±11) and post-treatment of 49 (±34), with changes in the mean displayed in Figure 3.3.

Figure 3. 2 Mean OHIP-14 compared pre and post treatment (max score 56)
Post-treatment data was only captured from 10 of the 35 patients who provided pre-treatment data, due to the audit deadline being reached. The pain VAS and VAS-A tools showed a mean reduction in PROMs, indicating an improvement in OHRQoL, as shown in Table 3.2. The decrease in anxiety was the most marked of all PROMs changes following treatment. OH-VAS underwent a mean reduction indicating worsened OHRQoL following treatment. The OHIP-14 tool exhibited a mean reduction post-treatment, indicating that patients OHRQoL improved following endodontic treatment.

<table>
<thead>
<tr>
<th>PER INDIVIDUAL SAMPLE IMPROVEMENT IN SCORE</th>
<th>OHIP-14</th>
<th>PAIN VAS</th>
<th>VAS-A</th>
<th>OH-VAS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>80%</td>
<td>60%</td>
<td>80%</td>
<td>30%</td>
</tr>
</tbody>
</table>

Table 3. 2 Individual comparison of sample pre and post treatment
3.5 Discussion

The results revealed decreased pain and anxiety following treatment, and a reduction in mean OHIP-14 score. However, oral health state decreased following treatment. It had been expected that an improvement in oral health state would be established, as patients’ oral health awareness and satisfaction grew following endodontics, in line with the OHIP-14 results.

The reason the OH-VAS score decreased was likely a result of poor wording of the question, which affected the validity of the results gathered. The 3 visual analogue scale questions were placed together. The pain and anxiety questions were worded as follows:

1) How much pain you are in, 0 being no pain to 100 worst pain imaginable
2) How anxious you are, 0 being not anxious at all to 100 most anxious I can imagine
3) What is your own oral health state today from 0-100? 0 being worst imaginable health state to 100 best imaginable health state

Evidently, question 1) and question 2) were worded such that 0 indicated no pain and no anxiety. However, in question 3) assessing oral health state, the wording implied that 0 was the worst imaginable health state.

This appeared to cause confusion with participants and subsequently the information gathered was potentially inaccurate. Of the ten samples gathered, seven appeared to be skewed when compared to the other self-reported outcomes they had given. Despite the audit being under-powered, it provided useful and clear messages on questionnaire design.
3.6 Changes made following the pilot study

The wording of the OH-VAS question was modified, as discussed above. Additionally, the visual aspect of the three VAS scales was changed, making the VAS scale a horizontal rather than vertical line. The scales were vertical during the pilot, simply to ensure the questionnaire fitted onto a single OMR sheet. However, this changed the appearance of the VAS scale, and as a result affected the scales validity. The updated styling of VAS scales is shown in Appendix 6.

Furthermore, it was felt that standardising of the staff taking part in the research would also be useful, to ensure patients received similar information about how to fill in the form and the nature of the questions, as this may have created inconsistencies in results gathered. Accordingly, staff were trained to ensure they gave consistent information to patients about the consent procedure and queries from patients when filling in the questionnaire. An introductory note was developed to help guide patients before filling in the questionnaire to ensure they all received the same information (see figure 3.5):

The second change made following the pilot study was to change the wording of the OHIP-14 question. During the pilot, each question had been adjusted so that each question was asked in relation to “your tooth”. However, this affected question validity, by adapting the OHIP-14 and potentially changing the patients’ interpretation of the question, so the
questioning was returned to its original wording, “your teeth, mouth or dentures.” Changes made following piloting of the tool aimed to improve the reliability of the tool and ease of use for patients.

Thank you very much for agreeing to complete this questionnaire. The aim is to have a patient centred approach to health care by recording treatment outcome from your perspective. Please answer the following questions based on how you feel the effect your dental problem has had on your general oral health, pain levels and anxiety levels. It should only take a few minutes to complete. The information gathered will be anonymous. We hope this will help health care professionals to monitor and improve patient care at Liverpool University Dental Hospital. We would appreciate if you could take your time answering the questions. We are very grateful for your participation.

Figure 3.4 Introductory note to participants

3.7 Conclusions

In this pilot study, tool development and testing was carried out to assess its ability to record PROMs of a small sample of patients following endodontic treatment. The findings of the pilot suggested that endodontics resulted in improved OHRQoL, although further testing on a larger sample was required. The pilot study highlighted improvements required to the questionnaire, in terms of visual design and wording of questions. In addition, data obtained helped calculate sample size for a prospective longitudinal study.
CHAPTER 4 PATIENT REPORTED OUTCOMES IN A PROSPECTIVE LONGITUDINAL STUDY COMPARING PATIENTS BEFORE AND AFTER ENDODONTIC TREATMENT: A QUANTITATIVE STUDY

4.1 Introduction

Following piloting of the questionnaire tool (see Chapter 3) highlighting changes required to tool design, the PROMs of a sample of patients' treated at Liverpool University Dental Hospital were analysed in a prospective longitudinal study, comparing patients before and after endodondtcs.

PROMs are a useful method to measure outcomes, but have been rarely utilised in endodontics. Liu and McGrath carried out a series of studies assessing endodontic PROMs on a group of patients treated in a dental school in Hong Kong (Liu et al., 2014a, Liu et al., 2012, Liu et al., 2014b). The primary study was a case-control study comparing a cohort of 100 endodontic patients to 100 periodontal patients (the control). OHIP-14 and the General Health Questionnaire (GHQ) tools demonstrated a significant change in OHRQoL, in the patients undergoing endodontic treatment. This was followed by a prospective longitudinal study in 2014 of endodontic patients showing the improvement in OHRQoL that occurs following treatment. The third study in the series attempted to identify the key
endodontic factors that affect OHRQoL, finding that those who require multiple endodontic treatment had poorer OHRQoL than other patients.

A study assessing the value and use of QoL studies in primary dental care, highlighted that QoL studies gave patients a chance to describe their thoughts to clinicians and attach value to their experiences (McGrath and Bedi, 1999). For clinicians, QoL studies are a valuable measure of treatment quality to, ‘restore function, prevent disability and attain the goal of oral health’ rather than focusing purely on technical outcomes.

A number of questions in OHIP-14 appeared to be relevant to endodontic PROMs, and comparable to questions asked using visual analogue scales. For example, the OHIP-14 question, ‘Have you had painful aching in your mouth?’ shares a similarity with the VAS scale question, ‘Please rate your pain level on the scale, where 0 is no pain and 100 is the worst pain you can imagine?’

Visual analogue scales were used to assess pain (pain VAS), anxiety (VAS-A), concern (VAS-C) and oral health state (OH-VAS). These measures were selected as they are key components relevant to patients’ undergoing endodontic treatment. Pain VAS and VAS-A are validated measures (Gallagher et al., 2001, Luyk et al., 1988, Todd et al., 1996). VAS-C was a new measure, and was chosen as a way to measure patients’ worries regarding treatment processes and outcomes. OH-VAS was adapted from the overall health state VAS used in the EQ-5D tool. The EQ-5D is used
to measure PROMs in four surgeries carried out in general healthcare, and is the most frequently used instrument of its kind in the UK and Europe (Brooks, 1996). The aim of OH-VAS was to replicate the main themes of OHIP-14 in a shortened version that improves patient completion and compliance.

The relevance of this study was that no questionnaire tool existed that was specifically designed for capturing endodontic PROMs, and no similar and comparable study had been carried out in the UK. OHIP-14 was used as this tool has been validated for use in dentistry (Slade, 1997), and allowed assessment of the specificity and responsiveness of the VAS scales in relation to OHIP-14. Using OHIP-14 also allows comparison of the results from this study with previous PROMs studies using OHIP-14, and is generalisable in different fields of dentistry.
4.1.1 Research aims and objectives

Aims

- Assess the validity of the questionnaire tool, by measuring the impact of endodontic treatment on PROMs of patients treated in a secondary care setting by postgraduate endodontics students.

Objectives

- Assess change in mean OHIP-14 following endodontic treatment.
- Assess the validity of specific visual analogue scales in PROMs data collection.
- Assess whether the reported clinical findings mirror the change in PROMs.

Hypothesis

- The research hypothesis is that endodontics leads to improved patient reported outcomes

Null hypothesis

- There is no difference between the mean OHIP 14 scores of patients before and after endodontic treatment performed by postgraduates at LUDH.
4.2 Methods

This study was a prospective longitudinal study of PROMs following endodontic treatment. Ethical approval was obtained (IRAS ID 212099). An electronic questionnaire was designed consisting of four VAS questions (discussed in section 4.1) and OHIP-14. Data was also collected regarding patient age, gender, ethnicity, first half of postcode, need for painkillers, type of treatment, and tooth being treated. In addition, postgraduates provided clinical data related to signs and symptoms, quality of obturation, radiographic appearance of the tooth,

Questionnaires were designed and distributed, and data securely collected and stored in Qualtrics. Twelve postgraduate endodontic trainees recruited patients were recruited from a population of those referred to a Dental Hospital, for consultation and treatment of endodontic cases. Inclusion criteria were adult patients (age ≥18) requiring: RCT, ReRCT or apical surgery.

Digital questionnaires were completed by patients on iPads before treatment (T0), 2 months post-treatment (T1) via email link; and 6 months post-treatment (T2) via clinical recall/email link. Dentists completed questionnaires on the day of obturation, and 6 months post-treatment (T2). There were 216 patients recruited, with 53 of the recruited patients completing PROMs 6 months post-treatment. Data collection commenced in October 2016, and was completed in January 2018.
Data were collected using visual analogue scales assessing pain, anxiety, concerns and oral health state on a scale from 0-100, and the Oral Health Impact Profile-14 (OHIP-14) tool, which asks participants to rate frequency of adverse oral health outcomes on a 5-point Likert scale. Dentists provided clinical outcomes following obturation (T0) and at 6 month recall (T2).

4.2.1 Sample population

Patients with complex endodontic problems in the North West (predominantly Merseyside), were referred to the consultation clinic at LUDH for assessment and treatment. Acceptance of patients for treatment was based on the tooth being restorable, and suitable for endodontic StR training requirements. Two hundred and sixteen patients were initially recruited, with information on the exclusion and loss of patients illustrated in Figure 4.1.

4.2.2 Ethical approval

Following piloting of the tool, relevant paperwork was completed and a research protocol written. An application made in September 2016 was granted approval in January 2017 for a service evaluation overseen by the Royal Broadgreen Hospital trust clinical effectiveness team (see Appendix 2). An application made via the Integrated Research Application System (IRAS) website to REC and the Health Research Authority (HRA) was also submitted to make use of both retrospective and prospective service evaluation data.
The research was categorised as a study administering questionnaires/interviews for quantitative or mixed quantitative/qualitative analysis (see Appendix 15). The Proportionate Review Sub-Committee of the East of England – Cambridge Central granted a favourable opinion following assessment on 6th March 2017. Amendments to the original application
were made in October 2017 (see Appendix 13), and accepted on the 31st October 2017 (see Appendix 17).

### 4.2.3 Inclusion and exclusion criteria

The following inclusion and exclusion criteria were applicable as shown in Table 4.1.

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients requiring endodontic treatment of a tooth/teeth</td>
<td>Patients requiring non-endodontic treatment alongside endodontics, for example both endodontics and implant provision</td>
</tr>
<tr>
<td>Minimum 18 years old</td>
<td>Patients unable to provide informed consent</td>
</tr>
<tr>
<td></td>
<td>Patients unable to read and write in English with no translator present</td>
</tr>
<tr>
<td></td>
<td>Patients unable to access an email address</td>
</tr>
</tbody>
</table>

Table 4.1 List of inclusion and exclusion criteria

The operator and patients were not blinded as the patients were consented to the procedure, and the operator evidently knew which treatment was being provided. However, the operator did not see the patient questionnaire response thus reducing operator bias.
4.2.4 Sample size calculation

Power calculations were carried out to allow sample sizes calculation (Jones et al., 2003). The pilot data collected during tool development (see Chapter 3) was only collected from a sample of 10 participants, but was used for power calculations. In the pilot study, the mean OHIP-14 score was 19 prior to treatment and 13 post-treatment, with a standard deviation of ±12.

The pilot study findings were compared to the prospective longitudinal study by Liu and McGrath of patients attending Hong Kong Dental Faculty (Liu et al., 2014b), as described in Chapter 2.9. The baseline OHIP-14 mean score of that study was 15 and the 6-month follow up score was 8, with a standard deviation of ±8. This showed the pilot study data to be similar and thus useful for sample size calculations.

A power calculation was carried out with the significance level set at 0.05 and the power level at 0.80, as illustrated in Table 4.2.

A consideration was made of potential drop out of patients involved in this study. In the study by Liu and McGrath, less than 10% of the sample were lost to follow up, although sample size was calculated based on a hypothetical 25% loss of patients to follow up, calculated for two reasons:

- Patients were required to fill in questionnaires from home and may not follow up despite our best efforts (estimated 15%)
- Drop out may also occur due to withdrawal of consent (estimated 10%).
The calculation proposed collecting data from eighty patients during the study following sample power calculations illustrated in Table 4.2, which also allows for a 25% drop out rate as a precaution.

<table>
<thead>
<tr>
<th>What is the null hypothesis?</th>
<th>There is no difference in mean OHIP-14 score following endodontics.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level to avoid Type I Error</td>
<td>Set to 0.05</td>
</tr>
<tr>
<td>Level to avoid Type II Error</td>
<td>Set to 0.80</td>
</tr>
<tr>
<td>What is the 'clinically important difference' value</td>
<td>A reduction in mean OHIP-14 values</td>
</tr>
</tbody>
</table>

Standardised Difference = difference between the means / population standard deviation

Standardised Difference based on audit = (19-13)/12 = 0.5

Table 4.2 Power calculation adapted from (Jones et al., 2003).
4.2.5 Online tool development

To assess the PROMs of a group of endodontic patients at LUDH, an electronic tool was developed. The tool chosen was based on previous literature, aiming to make a user-friendly and simple endodontic-specific PROMs tool. The tool had already been developed and piloted on paper OMR sheets to assess patient response time, understanding of questions and logistics of collecting data on clinic.

The questionnaire allowed answers in many formats such as text entry, multiple choice, or a drop down menu of options. Significant time was required to build and finalise the questions to be included, and then grouping them into blocks to allow a specific group of questions to be asked relevant to each patient / dentist. A survey flow (see appendix 4) was developed which ensured only the relevant questions were displayed to the respondent.

4.2.6 Patient data entry

The first block of questions was titled ‘introduction’ and this data was always collected. This information gathered the participants’ research ID, whether it was their first time completing the questionnaire, what treatment was being provided, who was completing the questionnaire (patient or dentist), and the patient’s email address (see appendix 5).

If the patient was completing the questionnaire, they were directed to another block of questions. On their first time completing the questionnaire only (pre-
treatment), the patient was asked to provide their age, gender, ethnicity, and the first half of their postcode. In subsequent questionnaires, they were asked if they were happy to proceed, their current stage of treatment, and whether they had required painkillers in the last 48 hours.

Following this, four visual analogue scales were then shown asking the following questions, as shown in Figure 4.2.

- **How would you rate your level of concern regarding the treatment of your tooth, where 0 is no concern and 100 is the maximum concern possible?**

![0-100 VAS scale](image)

- **Please rate your current oral health state on the scale, where 0 is an ideal health state and 100 is the worst oral health state you can imagine?**

![0-100 VAS scale](image)

- **Please rate your anxiety level on the scale, where 0 is no anxiety and 100 is the most anxious you can imagine?**

![0-100 VAS scale](image)

- **Please rate your pain level on the scale, where 0 is no pain and 100 is the worst pain you can imagine?**

![0-100 VAS scale](image)

Figure 4.2 VAS questions

The patients were then asked to complete the OHIP-14 questions on a Likert scale ranging from; 0-(never), 1-(hardly ever), 2-(occasionally), 3-(fairly often) to 4-(very often), shown in Figure 4.3.
1) Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

2) Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

3) Have you had painful aching in your mouth?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

4) Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

5) Have you been self-conscious because of your mouth, teeth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

6) Have you felt tense because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

7) Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
8) Have you had to interrupt meals because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

9) Have you found it difficult to relax because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

10) Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

11) Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

12) Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

13) Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

14) Have you been totally unable to function because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Figure 4. 3 OHIP-14 questionnaire
4.2.7 Dentist data entry

When the dentist was completing the questionnaire, they were directed to an introductory block of questions asking when the case was completed, who provided the treatment (each postgraduate had their own code), and which teeth were treated. This was followed by questions detailing clinical history and assessment of obturation, as shown in Figure 4.5.

![Qualtrics data sheet completed by dentist on day of obturation](image_url)
The dentist repeated a similar round of questions 6 months post-treatment, shown in Figure 4.5.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the tooth symptomatic?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Is there a swelling present?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Is there a sinus tract present?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Is the tooth functional?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Is there a satisfactory coronal seal present?</td>
<td>Yes, No</td>
</tr>
<tr>
<td>Have you reviewed the patient clinically/radiographically today?</td>
<td>Yes, No</td>
</tr>
</tbody>
</table>

Figure 4. 5 Qualtrics data sheet completed by dentist 6 months post-treatment
4.2.8 When did patients and dentists complete the questionnaire?

Patients who attended for endodontic treatment were initially seen on a consultation clinic and then booked for treatment with the endodontic postgraduates. Patients filled in the questionnaire prior to starting endodontic treatment (T0).

Following completion of the endodontic treatment, the dentist then filled in a questionnaire with clinical information relating to the treatment. When the dentist completed the questionnaire, this automatically triggered an email to the patient. This requested that the patient fill out a questionnaire at a specific point post-treatment. The link the patient received was unique, meaning the user ID and email address were already inputted (patients did not need to remember their own unique ID), ensuring all data could be accounted for.

Patients filled in a post-treatment questionnaire within 2 months of completing their treatment (T1). When 6 months had passed, the patient was recalled for a clinical review. At this appointment, an examination was completed on the tooth treated to assess:

- signs and symptoms
  - History of pain/swelling/suppuration since obturation
  - Tenderness to percussion
  - Isolated deep pocket indicative of vertical root fracture
Tooth mobility
- Presence/quality of coronal seal
- PA radiograph to assess healing

Based on the information collected, the dentist filled in another questionnaire providing clinical outcomes, and the patient completed a final questionnaire to provide their outcomes 6 months following treatment (T2). For patients who could not be recalled, emails were sent asking them to provide 6-month outcomes, but the dentist did not complete a questionnaire as no clinical outcomes could be provided. A flow chart illustrates the timeline of questionnaire completion (see Figure 4.6).

