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How peoples' ratings of dental implant treatment change over time

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ABSTRACT

Objectives: Dental implant treatment (DIT) improves peoples' oral health related quality of life (OHQoL). Assessment of changes in OHRQoL may be undermined by response shift (RS). RS is the process by which quality of life change, independent of health status as a result recalibration, reprioritization or reconceptualization. Thus, this research aimed to identify RS in individuals receiving dental implant treatment and to determine the validity of three approaches to measure it; the then-test, the self-anchored scale and the classification and regression trees (CRT).

Methods: OHRQoL was assessed in 100 patients receiving DIT using the OHIP-Edent and the self-anchored scale before placement of the final restoration and 3 to 6 months after the treatment was completed. The OHIP-Edent was also used as a retrospective assessment at the follow-up. CRT examined changes in the OHIP-Edent total score as a dependent variable with global changes in oral health and each OHIP-Edent subscale score as independent variables.

Results: OHRQoL improved after treatment. The OHIP-Edent score decreased from 36.4 at baseline to 12.7 after treatment. On average participants recalibrated their internal standard downwards (-4.0 OHIP-Edent points). The CRT detected recalibration (5% downwards and 15% upwards). Reprioritization was observed among the social disability and psychological discomfort aspects of OHRQoL.

Conclusions: RS affects longitudinal assessments of OHRQoL in DIT reducing the apparent magnitude of change. Results of this study identified then-test and the CRT as valid complementary methods to assess RS.

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ABBREVIATIONS

CD	Conventional Denture
CRT	Classification And Regression Trees
DIT	Dental Implant Treatment
GOHAI	Geriatric Oral Health Assessment Index
HRQoL	Health Related Quality of Life
IDFTD	Implant-Supported Fixed Total Denture
ISFPD	Implant-Supported Fixed Partial Denture
ISC	Implant-supported crown
ISB	Implant-supported bridge
MID	Minimal Important Difference
OD	Overdenture
OHIP	Oral Health Impact Profile
OHIP-Edent	Oral Health Impact Profile for Edentulous
OHRQoL	Oral Health Related Quality of Life
QoL	Quality of Life
QoLIP	Quality of Life with Implant Prostheses
RS	Response Shift
SDI	Single Dental Implant
SEM	Structural Equation Modelling

1. INTRODUCTION

Behavioural, cognitive and affective processes can change an individual's appreciation of their health and perceived quality of life (QoL), yielding counterintuitive findings. For example, individuals tend to rate their health better than their caregivers or care providers' assessments (Norman, 2003, Ahmed et al., 2004). Furthermore, individuals with severe chronic illness report equal or better quality of life than healthy people or people with less severe illness (Breetvelt and Van Dam, 1991, Lacey et al., 2008, Finkelstein et al., 2014). Likewise, conventional methods to assess treatment effectiveness through simple comparisons of pre and post treatment data show ambiguous results (Ring et al., 2005, Kimura et al., 2012, Finkelstein et al., 2014). A potential inaccuracy of assessing Health Related Quality of Life (HRQoL) emerges: people's perceived health status changes not only due disease and/or treatment, but also due to changes in their perception, appreciation or meaning of QoL.

Response shift is the process by which quality of life can change, independent of health status. It has been defined by Sprangers and Schwartz (1999) as a "change in the meaning of one's self evaluation of quality of life as a result of change in the person's internal standards (recalibration), change in the person's values of the components of quality of life (reprioritization) or redefinition of quality of life (reconceptualization)".

Objective measures and self-assessments of health are not necessarily congruent; response shift may allow people to adapt to any benefits of treatment, so they may no longer realize their health has improved. Thus, understanding the

influence of response shift on self-reported outcomes is crucial in the evaluation of treatments using patients reported outcomes where it might under or overestimate important treatment effects.

Tooth loss has a considerable impact on peoples' lives and dental implant treatment (DIT) is one method to replace missing teeth. Frequently, persons have come through a long and arduous process before starting with the dental implant treatment. Multiple oral health problems lead to tooth loss, resulting in feelings of depression, anxiety and shame that are partly resolved with the dental treatment (Johannsen et al., 2012, Okoje et al., 2012). Nonetheless, it is not unusual to find people unhappy with their treatment, especially with conventional prostheses. Implants are offered as a method to replace teeth permanently and considered to be an optimal solution to restore peoples' mouths to a 'natural' state. Most people rate dental implant treatment as highly satisfactory and report improvement in quality of life. However satisfaction has been reported to decrease with time (Timmerman et al., 2004). Eventually, treatment can be taken for granted, or processes of coping and adaptation can influence the assessment of quality of life. Response shift explores changes in the meaning of quality of life over time and can be a possible explanation for these counterintuitive findings. Moreover, response shift has been observed masking important effects of dental treatment on quality of life (Ring et al., 2005, Kimura et al., 2012, Krasuska et al., 2014a).

Patients receiving dental implants offer a good participant base for studying response shift because the effect of implant-retained prostheses on QoL is marked (Heydecke et al., 2003b, Pjetursson et al., 2005, Raes et al., 2017). Thus, the aim of this research was to explore response shift in individuals receiving dental implant treatment.

This thesis is structured in six chapters:

Chapter Two is the literature review. It describes the response shift phenomenon, appraising its occurrence among patients receiving DIT to provide the background supporting the upcoming research. The chapter starts with an overview of tooth loss and dental implants, including patient reported outcomes in implant dentistry. Then, a review of the response shift phenomenon describes how it might influence changes in QoL in patients with DIT. In conjunction with the theory, approaches to assess response shift are reviewed to inform the selection of the methods to be used in the research.

Chapter Three describes the methods used in the research, describing the design approaches to investigate response shift and the analytic strategy in a cohort study of patients receiving dental implants.

Chapter Four presents the study results including the characteristics of the sample, psychometric properties of the OHIP-Edent and the investigation of response shift. Overall, the OHRQoL improved after the treatment but RS reduced the magnitude of change.

Chapter Five analyses the results. The distribution of the sample, the cross-sectional validation of the OHIP-Edent and the different approaches used to assess RS are discussed. Limitations and strengths of the study are included in this section.

Chapter Six presents the conclusions and makes recommendations for future research.

2. LITERATURE REVIEW

2.1. TOOTH LOSS AND DENTAL IMPLANTS

2.1.1. Introduction

Missing teeth can affect multiple aspects of people's lives by impairing their ability to eat, smile and talk, or their appearance and self-confidence.

Dentistry has dedicated millennia to the development of diverse methods to replace missing teeth. From conventional dentures to dental implants, the main goal has been to restore normal function of the oral cavity, re-establishing the person's comfort and aesthetics.

From the clinicians' point of view, dental implants can be considered as the best option to replace the teeth. Likewise, peoples' perception of this treatment is very good. Several studies report high levels of satisfaction and improved quality of life with dental implant treatment (Henry, 2000). However, even when all the clinical parameters are normal, persons still report lower improvement in areas such as pain or psychological aspects of oral health (Raes et al., 2012). Furthermore, the initial improvements in quality of life may diminish when the success of dental implants is assessed over time (Timmerman et al., 2004, Raes et al., 2017). Thus, individuals might report lower QoL in successive assessments due to changes in the meaning of their QoL. These implications for assessing the effects of any treatment might incorporate response shift as a possible explanation.

This chapter will review these areas in detail to inform the rationale for and design of the research at the heart of this dissertation.

2.1.2. Tooth loss: epidemiology

Tooth loss is considered as the final step of the pathway of most dental diseases and conditions. It is the result of events such dental extractions, the progression of periodontal disease or trauma. Studied as a relevant indicator of the oral health of a population, tooth loss provides information about dental disease prevalence, access to dental care, patients' and dentists' attitudes and dentist-patient relationship (Kida et al., 2006, Baelum et al., 2007). Significant differences exist between countries. The prevalence of total edentulism (loss of all teeth) ranges from 5% in Swiss adults (Zitzmann et al., 2008) to 55.9% in Malaysia in adults over 60 of age (Shamdol et al., 2009). European countries such as Poland show high numbers of missing teeth (mean 13.6) in adults between 18 and 60+ years (Panasiuk et al., 2013) and in the UK, where rates of edentulism have fallen considerably in the last 40 years, the mean number of remaining teeth in adult population is 25.7 (Chenery and Hill, 2011b, Chenery and Hill, 2011a). The age-standardized prevalence of severe tooth loss (having fewer than 9 remaining permanent teeth) in 2010 was significantly higher than the global mean (2.4%) in Brazil, Turkey, Iran, Mexico and New Zealand, whereas in China, Japan, Nigeria, Sri-Lanka and Sweden was significantly lower (Kassebaum et al., 2014).

Data from several countries show that missing teeth and edentulousness are more common in elderly and female people (Yolov, 2003, Brennan D S, 2004, Hugo et al., 2007, Medina-Solis et al., 2006, Zitzmann et al., 2008, Shamdol et al., 2009, Suominen-Taipale et al., 2008, AL-Dwairi, 2013, Ando et al., 2013, Panasiuk et al., 2013), those of low education (Yolov, 2003, Petersen et al., 2004, Hugo et al., 2007, Osterberg et al., 2006, Zitzmann et al., 2008, Shamdol et al., 2009, Suominen-

Taipale et al., 2008, AL-Dwairi, 2013, Ando et al., 2013, Panasiuk et al., 2013), in some geographical areas (Henriksen et al., 2003, Brennan D S, 2004, Suominen-Taipale et al., 2008), lower income (Petersen et al., 2004, Medina-Solis et al., 2006, Zitzmann et al., 2008, Suominen-Taipale et al., 2008, Health-Canada, 2010, AL-Dwairi, 2013) and smokers (Medina-Solis et al., 2006, Health-Canada, 2010, Chenery and Hill, 2011a, AL-Dwairi, 2013, Ando et al., 2013). Despite progress in public health policies, tooth loss and edentulism are still related to social disparities as measured by educational, income and socioeconomic level and living in rural areas. The social gradient in tooth loss occurs between and within countries. In high and low-income countries oral diseases are more frequent in socio-economically disadvantaged groups (Baelum et al., 2007). Thus, due to its prevalence, impact and inequality, tooth loss and edentulism remain a public health concern worldwide.

Once the tooth has been lost, a number of consequences impact on the individual. For many decades, dentistry has utilized the medical model to take decisions regarding health care; professional perspectives on the consequences of tooth loss are widely recognised in the literature (Joshi et al., 1996, Priest, 1999, Shugars et al., 2000, Chesterman et al., 2014). These professional perspectives are beyond the scope of this review, but include changes in vertical (over eruption) and horizontal position of the remaining teeth and alveolar bone loss (Craddock, 2010). Bone loss in edentulousness may arise, with an average reduction of 9 to 10 mm in the anterior mandibular ridge and 2.5 to 3 mm in the maxillary ridge over 25 years (Tallgren, 1972, Crum and Rooney, 1978).

Nonetheless, the person's perspective on the meaning of tooth loss has frequently been neglected and discrepancies between professional decisions and

individuals opinions of treatment arise. Lay perspectives of the significance of tooth loss are discussed in the next section.

2.1.3. Consequences of tooth loss to the individual

Evaluated as a tragic event in peoples' lives (Dashper, 2013), the subject of grieving comparable with the loss of a limb or the death of a relative (Fiske et al., 1998, Fiske et al., 2001) and involving feelings as sadness and depression (Okoje et al., 2012), tooth loss can be analysed from the persons' perspective, including its functional, aesthetic and emotional consequences.

Teeth are part of the oral cavity, thus they operate in functions such as eating and breathing and also contribute to important functions in human communication such as speaking, smiling or kissing. Therefore, is to be expected that tooth loss has great impacts on people's lives interfering in diverse daily activities. Scott and colleagues (2001) compared three different populations of edentulous individuals from the UK and Japan. Sixty-four per cent restricted their choice of foods, 31% avoided eating in public because of embarrassment and 50% had not enjoyed their food as much due their tooth loss and wearing dentures. Likewise, people with tooth loss are 2.7 times more likely to report chewing difficulty than those who are completely dentate (Gilbert et al., 2004). Chewing ability is reduced in edentulousness and is lower in people wearing conventional rather than implant-supported dentures (Allen and McMillan, 2002). Edentulous people (partial or total) have compromised ability to eat and enjoy food. Restricting the range of food that people eat, results in a poor diet and nutrient intake deficiencies, affecting their general health (Sheiham et al., 2002).

Aesthetics and satisfaction with one's teeth are significantly impaired when anterior teeth are lost, with variations between age, social classes, culture, regions and countries (Gotfredsen and Walls, 2007). People's concern about the replacement of teeth is higher when aesthetics are involved, independently of the reestablishment of dental function. Elias and Sheiham's review (1998) reported that the demand for replacement of a missing tooth is related to its position and aesthetic requirements. These factors are more important than function for many individuals and absent posterior teeth are not as important from a subjective perspective. Thus, people partially dentate with premolar occlusion, without any molars in at least one quadrant and with all anterior teeth intact (shortened dental arch) have sufficient teeth to conform to their appearance and function requirements (Kanno and Carlsson, 2006, Fueki and Baba, 2017).

The experience of losing a tooth, its meaning and the search for alternative treatments vary from person to person. Surprisingly, there is little research in people's experiences of tooth loss, although there is clear evidence that the physical appearance of the face, and particularly of the mouth are key in human communication (Lopez et al., 2013) and the self-concept of physical attractiveness (Bergendal, 1989).

Fiske and colleagues (1998) conducted one of the few studies exploring the emotional aspects of tooth loss. They identified a range of themes related with tooth loss raised in reflective interviews with 50 edentulous people and compared the patterns of emotions due tooth loss with the five stages of bereavement: denial, anger, depression, bargaining and acceptance. This pattern echoed the consequences of the loss of a limb or the death of a relative (Parkes, 1975, Horgan and MacLachlan, 2004). The length of grieving varied between people who

accepted their tooth loss immediately and others who were angry and depressed. The latter group might become difficult to treat, with very low success rates. Anxious and depressed patients can be poor candidates for prosthodontics treatment because their worries and concerns may be transferred to their dentures (Grieder, 1973, Winkler, 1989). The process of coping with tooth loss depends on the ability of the patient to emotionally redefine the self and is related with the roles he/she plays in society (family, work, culture) and the importance of that role held before the tooth loss.

Common aspects mentioned by people who lose their teeth are lack of acceptance and impacts on self-confidence, appearance and self-image, tooth loss as a taboo that people do not talk about, ageing and lack of preparation (Fiske et al., 1998). People with difficulties accepting their tooth loss are more likely to be less confident about themselves, are more likely to feel inhibited to take part in social activities, restrict their food choice, enjoy their food less, avoid laughing in public, avoid forming close relationships and avoid to looking themselves when not wearing their dentures (Davis et al., 2000, Davis et al., 2001).

More recent studies show that tooth loss is a serious life event causing sadness, depression, a feeling of losing part of the body and ageing (Okoje et al., 2012). In terms of psychological adjustments, modifications due to tooth loss can be seen as more important than experiences such as marriage, retirement or changing work. Tooth loss and/or the provision of dentures are perceived by people as requiring relatively high psychological readjustments, positioning them higher than the birth of a child (Bergendal, 1989).

Many options exist to replace missing teeth such as dentures, bridges and dental implants. Decisions regarding which is the best option depend on a number

of factors, including the clinical condition, patients' preferences and financial aspects. Nevertheless, dental implants are considered as a major advance in the treatment of tooth loss (Guillaume, 2016b).

2.1.4. Dental implants

Removable dentures, either total or partial, have been a relatively simple and popular method to replace teeth and restore oral health. Nevertheless, people wearing dentures tend to have poor oral health related quality of life (OHRQoL). Tooth loss and denture wearing are associated with avoidance of certain foods, difficulty with relaxation, pain, distress and avoidance of going out (Jones et al., 2003, Brennan et al., 2008, Gerritsen et al., 2010). Heydecke and colleagues (2004b) reported that 37.9% of edentulous people wearing dentures described reduced OHRQoL due to having pain, functional limitations and psychological discomfort.

With the advent of new technologies, people's preferences regarding dental treatments have also changed. Patients reject extractions and dentures demanding conservative treatment (Cronin et al., 2009). Dental implants have become a valuable alternative to dentures and their use is increasingly common.

Modern implantology became widely know thanks to the principles proposed by Branemark (1985), introducing osseointegration to dentistry and titanium as one of the most frequently used biomaterials. Basically, implants are titanium screws surgically positioned into the bone that (in the case of dentistry), support a crown, bridge or denture.

A wide range of implants is available. Classifications vary according to body shape (rounded, cylindrical, conical, pointed, more or less spaced threads), connector head/shape (internal, external, hex, octagon connectors), sizes (standard or wide platform), placement (endosteal or subperiosteal) or stages (single or two stage implants). Whatever type, all may be used to support single crowns (Single Dental Implants), bridges (Implant Supported Fixed Partial or Total Dentures), or overdentures.

The criteria for clinical success of dental implants include implant level, peri-implant soft tissue, prosthesis and patient's satisfaction (Papaspyridakos et al., 2012). The clinical success rate of treatments is high; ranging from 73% for maxillary overdentures to 100% for mandibular single-tooth restorations based on a minimum of 5 years of follow-up (Henry, 2000). These data explain why dental implants have been proposed as the standard and first choice for the uncomplicated replacement of a single tooth. Similarly, in totally edentulous patients, implant-supported fixed total dentures (ISFTD) and overdentures (OD) are amongst the more common treatment alternatives; even when the ISFTD has been reported as more successful (Henry et al., 1995), OD are considered more cost-effective (Heydecke et al., 2005b). However, despite extensive clinical evidence on implant success, clinical studies often omit people's perspectives of satisfaction and oral health related quality of life.

2.1.5. Dental implants and subjective outcomes

Studies incorporating subjective outcomes to assess success in DIT have increased. Several studies have identified instruments such as the Oral Health Impact Profile (OHIP) (Allen et al., 2001b, Heydecke et al., 2003b), the Geriatric Oral Health Assessment Index (GOHAI) (Fillion et al., 2013) and the Quality of Life with Implant Prostheses (QoLIP) (Preciado et al., 2013b) as measures to assess quality of life in individuals receiving dental implants.

Although comparisons between studies are difficult due to differences in the methods adopted, evidence points to high levels of satisfaction and improved OHRQoL in many dental implant modalities (Petricevic et al., 2012b).

Maxillary OD treatment studies have reported enhanced OHRQoL and satisfaction (Naert et al., 1998, Allen et al., 2001a, Allen and McMillan, 2003, Aarts et al., 2008, Balaguer et al., 2011, Al-Zubeidi et al., 2012b, Fillion et al., 2013, Tomasi et al., 2013, Zembic and Wismeijer, 2014). Nonetheless, while maxillary OD have improved OHRQoL, ratings on satisfaction are not significantly higher than those for conventional dentures (CD), suggesting that maxillary OD should not be considered as a standard treatment for patients with preserved bone ridges (de Albuquerque Junior et al., 2000). Likewise, two RCTs conducted by Heydecke and colleagues (2003a, 2004a) concluded that patients satisfied with their current denture had no significant increases in general satisfaction when restored with OD.

Improved OHRQoL and/or satisfaction has also been reported in patients restored with ISFTD (Allen et al., 2001a, Fischer and Stenberg, 2006, Penarrocha et al., 2007, Dierens et al., 2009, Erkapers et al., 2011, Fillion et al., 2013, Marra et al., 2013, Misumi et al., 2014, Penarrocha-Oltra et al., 2014) with higher ratings in

eating comfort (Dierens et al., 2009), phonetics and aesthetics (de Bruyn et al., 1997).

Satisfaction with mandibular OD is also high (Al-Zubeidi et al., 2012a, Bakke et al., 2002, Cune et al., 2005, Fartash et al., 1996, Mericske-Stern et al., 2009, Walton et al., 2009, Wismeyer et al., 1995) and remains stable over several years (Cune et al., 2010, Timmerman et al., 2004)

Studies comparing satisfaction between mandibular OD and CD have demonstrated higher levels of patient's satisfaction after implant treatment (Allen et al., 2001b, Allen et al., 2006, Al-Zubeidi et al., 2012a, Awad and Feine, 1998, Awad et al., 2000b, Awad et al., 2003a, Bakke et al., 2002, Boerrigter et al., 1995b, Boerrigter et al., 1995a, Burns et al., 1995, Cune et al., 2010, Ellis et al., 2009, Fartash et al., 1996, Geertman et al., 1996, Heydecke et al., 2008, Kapur et al., 1998, MacEntee et al., 2005, Meijer et al., 1999, Mericske-Stern et al., 2009, Pan et al., 2007, Pan et al., 2008, Rashid et al., 2011, Thomason et al., 2003, Timmerman et al., 2004, Walton et al., 2002, Wismeijer et al., 1997, Wismeyer et al., 1995). This satisfaction is dependent on gender; women rated their overall satisfaction with their dentures significantly higher than men (Awad and Feine, 1998) and predicted by education level; with better educated patients less likely to prefer either conventional or implant treatments compared to those with low education (Awad et al., 2000b).

Improvement of OHRQoL with mandibular OD has been confirmed by several reports (Allen et al., 2001b, Allen et al., 2006, Attard et al., 2006, Awad et al., 2000a, Awad et al., 2003b, Awad et al., 2014, Cakir et al., 2014, Emami et al., 2014, Geckili et al., 2011, Harris et al., 2013, Heydecke et al., 2003b, Heydecke et al., 2005c, Jabbour et al., 2012, Jofre et al., 2013a, Muller et al., 2013, Scepanovic et

al., 2012). This improvement is independent of attachment system (Bilhan et al., 2011, Kleis et al., 2010, Mumcu et al., 2012) and the number of implants placed (Mumcu et al., 2012).

Regarding mandibular ISFTD, studies show that patient's satisfaction and OHRQoL improves with implant treatment (Allen et al., 2001b, Ayna et al., 2014, Berretin-Felix et al., 2008, De Kok et al., 2011, de Grandmont et al., 1994, Dierens et al., 2009, de Bruyn et al., 1997, Marra et al., 2013, Misumi et al., 2014). Comparing ISFTD with OD, Zani and colleagues (2009) reported that OHRQoL assessed with the OHIP specific for edentulous (OHIP-Edent) was similar with OD and ISFD, but in contrast, Heydecke and colleagues (2003a, 2003b, 2004a) found that satisfaction is higher with OD than ISFD due to greater perceived ability to speak and clean the teeth.

Dental implant treatments in partially edentulous patients have not been so comprehensively examined. High satisfaction and improvements in OHRQoL have been observed among patients restored with implant-supported fixed partial dentures (ISFPD) and single dental implants (SDI) (Vieira et al., 2014, Bramanti et al., 2013, Dolz et al., 2014, Fillion et al., 2013, Kim et al., 2014, Nickenig et al., 2008, Persic et al., 2014, Petricevic et al., 2012a, Schropp et al., 2004, Swelem et al., 2014, Farzad et al., 2004, Kapur, 1991, Kuboki et al., 1999, Pjetursson et al., 2005, Vermylen et al., 2003). Improvement seems to be better in older patients (Petricevic et al., 2012a) and for anterior and premolar teeth (Ponsi et al., 2011).

Response shift has been reported as influencing changes in the OHRQoL after DIT (Ring et al., 2005, Kimura et al., 2012). The concepts of QoL and response shift are analysed in the next section.

2.2. QUALITY OF LIFE AND RESPONSE SHIFT

2.2.1 Concepts of Health

Health is a multi-dimensional concept and, so can be defined from diverse perspectives. Positive approaches define health as a 'state of well-being' (as that coined by WHO) whereas negative definitions such as 'the absence of disease or illness' have been inherent within the Western scientific model. But there are many other ways of thinking about health. Seedhouse (1986) and Aggleton (1990) argue that health is a commodity, i.e. something that can be bought (by investment in private health care), sold (via health food stores and health centres), given (by surgery and drugs) and lost (following accident or disease). Likewise, health has been regarded as a value, listed alongside other many values whose priority may vary according individual circumstances (Downie, 2000)

Concepts of health, illness and disease are not static or stable over time or within different contexts. The concepts have generally been linked with society and culture. Such concepts may be part of a cultural heritage passed through generations (Scriven, 2010). This dynamism increases the difficulties of finding a satisfactory definition of health, thus the development of different theoretical approaches and models helps us to understand what health is.

Two fundamental theoretical models of health have been proposed: the medical and the social models (Naidoo and Wills, 2009).

The traditional medical model, related to negative definitions of health, defines health as 'the absence of disease' and is based on the basic sciences (molecular biology, genetics, physiology, biochemistry). This model ignores the person as a whole, but regards the body as a machine, where each part works as a

mechanism in an independent way. Medicine has been based on this dualism and reductionism, where an essential distinction is the separation of mind from body. From this point of view, every explanation of life and biological processes, including behavioural and mental problems can be understood through physics and chemistry. Health is viewed is in terms of pathology, disease, diagnosis and treatment (Warwick-Booth et al., 2012).

The medical model is disease, rather than patient-oriented. It provides the scientific framework to explain how bodily mechanisms are involved in disease (Engel, 1978) and has been predominant in training health professionals and organizing health care, leading to the treatment and prevention of disease in Western societies (Daly, 2013). Dentistry, like many health sciences, has developed by the study of oral disease. Dentists are trained to diagnose and treat dental caries and periodontal diseases. The prevalence of these diseases has been widely studied using indices and indicators, which provide efficient and effective objective measures of the oral condition of the population (Allen, 2003). By developing biomedical research, it is possible to understand disease causation, guide diagnosis and conduct treatment from the pathological, biological and physiological point of view to obtain clinical outcomes (Wilson and Cleary, 1995).