4.2.9 Patient consent form and information sheet

A consent form was designed as per REC guidelines (see appendix 10). As the study data was collected as part of a service evaluation, consent forms were not required at that stage. Verbal consent was confirmed to take part in the service evaluation (Gibbard et al., 2017). Digital consent forms were used for data collected beyond 1st August 2017 as per the IRAS amendment. The Patient Information Sheet (PIS) provided additional information about the study as per Research Ethics Committee (REC) guidelines (see appendix 11).
Figure 4.6 Qualtrics patient and dentist response flowchart
4.2.10 Data collection management

Email and text reminders were sent to those who failed to reply in a timely manner. Patients filled in details on the questionnaire using an anonymised number that was given to them when they consented to taking part. All data was securely stored throughout the study. Data collection took place between September 2016 and January 2018. All treatment provided on patients who matched the inclusion criteria was recorded.

4.2.11 Funding and sponsorship

No funding was required for the quantitative arm of the study. The Qualtrics programme was already licensed and no other charges were incurred. The author applied for sponsorship of this research project through the Royal Liverpool and Broadgreen University Hospitals NHS Trust Research department, which was accepted (see appendix 16)
4.3 Results

The sociodemographic and treatment characteristics of the groups were analysed to compare between T0, T1 and T2, with groups remaining largely consistent throughout (see Table 4.3). The T0 group contained almost two-thirds females, but this decreased slightly in T1 and T2. Painkiller use was low in T0 and T2 groups with a small increase in the T1 group. Treatment type and tooth treated remained fairly consistent within the groups, and ethnicity was predominantly White British in all groups.

Postcode analysis was carried out using IMD analysis, and remained consistent in all groups. Postcodes were split into 10 groups ranging from least deprived to most deprived. The results displayed in Table 4.3 placed the participants into most deprived 30%, middle 40% and least deprived 30%. Of the sample at pre-treatment stage, 58.3% were from the most deprived three deciles.

Pre-treatment data collection revealed 40.5% of the cases treated involved RCT, 45.8% ReRCT, and 13.7% apical surgery. Upper incisors were the most commonly treated teeth (43.9%), and upper teeth in general were more commonly treated than lower teeth (70.6% upper). The most commonly treated lower tooth was the lower molar (16.1%).
<table>
<thead>
<tr>
<th></th>
<th>Completed T0 (n=168)</th>
<th>Completed T1 (n=55)</th>
<th>Completed T2 (n=53)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean ± Std Dev)</td>
<td>40.8 ±13.9</td>
<td>44.1 ±14.2</td>
<td>43.4 ±13.7</td>
</tr>
<tr>
<td>Gender (% (n))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>33.9 (57)</td>
<td>36.4 (20)</td>
<td>45.3 (24)</td>
</tr>
<tr>
<td>Female</td>
<td>66.1 (111)</td>
<td>63.6 (35)</td>
<td>54.7 (29)</td>
</tr>
<tr>
<td>Painkillers use (% (n))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>7.7 (13)</td>
<td>16.4 (9)</td>
<td>1.9 (1)</td>
</tr>
<tr>
<td>No</td>
<td>92.3 (155)</td>
<td>83.6 (46)</td>
<td>98.1 (52)</td>
</tr>
<tr>
<td>What treatment? (% (n))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RCT</td>
<td>40.5 (68)</td>
<td>50.9 (28)</td>
<td>37.7 (20)</td>
</tr>
<tr>
<td>ReRCT</td>
<td>45.8 (77)</td>
<td>29.1 (16)</td>
<td>43.4 (23)</td>
</tr>
<tr>
<td>Surgery</td>
<td>13.7 (23)</td>
<td>20.0 (11)</td>
<td>18.9 (10)</td>
</tr>
<tr>
<td>Which teeth were treated? (% (n))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper Incisors</td>
<td>43.9 (82)</td>
<td>45.0 (27)</td>
<td>51.8 (30)</td>
</tr>
<tr>
<td>Upper Canines / Premolars</td>
<td>12.8 (24)</td>
<td>18.3 (11)</td>
<td>15.5 (9)</td>
</tr>
<tr>
<td>Upper Molars</td>
<td>13.9 (26)</td>
<td>13.3 (8)</td>
<td>10.3 (6)</td>
</tr>
<tr>
<td>Lower Incisors</td>
<td>9.6 (18)</td>
<td>6.7 (4)</td>
<td>10.3 (6)</td>
</tr>
<tr>
<td>Lower Canines / Premolars</td>
<td>3.7 (7)</td>
<td>5.0 (3)</td>
<td>1.7 (1)</td>
</tr>
<tr>
<td>Lower Molars</td>
<td>16.1 (30)</td>
<td>11.7 (7)</td>
<td>10.4 (6)</td>
</tr>
<tr>
<td>Pre-treatment participant ethnicity (% (n))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>88.7 (149)</td>
<td>87.3 (48)</td>
<td>92.5 (49)</td>
</tr>
<tr>
<td>White Irish</td>
<td>0.6 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>White another</td>
<td>3.0 (5)</td>
<td>3.6 (2)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>White and Black Caribbean</td>
<td>0.6 (1)</td>
<td>1.8 (1)</td>
<td>1.9 (1)</td>
</tr>
<tr>
<td>White and Black African</td>
<td>0.6 (1)</td>
<td>1.8 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Indian</td>
<td>1.2 (2)</td>
<td>1.8 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pakistani</td>
<td>1.2 (2)</td>
<td>1.8 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Bangladeshi</td>
<td>0.6 (1)</td>
<td>0 (0)</td>
<td>1.9 (1)</td>
</tr>
<tr>
<td>Chinese</td>
<td>0.6 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Another Asian</td>
<td>0.6 (1)</td>
<td>0 (0)</td>
<td>1.9 (1)</td>
</tr>
<tr>
<td>African</td>
<td>1.2 (2)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Caribbean</td>
<td>0.6 (1)</td>
<td>1.8 (1)</td>
<td>1.9 (1)</td>
</tr>
<tr>
<td>Arab</td>
<td>0.6 (1)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Postcode analysis by IMD deciles (% (n))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Least deprived 30%</td>
<td>22.6 (38)</td>
<td>27.3 (15)</td>
<td>28.3 (15)</td>
</tr>
<tr>
<td>Middle 40%</td>
<td>19.1 (32)</td>
<td>12.7 (7)</td>
<td>11.3 (6)</td>
</tr>
<tr>
<td>Most deprived 30%</td>
<td>58.3 (98)</td>
<td>60 (33)</td>
<td>60.4 (32)</td>
</tr>
</tbody>
</table>

Table 4. 3 Sociodemographic and treatment characteristics of participants at T0, T1 and T2
4.3.1 Patient reported outcome data

The Paired Samples $t$ Test analysed the difference in the mean between participants at two different observation points. Fifty-three patients completed PROMs at T0-T2, with statistically significant differences in the measures VAS-A ($P = 0.005$) and VAS-C ($P = 0.001$), non-statistically significant reductions in Pain VAS ($P = 0.305$), OHIP-14 ($P = 0.067$), and OH-VAS ($P = 0.752$) (shown in Table 4.4 and graphically in Figures 4.7 and 4.8). The findings of the individual domains of the OHIP-14 are also displayed.
<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain VAS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>8.9 ±14.5</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>5.9 ±17.9</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>3.0 ±21.1</td>
<td>0.305</td>
</tr>
<tr>
<td><strong>VAS-A</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>32.6 ±31.8</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>19.7 ±28.6</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>12.9 ±32.1</td>
<td>0.005</td>
</tr>
<tr>
<td><strong>VAS-C</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>34.4 ±31.2</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>18.9 ±28.6</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>15.5 ±32.3</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>OH-VAS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>25.9 ±23.1</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>27.5 ±30.6</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>-1.6 ±35.8</td>
<td>0.752</td>
</tr>
<tr>
<td><strong>OHIP-14 Total</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>11.1 ±9.7</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>8.4 ±10.7</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>2.6 ±10.3</td>
<td>0.067</td>
</tr>
<tr>
<td><strong>Functional Limitation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>0.8 ±1.3</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>0.4 ±1.1</td>
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<tr>
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<td>0.043</td>
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<td></td>
</tr>
<tr>
<td>T0</td>
<td>2.4 ±2.0</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>1.6 ±2.0</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>0.8 ±2.3</td>
<td>0.019</td>
</tr>
<tr>
<td><strong>Psychological Discomfort</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>2.7 ±2.2</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>2.1 ±2.4</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>0.6 ±2.2</td>
<td>0.039</td>
</tr>
<tr>
<td><strong>Physical Disability</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>1.2 ±1.7</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>1.0 ±2.0</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>0.2 ±1.8</td>
<td>0.373</td>
</tr>
<tr>
<td><strong>Psychological Disability</strong></td>
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<td></td>
</tr>
<tr>
<td>T0</td>
<td>2.0 ±1.8</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>1.7 ±2.2</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>0.3 ±2.1</td>
<td>0.269</td>
</tr>
<tr>
<td><strong>Social Disability</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>1.0 ±1.6</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>0.7 ±1.6</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>0.2 ±1.8</td>
<td>0.362</td>
</tr>
<tr>
<td><strong>Handicap</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>1.0 ±1.3</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>0.9 ±1.6</td>
<td></td>
</tr>
<tr>
<td>T0 – T2</td>
<td>0.1 ±1.3</td>
<td>0.609</td>
</tr>
</tbody>
</table>

Table 4. 4 Paired Samples t Test comparing Patients at T0 – T2 (N=53)
A similar measure was carried out to assess PROMs at T0-T1 (see Table 4.5), and PROMs at T1-T2 (see Table 4.6). Significant reductions in VAS-A (P < 0.001) and VAS-C (P < 0.001) were also seen from T0-T1, and a significant reduction in OHIP-14 (P < 0.039) from T1-T2.
<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain VAS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>11.1 ±18.2</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>8.7 ±13.0</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>2.4 ±16.5</td>
<td>0.285</td>
</tr>
<tr>
<td><strong>VAS-A</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>36.3 ±30.3</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>19.4 ±24.8</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>16.9 ±31.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>VAS-C</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>39.3 ±30.5</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>20.1 ±26.2</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>19.2 ±32.5</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td><strong>OH-VAS</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>30.2 ±24.2</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>27.5 ±23.7</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>2.7 ±29.0</td>
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<tr>
<td><strong>OHIP-14 Total</strong></td>
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<tr>
<td>T0</td>
<td>10.2 ±8.2</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>10.6 ±8.5</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>-0.3 ±7.2</td>
<td>0.740</td>
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<tr>
<td><strong>Functional Limitation</strong></td>
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<td></td>
</tr>
<tr>
<td>T0</td>
<td>0.2 ±0.6</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>0.6 ±1.1</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>-0.4 ±1.1</td>
<td>0.007</td>
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<tr>
<td><strong>Physical Pain</strong></td>
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<td></td>
</tr>
<tr>
<td>T0</td>
<td>3.0 ±2.1</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>2.5 ±1.9</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>0.6 ±1.9</td>
<td>0.030</td>
</tr>
<tr>
<td><strong>Psychological Discomfort</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>T0</td>
<td>2.6 ±2.2</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>2.7 ±2.4</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>-0.1 ±2.1</td>
<td>0.750</td>
</tr>
<tr>
<td><strong>Physical Disability</strong></td>
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</tr>
<tr>
<td>T0</td>
<td>1.0 ±1.4</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>1.1 ±1.3</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>-0.1 ±1.3</td>
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</tr>
<tr>
<td><strong>Psychological Disability</strong></td>
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<td></td>
</tr>
<tr>
<td>T0</td>
<td>2.0 ±1.7</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>2.0 ±2.1</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>0.1 ±1.9</td>
<td>0.835</td>
</tr>
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<td><strong>Social Disability</strong></td>
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</tr>
<tr>
<td>T0</td>
<td>0.7 ±1.4</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>0.9 ±1.2</td>
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<tr>
<td>T0 – T1</td>
<td>-0.2 ±1.3</td>
<td>0.229</td>
</tr>
<tr>
<td><strong>Handicap</strong></td>
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<td></td>
</tr>
<tr>
<td>T0</td>
<td>0.6 ±1.1</td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>0.8 ±1.0</td>
<td></td>
</tr>
<tr>
<td>T0 – T1</td>
<td>-0.1 ±1.1</td>
<td>0.390</td>
</tr>
</tbody>
</table>

Table 4. 5 Paired Samples t Test comparing Patients at T0 – T1 (N=55)
Table 4. Paired Samples t Test comparing Patients at T1 – T2 (N=25)

<table>
<thead>
<tr>
<th></th>
<th>Mean ± SD</th>
<th>Sig. (2-tailed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain VAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>5.9 ±9.5</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>6.5 ±20.5</td>
<td></td>
</tr>
<tr>
<td>T1 – T2</td>
<td>-0.6 ±23.3</td>
<td>0.892</td>
</tr>
<tr>
<td>VAS-A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>13.4 ±21.3</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>16.0 ±27.4</td>
<td></td>
</tr>
<tr>
<td>T1 – T2</td>
<td>-2.6 ±35.5</td>
<td>0.721</td>
</tr>
<tr>
<td>VAS-C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>14.3 ±16.8</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>13.9 ±24.8</td>
<td></td>
</tr>
<tr>
<td>T1 – T2</td>
<td>0.4 ±31.5</td>
<td>0.950</td>
</tr>
<tr>
<td>OH-VAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>19.2 ±21.2</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>25.3 ±29.7</td>
<td></td>
</tr>
<tr>
<td>T1 – T2</td>
<td>-6.2 ±34.7</td>
<td>0.383</td>
</tr>
<tr>
<td>OHIP-14 Total</td>
<td></td>
<td></td>
</tr>
<tr>
<td>T1</td>
<td>8.5 ±8.0</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>4.5 ±4.9</td>
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</tr>
<tr>
<td>T1 – T2</td>
<td>4.0 ±9.0</td>
<td>0.039</td>
</tr>
<tr>
<td>Functional Limitation</td>
<td></td>
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<tr>
<td>T1</td>
<td>0.4 ±0.8</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>0.2 ±0.5</td>
<td></td>
</tr>
<tr>
<td>T1 – T2</td>
<td>0.3 ±0.8</td>
<td>0.090</td>
</tr>
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<td>Physical Pain</td>
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<tr>
<td>T1</td>
<td>2.2 ±1.7</td>
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</tr>
<tr>
<td>T2</td>
<td>1.1 ±1.1</td>
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</tr>
<tr>
<td>T1 – T2</td>
<td>1.0 ±2.2</td>
<td>0.028</td>
</tr>
<tr>
<td>Psychological Discomfort</td>
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<tr>
<td>T1</td>
<td>2.3 ±2.4</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>1.4 ±1.6</td>
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</tr>
<tr>
<td>T1 – T2</td>
<td>1.0 ±2.4</td>
<td>0.061</td>
</tr>
<tr>
<td>Physical Disability</td>
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</tr>
<tr>
<td>T1</td>
<td>1.0 ±1.1</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>0.4 ±0.6</td>
<td></td>
</tr>
<tr>
<td>T1 – T2</td>
<td>0.6 ±1.4</td>
<td>0.065</td>
</tr>
<tr>
<td>Psychological Disability</td>
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<td></td>
</tr>
<tr>
<td>T1</td>
<td>1.3 ±1.8</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>1.0 ±1.5</td>
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</tr>
<tr>
<td>T1 – T2</td>
<td>0.3 ±2.0</td>
<td>0.493</td>
</tr>
<tr>
<td>Social Disability</td>
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</tr>
<tr>
<td>T1</td>
<td>0.8 ±1.0</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>0.2 ±0.4</td>
<td></td>
</tr>
<tr>
<td>T1 – T2</td>
<td>0.6 ±1.1</td>
<td>0.020</td>
</tr>
<tr>
<td>Handicap</td>
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<td></td>
</tr>
<tr>
<td>T1</td>
<td>0.6 ±0.9</td>
<td></td>
</tr>
<tr>
<td>T2</td>
<td>0.3 ±0.6</td>
<td></td>
</tr>
<tr>
<td>T1 – T2</td>
<td>0.3 ±1.0</td>
<td>0.166</td>
</tr>
</tbody>
</table>
4.3.2 Clinical outcome data

The data presented in Table 4.7 reflects the data provided by dentists following obturation, and in Table 4.8 the data provided by dentists six months post-obturation.

<table>
<thead>
<tr>
<th>Dentists questionnaire data on day of treatment completion (n=142)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the tooth symptomatic?</strong></td>
</tr>
<tr>
<td>% (n)</td>
</tr>
<tr>
<td><strong>Is there a swelling present?</strong></td>
</tr>
<tr>
<td>% (n)</td>
</tr>
<tr>
<td><strong>Is there a sinus tract present?</strong></td>
</tr>
<tr>
<td>% (n)</td>
</tr>
<tr>
<td><strong>Was there a preoperative periapical lesion present?</strong></td>
</tr>
<tr>
<td>% (n)</td>
</tr>
<tr>
<td><strong>What is the radiographic quality of the orthograde obturation?</strong></td>
</tr>
<tr>
<td>% (n)</td>
</tr>
<tr>
<td><strong>What is the radiographic quality of the retrograde obturation?</strong></td>
</tr>
<tr>
<td>% (n)</td>
</tr>
<tr>
<td><strong>Overall quality of obturation (orthograde + retrograde)ência</strong></td>
</tr>
<tr>
<td>% (n)</td>
</tr>
</tbody>
</table>

Table 4.7 Data entered by Dentists on day of treatment completion

Dentists provided details about clinical signs and symptoms, and provided an assessment of the radiographic appearance of obturation (Ng et al., 2011a, Sjögren et al., 1990). At the 6-month review, clinical signs and symptoms
were analysed as well as assessment of the tooth’s functionality, coronal seal, and radiographic presence and size of periapical lesions.

<table>
<thead>
<tr>
<th>Dentists questionnaire data 6 months after treatment completion (n=48)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Is the tooth symptomatic?</strong> % (n)</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>91.7 (44)</td>
</tr>
<tr>
<td><strong>Is there a swelling present?</strong> % (n)</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>97.9 (47)</td>
</tr>
<tr>
<td><strong>Is there a sinus tract present?</strong> % (n)</td>
</tr>
<tr>
<td>No</td>
</tr>
<tr>
<td>91.7 (44)</td>
</tr>
<tr>
<td><strong>Is the tooth functional?</strong> % (n)</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>100 (48)</td>
</tr>
<tr>
<td><strong>Is there a satisfactory coronal seal present?</strong> % (n)</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>93.8 (45)</td>
</tr>
<tr>
<td><strong>In term of the lesion, has it?</strong> % (n)</td>
</tr>
<tr>
<td>Healed</td>
</tr>
<tr>
<td>46.7 (21)</td>
</tr>
</tbody>
</table>

Table 4. 8 Data entered by dentists 6 months following treatment completion

4.3.3 Assessing patient responses in relation to dentist responses

Comparisons were made between patients with presence or absence of periapical lesions prior to starting treatment, analysing the changes in PROMs between the groups (see Table 4.9 and Figure 4.9). Forty patients had a periapical lesion and thirteen had no periapical lesion. Results show that patients with no periapical lesion pre-treatment, reported significantly larger improvements in outcomes following treatment than those with periapical lesions.
### Paired Samples t Test comparing effect on PROMs of presence or absence of a pre-operative periapical lesion

<table>
<thead>
<tr>
<th></th>
<th>Presence of pre-operative periapical lesion (n=40)</th>
<th>Absence of pre-operative periapical lesion (n=13)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD</td>
<td>Mean ± SD</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed)</td>
<td>Sig. (2-tailed)</td>
</tr>
<tr>
<td>Pain VAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TO</td>
<td>9.0 ± 14.8</td>
<td>8.6 ± 14.1</td>
</tr>
<tr>
<td>T2</td>
<td>7.5 ± 20.4</td>
<td>1.0 ± 2.8</td>
</tr>
<tr>
<td>T0 – T2</td>
<td>1.5 ± 23.1</td>
<td>0.684</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.6 ± 12.7</td>
</tr>
<tr>
<td>VAS-A</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TO</td>
<td>32.9 ± 33.3</td>
<td>31.8 ± 27.8</td>
</tr>
<tr>
<td>T2</td>
<td>23.3 ± 30.9</td>
<td>8.5 ± 16.2</td>
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<td>T0 – T2</td>
<td>9.6 ± 33.0</td>
<td>0.073</td>
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<td></td>
<td></td>
<td>23.2 ± 27.8</td>
</tr>
<tr>
<td>VAS-C</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TO</td>
<td>36.0 ± 31.9</td>
<td>29.3 ± 29.7</td>
</tr>
<tr>
<td>T2</td>
<td>23.9 ± 31.2</td>
<td>3.6 ± 7.6</td>
</tr>
<tr>
<td>T0 – T2</td>
<td>12.1 ± 33.3</td>
<td>0.027</td>
</tr>
<tr>
<td></td>
<td></td>
<td>25.7 ± 27.6</td>
</tr>
<tr>
<td>OH-VAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TO</td>
<td>26.6 ± 24.6</td>
<td>23.7 ± 18.2</td>
</tr>
<tr>
<td>T2</td>
<td>30.0 ± 32.9</td>
<td>19.6 ± 21.5</td>
</tr>
<tr>
<td>T0 – T2</td>
<td>-3.4 ± 39.5</td>
<td>0.589</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4.1 ± 21.4</td>
</tr>
<tr>
<td>OHIP-14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TO</td>
<td>11.3 ± 10.6</td>
<td>10.3 ± 6.4</td>
</tr>
<tr>
<td>T2</td>
<td>9.5 ± 11.6</td>
<td>5.2 ± 6.2</td>
</tr>
<tr>
<td>T0 – T2</td>
<td>1.8 ± 10.9</td>
<td>0.297</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.2 ± 7.9</td>
</tr>
</tbody>
</table>

Table 4. Paired Samples t Test comparing patients PROMs with presence or absence of a pre-operative periapical lesion.
Figure 4. Graphical representation of effect on PROMs of pre-operative periapical lesions.
4.4 Discussion

4.4.1 Discussion of patient reported outcome data

The questionnaire tool allowed successful collection and analysis of patients’ endodontic PROMs. Analysis of results was made between T0 - T2 as patients generally attended for review or completed the questionnaire at home having already completed all treatment. The data at T0-T1 and T1-T2 (as seen in Tables 4.5 and 4.6) was not utilised as it was not as relevant and useful in comparison to T0-T2, and due to the difficulty in collecting T1 data at a uniform time point. Additionally, sample size was small and the data analysis was not useful at T1-T2. In addition, post-endodontic restorations were not always completed at T1; often meaning patients had related functional and aesthetic concerns (for example temporary crown still in situ until full healing evident, or tooth still settling post obturation).

The null hypothesis assessed change in the mean OHIP-14 score following endodontic treatment. The results showed a non-statistically significant mean reduction (P=0.067) of OHIP-14 values, from 11.1 (±9.7) to 8.4 (±10.7), and therefore the null hypothesis was accepted. However, when analysing the 7 domains that make up OHIP-14, statistically significant mean reductions were seen in the domains of functional limitation (P = 0.043), physical pain (P = 0.019) and psychological discomfort (P = 0.039). Comparing the OHIP-14 results to similar studies in the literature, the assessment of endodontic PROMs in Hong Kong showed larger reductions in OHIP-14, from 15.1 (±10.2) pre-treatment to 7.8 (±8.0) 6 months post-treatment (Liu et al.,
Analysing group characteristics and socio-demographics, the samples were similar in terms of age, gender, and presence of periapical lesion, but differences existed in type of tooth treated (over 50% molars and over 50% retreatments in the Hong Kong study), painkiller use and cultural differences between a UK and Hong Kong population that make precise comparison problematic.

Problems with the OHIP-14 were twofold: firstly, the tool did not capture the full depth of OHRQoL, possibly because it is a generic tool not designed solely for endodontic PROMs. Secondly, completion of OHIP-14 was time-consuming for patients, who appreciated the styling and user-friendly nature of the VAS questions.

Anxiety measured using VAS-A showed mean reduction from 32.6 (±31.8) to 19.7 (±28.6), that was statistically significant (P=0.005). Concern levels measured using VAS-A underwent statistically significant reduction in mean (P=0.001) from 34.4 (±31.2) to 18.9 (±28.6). The fact that anxiety and concerns dropped significantly following treatment is unsurprising, because for many patients’ the uncertainty surrounding treatment success effects these measures, relating to possible tooth-loss and related consequences (see qualitative study in Chapter 5). The high clinical success rates, seen by evidence of periapical healing (77.8%), optimal obturation quality (85.2%) and absence of symptoms at review (91.7%) therefore act to decrease anxiety.
Levels of pain evaluated by Pain VAS decreased from 8.9 (±14.5) to 5.9 (±17.9), which was not statistically significant (P=0.305). This minimal decrease in pain was due to the low pre-treatment pain values, theorised to be because patients who attended LUDH for treatment were not experiencing acute toothache. Many patients had undergone initial treatment to manage toothache (endodontic access / antibiotics) or had asymptomatic pulpal necrosis or chronic periapical periodontitis. The chronic lesions were not causing a high degree of pain to the majority of patients seen, so the improvement post-treatment was less significant. This point was further emphasised by the fact that only 7.7% of the sample had required painkillers within 48 hours of starting treatment. However, the literature actually reports higher prevalence of endodontic pain. A systematic review of pain levels in endodontics found mean pre-treatment pain of 54 normalised to a 100-point scale, although it was highlighted that many studies predominantly measured patients attending emergency clinics with acute pain (Pak and White, 2011).

The OH-VAS scale allowed measurement of patients’ oral health state, acting as a condensed measure of OHIP-14. OH-VAS mean scores increased from 25.9 (±23.1) at TO, to 27.5 (±30.6) at T2. In comparison, the OHIP-14 showed a slight reduction from 11.1 (±9.7) at T0 to 8.4 (±10.7) at T2. This suggests that the impact of endodontic treatment was not significant on overall QoL, which was reflected in parts by the qualitative data in Chapter 5. Many participants indicated that endodontic treatment only had a short-term effect on oral health state, and endodontics may not have a significant impact on oral health state. The reasons for the limited effect on
oral health state are complex, but the patients in this sample were predominantly more deprived (from IMD analysis only), and may value their own oral health differently. Patients’ oral health state was also impacted by other dental issues, such as discoloured or misaligned teeth affecting aesthetics, spaces in the dentition, or functional issues such as toothwear or non-odontogenic pain. These issues may act to outweigh the positives of successful endodontics and tooth survival, masking the improvements in QoL that follow. It appears the question may have different meanings to different sample participants, and requires re-wording to decrease ambiguity of meaning.

The VAS section asked patients’ specific questions, but they also correlated with certain sections of the OHIP-14, as shown in Table 4.10. Results of the VAS questions followed similar trends in terms of mean reductions as their related OHIP-14 domains. For example, VAS-C had a significant reduction (P=0.001) in the mean from T0 to T2 of 15.5 (±32.3), whilst psychological discomfort also displayed a significant reduction (P=0.039) in the mean from T0 to T2 of 0.6 (±2.2).
<table>
<thead>
<tr>
<th><strong>VAS scale</strong></th>
<th><strong>OHIP-14 domain</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pain VAS</strong></td>
<td><strong>Physical Pain</strong></td>
</tr>
<tr>
<td>• Please rate your pain level on the scale, where 0 is no pain and 100 is the worst pain you can imagine?</td>
<td>• Have you had painful aching in your mouth?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>VAS-A</strong></td>
<td><strong>Psychological disability</strong></td>
</tr>
<tr>
<td>• Please rate your anxiety level on the scale, where 0 is no anxiety and 100 is the most anxious you can imagine?</td>
<td>• Have you found it difficult to relax because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>VAS-C</strong></td>
<td><strong>Psychological discomfort</strong></td>
</tr>
<tr>
<td>• How would you rate your level of concern regarding the treatment of your tooth, where 0 is no concern and 100 is the maximum concern possible?</td>
<td>• Have you been self-conscious because of your mouth, teeth or dentures?</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>OH-VAS</strong></td>
<td><strong>Handicap</strong></td>
</tr>
<tr>
<td>• Please rate your current oral health state on the scale, where 0 is an ideal health state and 100 is the worst oral health state you can imagine?</td>
<td>• Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?</td>
</tr>
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</table>

Table 4. 10 Comparison of linked questions from VAS scales and OHIP-14

### 4.4.2 Discussion of clinical outcome data

Clinical findings indicated that obturation was of an optimal quality in 85.1% of non-surgical RCT (n=121) and 85.7% of apical surgeries (n=21). At the 6-month review, 91.7% of teeth were asymptomatic, 93.8% had a satisfactory coronal seal and 100% of teeth were functional. Radiographs revealed
lesions were healing or fully healed in 77.8% of cases, which matches similar studies in the literature, involving endodontics provided by postgraduates in a hospital setting (Ng et al., 2011b).

Success rates were not as high as other figures quoted in the literature, such as the 94% success of specialist endodontists (Imura et al., 2007). However, this must be tempered by the fact full healing cannot be fully assessed at 6 month review, with guidelines advising periapical health should be monitored for up to 4 years post-treatment (2006). In addition, 78.2% of the teeth treated had pre-treatment periapical pathology, which impacts on success rates (Friedman et al., 2003, Ng et al., 2011b, Sjogren et al., 1990). To investigate whether this was replicated in the data, Paired Samples t Test was used to examine PROMs with the sample split into those teeth with presence of pre-treatment periapical lesion (n=40), and those with absence of lesion (n=13).

Assessing change in the mean from T0-T2, Pain VAS mean scores showed a non-statistically significantly mean reduction in the absence of periapical lesion group of 7.6 (±12.7) (P=0.051).

VAS-C mean scores statistically significantly reduced in both the presence and absence of periapical lesion groups, with mean reductions of 12.1 (±33.3) P=0.027 and 25.7 (±27.6) P=0.006 respectively.

VAS-A only showed statistically significant reduction in the absence of periapical lesion group, with a mean reduction of 23.2 (±27.8) P=0.011.
OH-VAS showed no statistical changes in both groups, although in the presence of lesion group, mean scores increased by 3.4 (±39.5) (P=0.589), whilst in the absence of lesion group, mean scores decreased by 4.1 (±21.4) (P=0.504). The OHIP-14 mean values showed statistically significant decrease in the absence of lesion group, with mean reduction of 5.2 (± 7.9) (P=0.036).

Clinical outcome studies have previously shown the impact that presence of a periapical lesion has on endodontic outcomes. The Toronto study phase 1 reported 4-6 year success rates of 81%, but cases without a lesion healed in 92% of cases, as opposed to 74% where a lesion was present (Friedman et al., 2003). Similarly, absence of periapical lesion was a significant prognostic factor in both a systematic review and prospective study of endodontic outcomes (Ng et al., 2011b, Ng et al., 2008). Hence, the findings of this study support the existing literature, and highlight that PROMs are sensitive to pick up prognostic factors of treatment detected clinically.

4.4.3 Review of tool wording and relevance

The exact wording of the questions can be improved to ensure the tool is more focused to endodontics. This is because some of the themes captured in the VAS scales are repeated in the OHIP-14 questions, and other OHIP-14 questions have limited relevance to endodontics (such as questions about worsened taste). In addition, the inclusion of the word dentures in the majority of questions may be confusing to participants.
The OH-VAS scale was attempting to answer the questions of OHIP-14 in a condensed fashion that is more patient friendly, but did not achieve this. The wording of the question asked patients to value their oral health state, but may have been interpreted in different ways by participants (for instance referring to functional health of dentition, aesthetics or general oral hygiene).

In addition, patients did not utilise the full scale in the OHIP-14, with pre-treatment mean of 11.1 indicating the average value of answers per question was 0.8 on the Likert scale, where 0 = never, and 1 = hardly ever. This indicates that the tool is either not sensitive enough to detect changes in quality of life following endodontics, or that endodontics does not have a major impact on OHRQoL, as opposed to other dental disciplines.

### 4.4.4 Review of sample population

The patients included were those referred to secondary care for treatment, which is slightly different to the generalised population, as the hospital often treat advanced dental problems, or complex patients with regards medical health or treatment difficulty. The expectation was that with the sample size suggested this would generate roughly equal amounts in each group with regards:

- Males and Females
- Age ranges
- Teeth being treated (molar, premolar, anterior)
This was not controlled as the patients were solely treated based on what was triaged following consultations of referred patients, and no randomising of patients occurred. Average age of participants was 40.8 at T0 and this was similar at T1 (44.1) and T2 (43.4). There were more females than males in all groups, with two thirds of patients recruited pre-treatment being female.

The group of teeth most frequently treated were upper incisors, with maxillary teeth in general being treated more often than mandibular teeth. This may be as a result of dentoalveolar trauma which is a frequent occurrence and predominantly affects upper anterior teeth (Petti, 2015, Petti et al., 2018). Molar teeth only accounted for 30% of the sample, which was expected to be higher due to the increased difficulty of these teeth to treat endodontically. Comparatively, 50% of teeth treated in a study of postgraduate endodontics performed in the UK were molars (Ng et al., 2011b). The social demographic of the patients treated may have influenced the lower number reported in this study, as patients may have been more likely to opt for extraction of molar teeth rather than referral to secondary care.

Cases involved 40.5% RCT, 45.8% ReRCT and 13.7% surgery at T0. This reflects the nature of referrals to the dental hospital, with surgical cases referred less frequently, and often not the appropriate treatment option before initial non-surgical endodontics.
Nearly 60% of the participants who completed pre-treatment PROMs were from the lowest three deciles with regards IMD, rising to 60% at T1 and 60.4% at T2. This is relevant as there is research that shows less tooth loss and more functional dentitions, as level of social class increases (Bernabe and Sheiham, 2014). The vast majority of patients treated were White British (88.7% at T0). This correlates with the demographic reported in the 2011 Census which reported 91.8% of Merseyside residents and 87.1% of the North West population were White British (Office for National Statistics, 2011).

4.4.5 Discussion of Inclusion / Exclusion Criteria

The minimum age was set at 18 years old because endodontic management of under 18s provided on the paediatric clinic often involves distinctly different treatment management and prognosis, and often involves multidisciplinary care with the orthodontics department.

In the pilot study, patients with complex medical histories, or those with chronic issues that could affect their outlook such as a recent death in the family, or depressive illness, were excluded. However, patients with complex medical histories were included in this study as they were deemed to be representative of society and secondly, and their post-treatment result was relative to their pre-treatment result.
Patients requiring multiple endodontic treatments were included in the study. Exclusion of cases involving multiple teeth was considered due to the fact different teeth requiring endodontic treatment may have caused significantly different impacts and subsequently PROMs outcomes for the patient. However, contrary to this a number of the endodontic cases seen involved more than one endodontically involved tooth, but with one common aetiology. For example, trauma involving several upper central incisors may have required numerous endodontic treatments, but the patient judged this as a singular problem when considering their dental trauma.

Another group of patients underwent multiple different treatments as well as endodontics. These patients were excluded from the study, due to the potential for this to affect the validity and reliability of the patient response. As an example, a number of patients underwent endodontic treatment and neighbouring replacement of an extracted tooth with an implant. For some patients this treatment was occurring concurrently, and would have led to difficulties ascertaining which tooth and procedure was governing their PROMs responses, invalidating the patient responses (Alzarea, 2016).

4.4.6 Review of Qualtrics

The benefits of developing an electronic questionnaire tool were that it allows future editing and use of the tool, and allows simple and secure data storage. The Qualtrics programme allowed construction of a sophisticated questionnaire with multiple features, to allow excellent usability for both the
dentist and patient. In addition, Qualtrics had 24-hour telephone support, enabling speedy resolution of technical difficulties that arose during tool development or data collection.