The biomedical model has been widely criticized. Social scientists in health psychology and medical sociology argue that ill health is caused by a combination of biological (e.g. genetics), social (e.g. poverty), psychological factors and predispositions; in this context, biomedicine is unable to explain much reported illness (Bowling, 2009). The medical model focuses on aetiology and specific causes of disease, but many contemporary long-term chronic diseases in

developed countries are often 'social', thus medicine must recognize that disease would be placed in a social context.

In contrast, the biopsychosocial model emphasizes the person as a whole, in a close relationship with their environment. A broad range of factors must be considered when conceptualizing health, including social, psychological, cultural, political, economic and environmental, without neglecting the biological component. This model recognizes individual differences in health experience as being socially produced and seeks explanations for why these differences exist (Warwick-Booth et al., 2012). The biopsychosocial model focuses on prevention rather than treatment, with more attention on collective and social responsibility for health (Naidoo and Wills, 2009). From this perspective, WHO (1946) defined health as 'a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity' and later, in 1986 with the Ottawa Charter for Health Promotion Conference, the WHO recognized that in order to reach health 'an individual or group must be able to identify and to realize aspirations, to satisfy needs, and to change or cope with the environment' (WHO, 1986).

This model has been criticized for being too broad. Although social aspects of health-disease must be considered, the medical model is essential in the understanding of pathological processes. Moreover, its greatest emphasis in prevention at the community level might leave behind problems that can be tackled on a small scale.

A third model, the foundations theory (Seedhouse, 2001), defines health as 'foundations for achievement'. Social, environmental and personal factors are part of the foundation figure's state of health. This approach recognizes that health

problems can be caused by disease with social and environmental causes, but does not accept a special distinction between problems of disease and other problems in life. The most important foundations required for a person's health are: (1) basic needs of food, drink, shelter, warmth and purpose in life (including spirituality and meaningfulness), (2) access to information about all the factors which have an influence on a person's life, (3) skills and confidence to assimilate this information and (4) the recognition that an individual is never totally isolated from the other people and the external world. Seedhouse highlights that a person's health is intimately linked with his/her quality of life.

The biopsychosocial and foundations theories incorporate the concept of quality of life in the definition of health and well-being; including terms such as general quality of life (e.g., housing and education), clean environment and psychological or spiritual quality of life (Hewa and Hetherington, 1995, Younossi et al., 1999).

2.2.2 Quality of Life and Health Related Quality of Life

'Quality of life' refers to something much wider than health. The term has been used in multiple contexts, such as health status, physical functioning, symptoms, psychological adjustment, well-being, life satisfaction and happiness. In this sense, for example, the term "physical functioning" could refer to pathophysiological changes or functional deficits; that would correspond to a health status measure. Thus, concepts of health and quality of life are elusive and abstract; while we know intuitively what they mean, they are difficult to define (Locker, 1997).

The wide range of definitions of Quality of Life (QoL) demonstrates the lack of consensus on the concept. In part this is due its variability between and within individuals (Table 2.1). The term "quality of life" has been commonly used to mean health status, physical functioning, symptoms, psychosocial adjustment, well-being, life satisfaction, and happiness. Therefore, an extensive array of concepts and definitions has been proposed (Fitzpatrick et al., 1998, Ferrans, 2005).

Table 2.1: Examples of definitions of quality of life

Gillingham and Reece (1979)	*'Is the satisfaction that a person achieves from his consumption of market goods, leisure, public goods and the physical and social characteristics of his environment'*
McCall (1980)	*'QOL consists in the availability, throughout a society, of the general happiness requirements'*
Calman (1984)	*'The difference, or the gap, at a particular period of time between the hopes and expectations of the individual and that individual's present experiences'*
Clark and Bowling (1989)	*'Is not limited to functional ability, level of activity, mental state and longevity, but encompasses the concepts of privacy, freedom, respect for the individual, freedom of choice, emotional wellbeing and maintenance of dignity'*
WHO (1998)	*'An individuals' perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns'*

A useful taxonomy has been proposed by Farquhar (1995) who classified QoL definitions as expert/professional or lay.

Expert definitions comprise four groups: (1) '*global definitions*' (Type I) that express QoL in general terms, such as the degree of satisfaction/dissatisfaction or happiness/unhappiness. For example, McCall (1980) defines globally QoL as ' the

provision of the necessary conditions for happiness and satisfaction'. (2) '*Component definitions*' (Type II) break down QoL into a series of components or dimensions such as health, life satisfaction and psychological well-being, as those described by Patterson (1975) as key components of QoL 'health, function, emotional response and economics'. (3) '*Focused definitions*' (Type III) consider only small components of QoL. For example, within health services, QoL often focuses on health and functional status (Bowling, 2005). (4) '*Combination definitions*' (Type IV) overlap types I and II because they are global, but also contain specify components.

Lay definitions of QoL have been recognized, but are not exempt from criticism due to their variability and validity. QoL can only be described and measured in individual terms, because its components are personal (Calman, 1984). For example, older people identify family, social contacts, health, mobility/ability, material circumstances, activities, happiness, youthfulness and the living environment as the most important dimensions of QoL (Farquhar, 1995). In the same way, adults were asked to identify the most important things in their lives and chose relationships with family or relatives, their own health, the health of another close person, finances/standard of living/housing and social life/leisure activities as their top five (Bowling, 1995). Both groups show similarities, but it is not expected that older people define QoL in the same terms as younger generations. Unlike adults, older people define QoL in terms of its positive aspects but also have negative connotations. Family relationships have the same or even more value than general health. Furthermore, QoL is influenced by the context (economical, historical, social) and the individual life experience (Bond, 2004).

In conclusion, QoL is a multidimensional and complex construct where subjective and objective dimensions interact in a dynamic way (Bowling, 2001). One dimension that narrows the concept of quality of life is health.

2.2.2.1 Health Related Quality of Life

Health-related quality of life (HRQoL) incorporates the impact of health conditions and their treatment on the person's emotional, physical and social functioning and lifestyle (Bowling, 2009). Thus HRQoL provides a way to measure people's experience of their health, illness and treatment.

In terms of health-disease processes, HRQoL is quality of life as affected by health, as judged by individuals comparing their expectations with their experience (Carr et al., 2001). It is generally accepted that HRQoL is multidimensional (including physical, functional, emotional and social aspects) (Sprangers, 2002) and subjective because QoL can only be understood from the person's perspective (Cella, 1994). As is the case with QoL, there are several examples of definitions (Table 2.2).

Table 2.2: Examples of definitions of health-related quality of life

Patrick and Erickson (1993)	*'HRQoL is the value assigned to duration of life as modified by the impairments, functional states, perceptions and social opportunities that are influenced by disease, injury, treatment, or policy'*
Testa and Simonson (1996)	*'Physical, psychological and social domains of health that are unique to each individual'*
Bowling (2001)	*'Optimum levels of mental, physical, role, and social functioning, including relationships, and perceptions of health, fitness, life satisfaction, and well-being.*

Ferrans (2005) classified definitions of HRQoL in three groups based on their scope. The first group is limited to the purview of health care such as physical dysfunction, symptoms, mental health problems and work-related disability. Schipper and colleagues (1996) definition of QoL in clinical medicine as the '*functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient*' exemplifies this. The second group of definitions focuses on the impact of illness and treatment on QoL, considering the effects of disease on different aspects of life. For example, Revicki and colleagues (2000) defined HRQoL '*as the subjective assessment of the impact of disease and its treatment across the physical, psychological, social, and somatic domains of functioning and well-being'*. Finally, the third category focuses on QoL for the individual who has an illness such as in the definition of HRQoL proposed by Osoba (1994) as *'a multidimensional construct encompassing perceptions of both positive and negative aspects of dimensions, such as physical, emotional, social, and cognitive functions, as well as the*

negative aspects of somatic discomfort and other symptoms produced by a disease or its treatment'.

In summary, different perspectives and definitions of HRQoL have been developed but all concluded that HRQoL is multidimensional, including physical and mental health, social functioning, perceptions of health, life satisfaction and well-being.

2.2.2.2 Oral health and quality of life

This acknowledgement of the impact of psychosocial factors on health and the measurement of its subjective aspects are consistent with the aim of contemporary dentistry, which is to obtain and maintain a functional, pain-free, aesthetically and socially acceptable dentition for the lifespan of most people (Sheiham, 1992). This broader approach to oral health also leads us to think of Oral Health-Related Quality of Life (OHQoL), or the extent to which oral conditions affect everyday life.

As is the case for definitions of health, several approaches have been proposed to conceptualize oral health. Dolan (1993) defined oral health as: '*a comfortable and functional dentition that allows individuals to continue their social role'.* The Department of Health UK (1994) developed a definition of oral health that incorporates social aspects and reflects the WHO definition and bio-psychosocial concepts of health: '*oral health is a standard of health of the oral and related tissues which enables an individual to eat, speak and socialise without active disease, discomfort or embarrassment and which contributes to general well-being'*. Both definitions are compatible with the WHO definition of oral health: '*a state of*

being free from chronic mouth and facial pain, oral and throat cancer, oral sores, birth defects such as cleft lip and palate, periodontal (gum) disease, tooth decay and tooth loss, and other diseases and disorders that affect the oral cavity that limit an individual's capacity in biting, chewing, smiling, speaking, and psychosocial well-being' (WHO, 2012) and this latter definition of oral health will be used in this thesis.

Conceptualising oral health in this way requires multidisciplinary indicators with contributions from psychology, sociology and statistics, incorporating daily activities and the effects of oral conditions on life overall (Robinson et al., 2014). Thus, OHQoL links clinical variables and person centred self-reported measures establishing a multidimensional construct that refers to the extent to which oral disorders disrupt an individual's normal functioning (Baker, 2007). One of the latest definitions of OHRQoL was proposed by Locker and Allen (2007) as: 'the impact of oral disorders on aspects of everyday life that are important to patients and persons, with those impacts being of sufficient magnitude whether in terms of severity, frequency or duration, to affect individual's perception of their life overall'. This definition will be used in this thesis throughout.

OHRQoL measures may be generic, assessing general OHRQoL across different populations or condition or disease-specific, which focus on particular impacts of specific oral health problems. Examples of generic measures used to assess QoL in patients restored with dental implants are the Oral Health Impact Profile (OHIP) with the complete and shortened versions (Lam et al., 2014, Persic et al., 2014, Marra et al., 2013), the UK Oral Health-Related Quality of Life Measure (OHRQoL-UK) (Cakir et al., 2014), the Oral Impacts on Daily Performances (OIDP) (Berretin-Felix et al., 2008) and the Geriatric (General) Oral Health Assessment

Index (GOHAI) (Fillion et al., 2013). Condition-specific measures, such as the Dentine Hypersensitivity Experience Questionnaire (Boiko et al., 2010) are more likely to detect subtle changes caused by particular conditions and thus have better responsiveness. The limitation of specific instruments is that the statements and domains within them are only relevant to the clinical condition being assessed (Robinson et al., 2003b, Allen, 2003). One instrument has been developed to measure the impact of dental implants on QoL specifically, the Quality of Life with Implant-Prosthesis (QoLIP) questionnaire (Preciado et al., 2013a, Preciado et al., 2013b).

2.2.2.3 Theoretical Models applicable to OHQoL

Theoretical models are tools designed to explain and conceptualize complex relationships between factors. Bakas and colleagues (2012) describe in their systematic review the most frequently HRQoL models used: the Wilson and Cleary model (Wilson and Cleary, 1995) which incorporates the biomedical and social components of health, Ferrans and colleagues' model (2005) that is a revision of the Wilson and Cleary model explicitly defining individual and environmental characteristics and the World Health Organization International Classification of Functioning Disability and Health (WHO-ICF) (WHO, 1980) which provides a description of health and health-related domains. Nonetheless, two theoretical models have predominantly been used in OHQoL research: Locker's conceptual model of oral health and Wilson and Cleary's model linking clinical variables to quality of life.

Locker (1988) proposed a multidimensional model that provides a scientific basis for the understanding of oral disease and its consequences. This model was derived from the International Classification of Functioning, Disability and Health (ICIDH) to consider the relationship between oral disease, impairment, disability and handicaps (WHO, 1980).

According to Locker's model, oral disease entails five consequences: impairment, functional limitation, pain/discomfort, disability, and handicap (Figure 2.1). Impairment is defined as any anatomical loss, structural abnormality or disturbance in physical or psychological processes either present at birth or arising out of disease or injury. Functional limitations are defined as restrictions in the functions normally expected of the body. Discomfort is defined by self-reported physical and psychological distress, including pain and other states not directly observable. Disability is a behavioural concept defined as any limitation in or lack of ability to perform the activities of daily living. Handicap is defined as the disadvantage experienced by impaired and disables people as a result of failing to meet the expectations of the society they live.