4.4.7 Challenges encountered

4.4.7.1 Timing of completion of the questionnaire and loss of patients to follow up

Patients completed pre-treatment PROMs prior to starting endodontic treatment. On some occasions, this was on the day of consultation, which may have been a significant amount of time before they started treatment as they were then placed on a waiting list. Other patients completed the questionnaire immediately prior to starting treatment, either in the waiting room or in the dental chair. This may have affected the pre-treatment PROMs, as patients were generally more anxious on the day of treatment. There may also have been an effect associated with PROMs questionnaire completion in the dental chair, where patients often experience heightened anxiety linked to historical dental events or preconceptions (Pawlicki, 1991).

When treatment was completed, dentists were asked to immediately complete a questionnaire detailing information about the clinical case. This triggered an email to the patient on the day of treatment, and 7 days later reminding them to fill in a post-treatment questionnaire. However, uptake of this questionnaire was low by patients. In addition, dentists regularly forgot to
fill their questionnaire amongst their other daily clinical and clerical duties, which meant a trigger email was not activated or delivered to the patients email immediately.

In response to this, an amendment was made via IRAS to allow T1 data collection any time in the 2 months post-treatment (see Appendix 13). All non-responding patients were identified following regular review of the data collected. These patients were emailed and/or called to remind them to complete the questionnaire as soon as possible, with varied success. The result was that the T1 data collection was very varied in terms of time of collection, which affected the validity of the T1 results, and led to them subsequently not being analysed.

Ensuring patient follow up proved to be difficult for a number of reasons, and led to being unable to achieve a sample size of eighty patients as proposed in the power calculation (see section 4.2.4). Patients who were asymptomatic were often not keen to return to LUDH for clinical review due to the inconvenience, such as time off work and parking costs. In addition, some of the postgraduates struggled to schedule time to review their cases due to having other training requirements. As a result, the main researcher arranged additional *ad-hoc* clinical sessions to review patients clinically and radiographically, whilst also ensuring PROMs data was collected. Despite contacting patients and reminding of review appointments, attendance for these sessions was still low. All patients who had not responded were contacted to remind them that their questionnaire response was required,
with 150 emails sent including a personalised patient survey link (see Appendix 14), however unfortunately the majority of patients ignored the reminders and did not provide post-treatment PROMs. A suggestion to improve post-treatment data collection would be to collect immediate post-treatment PROMs from the patient following obturation, although the local anaesthetic and procedure may impact on the patients’ reported outcomes.

The result of the loss to follow up was that PROMs were only gathered at both T0 and T2 for 53 participants, which was less than what was planned in sample size calculations (although recruitment was higher than initially planned in calculations). It is hypothesised that with increased data, differences between the groups would have been more apparent, with more statistically significant P values expressed

**4.4.7.2 Dentist compliance**

In light of the lack of compliance from the dentists to fill out questionnaires immediately following treatment, systems were devised to try to prevent this. Clinicians were reminded of their tasks at each session by the main researcher, and all clinical day lists were checked to ensure patients who were involved in the study were highlighted. Signs were put in the treatment units reminding postgraduates of the need to collect PROMs data, and nurses were also involved in providing reminders to dentists at each session. iPads with pink covers were utilised solely for research data collection as the brightly coloured cover made them easy to remember and find on clinic.
Consequently, the phrase ‘pink iPad’ became synonymous with the research project.

T2 data collection was collected either by the patient completing the form in their own time, or when they attended for review at LUDH. Those seen at LUDH often underwent a clinical and radiographic examination, which may have provided reassuring information such as, ‘healing is progressing well’ or disconcerting information such as, ‘the lesion has not responded well on the radiograph and further treatment may be required.’ This may have influenced the resultant PROMs provided. In addition, there may have been a bias when completing repeat questionnaires at the hospital, as patients may have felt they were assessing the work of the dentist who carried out their treatment (gratitude was displayed in some qualitative interviews, see Chapter 5). To overcome this, dentists were advised to give the patient time, space and privacy to complete the PROMs without feeling observed, or that their responses were being scrutinised.
4.5 Conclusions

The null hypothesis was accepted as OHIP-14 mean reduction did not show statistical significance, although this was seen in the individual domains of functional limitation, physical pain and psychological discomfort.

The secondary objective to analyse VAS measures showed the pain, concern and anxiety VAS scales tools to be valid in comparison to OHIP-14 (relating individual domains to individual VAS scales). The OH-VAS scale was not able to detect improvements in OHRQoL following endodontics.

Data collection proved an ongoing challenge, and additional follow up data would have been helpful to firstly strengthen the validity of the result, and secondly highlight more significant differences between the groups. Unfortunately, despite all efforts made to increase compliance, dropout levels were still far higher than expected.

The research findings are important to our profession in the progression towards a more patient-centred approach to healthcare. Further adjustment and tweaking of the tool will be required and use of the tool on a larger sample is required to improve the reliability of the results (discussed in Chapter 6.2).
CHAPTER 5 QUALITATIVE TELEPHONE INTERVIEWS TO EXAMINE PROMs FOLLOWING ENDODONTICS AT LUDH

5.1 Introduction

The aim of carrying out qualitative research was to elicit more detail from patients’ who completed questionnaires before and after endodontic treatment as part of the quantitative study. The qualitative study examined the patient journey from referral to the dental hospital, assessing concerns and anxieties, effect on quality of life, and reflections on treatment and future outcomes. It also allowed assessment of whether the questions asked in the quantitative study were appropriate to capture the patients’ thoughts and feelings regarding treatment. This will help in concluding whether the questionnaire covered all relevant topics in the patients’ view, or whether it was missing crucial and significant questions that would improve the tools validity.

5.1.1 Background

There is a scarcity of qualitative endodontic research, but there are a number of relevant papers in the literature. Studies have tended to explore the impact of endodontics at a personal or structural level. An example of the former is a focus group study carried out in a US dental school, analysing the effect on QoL following treatment with either: endodontics of a single tooth, or
replacement with an implant supported prosthesis (Gattan et al., 2011). The main themes that endodontic patients reported was a desire to maintain their teeth, learning from experiences of other family members who had lost teeth, and a desire to look after their teeth more diligently since having treatment. This study found endodontic treatment had high levels of patient satisfaction, with only a transient effect on their QoL. The study involved patients between 1-6 years post-treatment showing outcomes are meaningful for patients not only at the time of treatment but rather have a long-lasting effect.

An example of the structural barriers patients may face can be found as part of a Brazilian public health services study using semi-structured interviews and a field diary (Melgaco-Costa et al., 2016). The aim was to determine patients’ perceptions of endodontic treatment. Access to service and quality of service were identified as important themes of the interviews and, discussed in detail. In addition, patients talked about their perceived fear of endodontic treatment and the reality when they reflected post-treatment. The relevance of this study to a UK population is the importance of access to services for endodontic treatment, and the ongoing belief that endodontic treatment is painful that is fear inducing for patients.

Experiences of dentists in relation to endodontics were analysed qualitatively (in-depth interviews with GDPs) The interviews investigated the behaviour of GDPs in their practice of endodontics (McColl et al., 1999). The interviews found that a key barrier to endodontic treatment quality was the NHS remuneration scheme, due to constraints on choice of technique and
materials, and effect on time available for each case. Anxieties presented in those GDPs who had a perceived lack of expertise, inexperience or inappropriate equipment or materials.

A similar study was carried out (focus group interviews involving thirty-six dentists) with a population of Swedish GDPs (Dahlström et al., 2017). Anxiety, frustration, stress and exhaustion were associated with providing endodontic treatment, as well as a feeling of loss of clinical control during all procedural steps. As with the UK GDPs interviewed above, similar stress was created by the remuneration scheme, with dentists either working beyond the time available, or accepting suboptimal outcomes.

The existing literature provides information from a patients’ perspective of the quality of life when undergoing endodontic treatment or replacement with implant. From the limited research available, it appears that outcomes and service provision are meaningful concerns for this group of patients. Previous research has also considered dentists opinions on endodontic treatment quality and single vs multi visit regimes. This body of work with dental professionals suggest there a number of key barriers to providing endodontic treatment within services and the constraints of time and resources.
5.1.2 Research questions

1) What are the primary anxieties and concerns of patients seen for endodontic treatment at LUDH?
2) Did the treatment affect oral health-related quality of life?
3) What were patients’ reflections on outcomes?
4) Did the questionnaire (specifically OHIP-14) ask relevant questions with regards patients’ main concerns?

5.2 Method

5.2.1 Interviews

Qualitative approaches adopt a naturalistic interpretivist perspective to research in which people in ordinary settings are studied to explore their experiences and how they construct meaning in their daily lives (Denzin, 2001). In particular, these perspectives are useful to examine, ‘how people view an object or event and the meaning that they attribute to it’ (Rubin and Rubin, 2005). There are various methods of collecting data in qualitative research depending on the scope (narrow/broad) and subject (meaning/description) of the research focus. This study was interested in a particular experience (endodontic treatment in secondary care at LUDH) and the meanings patients attached to that experience. As such, semi-structured interviews were an appropriate method to answer the research questions. Interviews can be described as a conversation in which a researcher guides a conversational partner in a detailed discussion on a topic (Rubin and
Rubin, 2005). Semi-structured interviews focus on a particular topic whilst being flexible to allow interviewees to contribute their own experiences. The adaptable approach aimed to allow interviewees to talk from their own perspective and use their own frame of reference.

In this study, semi-structured interviews were conducted over the telephone. Telephone interviews often allow people to be more relaxed and therefore disclose more sensitive data, from the comfort of their own home. Some patients also travel considerable distances to attend at LUDH, so telephone interviews limit inconvenience to the participant (Novick, 2008). This also leads to saving in resources of time for the participant as they do not need to travel and money to the research institution in reimbursing travel (Shuy, 2003). The other major benefits are that telephone interviews are usually less intense and provide greater anonymity than face to face interviews, and can lead to participants relaxing and speaking freely during the interview (Kavanaugh and Ayres, 1998). This has led to telephone interviews being an increasingly appealing option amongst qualitative researchers. However, there are concerns over the quality and effectiveness of telephone interviews in information gathering compared to face to face interviews, and methodological textbooks have highlighted the loss of non-verbal cues and rapport building, as well as shortened length of interviews and subsequent decreased depth of coverage of the themes (Irvine, 2011). Given the difficulty in recruitment for this population, however, telephone interviews were considered the most flexible approach for participants.
5.2.2 Procedure

Ethical approval was gained as part of an amendment to an earlier IRAS application (see section 4.2.2 IRAS amendments). Participants were recruited by asking a purposive sample of patients who attended Liverpool University Dental Hospital for endodontic treatment, completed the questionnaire, and consented to take part in a telephone interview. The patients were called at least one week following treatment completion, to ensure immediate post-operative pain did not affect patient responses. The aim was to contact a range of patients in terms of age, gender, ethnicity, postcode, tooth treated and procedure type. Patients were also recruited who failed to complete follow up questionnaires. Those who took part were sent a £10 ‘Love to Shop’ Gift Card by post. Each participant interview was coded to ensure anonymity and confidentiality during recording and transcribing.

A previous ethical approval application had been accepted (see Chapter 4) for quantitative PROMs research, and an amendment was made on IRAS to inform REC and HRA that a qualitative arm of the study was also planned. The Qualitative protocol, consent and participant information sheet were added and approval was granted on the 31st October 2017 (see appendix 17).

The telephone interviews were recorded with two hand held recorders and took place at Liverpool University Dental Hospital. Participants were initially informed of the aim of the study. Consent was given verbally and patient information leaflets were sent out to the patient in the post.
The participants were then asked a series of questions that followed a schedule to ensure all topics were covered sufficiently. Questioning followed a style of open-ended questions designed to allow participants a chance to express and elaborate on their thoughts. The skills of active listening, and reflection were used to ensure information gathered was accurate and to encourage further disclosure from participants (Bredart et al., 2014). A secretary at Liverpool University Dental Hospital transcribed all interviews immediately following each telephone interview.

All participants were adults that had attended LUDH for endodontic treatment between 2017 and 2018, following referral from primary dental care. All interviews were semi-structured telephone interviews carried out at LUDH by the same researcher, with the topic guide updated during the interview process following review. Interviews varied in length between five minutes and twenty-six minutes, with an average call time of twelve minutes.

5.2.3 Consent process

Potential participants were called to discuss recruitment to the study. They were informed that interviews would take 10-20 minutes, and that speech from the interviews may be used anonymously in a future publication. The participants were informed that interview data would be securely stored, and that verbal recordings would be deleted and written transcripts shredded at the completion of the study. They were aware that they could decline taking
part at any time with no effect on their future treatment and were given contact information if they had any further queries. If the participant consented, the interview time was verbally arranged, and this occurred immediately after consent, or shortly after initial contact and consent.

5.2.4 Interview schedule

An interview schedule was formulated (see Figure 5.1), and data collection started in December 2017. Ten interviews were recorded and transcribed in a six-week period. These transcripts were then reviewed with a supervisor working in qualitative research. The schedule was then adapted to ensure more open questions and therefore a greater amount of data collection from participants (see Figure 5.2). This also had the benefit of giving the patient enough time to fully express what they were trying to articulate. This resulted in a further eleven interviews, leading to a total of twenty-one participants.
Initial interview schedule

- Do you remember filling in a questionnaire before you started treatment?
- Can you remember how you were feeling at that time? Main concerns/anxieties
- How did you feel after treatment?
- Was the treatment successful from your perspective?
- Did the questions we asked reflect what mattered to you (remind patients we asked about level of pain, anxiety, concerns, oral health state)
- Did treatment have an impact on life such as missing work? Time in chair?
- Would you have same concerns if starting RCT again tomorrow?
- Was the process worthwhile?
- What was especially important to you?
- What changed after the treatment?
- Has the treatment you had influenced your overall feeling about your own oral health?

Figure 5. 1 Initial interview schedule
Revised interview schedule

Consultation and pre-treatment phase

- Can you tell me what led you here (to the Dental Hospital)?
- How was the problem with the tooth affecting you?
- Did you have some concerns before you started treatment?
- Were you concerned about losing the tooth?
- What in particular worried you?

Treatment phase

- Can you tell me about your first appointment for treatment?
- Can you tell me about further appointments you attended?
- Two questions were then read from the OHIP-14 with patients asked to explain the relevance of the questions to them.
- 'Have you had trouble pronouncing any words due to problems with your mouth, teeth or dentures?'
- 'Have you been totally unable to function due to problems with your mouth, teeth or dentures?'
- If no – prompt – what concerns were most important to you?

Post treatment phase

- Do you feel differently now that treatment is complete?
- Did the treatment meet your expectations?
- Would you change anything about the treatment you received?
- Follow up questions re drop-out if applicable

Figure 5. 2 Revised interview schedule
5.3 Data analysis

In terms of analysis of the interviews, thematic analysis was chosen as the method of data investigation. Thematic analysis is defined as a method for identifying, analysing and reporting patterns (themes) within data (Braun and Clarke, 2006). Thematic analysis is seen as a fundamental method for analysing qualitative research, and is a flexible and useful tool as it can be used with a range of research methods, without having to change how the method is applied (Braun and Clarke, 2006).

A theme captures important subjects and concepts presented in the data in relation to the research question, and characterises a pattern or value from within the data set. This study will follow an ‘inductive’ thematic analysis style rather than ‘theoretical’ to ensure the themes identified are strongly linked to the data (Patton, 1990), rather than trying to fit the data into preconceptions of the researcher. Themes examined at a semantic or explicit level focus on what the participant said (describing the data). The themes in this study were instead examined at an interpretative level (Boyatzis, 1998), where there is an attempt to theorise the significance of the patterns to provide stronger meanings and implications of the data (Patton, 1990). This allows expression of the underlying ideas, assumptions and concepts of the data from the semantic content.

Following collection of the data, (Braun and Clarke, 2006) advise six phases of thematic analysis, shown in Figure 5.3.
1) Familiarization with the data – this involves data transcription, reading and re-reading the data, and noting down initial ideas and concepts.

2) Generating initial codes – codes identify a feature of the data that provokes interest in the researcher, and warrants further thought or analysis.

3) Searching for themes – this involves collating coded items into themes, by analysing the codes and seeing how they are combined and related. Mind maps at this stage can be useful to visualise the data.

4) Reviewing themes – here themes are reviewed to see if there is enough data to support them, or whether two themes are actually very similar and can be combined. In contrast, other themes may need to be broken down as they are covering too much information and losing the required detail.

5) Defining and naming themes – themes are ‘defined and refined’ by determining what aspect of the data is covered by the theme.

6) Producing the report – a concise and coherent report of the interview findings.

Figure 5. 3 Six phases of thematic analysis (Braun and Clarke, 2006)

Twenty-one interviews were conducted until data saturation (defined by no further themes being developed) was achieved. The average age of those interviewed was 46 years old, consisting of 8 males and 13 females. Ethnicity, treatment type and tooth treated of those interviewed are illustrated in Figures 5.4, 5.5 and 5.6 respectively.
Figure 5. 4 Pie chart detailing ethnicity of interview participants

Figure 5. 5 Pie chart detailing treatment carried out for interview participants

Figure 5. 6 Pie chart detailing the tooth treated of interview participants

Thematic analysis produced four themes following the twenty-one interviews undertaken. Figure 5.7 illustrates the themes produced from the thematic analysis, which will be discussed in further detail below.
Figure 5. Diagrammatic representation of the themes produced from the thematic analysis.
5.3.1 Complexity leading to referral

Several participants explained that the referral had been made due to complexity of the treatment. The reasons for referral to specialist services were:

- Anatomy

Anatomical complications were cited as the main cause for referral to the dental hospital. Commonly this occurred when the dentist attempted treatment but was unable to locate some or all of the canals. The dentist generally explained about the case complexity and the need for “specialists / specialist equipment.”

He tried on at least 2 separate sessions, he was able to get to 2 canals but he was unable to get through to the third canal, and he felt he needed, he didn’t have a microscope to actually visualise it properly in order to complete the treatment.

VV6084

I had root canal treatment at my dentist and continued to feel pain for some time afterwards. Ermm, I think she said we’d give it a year, no we’d give it 6 months and if it didn’t subside she would refer me to your clinic, because the equipment you had was better able to determine whether there was a 4th canal that she couldn’t see.