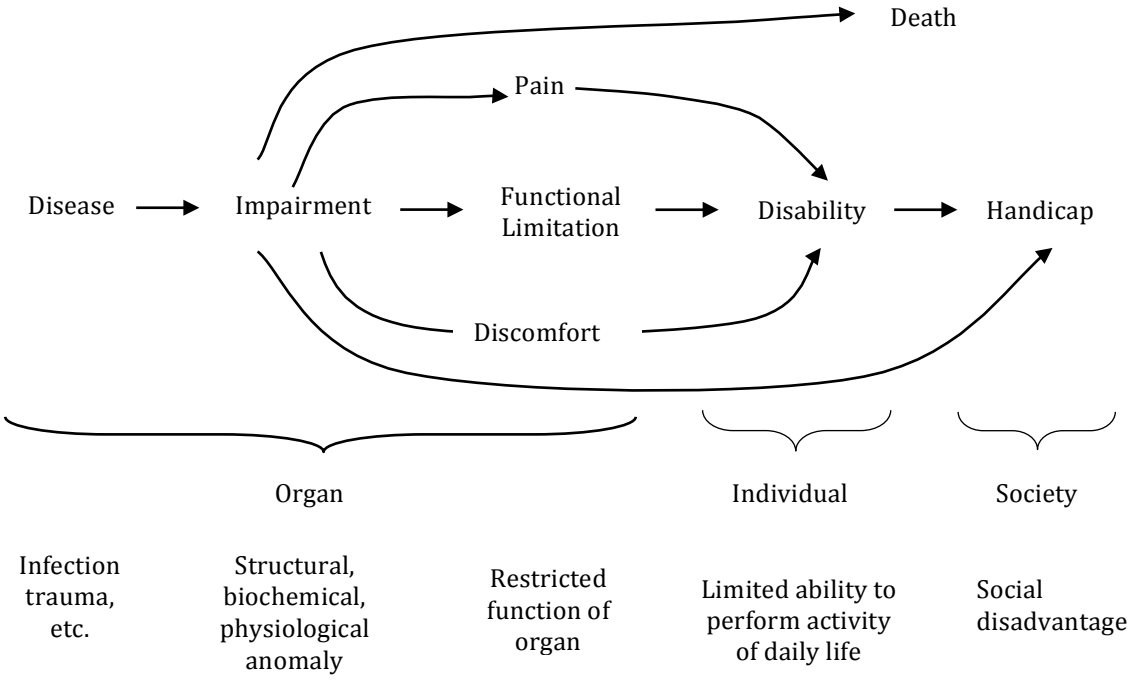


Figure 2.1: Conceptual Model of Oral Health (Locker, 1988)

For example, impairment (structural abnormality, *e.g.*, edentulousness) leads to functional limitation (restrictions in body functions, *e.g.*, difficulty chewing) and pain/discomfort (self-reports of physical and psychological symptoms), which in turn, lead to disability (limitations in performing daily activities, *e.g.*, unsatisfactory diet) and then to handicap (social disadvantage, *e.g.*, social isolation) (Baker, 2007). This model introduced a fundamental change in dentistry, from the biomedical approach widely used to a biopsychosocial perspective incorporating patients' views to assess oral health.

The Wilson and Cleary model (1995) interprets and conceptualises the relationship between clinical factors, HRQoL (or OHRQoL) and subjective well-being and provides a theoretical bridge between the biomedical and social science paradigms. The model describes five levels: biological and physiological variables,

symptom status, functioning, general health perceptions and overall quality of life or subjective well-being (Figure 2.2). The authors propose specific causal relationships between the five levels through which clinical variables are linked to measures of HRQoL. The interactions in the model go from the cell and individual level (biological aspects) to the individual as part of a society and how these aspects affect their quality of life. The relationships are likely to be complex with direct and indirect interactions at non-adjacent levels.

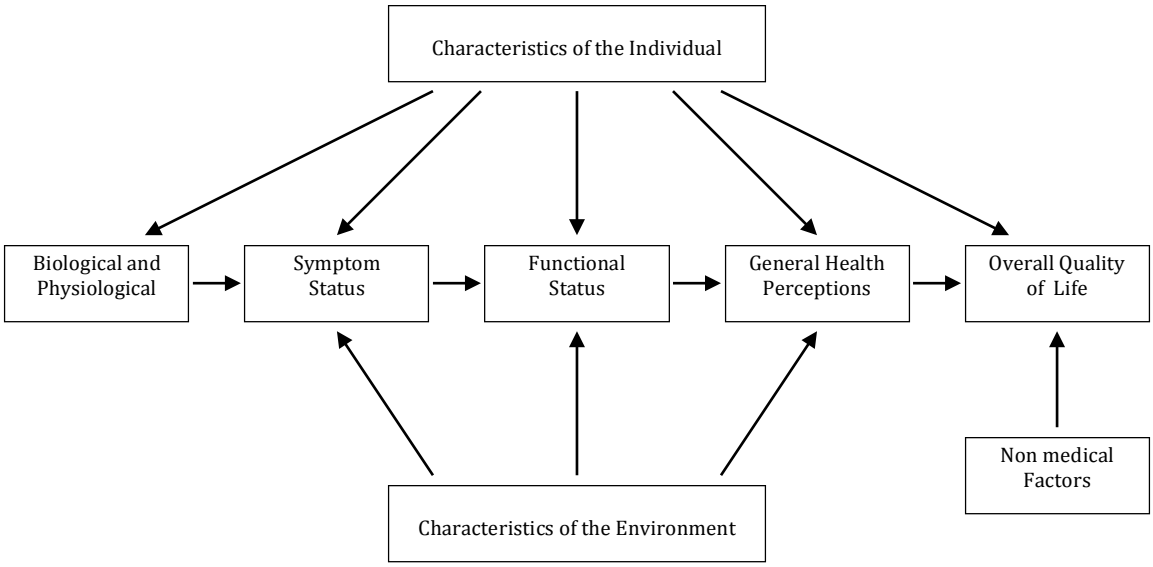


Figure 2.2: Wilson and Cleary Conceptual Model of linking clinical outcomes to quality of life (Wilson and Cleary, 1995)

The Wilson and Cleary model has been used and tested in oral health (Baker, 2007, Broder et al., 2014, Gururatana et al., 2014, Gupta et al., 2015, Santos et al., 2015) confirming its validity as a framework for studying OHRQoL. According to the model, environmental (socioeconomic status, culture, living conditions) and individual factors (personal preferences, emotional factors, psychological aspects) might influence OHRQoL. The pathways and relationships proposed by the model

have been successfully tested; according to different studies, individual factors and psychological characteristics influences OHRQoL in populations as varied as elderly people (Santos et al., 2015), children (Gururatana et al., 2014) and youth with cleft palate (Broder et al., 2014). Therefore, using the model as a framework may offer an opportunity to design targeted strategies of clinical trials or oral health promotion interventions (Gupta et al., 2015).

By incorporating assessment of individual factors such as indicators of life-satisfaction or self-esteem indicates that only patients or those directly affected are able to report accurately how these things impact upon their quality of life. Therefore, it is desirable take into account how people perceive and experience health-disease manifestations in their daily lives (Revicki et al., 2000). Assessments of health thus go beyond the presence of symptoms of disease and/or the treatment efficacy embracing also the subjective perspective of people's physical and mental health. Thereby, this consideration of the patients' perspective can be seen as an important step to incorporating lay people into clinical practice and research (Black et al., 2009, Robinson et al., 2014).

2.2.2.4 Using Patient Reported Outcome Measures (PROMs) to determine change in subjective health

Changes in patients' health outcomes have traditionally been measured by objective tests such as weighing, measuring blood pleasure, evaluating sugar levels or counting dental caries lesions. But there are clear limitations when assessing health from this simplistic perspective. First, objective measurements of health are

arbitrary. The cut-off points to determine normality or abnormality are established by professionals but are not inevitably valid (e.g. pre-prandial sugar levels of 5 mmol/l can be found in healthy or diabetic people). Second, there is frequent discordance between clinical and subjective assessments of health (people might be diagnosed as sick, yet feel healthy and vice versa). Third, some conditions defined by professionals as disease are considered normal by people (tooth loss is expected with ageing in some cultures).

Conditions with direct relevance to patients, such as fatigue, pain or the influence of oral health on daily activities cannot be assessed via these objective measures, but rather subjective criteria are required to assess self-evaluations of change (Doward and McKenna, 2004, McPhail and Haines, 2010a, Lohr, 2012). Self-Reported or Patient Reported Outcome measures (SRO/PROMs) measures are subjective indicators of health and QoL. (Fayers and Machin, 2007). A broad definition provided by the FDA (2012) for PROMs is "any report of the status of a patient's (or person's) health condition, health behaviour, or experience with healthcare that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else", such scales comprise measurements of physical, emotional and/or social functioning. PROM's provide the subject's perspective that is essential to assess the disease trajectory and effectiveness of treatments or intervention (Revicki et al., 2008). Clearly OHRQoL falls into this category.

2.2.3 **Measuring change**

Considering that one of the main goals of health care is to improve the health of individuals or populations then the role of health services research is to identify, measure and explain those changes in health status and its influence on people's QoL (Locker, 1998).

It has been proposed that the measurement of change in health status within individuals and within groups has two goals (Brown and Burrows, 1992). First, to detect differences between and within individuals and second, to infer treatment effects. The measurement of change in health status at individual or population level can be assessed through longitudinal research involving data collected at two or more points in time. Ideally, this design allows the description of change, the identification of predictors and explanations for the results obtained (Robinson and Donaldson, 2003, Menard, 2007).

According to Ziebland (1994) and Locker (1998), health changes in longitudinal research can be assessed in four ways: before and after comparisons, change scores, global transition judgements and global transition scales.

Before and after comparisons compare health status scores at baseline and follow-up. This approach is relatively simple although group means may mask within-subject change if positive and negative changes cancel each other out.

A variant of the before-after comparisons is the regression analysis using the baseline score as a covariate. Using the baseline score as a covariate in repeated measures is a way to test if the baseline score predicts the follow-up scores.

Change scores are calculated by subtracting the baseline from the follow-up score. Change scores can identify variations between individuals and groups and its interpretation must consider whether the change is clinically meaningful. Scores might be statistically significant when large samples are used, but not be clinically important (Osoba et al., 1998). Likewise, change scores are prone to regression to the mean, where natural variation of the data is interpreted as real change (Barnett et al., 2004) and systematic measurement error (Qiu and Rosner, 2010) may accentuate or mask changes.

Global transition judgements record participants' overall assessment of how their health has changed over time. Their use is relatively easy in clinical practice and incorporates patient values to determine clinically meaningful change. Global judgements may be relatively insensitive to small changes in health status and may not detect change if people improve in some dimensions but deteriorate in others.

Global transition scales are derived from a series of global transition judgements applied to different dimensions of health allowing comparisons and correlations with change scores obtained from clinical indicators.

Longitudinal research also involves different designs, including prospective cohort, quasi-experimental and randomized controlled trial, with the latter considered the most relevant approach to measure change in longitudinal data (Locker, 1998). Comparing average changes from before (baseline) to after (follow-up) treatment between experimental and control groups in clinical trials, allows inferences about whether individuals in one group change more than those in the other group, and thus, which treatment is most effective.

The analysis of the differences between baseline and follow-up values can be carried out by statistical tests such as the *t-test* and the analysis of covariance

(ANCOVA), but before and after treatment effects are far more complex than a simple score subtraction. Change scores can lead to false conclusions because they are systematically related to random error at any point of measurement (Cronbach and Furby, 1970). Thus, the baseline and follow-up scores have substantially lower reliability than the variable from which they were derived and conclusions concerning the predictors of change may be misleading (Locker, 1998)

Another key aspect to be considered in the analysis subjective outcomes are changes in the individual's internal scales of measurement (Robinson and Donaldson, 2003), i.e response shift. Response shift may mask the changes brought about by the treatment or progression of disease.

2.2.4 Defining Response Shift

Response Shift is a theoretical construct that, when applied to quality of life, posits that people can adjust how they think about their QoL when they receive new information (Wagner, 2005). Thus, people can change their meanings of self-evaluation of QoL as a result of changes in internal standards (recalibration), values (reprioritization) and conceptualization (reconceptualization) (Schwartz and Sprangers, 1999).

The original concept of response shift was established in the social sciences, particularly educational and organizational research. Campbell and Stanley (1963) introduced the term '*instrumentalization'* in educational research to refer to changes in the calibration of a measuring instrument or in the participant standards that may produce changes in the obtained measurements or

confounding effects (Campbell et al., 1963). Later, Howard and colleagues (1979b) defined response shift as the change in a subject's basis for determining his/her level of functioning on a given dimension. Response shift was reported as a negative aspect to be avoided and recognized as a bias responsible for 'contaminating' self-reported evaluations (Howard et al., 1979a).

In organizational research Golembiewski and colleagues (1976) defined three types of change that might occur with self-report data: alpha, beta and gamma change (Table 2.3).

Table 2.3. Distinctions between types of change (Golembiewski et al., 1976) and Response Shift Theory (Schwartz and Sprangers, 1999)

Types of change (Golembiewski et al., 1976)	*Response Shift (Schwartz and Sprangers, 1999)*	*Examples after dental implant treatment*
Alpha - Change in the level of some existential state, given a constantly calibrated measuring instrument related to a stable conceptual domain	*True change*	*Improvement in masticatory performance*
Beta - Change in the level of some existential state, complicated by the fact that some intervals of the measurement continuum associated with a constant conceptual domain have been recalibrated	*Recalibration - Change in the participant's internal standards of measurement*	*Person change the internal definition of being uncomfortable with dentures after treatment*
Gamma - Redefinition or reconceptualization of some domain, a major change in the perspective or frame-of-reference within which phenomena are perceived and classified	*Reconceptualization - Redefinition of the target construct*	*Person recognises how important is the influence of oral health in his/her QoL*
N/A	*Reprioritization - Change in the participant's values*	*Social activities are a priority in person's life after dental treatment*

Alpha change is typically measured in self-reports using the pre-post test designs; change is identified as differences in scores over time where the participant's report of change is taken on a constantly calibrated instrument (Terborg et al., 1980). Beta change involves recalibration of the intervals. It is an observed variation where the apparent change is due to an instrument that has been recalibrated by the participant between assessments (Golembiewski et al., 1976). Gamma change is a redefinition or reconceptualization of some instrument's domain by the participant. It is related to changes in the perspective or frame of reference of the participant (Golembiewski et al., 1976, Terborg et al., 1980).

However, RS might occur in any field using self-reported measures (Barclay-Goddard et al., 2009a). In health, these concepts form the basis for the response shift definition developed by Sprangers and Schwartz (1999). Their conception refers to changes in the meaning of one's self-evaluation of a target construct as a result of: a change in internal standards of measurement (recalibration), a change in values (reprioritization) or a redefinition of the target construct (reconceptualization) (Schwartz and Sprangers, 1999) (Table 2.3). For example, a person seeking for dental implants rates her OHRQoL as 'poor' because her dentures are loose. After the treatment, she is very pleased with her new dentures, so she rates her OHRQoL as 'excellent'. Nonetheless, after using her new dentures for a few months, she realises that she is not able to eat certain kind of food, so if asked to rate again her OHRQoL she would say that is just 'good'. Response shift has been proposed as an explanation for this phenomenon.

2.2.4.1 Response Shift theory and models

Sprangers and Schwartz (1999) proposed a theoretical model to understand how response shift may affect perceived quality of life. The model has five major components: catalyst, antecedents, mechanisms, response shift and perceived quality of life (Figure 2.3).

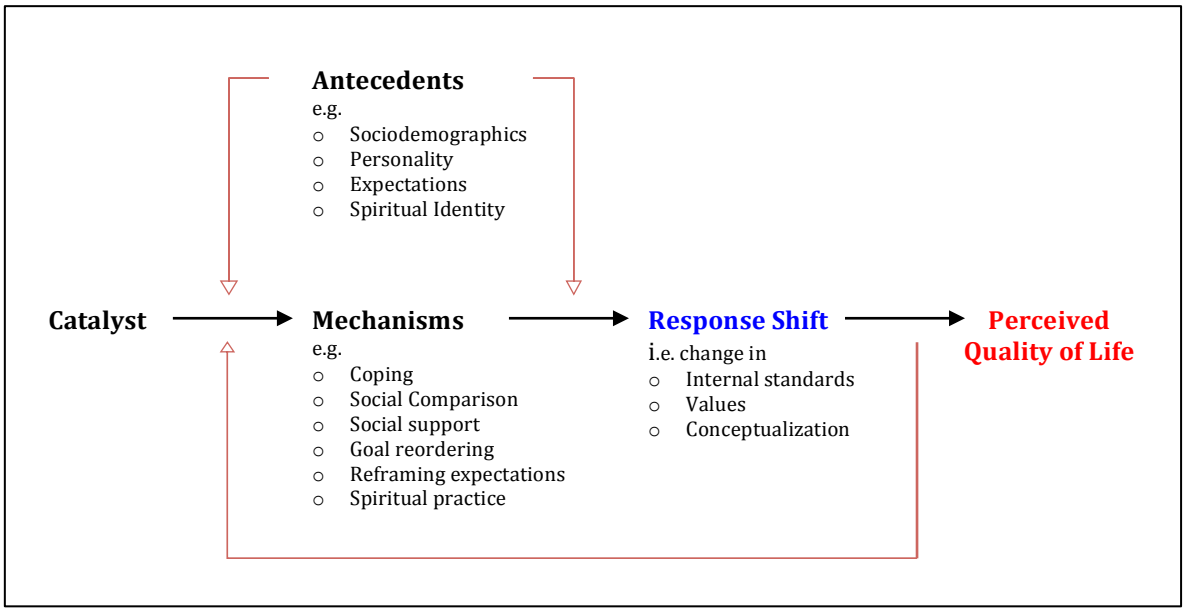


Figure 2.3. The Sprangers and Schwartz theoretical model of response shift model and quality of life

A *catalyst,* for example, the onset of illness or treatment, may induce *mechanisms* to accommodate changes in health. The mechanisms depend on the specific change and on stable and inherent characteristics of the individual, i.e *antecedents* (sociodemographics, personality, etc.). The catalysts, mechanisms and antecedents may induce *response shift* that in turn affects the *perceived* quality of life.

The process is dynamic and iterative; changes in individual's health status may induce behavioural, cognitive and affective processes to cope with the illness, potentially changing the individual's standards, values or conceptualization of quality of life so influencing their perceived quality of life. For example, a woman who has been edentulous and wears conventional dentures for many years may have achieved a certain ability to cope with her disability and may regard her oral health related quality of life as good (Figure 2.4). Seeking dental treatment to renew her dentures, she meets another person (also edentulous), but who has been treated with implant-supported overdentures (catalyst). During their conversation the woman with implants might explain how she dreaded her conventional dentures coming loose in an unexpected moment. With her new treatment she is more confident; she has joined a church group recently and is planning holidays. She feels back to life.

The woman with conventional dentures compares herself with the other person and re-evaluates her ability to use her prostheses (recalibration). She realizes that she rarely goes out because she is embarrassed about her mouth. She recognises that her quality of life is affected by lost social life (reconceptualization) and if asked to rate her quality of life now she would say that it is lower than she rated it originally (recalibration). In this example, 'social comparison' acts as a mechanism to reappraise significant life events and changes in self-perspective. Social comparison brings the perspective from another that can produce a different perception of one's situation or quality of life, mediating in this sense the response shift processes (Gibbons, 1999). Thus, the social comparison has introduced her to new benchmarks of quality of life and she has recalibrated her internal standard upward, meaning she now rates her OHRQoL as worse than she

originally thought.

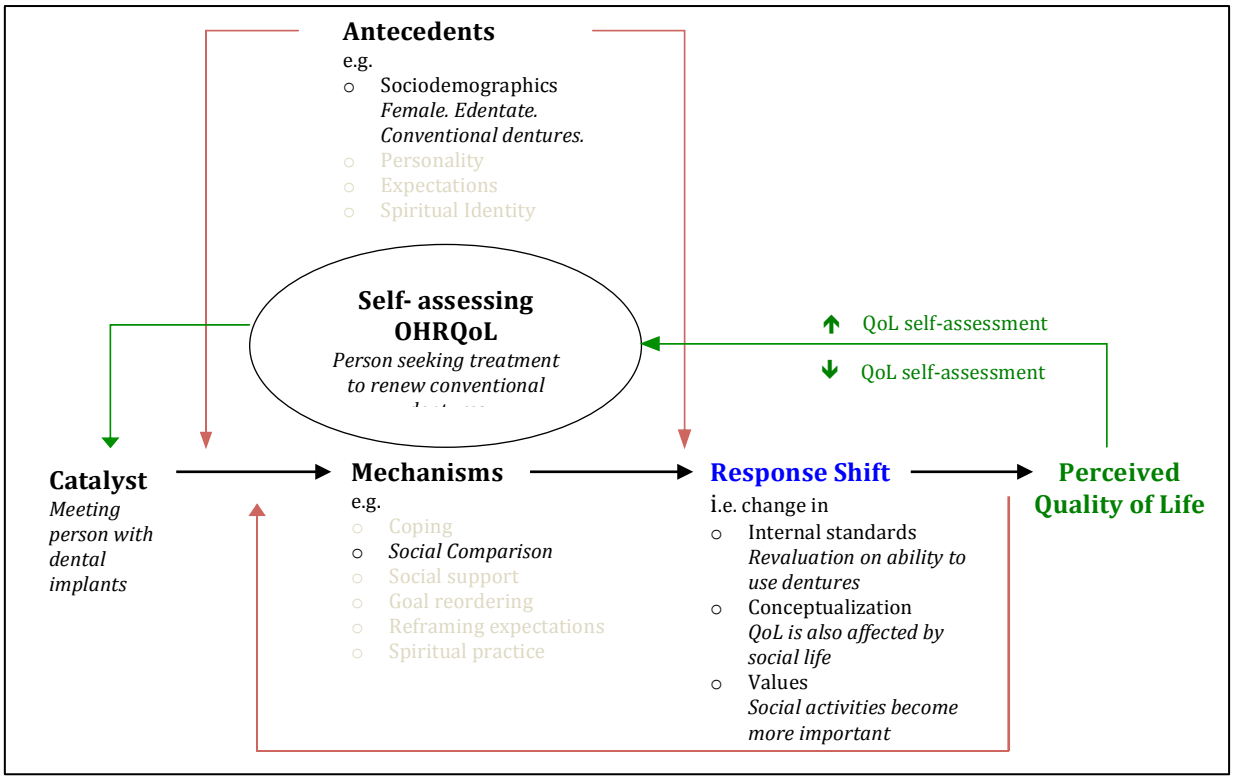


Figure 2.4: Example of Sprangers and Schwartz theoretical model of response shift and quality of life

Several studies have tested Sprangers and Schwartz's model of response shift, mainly assessing the relationship between the catalysts and/or antecedents and response shift, with diverse results. Razmjou and colleagues (2006) investigated 125 patients with degenerative arthritis undergoing total knee arthroplasty (TKA). Participants completed a disease specific QoL questionnaire at baseline and 6 months after surgery. Response shift was not affected by gender, age, amount of recovery, or comorbidity (antecedents) when adjusted for the preoperative level of disability. The authors concluded that response shift did not alter the interpretation of clinical outcomes as it had insignificant confounding

impact over the unadjusted scores. Later, the same researchers assessed the quality of life of 236 patients, this time 6 months and 1 year after surgery (catalyst). Response shift increased with time; 27% had positive recalibration (i.e. overestimated their preoperative disability), 9% had a negative recalibration and 64% had no recalibration. These results may indicate that patients who adapt better to quality of life conditions after surgery perceived their quality of life as worse at baseline; i.e. they change their internal standards. Thus, response shift had substantial impact on measuring different patterns of recovery (Razmjou et al., 2009).

Similarly, the health status of one hundred and forty-eight patients was assessed one-week post stroke (baseline) and 6 and 24 weeks later using the EQ-VAS. There was a change in internal standards, but none of the sociodemographic variables (antecedents) predicted the magnitude or direction of response shift (Ahmed et al., 2005a).

Yardley and Dibb (2007) studied recalibration predictors in 301 patients with Ménière's disease and concluded that higher levels of catalyst such as vertigo severity and mechanisms such as upward social comparisons predicted greater response shift.

A comprehensive analysis of the Sprangers and Schwartz's model was conducted by Visser and colleagues (2013) in 202 patients with cancer. They aimed to explain the degree of bodily pain using the catalyst, antecedents and mechanisms through structural equation modelling and sequential regression analysis. Many effects and interactions between the variables were found, as hypothesized by the model. For example, having undergone surgery for lung cancer was related to more negative impacts on social comparisons (effects of the

catalyst on mechanisms); optimism was negatively related to social comparisons (effects of antecedents on mechanisms); post-traumatic growth was related positively to the magnitude of recalibration response shift (effects of mechanisms on response shift) and the direction of recalibration response shift was not related to bodily pain.

The model has been criticized, as it does not differentiate response shift from the mechanisms and outcomes, which causes problems of logical circularity. For instance, changes in values of QoL (reprioritization) may overlap with reframing expectations (mechanisms) (Rapkin and Schwartz, 2004, Schwartz et al., 2007).

In response to this challenge, Rapkin and Schwartz (2004) expanded the Sprangers and Schwartz's model. The main contribution of this new model is that RS depends on changes in appraisal processes (Figure 2.5). They proposed that any response in quality of life assessment could be understood as a function of an appraisal process. Four distinct cognitive processes were proposed corresponding to psychological aspects of coping and adjustment: (1) induction of a frame of reference, (2) recall and sampling of salient experiences, (3) use of standards of comparison to appraise experiences and (4) application of a subjective algorithm to prioritize and combine appraisals and formulate a response.