LF0139
• Lacking equipment

Dentists often cited a lack of equipment as the reason for referral of patients to secondary care. For example, it is not common for GDPs to own an operating microscope, which greatly aids location of endodontic anatomy and overall management of the case although there is no evidence this improves endodontic outcomes (Del Fabbro et al., 2015, Ng et al., 2011b). Dentists generally attempted treatment and only referred when they encountered difficulty.

_Me own dentist didn’t have the equipment to do the work himself, so that’s why I had to be referred to the Dental Hospital._

_BT7849_

_Ok ermm, the reason was, the problem was, my dentist recommended, tried to, he attempted to try and do a root canal treatment for my lower, I think LR6 I think and he found it very difficult. I think he tried quite hard and he felt he won’t, he doesn’t have the right equipment to continue with the treatment, he felt better that he referred me to the dental hospital and that’s how I ended up being referred to the erm restorative dentistry department._

_VV6084_

_Yes she had already conducted the treatment but it it wasn’t healing in the manner that she hoped it would. And so she said this is more advanced, there is more advanced equipment at the hospital which I don’t have here and they will be able to identify what else is going on._

_LF0139_
• **Referral to secondary care required**

Patients were referred when diagnosis was unclear, and a second opinion was required, or more detailed radiographic assessment such as the use of CBCT may have proved helpful to diagnosis and/or management.

*He saw me there and he had a look at the tooth and he said on our x-ray we can’t see a file but it is very tender on the gum. So he said I want to take you to the dental hospital and they can do a big in depth you know x-ray which they did and they found the file in the tooth.*

*JH3332*

A further reason that warranted referral was medical complications, such as patients taking bisphosphonates for whom extraction is contraindicated.

*Ermm, I took allendronic acid I think it’s called, yes and that leads to complications to dental work. And I had… a tooth broke a bit, and the dentist was saying it would be difficult to fix, and removing it would be difficult because of the drugs so he referred me to the hospital.*

*BD2220*

• **Procedural error by referring GDP**

A number of participants were referred due to procedural errors from the referring dentist, often involving separation of endodontic instruments, which are difficult to remove without specialised equipment and additional training.

*I went in for a root canal and during the process of my dentist doing that root canal, she left a little bit of drill bit in my tooth.*

*RJ7032*
He said ok we'll do this, did the root canal and actually the tool broke off in the root of my tooth

KL3535

- **Unclear reason for referral to secondary care**

When questioned on what had led the patient to the dental hospital, some participants lacked clarity for the reason for transfer to LUDH. They often hinted at treatment complexity, but also appeared to be suggesting that they felt their treatment had been a burden for their dentist to complete.

*I don’t think she done a root canal but it was maybe taking up too much of her time I don’t know, I don’t know to be honest with you but I just went by what she said she done something that wasn’t.. I don’t think she’s done one.*

GD7845

*For many years I had a discoloured front tooth, so I mentioned that to the dentist and he erm started to do some investigations as to why it was the way it was and then found after an x-ray that it was dead, erm and that there was nothing really he could do about it. So he discussed with me whether or not I wanted to, all the different options I had and I chose to see you at the Dental Hospital.*

*Erm well yeh, I mean I guess he just said that that was something for, you know that, you wouldn’t have done at the NHS surgery. Erm that I could either go private, or either just wait for it to sort of run its course and either become infected or get an abscess or whatever and come out of its own accord*

RJ1476
• Theme summary

Dentists referred patients to secondary care when they felt unable to provide optimum endodontic treatment. This was caused by anatomical difficulties or procedural errors that prevented the dentist from gaining patency. There was also a suggestion of referral due to burden of care being too great for the GDP, in terms of time or financial constraints or lack of confidence carrying out endodontic procedures.

5.3.2 Patient trust receiving treatment at the dental hospital

• Management of concerns and consent procedure

The chance to discuss treatment options gave patients confidence and validated their consent to undergo treatment. Patients explained they felt more control when they knew what was planned in their treatment. The opportunity to have protected time to fully discuss treatment options, and for the patient to convey their opinions, was shown to be an important and valued part of the patients’ treatment experience and something they may not have had previously in primary care due to the time pressures GDPs experience.
That it was like you talked me through a lot of options not just losing the tooth like I thought I was going to, I said I didn’t want to lose the tooth so you did try something else and it worked to be OK, so I was glad you give me a few options rather than going and just taking the tooth out.

JMS5991

I was actually quite interested to understand what they were going to do with the tooth moving forward to see you know what the treatment plan was going to be because I’d been dealing with the pain for some time by that point…. the dentist kept me really well informed throughout the entire process before he’d even, you know, he’d look in my mouth and then he’d say this is what I want to do, are you happy with that? This is how many times I think you’ll have to come, which was an accurate reflection on how many times he wanted to see me as well which I appreciated.

LF0139

It was explained to me very clearly what the problem was. There was a bit of drill in my tooth and they had to get it out, and it was explained to me very clearly that we don’t know if we’ll be able to get it out or not and we will see. So I was kinda prepped, it was like an exploratory session if that makes sense and so I was kinda knew I was going to be there a long time, it didn’t come as any surprise to me, so I just kinda took it as it was.

RJ7032

- Technology leads to confidence in procedure

In contrast to this, the equipment/technology used at the dental hospital, along with the supervision provided, was comforting to the patients. There was a belief that the equipment had an effect on the quality of treatment provided. The patients felt this technologically advanced equipment illustrated the difference to the ‘bog-standard’ equipment used in their primary care setting.
I was being seen by you know, people specialising in this treatment you know again with a tutor I felt I was in the best possible place. And obviously equipment and everything else coz you know you have got all the latest equipment so you know that really made me feel confident.

SB7838

Well obviously, the technology was amazing, it’s more than I get at my local dentist… I’d rather go there all the time if I could

AM7410

I mean I wasn’t very worried because I am very philosophical but when you actually get to the Royal Liverpool it is an amazingly hi-tech place and there are loads of people who seem to know what they are doing.

AB5974

• Dental professionals / expertise at LUDH

Participants reported feeling calmness and trust in the dental professionals providing treatment at LUDH. The patients felt valued in terms of ensuring good clinical outcomes and the importance of their individual treatment, even if it took considerable time and effort.

The environment, the maturity, its professional and the fact that although they are learning, they are very well supervised as well which you need to be when you are learning.

AB5974

I kinda felt like I was in safe hands and knew I’d be treated well so my level of anxiety wasn’t bad because of that. Ermm, I kinda had trust that it was all gonna go well I guess, which is what maybe helped me get through it.

JQ2443
It was clear from all the effort that was being taken in terms getting second opinion and then other people to come and look at it… in terms of the time, I kind of accepted it and I realised into the treatment, I realised how complex it is. what I really appreciate is the fact that there was a sense, the doctor especially, what I really appreciated was the fact that he kept persisting and so.. you would probably get that level you think if you going private.

VV6084

The patients also felt greater trust when their clinicians discussed the case and got a second opinion, again making their treatment feel more valuable and individualised. Patients found this communication, senior support and professionalism reassuring and this built trust between the patient and clinician.

Yeh I’m really pleased, so I have finished all the treatment now. Like I say, they were very thorough, when the trainee wasn’t sure of whether he was doing the right thing, he went and got advice and there was some debate about what type of crown they were going to put on and so he, he consulted with 2 or 3 of his supervisors and the consultant and he didn’t start anything until he was 100% sure. So yeh, it was a good experience to be honest.

WP9072

I’m still scared of dentists but that is never going to go away, but the way they handled it and the way that they consulted with each other and kept be constantly informed of what they were talking about and why they were talking about, yeh it built my trust in that dentist I have to say.

WP9072

A feeling of distrust with the dental profession was evident in other patients, with a history of failed treatment often mentioned.
I think I was worried because I had had a lot of treatment with my dentist that had gone wrong so I couldn’t actually go to a dentist and I was just panicking about my teeth going wrong putting them in someone else’s hands.

JMS5991

I was very frustrated about the whole thing to be honest because I went in for a root canal and I wanted a white filling rather than the mercury type filling and he said, OK we’ll do this, did the root canal and actually the tool broke off in the root of my tooth.

KL3535

- **NHS quality assurance and Liverpool University Dental Hospital**

Trust in the NHS to look after patients was evident in patient interviews, as well as a belief that being treated at LUDH was more likely to lead to a successful procedure.

*No, there was no pain and I trust the Royal Liverpool.*

AB5974

*I didn’t think they would take it on if they didn’t think they could make a good go of it, so yes I trusted they would do something.*

BD2220

*I was confident of you know being at Liverpool dental hospital you know because it is a university. I know you’re studying but I knew I would be in good hands so I wasn’t really concerned.*

SB7838
• Theme summary

Patients appreciated the chance to talk through their cases in detail, and recognised the improvement in understanding and thus consent to their treatment. Many patients recognised the additional equipment on offer at LUDH, and the feeling of a hi-tech environment. The professionalism and specialist knowledge of staff on the endodontic clinic was recognised by patients, and allowed them to feel valued and safe during treatment.

5.3.3 The impact of symptoms on QoL, and the effects of endodontic treatment

• Pre treatment

A number of participants did not experience pain before starting treatment, claiming that the problematic tooth had no effect on their daily lives, and was simply an inconvenience.

*There was no pain or anything, I mean it was, I had to have the root canal obviously and there was a bit of irritation that came with that but there was no real pain or anything…*

*No no, it was more like having, I don’t now, when you have a list of jobs to do and it’s that one you can’t tick off the list for a while, that level of irritation due you know what I mean?*

*RJ7032*

*No, I was in no pain at all; the teeth had actually been broken for about 3 years.*

*WP9072*
Participants spoke of the loss of function that occurred prior to receiving endodontic treatment, due to pain from the tooth, or concerns that they could make things worse for example cause pain when eating. Patients gave detailed descriptions of the pain they were experiencing at the time.

*No no, I just had to be careful where I ate because it was the tooth right at the very front so I just had to be more careful where I ate*

GCE8828

*It was like, excruciating and I just needed to get something sorted there and then. I needed a quick fix, but in the pain leading up to that previous to that, it was very much on and off, I wasn’t too concerned about getting the treatment because I kinda knew when the pain would come that it would then go away. But when I got this really really bad pain, I didn’t want to experience that again which is what led me to wanting kind of a long term fix coz it was really severe. Something I hadn’t really felt before. I couldn’t eat, couldn’t work, couldn’t really go about my day to day life so I didn’t want to go through that again which is why I kinda wanted it done.*

JQ2443

*I was in a great deal of pain, I kept on getting infections in the gum just under the left nostril.*

GD7485

Other participants spoke of concern and uncertainty regarding whether treatment would be successful, and the long-term outlook for their teeth.

*I went into the whole situation not sure whether I was going to come out with something that was removable or whether I’d have fixed teeth again.*

DH6746
I was in terrible pain before, absolutely constant err toothache really err really bad. I wasn’t sure to be honest, and they weren’t sure whether or not they would be able to save the tooth to be honest…

Patients were concerned by recurrent episodes of infection and the need for repeat antibiotic prescriptions, which could affect their general health in the future.

Well the worry was that I had these infections, I had abscesses, I was developing abscesses at that site and I was needing antibiotics and it was happening more and more than one occasion so it was a chance it could recur many times, the abscess was there so the symptoms associated with that – the pain, the discomfort and then having to take antibiotics to try and manage the symptoms. So that’s when I went to have the treatment.

The process of getting an appointment also caused patients difficulty. This was in some cases due to toothache, but for other patients the uncertainty of when treatment would be scheduled initiated anxiety and concern.

I was phoning the Dental Hospital all the time to see whether or not there was a cancellation so I could take someone’s place, it was that bad… I wasn’t anxious or concerned about going in, I was just anxious when I was going to have an appointment more than anything. I wasn’t frightened of going and I didn’t feel like I wasn’t in safe hands, that wasn’t the issue, it was more the fact that there was a long waiting list and every time I phoned up they were saying we can’t give you a date, it could be 6 months, it could be 3 weeks. So I was anxious over that, thinking that my own dentist couldn’t help and I didn’t want to be in pain that amount of time, so that was my main anxiety and my main concern is how long I would have to wait to have an appointment not actually going in and having the treatment.
• Preconceptions regarding endodontics - associated pain and complexity

Participants made an association between treatment complexity and painfulness of the procedure.

There wouldn't have been too many concerns, pain probably would have been the only thing… I wasn’t sure how painful it was going to be because my own dentist had told me that they weren’t able to do it because of the skills involved and I like, assumed that to be difficult and painful at the same time bearing in mind they told me what was necessary to be done.

DH6746

Patients who had experienced pain during the endodontic procedure with their own dentist were also more apprehensive. Their main concerns were how painful it was going to be, and how long was the procedure going to take.

I don’t have any problem with the dentist, I have never been scared of the dentist, never had any pain, I’d happily go for a filling but this, the original root canal treatment was quite traumatic in that every time I went there I knew it was going to be painful.

I’d never go into any form of treatment without doing a bit of research and I knew that root canal should not be painful so to have experienced the previous pain, you know going into this, that was something that was really worrying about me, that was like, I just wanted it to be resolved.

LF0139
Patients who had undergone historical root canal treatment often had memories of treatment that they associated with pain and lack of control. This often caused anxiety and appeared to be linked to generational experiences of dental care. Patients appreciated the empathy dental professionals demonstrated when discussing their dental anxieties.

*Dentistry wasn’t as good as it is now like and it was in North Scotland and it was very painful…To be honest with you, when they did the root canal in Scotland me head was being thrown about all over the place, it was like shoving a spike in there you know! It was horrendous, like being beat up.*

GD7845

*I do have a fear of dentists and that if they were going to take the teeth out then they would have to actually put me under, they couldn’t remove any teeth while I was awake, I had a really bad experience as a child. They were aware that I had a phobia of dentists and they were very sympathetic to that.*

WP9072

**Avoidance**

Some patients managed toothache with temporary measures and then avoided definitive endodontic treatment. Others avoided dealing definitively with problems, citing time and money as complicating factors.

*I had severe pain in my right bottom tooth, and I went to the dentist who said I needed root canal treatment. I then kinda put it off for a couple of months coz the pain went away, and then it got really severe and I had a treatment I can’t remember where. They extracted the nerve or something to that effect there and then and then led me to having to book an appointment with yourselves.*

JQ2443
The tooth was flaring up now and again when there was infection and because I was pregnant with the second child they mentioned I could do in the hospital for free but I would have to wait a little bit. So I agreed to wait and I think I waited only 3 years....

It doesn’t bother me, only when I’m ill. I’m happy to wait but that’s obviously expensive treatment isn’t it, they said about £500-£600 it would cost me to do it....

When you have two kids you don’t really have time to worry about yourself, so I don’t think I think about it too much.

MT4383

- Self-conscious about appearance

Facial swellings and abscesses had a large impact in participants’ daily lives, with resultant loss of function and QoL. There was also resultant self-consciousness associated with this.

Yeh definitely yeh before that I couldn’t smile, I had a big lump, I was really paranoid over it

JMS5991

When I came I actually had a piece missing, and it kept on falling off and gluing it on, and I felt a bit conscious of that and eating certain things

DH6746

Another participant described being able to taste an infection in her mouth. Although this was not causing pain, it caused a bad taste in her mouth that affected her ability to feel comfortable in social surroundings, both in social interactions but also with her partner.
Ye, the only thing that I have, sometimes it’s awful I explain to him, I take a mouthwash with me, and I need a spray. Because sometimes, I can taste it. That’s the only concern I have really….Yes and obviously when you are out, and I can taste and smell it, I don’t like talking to people straightaway, I use my mouth wash straightaway.

JA8529

- **During treatment**

There was very little mention of post-operative pain or flare ups, although a patient who underwent apical surgery explained that surgery had a significant affect due to tiredness and swelling post procedure. Another patient explained that a temporary dressing caused significant discomfort with associated effect on quality of life due to disrupted sleeping and eating.

*Afterwards my face was massive! And I was really tired, it was really odd how wiped out I felt, so that’s the only difference.*

RJ1476

*They said well we’ll have to just pack it up and come back but because they had injected some medication I assume, into my tooth. But because I had a tear in the tooth, the medication was seeping into my jaw bone so it was actually extremely painful, to the point that for 2 weeks, I was struggling sleeping and eating*

KL3535

The procedure itself was often described as uncomfortable rather than painful. This was related to the dental chair, sitting still for long periods, and keeping the mouth open to allow treatment to continue as opposed to pain from the tooth being treated.
I’d say rather than pain, I’d say uncomfortableness was what was at the top of my difficult chart if you wanna say. I just felt uncomfortable, I wasn’t necessarily in pain as such, kinda having my mouth wide open for a long period of time I found quite uncomfortable. Weirdly as well, I suffer with a bad back and pain in my back on the dental chair was probably more pain than I had in the actual mouth. Again, that was kinda more of an uncomfortable thing.

JQ2443

I think having my mouth open for long periods of time and he has put some sort of a retainer something to keep it open and so that was quite difficult yeh, long periods of time.

VV6084

In addition, the specialist equipment used was often new to the patients. In some patients, this introduction to new equipment caused anxiety because it indicated a more involved or complex procedure that they hadn’t undergone before.

So I had, again I don’t know the correct terms but I had that sheet inside my mouth and that was something I’d kinda never had before which made me feel a bit uncomfortable just because, I don’t know why, maybe emotionally it felt like it was a bigger deal than anything I have had done before in my mouth or with my teeth, ermm cos I’ve never had that equipment ever.

JQ2443

Patients talked about the impact of endodontic treatment in terms of time, scheduling and the difficulties it caused. When asked about impact on life, a participant responded:
To be honest it was quite a lot cos I had to keep leaving and missing lots of work and stuff, the amount of times I had to go, it was having an impact on work and travelling there and back as well was quite a lot.

I work in Warrington. I’d be going to work, coming out of work, and then going back to work. Cos I think the only days you did was a Monday and Tuesday, and I only work Monday, Tuesday, Wednesdays so it was a bit of trouble with work having to sort that out as well, but I mean they were accommodating.

AP1521

Participants questioned whether the time taken was worthwhile, especially if the treatment was not ultimately successful.

I was thinking to myself what if we go back into this tooth again and it doesn’t actually resolve the problem and it’s now two years down the line, two root canal treatments later, you know it’s a lot of work… It’s hard to get time off work for repeated incidences of going back to the tooth and I was just thinking, is it worth my trying to save this tooth when I’m taking all this time off work.

LF0139

- **Theme summary**

Patients discussed the negative impact on QoL due to pre-treatment symptoms such as pain, swelling and effect on sleeping and eating due to dental problems. Patients displayed concerns regarding cosmetics following tooth loss which were key factors in attempting to save the tooth. The time taken for treatment created difficulties with regards time off work and discomfort sitting in the chair.
5.3.4 Patients’ reflections following treatment

- Outlook post-treatment

When treatment had not gone to plan, and the optimum outcome had not been achieved, this often left the patient feeling frustrated. This was in terms of the struggle to carry out treatment for little reward, with inconveniences encountered.

And we are just going to monitor it, and the whole process for me would be one, very frustrating. And I had to use a lot of annual leave, and give up a lot of time in work to attend long appointments, to the end result of not getting anywhere to be honest. So I now had a broken off tool still in the root and I now have a half crown on my tooth which I have been told it may come off so we have got to monitor it. So I suppose at the end of the day I hadn’t lost a tooth I didn’t have a gap in the line of my tooth gum, so that’s a bonus… but the whole thing has been very protracted and very frustrating

KL3535

However, there was an acceptance from patients that symptoms may still occur for a period of time, even after treatment has been completed. This seemed accepted following advice from dental professionals whom the patients trusted.

Yes there were occasional funny sort of twinge things, but he said it takes up to 2 years for everything to settle down, he said you will get very very short intermittent.. not very frequent. Which I didn’t know, I kind of assumed it was all finished and done.

AB5974
Participants commented on the tooth returning into their subconscious and no longer occupying their thoughts once they had completed treatment. This indicated an important return to normal life with no effect on daily function such as avoiding eating on side.

*Seven days after it was kind of as if it had never happened you know I wasn’t really thinking about it, or I wasn’t thinking about it at all. I was quite confident and happy with how it had all gone.*

*JQ2443*

Patients reflected that their thoughts about endodontic treatment had changed in relation to their pre-treatment thoughts. Patients would still find treatment time consuming and a nuisance, but would not be as apprehensive about future endodontic treatment when their outcome had been positive.

*Erm no, if someone told me that I needed this re-doing because 15 years down the line it started to fall to pieces again, I wouldn’t be apprehensive at all. First of all I’d know that it wouldn’t be that painful, I’d know that it was achievable and I know the dentist would get a good outcome.*

*DH6746*

*I would advise anyone to get that treatment as it does save a tooth.*

*IF8649*

In contrast, patients with negative experiences were apprehensive at the thought of endodontic treatment in the future.

*I think I would be nervous initially, initially nervous that the tools they were using were not up to scratch and they would break, and I know the odds of that happening again are quite remote but it wouldn’t prevent me from doing
it. But it would certainly be the thing going through my mind as I was going through the treatment.

KL3535

Other patients expressed gratitude at receiving free NHS treatment.

Yeh I got an overlay and you know being blunt I saved quite a lot of money by getting it done at the dental hospital as opposed to getting it done at my own dentist, so I’m happy with that as well.

RJ7032

A number of participants mentioned that their general oral health had improved, with treatment reminding them how important it is to maintain good oral hygiene to prevent future issues and improve the longevity of the treatment undertaken.

Yeh, you gave me a lot of good advice, and how to continue having had the work done and how to look after them and how to generally look after me teeth as a result of having that done so it is all positive

DH6746

Strangely enough, I feel that my mouth is a lot healthier any way because of the hassle I have gone through. I have had so much dental check-ups in the last 2 years, also I’ve been able to have access to a hygienist so I have been getting treatment like cleaning every 6 months or so, I do generally feel that my mouth is actually in a much better position than it was before. So there is always a positive that comes out of everything isn’t there.

KL3535

I think you know with the treatment I received you know and my dentist, I am very comfortable with my oral health now you know it has improved.

SB7838
• **Consequences of losing the tooth**

Participants often discussed tooth loss and replacement. A common theme was that patients were very keen to keep hold of their teeth, and felt this was better than any replacement alternative.

*Well that’s it. I have lost a couple of them, I have got a couple of spaces, but I can’t really afford to lose any more. I’d have to think about replacement of sorts.*

*BD2220*

*I didn’t think much of the consequences initially but later after having had a conversation with him yes I thought it makes sense to continue with the treatment yeh, to try and preserve the tooth rather than to take it out altogether.*

*VV6084*

There was a dishonour and shame attached to losing teeth and requiring dentures, especially when the patient felt they should still have their teeth at that age. This had an effect on overall quality of life, with the patient not seeing her friends and family due to the pain and problems she was having with her oral health.

*Yes I have had a denture and it just, I mean you know you see elderly people and I’m not young, I’m 68 but I’m a young 68, I see people who sort of are always sucking you know always doing this. And they have got false teeth and yet when I had that denture, I only had to suck and it would pop out you know it just wasn’t comfortable.*

*I live on my own so I haven’t got you know but my family, like I’ll put it this way, I didn’t see my son in Bulgaria, he lives in Bulgaria for 3 years and I wouldn’t go because I was in so much pain with my teeth*
Well, my whole personality has changed. I am conscious, I won’t go out and eat a meal now, because as soon as I start eating I have got to put my hand to my mouth and sometimes the pain shoots right up into my face, up to my head and then down.

All JH332

When discussing implant replacement, cost of treatment was a regular concern, rather than outcomes or experiences of the endodontic treatment. Replacement with dentures made participants feel anxious and paranoid regarding eating and functioning or social embarrassment.

Yeh, certainly the cost, sorry, the cost of replacing a tooth with an implant that was my biggest worry because I don’t have that money, you know money like that just to just to get a replacement at any time.

RJ1476

I mean the cost yeh, and the loss of function probably not too much. To be honest, I have never lost a tooth before - I don’t know what the loss of function would have been. Yeh, the cost and the cosmetics would have been the 2 driving factors for me.

RJ7032

No when I’m eating that doesn’t worry me, its just more losing the tooth than anything. Because, obviously it is still seeping erm, and bones getting smaller as well as it’s been left that long, if I lost it then you said I’d have to have a denture, then I would be paranoid, with eating, do you know what I mean?

JA8529

Other participants talked about the general concerns regarding health in a general sense, and the fear of resultant loss of function.
Because you get older and wiser I think, and bits of you stop working properly as you will discover. You get more concerned about health generally, the longevity of the bits of you that stop working properly.

• **Impact of aesthetic concern on treatment choice**

The way that people were judged or considered with regards appearance was important to participants, and the attempt at ‘normality’ and hiding dental disease appeared to drive treatment choices. Various patients discussed the cosmetic effect of losing the tooth as worrying them more than functional or emotional loss of the tooth.

Yes, cosmetics as well. My root canal treatment was on a back tooth so in reality you probably wouldn’t be able to see if the tooth was removed, but I was thinking you know, I was going to say I’m quite young!! But I was 29 when I started the treatment and I thought well.. I don’t want a gap in my mouth or you know and what then, do I get an implant, am I going to have a denture you know that sort of thing was playing on my mind.

But I think it is more aesthetics, you know, to look nicer, but in terms of anxiety about losing the tooth or anything I was kinda fairly relaxed… To be honest I have never lost a tooth before I don’t know what the loss of function would have been, yeh the cost and the cosmetics would have been the 2 driving factors for me.

Other patients explained they simply didn’t want to have poor cosmetics and that they disliked the appearance of the tooth in question, and the associated stigma of poor dental cosmetics.
Erm yeh, it’s a cosmetic thing isn’t it, you don’t really want to be knocking around with just one tooth missing do you?

GD7845

It wasn’t affecting me, I have always hated it has been a different colour and I didn’t know at the time it was dead… I just realised it isn’t normal to have different coloured teeth so something must be up.

RJ1476

One patient initially underwent treatment to change an amalgam restoration that her dentist advised to replace, but then led to endodontic treatment. When asked what led her to undergo the initial treatment, the patient explained the cosmetic concerns that underlined her treatment choices.

Just vanity, it was a pure vanity. Yeh well I, I am generally quite a happy smiley person so when I smile, and laugh obviously my mouth opens up and I don’t want to see, and I don’t want people to see a silver filling. I am conscious about that so when it was time for a review and I said ok, we’ve had that one in for quite some time now, he said there was a slight crack on the end of the tooth. So he said we will need to replace it and that’s when I said I wanted it to be a white replacement rather than an amalgam, and it purely was nothing to do with you know it was causing me a problem, it was pure vanity at the end of the day and I accept that.

KL3535

However, there was a sense of embarrassment that vanity was connected with decisions regarding personal healthcare. This was especially apparent as the tooth went further back in the dentition, with less stigma associated with cosmetics anteriorly.
There was a case where I think the dentist at one point said I could just extract the tooth, but that would have been a concern as I wouldn’t have wanted that to happen. Purely I guess for vanity reasons as a number one reason, erm ye yes I guess that was the main reason. Even though not one of my front teeth as such, but it would definitely be seen if I was laughing or had my mouth wide open so that was kinda my main concern, as soon as she mentioned that was an option I kinda went down any other route than that.

JQ2443

Having your two front teeth missing as well like, it may be alright for the anaesthetist to get the tube in but it doesn't look very good does it, ya know?

GD7845

- Theme summary

Patients discussed the frustration when treatment at the dental hospital did not achieve ideal outcomes. In terms of apprehension regarding treatment, positive experiences left patients far less concerned about the thought of future endodontics. An improvement in general care for oral health was noted. Patients were very keen to maintain their natural teeth, with loss causing a profound effect on QoL. Replacement with implants was seen as very costly, and with dentures an unsuitable option. Treatment choice was linked to cosmetic concerns, and related or perceived stigmas associated with tooth loss.
5.3.5 Lack of relevance of OHIP-14 questionnaire

Two questions from the OHIP-14 were read to participants who were asked to discuss the relevance of the question specifically to them. The two questions read out to the patients were as follows:

1) Have you been unable to function due to problems with your mouth, teeth or dentures?
2) Have you had trouble pronouncing words due to problems with your mouth, teeth or dentures?

These two questions were chosen for two reasons. Firstly, the mean score pre-treatment was low indicating they were not of high value or relevance to participants, and the change in the mean at 6 months post-treatment was also small, indicating the intervention (endodontic treatment) had not caused an effect on response to that question.

The majority of patients felt both questions were not relevant, but a number of patients did feel the questions had a certain relevance, even if they reflected it was not relevant to them personally.

Regarding inability to function:

*I could function, yes it is relevant the question you are asking is that that question relevant yet it is..*

*I could function yeh except maybe the discomfort associated with err having the abscess at that particular time it was a headache but otherwise it was ok in between times it was ok.*

VV6084
I wouldn’t say totally unable to function, but there was a level of embarrassment.

WP9072

Well actually yeh! And I feel quite dramatic saying it, but I was like for 2 days, I was warned, but for 2 days I just slept I couldn’t stop sleeping.

RJ1476

Regarding trouble pronouncing words:

I suppose the speech one may be relevant who have large gaps or you know ermm, their life completely changed is a bit out there, but I suppose maybe if you had front teeth or were unable to eat properly, I could see why if you were in exceptional amounts of pain, I could see why it would be relevant for that, but for me it’s kind of irrelevant.

LF0139

Yeh I do actually, sometimes I feel as though my tongue isn’t in the right place if that makes any sense and I say a word that I feel as though I have said it with my tongue up on the roof of my mouth, that’s the only way I can explain it and I can’t think, I just..

JH3332
5.4 Discussion

5.4.1 Examining the reasons GDPs refer endodontic cases to secondary care

Complex endodontic anatomy and equipment were cited as the main two reasons why patients believe they were referred to the dental hospital. The importance to patients is an understanding that their case was complex and subsequently that the tooth may have a reduced lifespan as a result. This created concern in a number of ways. Firstly, patients perceived this complexity as an unwanted complication, as they recognised treatment was going to be difficult / non-routine and may not have a good outcome. This led to concerns regarding impact of tooth loss and effect on their quality of life that are discussed further below. To further analyse the association between complexity and anatomy, combining a complexity tool with endodontic PROM data would be an interesting way of formally assessing this link.

Anatomical considerations are important with regards endodontic treatment outcome. Location and instrumentation of root canals is much more complex without magnification. This relationship was highlighted in a study assessing canal morphology of maxillary molars using a microscope (Stropko, 1999). Stropko found an MB2 in 70% of first molars, rising to 90% when the operator became experienced and proficient. When canals can not be located and instrumented, there is a greater chance of future symptoms and
treatment failure. Hence, having the correct magnification equipment is a key way of improving endodontic outcomes (Monea et al., 2015).

Other patients recounted that the dentist had referred them due to diagnostic difficulty or procedural errors, such as instrument separation during the GDPs attempt at endodontic treatment. Patients understood that referrals of this nature complicated the further treatment and reduced the prognosis. Procedural errors have been shown to affect prognosis such as presence of perforation (Ng et al., 2011b, Saed et al., 2016), or over/under extension of root filling (Sjogren et al., 1990). Dentists are also advised that referral is a sensible and prudent option if an instrument separation occurs, due to the complexity of retrieving it and the potential complications that can occur (McGuigan et al., 2013).

A study conducted in the UK found 10 year survival rates of Endodontically treated teeth of 74% (Lumley et al., 2008). This survival rate is lower than other survival rates in the literature (Ng et al., 2010, Salehrabi and Rotstein, 2004). As discussed in the introduction, qualitative studies have interviewed GDPs in the UK and Sweden about the difficulties of providing optimum endodontic care (Dahlström et al., 2017, McColl et al., 1999). Endodontics is a complex treatment requiring a lot of specialised equipment, and made more complicated in the UK by the remuneration provided for endodontic treatment within the current NHS contract. The negative incentives of providing NHS endodontics has led to a decrease in endodontic treatment provision, as seen by figures produced by the NHS. A report of NHS
treatment estimated that 609,300 endodontic treatments were carried out in England in 2010/11 (NHS Digital Primary Care Domain, 2010). However, this figure dropped to 545,500 in 2015/16 (NHS Digital Primary Care Domain, 2016), indicating a 63,800 decrease in provision of endodontic care. Concurrently, the number of extractions carried out increased from 3,060,000 in 2009/10, to 3,126,000 in 2015/16, an increase of 66,000. This has coincided with an upsurge in provision of implants following tooth extraction. This multifactorial effect on endodontics has subsequently lowered the confidence and proficiency of some GDPs.

In addition to this, the introduction of the postgraduate endodontic programme at Liverpool University has allowed more treatment of complex endodontic cases in secondary care. This is due to more staff availability (postgraduate students), access to required equipment, teaching and supervision. As a result, the number of referrals has increased from the GDPs in the region.

5.4.2 How were patients concerns and anxieties managed during treatment?

Patients noted the importance of a comprehensive discussion of their treatment options, prognosis and subsequent to treatment. This discussion often involved risk assessment of the treatment required with explanation of treatment complexities and effect on prognosis.
The equipment on offer for providing endodontic treatment was significant to participants. The patients perceived a link between technology, which was seldom available with their own GDP, and competence of treatment providers.

Participants trusted the dentists undertaking their treatment at LUDH, and this decreased their anxiety towards treatment. This perception was likely to have resulted from the consultation, the equipment on offer, but also the supervision of postgraduate students by consultants, which the patients found very reassuring. Patients recognised that consultants hold senior positions due to experience and competence, and were reassured that they were overseeing their treatment. Participants appreciated the environment of the clinic where postgraduate clinicians discuss case management and seek second opinion from more experienced colleagues. Patients were aware of the efforts being made to achieve positive outcomes, which enhanced their trust towards the treatment providers. These thoughts were reflected in the qualitative work discussed in section 5.1, with regards access and quality of services on offer (Melgaco-Costa et al., 2016).

The association of treatment in an NHS institute and well-respected university teaching hospital gave patients confidence in their treatment. Patients were asked to assess their trust in NHS institutions via a postal questionnaire, with the mean level of confidence (trust) in the healthcare system being 6 out of 10. The specific areas that patients did have trust was
with regards patient centred care and professional expertise (Calnan and Sanford, 2004).

5.4.3 The effect of endodontic symptoms on patients’ quality of life

Patients vividly recounted experiences of their toothache and the effect on daily life. Others spoke of the concern and stress that transpired related to treatment uncertainty. A recurring theme was the ambiguity surrounding their treatment and its prognosis. Symptoms such as long lasting swellings and being unable to eat on the tooth led to patients questioning whether treatment would be successful and lowering their expectations of treatment success. The question of whether the tooth was saveable, and time waiting for scheduling of appointments (especially with discomfort) was stressful for participants.

Participants discussed their expectations of root canal treatment, with many expressing that they expected the endodontic procedure to be painful, or believed this to be case after being informed they required referral to the dental hospital. Research into the level of anxiety and pain perception of endodontic patients has shown that patients’ expectation of pain intensity is higher than actual pain experienced (Perković et al., 2014).

Patients felt self-conscious due to dental infections, swellings and associated malodours. One patient explained the effect of a bad taste in her mouth,
which led to her relying heavily on mints and mouthwash in social settings. The effect of halitosis has been studied with a strong emotional impact on quality of life, with the consequence of avoidance of social interactions and effect on relationships with others (Settineri et al., 2010).

Patients described endodontic treatment as uncomfortable, but were referring to having a sore back from lying still for a long period of time, or a stiff jaw after remaining open for the whole appointment, rather than pain from the tooth. The process had a relatively short effect on their oral health outlook and quality of life. Use of microscopes may have contributed to this as patients are requested to stay still when possible to maintain image focus and thus treatment efficiency. New equipment had the effect of unsettling some patients, such as the rubber dam used to aid asepsis during endodontics, with the patient explaining this seemed to increase the significance of the treatment complexity.

Patients questioned whether treatment was worthwhile, with the main concerns centred on travel time to appointments, and time off work rather than the treatment length. The patients had also experienced attempts by their own GDP to complete treatment so felt they were repeating the process with no guarantee of success.
5.4.4 Patients reflections of treatment outcomes

 Patients reflected that being informed of a guarded prognosis following treatment was very disheartening and led to them questioning the value and worth of attempting endodontic treatment. The participants had often been through long periods of treatment only for the dentist to communicate treatment may not be successful and the tooth may still require extraction.