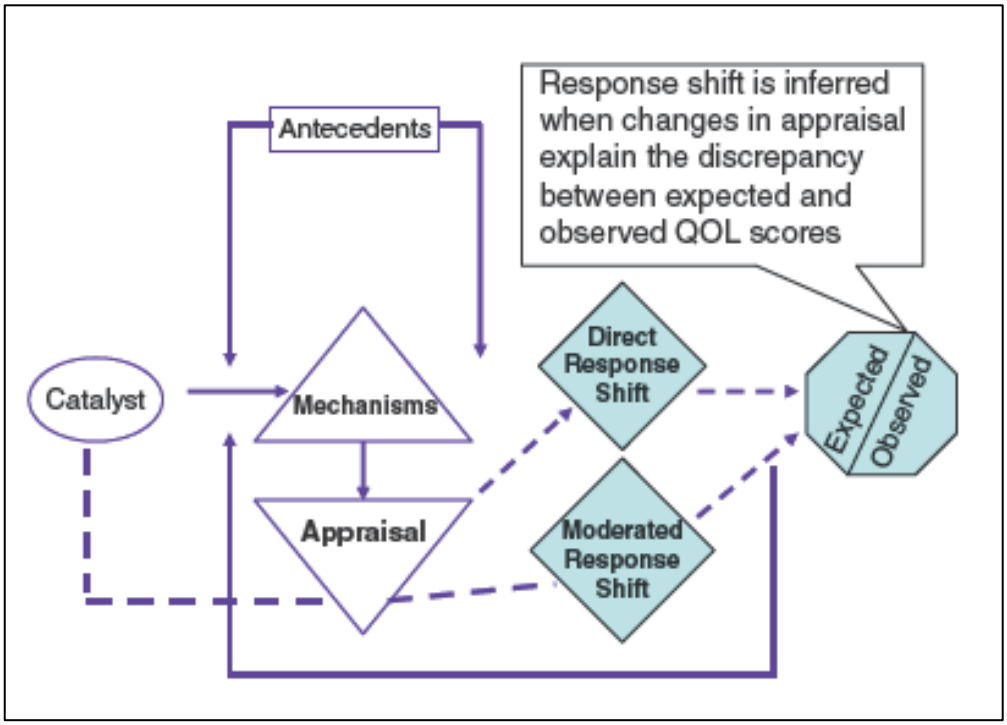


Figure 2.5: Rapkin and Schwartz theoretical model of Response Shift

This operationalization defines reconceptualization as changes in the frame of reference, reprioritization as changes in strategies for sampling experience within one's frame of reference and changes in factors that determine the relative salience of the events and recalibration as changes in standards of comparison for evaluating one's experience. Importantly, in this way, RS cannot be confused with mechanisms or outcomes, thus the model is more testable and the circularity problem seems to be solved (Schwartz, 2010).

This model was tested by Wyrwich and Tardino (2006) who assessed the cognitive processes used by patients with chronic diseases when appraising their HRQoL in global transition assessments. The model was useful in analysing the content of the interviews, explaining and combining the thought processes expressed by participants. Similar findings were obtained by Bloem and colleagues (2008) who used the model to describe the cognitive processes of cancer patients

when answering QoL items, but with the special conclusion that the content of the cognitive component when someone is responding a questionnaire may differ not only between participants but also within individuals over time. Conversely Rapkin and Schwartz established that individuals use the same cognitive processes in answering all the questionnaire items.

Li and Rapkin (2009) tested the model using the Recursive Partitioning Regression Tree (RPART) analysis. The cognitive variables helped to account for response shift and the model was useful in identifying diverse patterns of response shift. Testing both the Schwartz and Sprangers and the Rapkin and Schwartz theoretical models made it possible to analyse pathways and the level of influence that catalysts, mechanisms, antecedents or appraisals played in determining response shift. Finding these patterns might predict for example, who would undergo response shift or what factors would induce a certain response.

However, the revised model has also been criticised. According to Sawatzky and colleagues (2017) the concept of appraisal implicitly reflects a process that is cognitive, but responses to questions are not necessarily cognitively derived. For the authors, RS is better defined as a change in the response processes or a change in how individuals interpret and respond to measurements items.

The whole concept of RS has also been criticised. Ubel and colleagues (2010) suggest that the term response shift creates a conceptual confusion in research, because it merges sources of measurement error (for the authors, scale recalibration) with true change in quality of life (hedonic adaptation). The authors add that due to misleading interpretation in RS, the concept may suggest that high QoL reported by people seriously ill, is merely a measurement artefact. Thus, such

people cannot actually experience good QoL, but rather their responses have shifted.

For their part, Sprangers and Schwartz (2010) response suggest that abandoning the term of RS is not solving the conceptual issue. They propose that adaptation is a mechanism and scale recalibration (and reprioritization and reconceptualization) is the outcome. They agree with Ubel and colleagues that conceptually RS is confusing because of its complexity, but more investigation is needed.

2.2.5 Response Shift Assessment

Subjective assessment of changes in health can be obtained through person-reported outcome measures (PROMs). When using PROMs to measure change, traditional pre and post assessments may not capture accurately those changes if response shift is not accounted for. Reconceptualization, recalibration and reprioritization might mask important findings, attenuating or exaggerating estimates of treatment effect. Therefore, methods to assess response shift are useful in the evaluation of treatment effects and the impacts of disease in affected people, adding valuable information to understand how people cope with disease (Schwartz and Sprangers, 1999, Barclay-Goddard et al., 2009a).

2.2.5.1 Person-reported outcome measures in light of Response Shift

In the light of response shift, Schwartz and Sprangers (2010), classified PROMs into three types: performed, perception and evaluation-based, each contributing with different explanations of change and with different susceptibility to response shift.

Performance–based measures assess objective functioning, independent of a subjective judgement. They quantify what an individual can do. Frequently they assess physical functioning by timing, weighting, counting, etc. and may be clinical or self-reported (Dobson et al., 2012). These measures are not expected to be susceptible to response shift (Wilson, 1999, Schwartz, 2004, Barclay-Goddard et al., 2011) because physiological changes often are not determined by self-report and do not measure changes in one's self-evaluation. Nonetheless, observed scores obtained in performance-based measures are understood to be an estimate of a "true score" (Rapkin and Schwartz, 2004) and may be used as universal standards or referents to correct biases increasing the accuracy of PROMs (Daltroy et al., 1999). Daltroy and colleagues. (1999) found that participants tested physically provided more accurate self-reports of functional limitations and observed that people may recalibrate their self-assessments based on recent health problems. The authors hypothesized that people who suffered a recent loss of function might be reassured by a performance test that counteracts a response shift.

Perception-based measures involve individual judgements concerning the occurrence of an observable phenomenon and are highly dependent upon the individual making the rating (Schwartz and Rapkin, 2004). Discrepancies between reported and expected scores would reflect response bias.

Evaluation-based measures involve judgements using idiosyncratic and subjective criteria. Each participant would have their own evaluative standards to answer the questions, as the subjective perspective of the observer is absolutely intrinsic to the phenomenon of interest (Schwartz and Rapkin, 2004). In this sense, each patient has his or her own true score and no other person shares the same internal standard. For this reason, discrepancies between reported and expected scores for these types of items would correspond to response shift.

Thus, the three types of self-reported outcome measures (performance, perception and evaluation-based) influence the QoL scores obtained. Hence, the incorporation of both performance and perception-based measures may be useful to validate the results. Finkelstein and colleagues (2014) investigated recalibration response shift after adjusting for bias associated with implicit theories of change (i.e. individuals retrospectively assess their health status inferring what their initial state have been based on the present status) in patients undergoing spinal surgery using a perception-based and an evaluative-based measure. Recalibration and implicit theories of change were both sources of bias in patient-reported outcome assessment, but the implicit theories of change were a greater threat to validity in this patient sample.

2.2.5.2 Methods to Assess Response Shift

A number of approaches have been proposed to assess response shift (Schwartz and Sprangers, 1999, Barclay-Goddard et al., 2009a). In broad terms, the

methods may be classified as: design, individualized, qualitative, statistical and idiographic approaches.

2.2.5.2.1 Design approaches

Retrospective ratings

The most common method to assess response shift is using a retrospective rating of pre- and post-treatment health status. As well as the standard baseline and follow-up data, the 'then-test' collects a retrospective judgement of baseline QoL levels at the follow-up ('then'). It is based in the idea that the close temporal proximity of the 'then' and post-test means that participants rate their QoL using the same internal standards, values and concepts (Schwartz and Sprangers, 1999)

Numerically speaking, the difference between the then-test and the pre-test score represents recalibration and the post-test-minus-then-test represents the adjusted treatment effect.

The then-test has been widely used to assess response shift in disease populations such as those with cancer (Korfage et al., 2007), arthritis (Razmjou et al., 2006), edentulousness (Kimura et al., 2012) stroke (Ahmed et al., 2004, Mayo et al., 2009) and dentine hypersensitivity (Krasuska et al., 2014a) with positive results.

The approach is relatively easy to apply, does not require large samples and is simple to analyse with common statistical techniques. But it also has drawbacks: it is susceptible to recall bias, implicit theories of change, social desirability and effort justification bias. Consequently, it must be interpreted with care. For

instance, recall bias occurs when participants are not able to accurately recall their health (or health ratings) or if they have adopted new standards. People with memory loss after stroke had greater variability in response shift effects than those with 'good' memory (Ahmed et al., 2004).

Implicit theories of change will bias the then-test when assessing their QoL retrospectively if individuals reconstruct their former QoL from their current state, assuming their QoL has probably changed (Norman, 2003). That is, to assess their previous status according to the implicit theory of change, patients start by evaluating their present state ("How is my mouth today?") and use their judgement to infer what their state must have been ("my old dentures were really useless, so today's pain is not so bad… I was worse before this new treatment"). In this sense, the theory presumes the retrospective judgement of the initial state is reconstructed and the prospective judgement is more valid (Finkelstein et al., 2014)

Social desirability refers to the tendency of the participants to choose responses they think are more acceptable (Grimm, 2010). Social desirability bias may make retrospective ratings worse because socially an improvement is expected after the treatment.

Effort justification bias changes the value of existing experiences, as individuals are motivated to value a goal that has required effort to accomplish (Aronson and Mills, 1959, Cooper and Axsom, 1982). Thus, participants may report improvement to justify the time and energy they have invested during the treatment and retrospectively assess themselves as 'worse'.

Nonetheless, defenders of the then-test to assess response shift, propose that if people recall their prior health status accurately, it provides an additional

judgment with new insights or new standards representing a stable change (Schwartz and Sprangers, 1999).

Ideal Scale Approach

Originally used in organizational research to assess workers' expectations regarding leadership behaviour (Fleishman, 1953), the ideal scale asks participants to complete a questionnaire with reference to their actual status and then, a second questionnaire evaluating their *ideal* status (e.g. how they would like their QoL ideally to be). Administering the ideals at different points in time, allows estimation of changes in internal standards as indicated by changes in ideals scores over time. Participants might also be asked to define their 'ideal' QoL. Changes over time in these concepts might indicate reconceptualization as well as reprioritization (Schwartz and Sprangers, 1999). The ideal approach assumes that response shift influences the actual scores to the same extent as the ideal scores (Visser et al., 2005)

Dabakuyo and colleagues (2013), explored response shift in 320 patients with breast cancer using the ideal scale approach to assess changes in internal standards by comparing health and QoL expectancies (health status will not change, will deteriorate or will improve) between baseline and the end of the first hospitalization. The ideal scale approach was able to detect changes in internal standards.

One problem with ideals scales is the risk of floor and ceiling effects. Participants are likely to indicate the negative or positive end of the scale so it may be difficult to identify differences at high or low levels of QoL (Terborg et al.,

1980). To correct this, it may be useful to collect scores at both ends of the scale. Similarly, it may also be difficult to define the concept of "ideal". For some it refers to what a person "would like", for others, what a person "needs" or "expects". This could be corrected by asking the participants to establish their own ideals or anchors (Terborg et al., 1982). Assessing shifts in personal anchors definitions over time would assess recalibration and translating these anchors into transformed scores, might avoid floor and ceilings effects.

The method is well illustrated in the research conducted by Visser and colleagues (2005). They used a variant of the ideal scale approach to assess recalibration in patients with cancer: the anchor–recalibration task. Patients rated their current QoL (1 to 10 points) from the 'best´ to 'worst' imaginable, then described 'anchors' relating to what they imagined to be the worst and best (ideal) QoL. This process was registered at baseline and during the follow-up period. At the follow-up interview, patients were shown their previous descriptions and asked whether these first anchors meant the same to them as the second description or meant something worse or better. Depending on the position of these new anchors, recalibration could be estimated using quantitative information about the position of the first and second anchors and reconceptualization may be assessed as changes in the concepts regarding the best and worse. Visser's research showed that the anchor-recalibration task correlated with the then-test and structural equation model, with the absence of response shift in 4 of 7 subscales. The authors concluded that defining anchors in this task was unusual and too difficult for the participants and did not provide a sound basis for the assessment of response shift effects.