In contrast, other patients spoke of the tooth quickly returning to their subconscious, which indicated an absence of concern and anxiety regarding the tooth following treatment.

The risk of losing the tooth made participants feel anxious with high levels of concern. A systematic review of tooth loss and effect on OHRQoL found a significant effect, especially as the tooth is further anterior (Gerritsen et al., 2010). Another study echoed these statements with significantly shortened dental arches also having a large effect, with more significant consequence to younger or female participants (Nassani and Kay, 2011).

Patients talked of losing teeth in the past and feeling they would not function well with additional tooth loss. This relates to the impact on function and quality of life, as shown by studies assessing effect of tooth loss on chewing, well-being and appearance (Brennan et al., 2008, Saintrain and de Souza, 2012). In addition, there is an emotional reaction to losing teeth, which for some patients was strong enough to change their social life and relationship with family. A questionnaire studied the emotional reaction to tooth loss and
found patients were unable to accept tooth loss, less confident about themselves, and inhibited with regards carrying out daily activities (Davis et al., 2000).

Aesthetic concerns played a significant role in patients’ choice of treatment, but patients often expressed embarrassment about this. For some, the cosmetic loss of the tooth caused greater anxiety than the functional loss. A stigma was attached to evidence of dental disease, whether that be trying to mask restorations by ensuring they were tooth coloured rather than metal, or ensuring any tooth loss was masked. Anterior teeth did not cause greater concern, but patients felt cosmetic concerns were more understandable and justifiable as the tooth was more anterior. The impact of tooth loss was discussed in great detail in a qualitative study of thirty-nine participants who had experienced tooth loss and replacement (Rousseau et al., 2014). Similar thoughts were shared in this publication regarding the significant impact that tooth loss had for some (but not all) participants, with a recognition of the vital role the mouth and dentition play in everyday social interactions.

5.4.5 Ability of questionnaire to capture patient concerns

The VAS measuring levels of pain, concern, anxiety and oral health state adequately captured the themes described in the qualitative data, although linking this to case complexity would further enhance this. In addition, patients may value the meaning of ‘oral health state’ differently, with some
measuring the question with regards function and others with regards aesthetics.

The OHIP-14 had questions that were relevant to all patients, although some questions were only relevant to small numbers of participants in the current study. In general, the OHIP-14 scores matched the thoughts articulated in the interviews, which was that endodontic treatment has an effect on OHRQoL, but that it was only short-lived and not significant in the long term.

The seventh domain of OHIP-14 titled handicap assesses life in general and ability to function. For the majority of patients, this question is not relevant. However, a number of patients understood how it may be relevant for others, even if not to them personally. A further group of patients explained the significant impact on their QoL. In one of the interviews, a patient described the dramatic change in their social life, function, and overall QoL. This was matched in their personal OHIP-14 scores, which were vastly greater than the average.

This suggests that although OHIP-14 may not be relevant to all patients, and is not a perfectly relevant tool, it still has relevance to a section of patients in the study sample.
5.4.6 Strengths and weaknesses of interviews

Interviewing is an iterative process involving repeated cycles and analysis of results of interviews, and the adaptation of the topic guide occurred as a result of learning from other interviews. The early interview schedule did not feature open questions that encouraged the respondent to speak freely and openly. This led to an initial failure to fully develop and investigate statements from participants to gain deeper insight. However, the change in presentation of the interview by adaptation of the topic guide led to richer data, as it allowed the patients to share their PROMs through their treatment journey, from referral to thoughts post-treatment.

All participants were aware that the researcher (carrying out the interview) was also a clinician who was part of the endodontic team at LUDH. Some participants had received their endodontic care from the interviewer. This had the potential to shape the responses received, and there was some limited evidence of providing praise for treatment provided. At the same time, familiarity can help to quickly establish a rapport and trust with interviewees, especially in the context of telephone interviews.

Patients generally agreed to take part in interviews due to gratitude, positive feedback or negative feedback. With regards gratitude, a number of participants appeared to feel they should involve themselves in the qualitative interview as a thank you for the treatment provided, which may have introduced positive bias into the data. Similarly, other patients agreed to
participate so they could vent frustration at aspects of their treatment, which may impart negative bias to the data.

Telephone interviews were an effective method of capturing information from the cohort of patients. The main difficulty was in recruiting patients to take part, but this may have proved even more difficult if patients were required to travel to LUDH for the interview, causing further inconvenience to them.
5.5 Conclusions

The impact of tooth loss on function and aesthetics was a key concern regarding outcome. For others, the impact of symptoms and the procedure created significant concern and anxiety, with negative impact on QoL.

Referral of patients requiring endodontics to secondary care is likely to continue as the issues for GDPs attempting endodontics (highlighted earlier in this chapter) continue. For patients, this creates concern about treatment complexity long-term outcomes. A qualitative study with dentists would be a useful way to further investigate the increase in endodontic referrals to secondary care, thought to be related to; overstretched and under-skilled GDPs, and inadequate endodontic remuneration in the current NHS contract.

Consent was highlighted by participants as an important part of their treatment and development of trust. Understanding risk is important for patients, and utilisation of endodontic complexity tools alongside PROMs may provide perspective to the patients on case difficulty and prognosis.

Overall, an extreme variation was seen in the effect of endodontics on QoL, distorting the narrative provided. More research is required to further investigate the variability in patient experience, which for some were straightforward and others extremely complex. OHIP-14 captures the information discussed in this study, but only appears to be relevant to a small cohort of patients in the sample.
CHAPTER 6 CONCLUSIONS AND FUTURE RESEARCH

6.1 Conclusions

The aim of this project was to analyse the effect of endodontics on OHRQoL, by developing a relevant and user-friendly tool. To achieve this, a questionnaire was developed to analyse the change in PROMs following endodontics. This tool was tested in a prospective longitudinal study of patients at LUDH. In addition, telephone interviews assessed the impact of endodontic treatment and assessment of the validity of the questionnaire. The research findings were discussed comprehensively in Chapters 4 and 5, but the main conclusions were:

1) The null hypothesis of the prospective longitudinal study was accepted as OHIP-14 did not show a statistically significant reduction in change in mean score following treatment.

2) OH-VAS caused confusion with regards meaning of the question, and did not fully capture the themes of OHIP-14.

3) OHIP-14 is lengthy and time-consuming to complete and is not specific to endodontics, although it does capture some concerns regarding function.

4) Qualitative data revealed functional and aesthetic concerns related to tooth loss, and the complexities involved in endodontic referrals from
primary care. Elements of OHIP-14 were useful in measuring loss of function, for a small number of patients.

The primary objective of the quantitative study focused on a reduction in the OHIP-14 mean score following treatment. A reduction in the mean was shown although it was non-statistically significant. The benefits of OHIP-14 are its flexibility and generalisability, allowing its use across all fields of dentistry. Despite this, the OHIP-14 questionnaire is lengthy and time-consuming for patients to complete, and its use is limited in primary care, as GDPs find it consumes too much clinical time. OHIP-14 is not specific to endodontics or the measurement of changes in OHRQoL following treatment. To measure this change more effectively, an adapted tool involving two new VAS questions, replacing OHIP-14 (see section 6.2), aims to capture OHRQoL changes in a more concise fashion.

Visual analogue scales measuring pain, anxieties and concerns were a reliable and valid tool, but measurement of oral health state proved to have low specificity, which may be due to the wording of the question, or the minor impact that endodontics has on overall oral health. In addition, the OH-VAS scale was not sensitive enough to fully capture the themes arising from the questions in OHIP-14. The question was not well understood by patients and requires adaptation to improve its effectiveness.

Clinical outcomes from the data collected by LUDH postgraduates, presented similar outcomes to seminal endodontic outcomes in the literature.
Although patient follow-up was only 6 months, the results reflected high levels of asymptomatic patients (92%), with partially or completely healed periapical lesions viewed radiographically in 78% of cases. The effect of pre-operative periapical lesions on success of endodontics have been well documented in the literature. This finding was mirrored in this study, with patients reporting decreased PROMs scores and reduced improvements post-treatment when a periapical lesion was present.

The qualitative study raised three key points:

1) The important and meaningful impact of tooth loss on function and aesthetics. Patients discussed in detail the effect of tooth loss, with many expressing concern and anxiety in relation to experience of previous tooth loss, whilst a small sample of the group discussed the large impact their oral health problems have had on daily function and general life.

2) OHIP-14 is imperfect but does have the ability to capture some of the key issues regarding patient function. The majority of patients reported that endodontics only had a transient and minimal effect on overall oral health status. In these patients, OHIP-14 did not prove a particularly useful tool to measure self-reported treatment outcomes. However, for a small cohort of patients, function was significantly impaired following endodontic problems, thus affecting quality of life, and for these patients OHIP-14 remained a useful and valid tool.

3) The complexities surrounding patient referral to secondary care.
Referral of endodontic cases to secondary care is likely to continue as GDPs find providing endodontic treatment challenging in terms of equipment, expertise, and remuneration within the current NHS contract, which has been heavily scrutinised and criticised in the literature (Steele et al., 2009).

As shown in section 5.4.1, numbers of endodontic treatments provided in the NHS have dropped and numbers of extractions have increased, even though the data collected in this project shows that tooth loss is very important to patients, and that patients are keen to maintain their natural teeth.

Patients understood that their GDP had referred them to secondary care due to difficulties in providing endodontic treatment. This caused concern regarding treatment failure, tooth loss and effect on OHRQoL. Informing patients of case complexity was important to ensure informed consent was provided, and this was appreciated by patients.

The future NHS contract aims to prioritise prevention, group patients in terms of access to advanced care including endodontics, and provide a tiered system, where dentists with additional training carry out advanced dental procedures. This aims to improve access to care for dentally fit patients to more advanced dental services such as endodontic treatment.

Referral to secondary care resulting from case complexity was an important aspect of the patients’ overall endodontic treatment journey and PROMs. However, complexity was not assessed in the quantitative study by either patients or dentists. There is potential for use of a complexity tool such as E-Cat, to measure case complexity alongside endodontic PROMs,
hypothesizing that more complex cases would result in reduced improvement in OHRQoL, because patients would appreciate treatment complexity and thus potential for reduced successful outcomes.

6.2 Tool adaptations for future research

Further studies of endodontic PROMs with a larger sample size are still required. The quantitative and qualitative projects have highlighted that OHIP-14 has some relevance for patients, but the completion of fourteen questions was cumbersome and tedious. Therefore, this has been removed from the tool, and replaced by additional VAS scales that capture the essence of OHIP-14 in a user-friendly and concise fashion.

The VAS scales have been shown to adequately capture the PROMs of patients regarding pain, anxiety and level of concern. However, the OH-VAS has been removed, as it was not consistent in representing a condensed version of OHIP-14. This was because it did not fully capture all questions and themes emphasised by OHIP-14.

Revisiting the questions in OHIP-14 individually, 11 of the 14 questions are either: not relevant to patients undergoing endodontics, or have already been reported by the pain, anxiety and concerns VAS. However, the three questions illustrated in Table 6.1 are not captured by any of the VAS questions, including OH-VAS.
Table 6. 1 OHIP-14 questions not captured in VAS scales

<table>
<thead>
<tr>
<th>Question</th>
</tr>
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<tbody>
<tr>
<td>Have you been self-conscious because of your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?</td>
</tr>
<tr>
<td>Have you been totally unable to function because of problems with your teeth, mouth or dentures?</td>
</tr>
</tbody>
</table>

The two new VAS scales relate to effect on appearance (OHA-VAS), and effect on daily life (OHL-VAS). These questions capture the missing elements of the OHIP-14 and also the messages raised in the qualitative interviews regarding effect on function, daily life and appearance.

The question wording and style is consistent to ensure respondents understand and correctly interpret the question aim, with the intention of improving questionnaire validity. The proposed adapted tool is displayed in Figure 6.1.

In conclusion, these study has provided meaningful PROMs from a sample of patients in a university setting, capturing self-reported outcomes of the impact of endodontics on patients’ OHRQoL. Additionally, this study has provided valuable information to formulate the ideal endodontic-specific PROMs tool.
What is the level of pain from your tooth, where 0 is no pain, and 100 is the worst possible pain?

What is the level of anxiety regarding your tooth, where 0 is no anxiety, and 100 is the greatest possible anxiety?

What is the level of concern regarding your tooth, where 0 is no concern, and 100 is the greatest possible concern?

What effect is your tooth having on your appearance, where 0 is no effect on your appearance, and 100 is the greatest possible effect on your appearance?

How has your tooth affected your daily life, where 0 is no effect on daily life, and 100 is the greatest possible effect on daily life?

Figure 6. 1 Proposed updated endodontic PROMs tool
Appendices
Appendix 1 Approval of audit to pilot questionnaire tool at LUDH

From: Audit Systems - Rajavath Iljay [audit.oparisis@ludh.dha.uk]
Sent: 28 April 2016 14:00
To: Jasbir Rajput (RQb) LUDH/T
Cc: Jasbir Fid (RQb) LUDH/T
Subject: Dental Project Approved

This message has been archived.

Dear Robert Jacobs

Re: Evaluation of Patient Reported Outcome Measures of Root canal Treatment on a single tooth by postgraduate students in a University setting

I am pleased to inform you that I have approved your project proposal.

Please ensure that you complete the audit return form online once you have completed the audit report and devised an action plan if required. The Audit Return will then be reviewed and monitored at Directorate/Divisional Governance/Performance Review and/or Clinical and Cost Effectiveness Sub Committees if required. Failure to complete this form will result in escalation through the appropriate management structure.

Please note, any audit results demonstrating a risk to the organisation should be reviewed by the relevant management structure and added to the Trust risk register as appropriate.

If at any stage you or your team members require resource or assistance with the project please contact the Effectiveness Team who can advise as appro
Appendix 2 Approval of service evaluation of endodontic PROMs at LUDH

From: Audit Systems - Rajwat Raja [mailto:rajawat.raja@northteastern.nhs.uk]

Sent: 17 January 2017 16:13
To: Jackie Robins (RG2) RG2LUDH
Cc: Jane/Fad (RG2) RG2LUDH
Subject: Dental Project Approved

This message has been archived.

Dear Robert Jacobs

Re: Endodontic Service Evaluation of Patient Reported Outcomes at LUDH

I am pleased to inform you that I have approved your project proposal.

Please ensure that you complete the audit return form online once you have completed the audit report and devised an action plan if required. The Audit Return will then be reviewed and monitored at Directorate/Divisional Governance/Performance Review and/or Clinical and Cost Effectiveness Sub Committee if required. Failure to complete this form will result in escalation through the appropriate management structure.

Please note, any audit results demonstrating a risk to the organisation should be reviewed by the relevant management structure and added to the Trust risk register as appropriate.

If at any stage you or your team members require resource or assistance with the project please contact the Effectiveness Team who can advise as appropriate.

Please Click Here <http://RULUDPJA/ClinicalAuditsystem/area>
### PROMs in the management of Endodontically Involved Teeth

- **INTRODUCTION (DATA ALWAYS COLLECTED)** (6 Questions)

- **PIL AND CONSENT** (6 Questions)

- **INITIAL INFORMATION GIVEN TO PATIENT** (3 Questions)

- **ADDITIONAL INFORMATION GATHERING (ONLY FILLED DURING)** (4 Questions)

- **VISUAL ANALOGUE SCALES (SHOWN TO PATIENT EVERYTIME)** (6 Questions)

- **OHIP-14 (SHOWN TO PATIENT EVERYTIME THEY FILL IN QUEST)** (15 Questions)

- **INITIAL INFO DENTIST (DENTIST ASKED THIS EVERYTIME THE...** (4 Questions)

- **FILLED IN BY DENTIST IF COMPLETED ENDODONTIC TREATM...** (7 Questions)

- **FILLED IN BY DENTIST IF COMPLETED ENDODONTIC TREATM...** (7 Questions)
Appendix 4 Qualtrics survey flow
Appendix 5 Contents of Introduction block collected for all surveys completed on Qualtrics

- Q2: Please enter the patients ID?
  - $e://Field/id

- Q1: Is this your first time completing a questionnaire for this research study?
  - Yes
  - No

- Q3: What does the case involve? (FOR DENTIST TO COMPLETE ONLY)
  - Primary RCT
  - Re RCT
  - Apical Surgery
  - Implant
  - Other (e.g. crown lengthening)

- Q4: Who is completing the questionnaire today?
  - Patient
  - Dentist

- Q5: Please enter the patients email address (or alternative method of communication e.g. phone number)
  - $e://Field/email
Appendix 6 Qualtrics Visual Analogue Scales

How would you rate your level of concern regarding the treatment of your tooth, where 0 is no concern and 100 is the maximum concern possible?

0 100

Please rate your current oral health state on the scale, where 0 is an ideal health state and 100 is the worst oral health state you can imagine?

0 100

Please rate your anxiety level on the scale, where 0 is no anxiety and 100 is the most anxious you can imagine?

0 100

Please rate your pain level on the scale, where 0 is no pain and 100 is the worst pain you can imagine?

0 100
Appendix 7 Qualtrics OHIP-14

1) Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?

2) Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?

3) Have you had painful aching in your mouth?

4) Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?

5) Have you been self-conscious because of your mouth, teeth or dentures?

6) Have you felt tense because of problems with your teeth, mouth or dentures?

7) Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?
8) Have you had to interrupt meals because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

9) Have you found it difficult to relax because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
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<td>4</td>
</tr>
</tbody>
</table>

10) Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

11) Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

12) Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

13) Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
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</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

14) Have you been totally unable to function because of problems with your teeth, mouth or dentures?

<table>
<thead>
<tr>
<th>Never</th>
<th>Hardly Ever</th>
<th>Occasionally</th>
<th>Fairly Often</th>
<th>Very Often</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
Appendix 8 Qualtrics data sheet completed by dentist on day of obturation

Is the tooth symptomatic?

- Yes
- No

Is there a swelling present?

- Yes
- No

Is there a sinus tract present?

- Yes
- No

Was there a preoperative periapical lesion present?

- Yes
- No

Was the case orthograde or retrograde?

- Orthograde
- Retrograde

What is the radiographic quality of Obturation?