Krasuska and colleagues (2014a) assessed response shift in patients with dentine hypersensitivity, comparing the then-test and ideals. These two methods detected changes in internal standards in opposite directions. Whereas the ideals showed an upward shift in participants' internal standards, the then-test detected a downward shift, which may be explained by participants reassessing themselves retrospectively as better off than they did at the baseline when they overestimated the impacts of dentine hypersensitivity. Krasuska interpreted those findings as signs of the bias arising from the then-test as described by Norman (2003).

2.2.5.2.2 Individualized methods

Individualized methods attempt to capture the QoL parameters most important for each individual. Several methods have been developed to take individual priorities into account and translate them into relevant domains and anchors to obtain a single score. Those methods include the Repertory Grid Technique, Self-anchoring striving scale (Cantril's ladder) or the Schedule for the Evaluation of Individual QoL (Schwartz and Sprangers, 1999). All require participants to define aspects or anchors important to their health.

Most QoL questionnaires use psychometric scales with anchors to quantify the responses. Those anchors can be defined by the researcher (i.e. fixed anchoring scales) or the participant (i.e. self-anchoring scales) (Hofmans et al., 2009). The labels in fixed anchored scales may have different meanings for each participant, but the numeric value assigned is regarded as the same. In self–anchored scales participants evaluate their status with a value defined by their own perceptions, experiences, purposes, expectations, assumptions and goals. Thus, depending on

the purpose of the scale, participants are asked, for instance, about the 'worst' and 'best' life situation, health condition or quality of life.

Although these scales are useful at the individual level, they have disadvantages. They may increase the loss of participants because more cognitive effort is required to describe the anchor. Further, they can be affected by recency bias or the 'present state effect' which proposes that people use information on their current state to recall the previous state, thus if the person feels well at moment of the assessment, is likely that they infer that their health status has improved (Blome and Augustin, 2016). Studies suggest that self-anchored scales generated more positive ratings of physical health than fixed anchors if the participants describe their worst experiences first. In this sense, recent memories would be more readily available during the completion of the questionnaire and the tendency would be towards positive ratings (Acker and Theuns, 2010).

Only a few individualized methods have been used to evaluate response shift. The Schedule for Evaluation of Individual Quality of Life (SEIQOL) asks participants to nominate the cues they consider most important for their quality of life and to rate them according to their relative importance. Nominating different cues at each assessment may reflect reconceptualization, changes in the ratings of each cue may reflect recalibration, changes in the order of the cues, reprioritization (O'Boyle et al., 2000). Ring and colleagues (2005) assessed the QoL of 117 edentulous patients before and after receiving high quality conventional dentures. The SEIQoL identified reconceptualization and reprioritization response shift.

In the Patient Generated Index (PGI) the participant chooses five areas of their life affected by the condition under study, rates their ability in these areas

and then dispenses 12 tokens across these areas of importance. Assessing reconceptualization among persons with stroke during the first six months of recovery, Ahmed and colleagues (2005c) used the PGI and concluded that people reconceptualised and reprioritized domains of HRQoL over time. The information provided by PGI was counterbalanced by the added complexity of completing and interpreting such measures.

Korfage and colleagues (2007) proposed the rating of vignettes to assess response shift in patients with prostatic cancer. Vignettes described side effects such as urinary, bowel and erectile dysfunction as the most important to patients at 1 month post-diagnosis than 2 months pre-diagnosis. This change was interpreted as reprioritization among participants who became more aware after diagnosis of the risks of cancer treatment.

Although these methods can identify areas of response shift at a personal level, their results are not easily converted into numerical values (Barclay-Goddard et al., 2009a) and the analysis is more complex.

2.2.5.2.3 Idiographic approach

Closely related to the individualized methods, the idiographic approach ('pertaining to self; one's own, private or separate') refers to aspects of the subjective experience that make each person unique (Pagnini et al., 2012). Through the idiographic approach participants are asked to state personal goals in terms of situations they want to accomplish, solve or avoid, and which roles and relationships influence their life. After describing their goals, participants rate goal attainment in terms of level of difficulty, dependence and other performance

dimensions (Rapkin et al., 1994). This information helps to understand the meaning of QoL for each person and assesses the effects that illness and treatment have on peoples' lives (Morganstern et al., 2011).

The Schedule for Evaluation of Individual Quality of Life (SEIQoL) described previously as an individual method, is based on the idiographic method that analyses individual needs, belief and emotions (Ring et al., 2005, O'Boyle et al., 2000)

The QoL Appraisal Profile (QoLAP) is an idiographic instrument used as a semi structured interview schedule to address the four aspects of QoL appraisal process described by Rapkin and Schwartz (2004). Response shift is operationalized in terms of the residual variance in the QoL change scores that can be explained by changes in appraisal due to coping or other processes: reconceptualization (changes in frame of reference), reprioritization (changes in sampling strategies and factors that determine the relative salience of different experiences), recalibration (changes in standards of comparison) (Schwartz et al., 2007).

There is little evidence assessing this instrument, but apparently it has acceptable content validity (Li and Rapkin, 2009, Morganstern et al., 2011, Schwartz and Rapkin, 2012). The interviews and codification of each question are complex and require considerable time and resources, which makes this method less convenient.

2.2.5.2.4 Qualitative approaches (direct questioning)

Individuals may be questioned directly about their HRQoL to assess aspects of response shift (Schwartz and Sprangers, 1999, Barclay-Goddard et al., 2009a). Semi structured interviews with post stroke individuals completing the PGI were conducted by Ahmed and colleagues (2005c) to assess whether they had experienced response shift. Participants compared the areas provided in the PGI at follow-up and at baseline. Half of the participants completing the PGI were interviewed, but unfortunately, not everyone applied the effort needed to assess response shift. Many participants communicated very little during the interviews.

Gregory and colleagues (2005) interviewed twenty people with socially noticeable broken, decayed or missing teeth to find out how measures of oral health related quality of life (OHRQoL) varied between and within individuals. This study demonstrated that the relevance and meaning of quality of life changed over time, whether or not participants received treatment. The authors proposed 7 dimensions of oral health on which people changed in their 'margins of relevance'. These changes in the 'margins of relevance' can be seen as changes in internal standards. The margins ranged from super relevant to not relevant. Changes in the relevance of the dimensions were also identified and corresponded to reconceptualization of QoL. Thus, response shift occurred in relation to quality of life

Sinclair and Blackburn's (2008) qualitative study examined coping patterns reported by women with rheumatoid arthritis. In their interviews women reflected on adaptive strategies, changing priorities and reframed their situations in ways that were similar to the response shift processes.

Krasuska and colleagues (2014a) explored response shift qualitatively in patients with dentine hypersensitivity. This study contributed two new mechanisms to the original response shift model, 'acceptance' and 'habits'. Acceptance involved accepting symptoms of dentine hypersensitivity and recognizing that the condition is incurable. Habits were manifest as routinized changes in oral hygiene routines, eating and drinking to cope with dentine hypersensitivity, that became almost sub-conscious.

Qualitative assessments allow the incorporation of individual concepts of QoL and importantly, to test variations within those meanings. Such data obtained must be interpreted carefully. Due to the intensive effort and time applied in the interviews, the sample size is small. Further, the analysis may be subjective and depend on the skills of the researcher (Schwartz and Sprangers, 1999). Nonetheless, qualitative assessments are essential to illuminate QoL measures and to incorporate concepts of HRQoL into the different theories and models.

2.2.5.2.5 Statistical Approaches

With the development of technology and computational sciences, several new methods can be used in sophisticated data analysis. Statistical methods applied to the study of RS can be utilized in both primary and secondary data sets. Thus, large data sets are much more manageable for response detection and the analysis of different aspects of RS is more reliable (Schwartz et al., 2013).

Several statistical methods have successfully identified response shift in such different disease populations as hypertension with coronary artery disease (Gandhi et al., 2013), stroke (Ahmed et al., 2005a) multiple sclerosis (Mayo et al.,

2009, Ahmed et al., 2011, Li and Schwartz, 2011, King-Kallimanis et al., 2011) cancer (Oort et al., 2005), obstructive pulmonary disease (Ahmed et al., 2009), and HIV/AIDS (Li and Rapkin, 2009). Those include techniques such as Structural Equation Modelling, Recursive Partitioning and Regression Trees Method (RPRT) and Trajectory Analysis with subject- centred residuals. Moreover, an increasing body of evidence supports the convergence among statistical and other methods of detection of RS (Mayo et al., 2008, Visser et al., 2005, Ahmed et al., 2005b), empathizing their inclusion in any study on RS.

Structural Equation Modelling

Structural Equation Modelling (SEM) uses different types of models to illustrate relationships among observed variables to test a theoretical model quantitatively. The aim of SEM is to determine the extent to which the theoretical model is supported by the sample data. It represents an extension of general linear modelling procedures such as ANOVA, multiple regression and confirmatory factor analysis (Bollen, 1995).

SEM defines two types of variables: observed and latent. The observed variables are measured whereas latent variables are indirectly inferred from the observed variables. For instance, a latent variable of socio-economic status could be considered by combining data on education, income and occupation. Thus, SEM tests the overall fit of a model and assesses direct and indirect links between observed and latent variables.

To test response shift, a common factor model is used to describe the observed means, variances and covariances. After accounting for possible

response shift, the difference between common factor means is used as a measure of true change (Visser et al., 2005).

After this analysis, response shift components are operationalized as follows (Oort et al., 2005):

- Recalibration is inferred from residual change in responses as a function of time or change in intercepts.
- Reprioritization is inferred from the change in variance in factors loading values over time.
- Reconceptualization is seen as zero versus nonzero factor loading pattern changes over time.

SEM has been useful in detecting response shifts in patients with cancer (Oort et al., 2005, Visser et al., 2005), stroke (Barclay-Goddard et al., 2009b), hypertension with coronary artery disease (Gandhi et al., 2013) and multiple sclerosis (King-Kallimanis et al., 2011). The main limitation of this method is that in the absence of external criteria, response shift cannot be detected if it affects most of the results in the same way (Schwartz et al., 2011). Furthermore, this method requires large samples (n>200).

Classification and Regression Trees (CRT)

Classification and Regression Trees (CRT) is a non-parametric statistical method developed by Breiman and colleagues (1984) commonly used in data mining to create predictive models. Different abbreviations found in the literature such as Classification and Regression Trees (CART, CRT, C&RT), Recursive Partitioning and Regression Trees (RPART) or Regression Trees Analysis (RTA),

are referred to the same method depending on the software employed, but this review will use the term CRT throughout.

CRT creates a regression tree as a representation of the data. Each of the terminal nodes or leaves of the tree represents a cell of the partition, and has attached a simple model that applies to that cell only. The members of the studied population are classified based on several dichotomous dependant variables (Li and Schwartz, 2011). CRT is non-model based, thus it enables intuitive predictions without predefinition of possible interactions among factors and allows exploration of non-linear relationships among variables in a graphical representation (Hastie et al., 2013).

This method has been used in data mining to detect different patterns and trajectories of response shift. (Li and Rapkin, 2009, Li and Schwartz, 2011). The different forms of response shift have been operationalized as follows (Schwartz et al., 2011):

- Recalibration is inferred by using trees indicating relationships between predictors and outcomes scores using different group-specific thresholds or cut points for selected predictors variables. The interaction terms are used to identify homogeneous groups over time.
- Reprioritization is inferred from changes in the order of domains in tree pathways over time.
- Reconceptualization is inferred from changes in the content and/or number of domains by group in a pruned tree over time.

The limitations of this method are that involves substantial qualitative interpretation of the results and there are no specific codes to detect different aspects of response shift.

Trajectory Analysis with subject- centered residuals

Latent Trajectory Analysis with subject-centered residuals (Mayo et al., 2009) consists of developing a predictive General Health model to examine patterns in discrepancies between expected and observed scores. A longitudinal model with a random intercept is created to predict General Health using only significant predictors, excluding predictors if their association with the outcome varies over time. This method detects reprioritization and reconceptualization as fluctuations in differences between observed and predicted scores or residuals over time (Ahmed et al., 2011).

Due to random error, there will be always some random variation in the data with over and underestimation, so masking the response shift detection. Likewise, to correctly interpret residuals in terms of response shift, an external criterion such an appraisal process is required.

Disadvantages of statistical methods to detect RS

Several of the statistical approaches used to explore RS are not based on the theories of RS, but lies in the study design, sample size or variable distributions (Sawatzky et al., 2017). Additionally, some methods are parametric, assuming a normal distribution and homogeneity of data. Such assumptions are not always met in QoL data, which are often skewed and show substantial variability across groups (Beaumont et al., 2006). Thus, the replicability of the results may be limited and individual effects may be masked when observing group level data (Barclay-Goddard et al., 2009a).

However, as each major approach to study response shift (design-based, individualized) relies on a different operationalization, the use of a statistical approach in any study of RS is strongly encouraged (Ahmed and Ring, 2008).

2.2.5.3 Comparative studies of the different approaches.

There is no consensus about which method is the most effective to measure RS nor any gold standard. Furthermore, using only one method is unlikely to assess accurately each of the components of RS at the same time. Validation of the approaches requires triangulation of several methods to test their convergence (Schwartz and Sprangers, 2010).