- Optimal (Between 0-2mm of apex AND no clinically relevant voids AND well condensed)
- Suboptimal (Obturation more than 2mm short of apex OR beyond apex OR voids present OR poorly condensed)
Appendix 9 Qualtrics data sheet completed by dentists 6 months post-treatment

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the tooth symptomatic?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a swelling present?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a sinus tract present?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the tooth functional?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is there a satisfactory coronal seal present?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Have you reviewed the patient clinically/radiographically today?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Choose the appropriate answer for each question.
Appendix 10 Quantitative consent form

The Royal Liverpool and Broadgreen University Hospitals

NHS Trust

Liverpool University Dental Hospital

Centre Number:

Study Number:

Participant Identification Number for this trial: __________

CONSENT FORM

Title of Project: Development and Validation of a tool to examine Patient Reported Outcomes Measures in the Management of Endodontically Treated Teeth

Name of Researcher: Robert Jacobs

Tick Box to confirm

1. I confirm that I have read the information sheet dated 20/10/2017 for the above study.
   I have had the opportunity to consider the information, ask questions and have
   had these answered satisfactorily.

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

3. I understand that data collected during the study, may be locked at by individuals from the
   NHS Trust, where it is relevant to my taking part in this research. I give permission for
   these individuals to have access to my records.

4. I understand that the information collected about me will be used to support other research in the
   future, and may be shared anonymously with other researchers.

5. I understand that my data will be securely stored in Utah, USA

6. I agree to take part in the above study.

_________________________  __________________________  __________________________
Name of Participant                 Date                        Signature

_________________________  __________________________  __________________________
Name of Person taking consent       Date                        Signature

Version 8                      IRAS ID 212059                      20/10/2017
When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.
Appendix 11 Quantitative participant information sheet

PARTICIPANT INFORMATION SHEET

Name of the Study

Development and Validation of a tool to examine Patient Reported Outcome Measures in the Management of Endodontically Treated Teeth

Introduction

The aim of the research project is to find out patient reported outcomes for patients undergoing root canal procedures at Liverpool Dental Hospital.

What is a patient reported outcome?

A patient reported outcome is any report of the status of a patient’s health condition that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.

Currently, root canal treatment is judged by traditional methods such as the quality of the root filling judged on a radiograph, as well as patients’ signs and symptoms such as pain, swelling and infection.

However, research of this type will help us understand how patients view the treatment from their own perspective and how it affects their own oral health related quality of life.

We hope this will help health care professionals to monitor and improve patient care at Liverpool University Dental Hospital. We would appreciate if you could take your time answering the questions. We are very grateful for your participation.

Methods

We would be very grateful for your participation in this research study being conducted in the hospital. The aim is to develop a patient centred approach to health care by recording treatment outcome from your perspective.

Taking part will involve filing in a total of 4 quick surveys;
- Prior to starting treatment
- 7 days following treatment
- 6 months following treatment

www.rbuh.nhs.uk

Version 1 23 October 2016
12 months following treatment
Each survey takes 3-4 minutes to complete and can be completed on your phone, tablet, laptop or
desktop. Your data will be stored securely and will be anonymous. Any information given will not
harm the quality or type of treatment received at the hospital.

The answers to the questionnaires will be stored and will be analysed to assess the difference
between patients’ responses before and after treatment.

This will allow comparison of differences in responses over time for the whole group of patients
recruited. Your data will not be revealed or analysed personally, but only as part of a group.

You will be free to withdraw from the study at any time, and this will have no affect on the quality
of treatment or number of appointments provided at Liverpool University Dental Hospital.

Purpose of study
The purpose of the study is to help us understand how patients view the treatment from their own
perspective and how it affects their own oral health related quality of life.

We hope this will help health care professionals to monitor and improve patient care at Liverpool
University Dental Hospital. We would appreciate if you could take your time answering the
questions. We are very grateful for your participation.

Confidentiality
The survey information will be stored on a password encrypted database. The data will be
reviewed by researchers at The University of Liverpool as part of a
doctorate degree research by a restorative consultant and specialty registrar in Endodontics.

Contact
If there are any issues with the use of this tool, please do not hesitate to contact me on the
following email address or contact detail:

Robert Jacobs
Liverpool University Dental Hospital
Pembroke Place, Liverpool
rjacobs@liverpool.ac.uk
Third Floor, 0151 780 5240

Your valuable time and thoughts on this will be highly appreciated.

Best wishes

development to support labeling claims: draft guidance. Health Qual Life Outcomes
23 October 2016
Appendix 14 Copy of email reminder sent to non-responding PROMs patients

From: Liverpool University Dental Research
To: [Redacted]

Patient Questionnaire at Liverpool Dental Hospital
5 October 2017 at 16:59

Good Afternoon,

You were kind enough to volunteer to take part in a questionnaire relating to your treatment at the Dental Hospital.

If you can spare a moment to fill in the questionnaire today it would be greatly appreciated.

When asked which stage of treatment - please select TREATMENT COMPLETED 6 MONTHS AGO

Please click the link below to begin the survey:

Patient Survey Link

Thanks again

Liverpool University Research Team
Appendix 15 HRA Approval letter 6th March 2017

Health Research Authority

Mr Robert Jacobs  
SIR Endodontics  
University of Liverpool  
School of Dentistry, University of Liverpool  
Pembroke Place  
Liverpool  
L3 5PS  

06 March 2017  

Dear Mr Robert Jacobs

Letter of HRA Approval

Study title: Development and Validation of a Patient Reported Outcome tool in Endodontic treatment at Liverpool University Dental Hospital.

IRAS project ID: 212059
Protocol number: 5316
REC reference: 16/EE/0539
Sponsor Royal Liverpool & Broadgreen University Hospital

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

Participation of NHS Organisations in England

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

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

- Participating NHS organisations in England – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- Confirmation of capacity and capability - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria) - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.
Dear Dr Jacobs

RD&I No: 5316
PROMs in management of Endodontically treated teeth at LUDH

I am pleased to confirm that the Trust accepts the responsibilities of sponsor for the above study.

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

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

- Inform RD&I within 24 hours of awareness of any SUSAR’s or SAE’s within the Trust as per Trust policy
- Provide copies to RD&I of annual progress and safety reports to Ethics and if appropriate the MHRA
- Complete and return the RD&I annual report form within 28 days of receipt
- Ensure annual review of the IB/SMPC if appropriate
- Comply with the Research Governance Framework 2nd Ed 2005 including but not limited to the Medicines for Human use (Clinical Trials) 2004 act plus it’s appendices, the Data Protection Act 1998 and the Human Tissue Act 2004
- Ensure biannual training in GCP of all essential research staff on the study
- Read, disseminate to research team and acknowledge to RD&I, Trust research SOP announcements
Appendix 17 REC and HRA amendment approval 31st October 2017

Health Research Authority

East of England - Cambridge Central Research Ethics Committee
Royal Standard Place
Nottingham
NG1 6PS

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

31 October 2017

Mr Robert Jacobs
SR Endodontics
University of Liverpool
School of Dentistry, University of Liverpool
Pembroke Place
Liverpool
L3 5PS

Dear Mr Jacobs

Study title: Development and Validation of a Patient Reported Outcome tool in Endodontic treatment at Liverpool University Dental Hospital

REC reference: EEE/0539
Protocol number: 5316
Amendment number: 1
Amendment date: 06 October 2017

IRAS project ID: 212099

The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence on 20 October 2017.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

IRAS PROJECT ID 212099, REC Reference 16/EE/0539 Confirmation of Amendment Assessment

Dear Mr Jacobs,

Further to the above, I am pleased to confirm that HRA Approval has been awarded for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work in collaboration with participating Trust organisations in England to implement the amendment as per the below organisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards,

Lauren

Lauren Allen
Assessor

Health Research Authority
Appendix 18 Qualitative consent form

The Royal Liverpool and Broadgreen University Hospitals

Liverpool University Dental Hospital
Centre Number:
Study Number:

Participant Identification Number for this trial: __________

CONSENT FORM

Title of Project Telephone Interview to examine patient reported outcomes of endodontics at Liverpool University Dental Hospital

Name of Researcher: Robert Jacobs

1. I confirm that I have read the information sheet dated 01/10/2017 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

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

3. I understand that data collected during the study will be recorded and stored for the duration of the study, may be looked at by individuals from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

4. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

5. I understand that data provided in telephone interviews may be used anonymously in journal Publications

6. I agree to take part in the above study.

______________________________  ________________________________  ____________
Name of Participant         Signature of Participant         Date

______________________________  ________________________________  ____________
Name of Researcher          Signature of Researcher          Date

Version 1

IRAS ID 212059
01/10/2017

When completed: 1 for participant; 1 for researcher site file; 1 (original) to be kept in medical notes.
Appendix 19 Qualitative participant information sheet

Participant Information Sheet

TELEPHONE INTERVIEWS TO EXAMINE PATIENT REPORTED OUTCOMES OF ENDOdontICS AT Liverpool UNIVERSITY DENTAL HOSPITAL

INTRODUCTION

- You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Talk to others about the study if you wish.
- You are free to choose whether you want to take part. If you choose not to take part, it will not affect the care provided to you.
- Please feel free to ask if you have additional questions after reading this information.

WHAT ARE WE TRYING TO ACHIEVE?

- We are interested in gathering feedback from the patients who have completed questionnaires regarding their treatment at the Dental Hospital.
- This will be in the form of a telephone interview.
- Here, you will be asked a number of questions about your treatment and how you perceived your care.
- The interview will take around 10 minutes to complete.

HOW WILL DATA BE USED AND WHO WILL IT BE SHARED WITH?

- The interview will be recorded on-site at Liverpool Dental Hospital.
- This recording is then transcribed and analysed.
- The findings may be used anonymously as part of a journal publication.
- The recording will be securely stored until the study is complete and then deleted. The recording will also be transcribed and all paper copies will be shredded when the study is complete.

WHY HAVE YOU BEEN ASKED TO TAKE PART?

- You have been asked as you have agreed to have root canal treatment completed at Liverpool University Dental Hospital, and have previously agreed to complete questionnaires with regards your treatment.

DO YOU HAVE TO TAKE PART?

- No, you do not have to take part.
- You will receive the same level and quality of care regardless of whether you choose to participate in the research.
- You are also free to agree to take part and then change your mind and decide you do not want to take part.
WHAT DO YOU HAVE TO DO?

- Initially, you will be invited to participate in the telephone interview and consent given.
- Following this, you will be asked a number of questions regarding the treatment you have received.
- As a thank you and reimbursement of your time, a £10 Amazon gift card will then be offered to you.

WHAT ARE THE PROS AND CONS OF TAKING PART?

- The benefits will be that you will provide information that together with other patients will help shape and improve the care provided on our clinic.
- The only downside is that the interview will take about 10-20 minutes of your time to complete.

WHAT WILL HAPPEN WITH THE RESULTS OF THIS RESEARCH?

- The findings of this research project will hopefully be published in a peer-reviewed scientific journal.
- All participants will be sent a report detailing any findings if requested.
- Patients participating in this research project will not be identified in any report or publication.

HOW TO CONTACT US

- If you have any questions before taking part, or if you have any queries whilst participating in the study
  Please contact:
  Dr. Fadi Jarad
  Tel: 01517065219
  Email: fjarad@liverpool.ac.uk
Appendix 20 Initial qualitative interview schedule

**Initial interview schedule**

- Do you remember filling in a questionnaire before you started treatment?
- Can you remember how you were feeling at that time? Main concerns/anxieties
- How did you feel after treatment?
- Was the treatment successful from your perspective?
- Did the questions we asked reflect what mattered to you (remind patients we asked about level of pain, anxiety, concerns, oral health state)
- Did treatment have an impact on life such as missing work? Time in chair?
- Would you have same concerns if starting RCT again tomorrow?
- Was the process worthwhile?
- What was especially important to you?
- What changed after the treatment?
- Has the treatment you had influenced your overall feeling about your own oral health?
Appendix 21 Revised qualitative interview schedule

**Revised Interview schedule**

**Consultation and pre-treatment phase**
- Can you tell me what led you here (to the Dental Hospital)?
- How was the problem with the tooth affecting you?
- Did you have some concerns before you started treatment?
- Were you concerned about losing the tooth?
- What in particular worried you?

**Treatment phase**
- Can you tell me about your first appointment for treatment?
- Can you tell me about further appointments you attended?
- Two questions were then read from the OHIP-14 with patients asked to explain the relevance of the questions to them.
- ‘Have you had trouble pronouncing any words due to problems with your mouth, teeth or dentures?’
- ‘Have you been totally unable to function due to problems with your mouth, teeth or dentures?’
- If no – prompt – what concerns were most important to you?

**Post treatment phase**
- Do you feel differently now that treatment is complete?
- Did the treatment meet your expectations?
- Would you change anything about the treatment you received?
- Follow up questions re drop-out if applicable
CONTROL ID: 2954383

TITLE: What Effect do Endodontic Treatments Have on Patient Reported Outcomes?

PREFERRED PRESENTATION TYPE: No Preference

CURRENT SCIENTIFIC GROUPS & NETWORKS: Behavioral, Epidemiologic and Health Services Research

PRESENTER: Robert Jacobs

PRESENTER (INSTITUTION ONLY): Liverpool University Dental Hospital

AUTHORS (FIRST NAME INITIAL LAST NAME): R. Jacob, F. Jarad, R. Harris, S. Desmon

AUTHORS/INSTITUTIONS: R. Jacob, F. Jarad, Endodontics, Liverpool University Dental Hospital, Liverpool, UNITED KINGDOM. R. Harris, Health Services Research, Institute of Psychology Health and Society, University of Liverpool, Liverpool, UNITED KINGDOM. S. Desmon, Restorative Dentistry, Liverpool University Dental Hospital, Liverpool, UNITED KINGDOM

ABSTRACT BODY:

Objectives: Patient Reported Outcome Measures (PROMs) have the ability to improve quality of care by measuring the effectiveness of treatment from patients’ perspectives. The study aimed to measure PROMs of endodontic treatments provided by UK dental postgraduate trainees.

Methods: Ethical approval was obtained (ID212099). Postgraduate endodontic trainees recruited patients from a population of those referred to a Dental Hospital for consultation and treatment of endodontic cases. Eligibility criteria were adult patients (age ≥18) requiring: Primary Endodontic Treatment (RCT), Endodontic Retreatment (ReRCT) or Apical Surgery (Surgery). Computerised questionnaires were completed before treatment (T₀), 2 months post-treatment (T₁) via email, and 5 months post-treatment (T₂) via clinical recall/email. Data was collected using the Oral Health Impact Profile-14 (OHIP-14) tool, which asks participants to rate frequency of adverse oral health outcomes on a 5-point Likert scale ranging from: 0—(never), 1—(hardly ever), 2—(occasionally), 3—(fairly often) to 4—(very often). The null hypothesis was that there is no difference in OHIP-14 scores following endodontic treatment.

Results: The data of patients recruited at T₀ (n=168), were only analysed if patients also responded at either T₁ or T₂. Paired-Samples T-test was used. RCT T₀ - T₁ (n=28), showed a mean reduction of 1.8 (P=0.281) and from T₀ - T₂ (n=9) a mean reduction of 5.9 (P=0.005). ReRCT T₀ - T₁ (n=16), showed a mean increase of 2.4 (P=0.180) and from T₀ - T₂ (n=23) a mean reduction of 1.0 (P=0.725). Surgery T₀ - T₁ (n=11), showed a mean increase of 2.6 (P=0.042) and from T₀ - T₂ (n=11) a mean reduction of 0.5 (P=0.806).

Conclusions: Overall, OHIP-14 was not a sensitive measure of patients’ outcomes following endodontics. In addition, the high dropout rate and small sample sizes of individual treatments affected the strength of the study results. Future studies require a larger sample size and a more sensitive tool, although high dropout rates may prove to be a recurring problem in measuring Patient-Reported-Outcome Measures of Endodontic treatment.
WHAT EFFECT DO ENDODONTIC TREATMENTS HAVE ON PATIENT REPORTED OUTCOMES?

Presenter—Robert Jacobs, University of Liverpool
Supervisors—Professor Jarad, Professor Harris and Dr Desmons (University of Liverpool)

Methods
Ethical approval was obtained and patients were recruited from a population referred to a Dental Hospital, for consultation and treatment of endodontic cases. Eligibility criteria were adult patients (age ≥18) requiring Primary Endodontic Treatment (RCT), Endodontic Retreatment (RReCT) or Apical Surgery (Surgery). All treatment was carried out by Postgraduate Endodontic trainees, with standardised protocols. Computerised questionnaires were completed pre-treatment (T0), a month post-treatment (T1) and 6 months post-treatment (T2) via clinical recall/email.

Data was collected using the Oral Health Impact Profile-14 (OHIP-14) tool. This asks participants to rate frequency of adverse oral health outcomes on a 5-point Likert scale ranging from: 0—(never), 1—(hardly ever), 2—(occasionally), 3—(fairly often) to 4—(very often). The null hypothesis was that there is no difference in OHIP-14 scores following endodontic treatment.

Results
The data of patients recruited at T0 (n=68), were only analysed if patients also responded at either T1 or T2. Paired-Samples T-test was used. RCT To-T1(n=45), showed a mean reduction of 1.2 (P=0.359) and from To-T2 (n=41) a mean reduction of 5.9 (P<0.001). RReCT To-T1(n=65), showed a mean increase of 1.4 (P=0.280) and from To-T2(n=31) a mean reduction of 1.0 (P=0.725). Surgery To-T1(n=31), showed a mean increase of 2.6 (P=0.042) and from To-T2 (n=41) a mean reduction of 0.5 (P=0.806).

Conclusions
Overall, OHIP-14 was not a sensitive measure of patients' outcomes following endodontics. In addition, the high dropout rate and small sample sizes of individual treatments affected the strength of the study results. Future studies require a larger sample size and a more sensitive tool, although high dropout rates may prove to be a recurring problem in measuring patient reported outcomes of Endodontic treatment.
References


Kavanaugh, K. and Ayres, L. (1998) "Not as bad as it could have been": assessing and mitigating harm during research interviews on sensitive topics, *Res Nurs Health*, 21(1), pp. 91-97.


NHS England Chief Dental Officer Team (2015) 'Guide for Commissioning Specialist Dentistry Services'.