Partial convergence has been found between the then-test, SEM and individualized approaches (PGI) in individuals with stroke (Ahmed et al., 2005b). The SEM did not demonstrate RS. However, correspondence in the detection of RS was found between the then-test and the PGI.

In dentistry, Ring et al. (2005) compared an individualized method (SEIQoL-DW) with the then-test to detect RS in edentulous patients receiving dentures. The SEIQoL-DW was able to detect reconceptualization and the then-test recalibration. Furthermore, accounting for RS using the individualized method, allowed improvement in QoL to be detected.

Response shift was studied among patients after diagnosis of prostate cancer using two methods (Korfage et al., 2007). The then-test detected successfully recalibration and using vignettes (individualized approach), identified reprioritization.

The variability across these studies makes it difficult to determine which method is preferable to assess RS. More importantly, each approach may detect different components of RS, which may even not occur at the same time or for the same domains of QoL. Therefore, triangulation of approaches is recommended (Ahmed and Ring, 2008).

2.2.5.4 Response shift in oral health

Response shift has been studied in oral health in populations such as people with decayed or missing teeth, those seeking for prosthodontic treatment and people with dentine hypersensitivity.

Gregory and colleagues (2005) qualitative study of people with broken, decayed and missing teeth identified seven domains of oral health (norm, attribution, trust, accessibility, commodity authenticity and character). Participants framed their experiences on those domains within their own 'margins of relevance'. These margins changed in the presence of a catalyst, so that their assessments of QoL also changed. For the authors, changes in QoL occurred partly through disease progression or treatment and partly from changes in the relevance that oral health held for each person. The findings are homologous to RS, where shifts in the margins of relevance may be interpreted as recalibration and changes in the importance of each dimension as reconceptualization.

Ring et al (2005) studied whether RS influences the apparent treatment efficacy in edentulous patients receiving conventional dentures. OHRQoL was assessed using the individualized approach Schedule for Evaluation on individual QoL (SEIQoL-DW), before and 3 months after treatment and retrospectively with the then-test. Reprioritization and recalibration were identified. Moreover, the positive impact of the treatment on OHRQoL of participants was only demonstrated when RS was accounted for.

Response shift was also identified among patients seeking prosthodontic care using the OHIP-49. Using the then-test, recalibration response shift increased the improvement in QoL after the treatment by 6.3 OHIP-49 points (Reissmann et

al., 2012). Likewise, response shift was detected with the then-test in patients receiving implant-supported prostheses. The improvement in OHRQoL was four times higher if RS was considered. Age (younger patients), number of replaced teeth (larger number) and baseline scores (lower scores) were significant predictors of greater recalibration (Kimura et al., 2012).

Krasuska and colleagues (Krasuska et al., 2014a) studied RS in people with dentine hypersensitivity. Two studies were conducted. The first study was designed to detect recalibration using two design approaches, the then-test and the ideals. Both identified recalibration in opposite directions and reduced the treatment effect. The then-test in this study apparently was more sensitive to recalibration than the ideals. However due to divergent results with the ideals it might be susceptible to recall bias. The second study explored RS qualitatively, identifying four mechanisms involved in its occurrence: acceptance, problem-orientated coping, habits and downward social comparison.

2.2.5.5 Limitations and sources of error when measuring response shift

This review has identified a number of sources of error when attempting to detect and measure RS. Prospective methods are susceptible to processes such as expectations, denial and impression management. Expectation affects internal standards of measurement because QoL can be conceptualized as the discrepancy between experienced QoL and expectations of it (Carr et al., 2001). Denial is a protective coping strategy from illness or disability that may affect measurements of QoL (Arthur et al., 2016). Impression management suggests that QoL self-reports are influenced by consciously or unconsciously trying to impress others (Schwartz et al., 2005)

There is evidence suggesting that recall bias and implicit theories of change are sources of error when response shift is assessed retrospectively (Schwartz and Sprangers, 1999, Finkelstein et al., 2014)

The then-test is subject to recall bias due to its retrospective nature (Schwartz and Sprangers, 2010). For example, participants report problems with eating on a daily basis before dental treatment. After treatment they report improvement but if they are asked to recall their status retrospectively, they might indicate having eating problems only occasionally before treatment. This observation might be explained by recall bias. The length of the follow-up is important to allow proper recall accuracy. If the time between each measurement is extensive, then the accuracy of recall decreases, with greater risk of recall bias. Moreover, recall bias can be directional, when the retrospective assessment of QoL is either over or underrated, or non-directional, then QoL is apparently recalled as better, sometimes worse than they actually were (Blome and Augustin, 2016).

Implicit theories of change posit that when patients retro judge their condition they do not remember their initial state but instead extrapolate backwards from their present state (Norman, 2003). This theory presumes that memory or recall of pre-treatment status is poor, so that the retrospective judgement of the initial state is reconstructed and the prospective judgement is more valid (Finkelstein et al., 2014).

Finkelstein and colleagues (2014) suggested that recalibration and implicit theories of change can both be sources of bias in patient-reported outcomes, but implicit theories of change are a greater threat to validity. The implicit theory of change may therefore undermine retrospective judgements such as global transition judgements and the then-test.

2.3 SUMMARY AND RATIONALE

This brief review has identified several implications for the design of a study of RS.

The response shift phenomenon challenges the traditional assessments (pre-post test) of changes on QoL and has been extensively studied in severe health conditions, but the evidence on response shift in dentistry is less well developed.

Several studies have reported that dental implant treatments can improve OHRQoL. This improvement has been reported to be better in older patients and in the anterior and premolar regions. Differences might be explained by the greater impact of missing an anterior tooth. However, if response shift is not accounted for in the assessment of this change, important benefits might be masked.

Patients being treated with dental implants provide a good participant base for studying RS because the effect of implant-retained prostheses on QoL is marked and the catalyst (receiving the final prosthesis) is known in advance.

Several methods have been proposed to assess RS. Further, one single method may not be enough to assess the different components of RS. There is also a lack of evidence comparing the different approaches. Triangulation of several methods has been proposed (Schwartz and Sprangers, 2010).

The most common method to assess RS is the then-test (Razmjou et al., 2009, Finkelstein et al., 2014, Rees et al., 2005, Nolte et al., 2012, Sprangers et al., 1999), which constitutes a retrospective judgement of pre-test quality of life levels at the time of the post-test. However this method is prone to recall bias (Krasuska et al., 2014a). The Ideals Scale Approach has been used to assess RS with

interesting results (Visser et al., 2005, Krasuska et al., 2014a). Statistical methods to assess RS include the Recursive Partitioning and Regression Trees, also known as Classification and Regression Trees (CRT), which has successfully analysed complex interactions between variables (Li and Rapkin, 2009, Li and Schwartz, 2011, Schwartz et al., 2011).

Therefore, this study will assess the quality of life of patients with dental implants before and after the definitive restorative treatment and will explore response shift using three methods: the then-test, the self-scale anchored approach and the classification and regression trees. Furthermore, this research will assess the convergent validity to determine the relative utility of the three methods.

2.4 AIM AND OBJECTIVES

2.4.1 Aim

To describe changes in internal standards (recalibration), values (reprioritization), and conceptualization (reconceptualization) in OHRQoL meanings, namely response shift, in individuals receiving dental implant supported prostheses.

2.4.2 Objectives

a. To identify response shift in participants after treatment with dental implants supported prostheses.
b. To study the convergent validity of three approaches to detect response shift (the then-test, the self-anchored scale, and the classification and regression trees approach).
c. To make recommendations on the assessment of response shift in participants treated with dental implants.

3. METHOD

3.1. Overview

Longitudinal questionnaire study in patients receiving Dental Implant supported prostheses.

Edentulous (partial or total) adults undergoing restorative treatment with dental implant placement completed a shortened version of the Oral Health Impact Profile appropriate for use in edentulous patients (OHIP-EDENT) and a self-anchored scale, before placement of the final restorative treatment and 3 months post treatment.

3.2. Selection of participants

- The target population was partially or total edentulous adults aged 16 years and above requiring restorative treatment after dental implant placement.
- The accessible population was members of the target population referred to the Academic Unit of Restorative Dentistry of the Charles Clifford Dental Hospital (CCDH), Sheffield, for restorative treatment. Patients attend these clinics for restoration, approximately one year after the dental implant was placed and most had a temporary prosthesis in place.
- The intended sample was members of the accessible population attending their first appointment with a restorative consultant to plan

the restorative treatment, who provided written consent to take part on the study.

- Exclusion criteria:
  - Patients below 16 years old.
  - People not eligible for implant and restorative treatment.

3.3. Sampling

The statistical method selected to assess response shift was classification and regression trees (CRT). The recommended sample size is 10 events per variable to obtain a reasonably predictive model with stable performance (Ahmed and Schwartz, 2010, van der Ploeg et al., 2014). The analysis used the 7 subscales of the OHIP-EDENT as the independent variables. Three additional predictor variables were included to detect antecedents of the magnitude and direction of RS (number, position of replaced teeth and treatment modality). Thus, the intended sample size was 100 participants. Due to the nature of treatment (patients carefully selected for implant surgery and the long waiting list after the surgery to receive the final restoration) only modest loss to follow-up was anticipated and an additional 20% of participants were recruited. Therefore, the incept cohort was 120 participants with an intended sample with complete data of 100 participants.

3.4. Procedure

Participant flow through the study is summarized in Figure 3.1 Participants were approached on the day of their first appointment with the restorative consultant to start the restorative treatment, at which time the research objectives and procedures were explained to them. Then, patients were invited to participate. People expressing an interest were informed about the study by the Chief Investigator (CM) and the information sheet and consent form were provided to take home and read.

During their second appointment, patients who agreed to participate were asked to provide written consent and to complete the baseline questionnaires. After completion of the questionnaires, patients continued their treatment as planned.

Participants who entered the study were given a second set of questionnaires at their routine post-restorative treatment check-up (between 3 and 6 months after the completion of the treatment). Participants who missed the review appointment, were mailed the questionnaires to their home address.

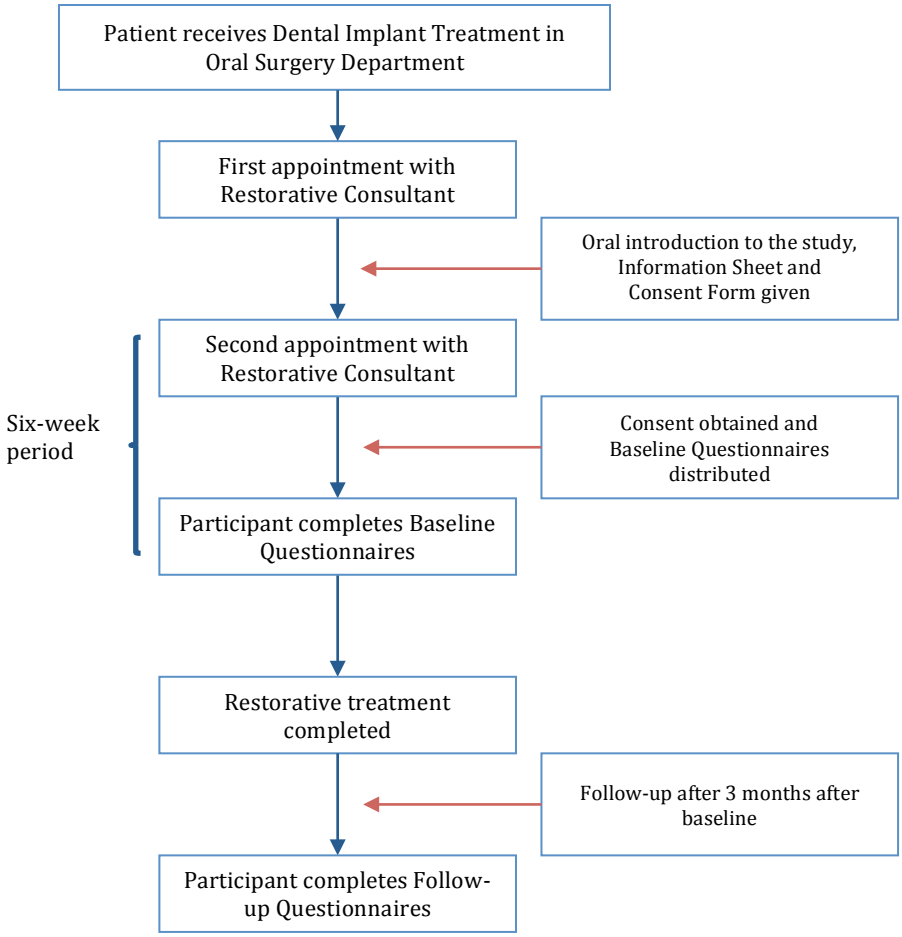


Figure 3.1. Study flowchart

3.5. Permission and Liaison

The study was approved by the National Ethics Research Committee Service (NRES) Yorkshire and The Humber (STH ref STH18703; REC ref 14/YH/1320)(Appendix A).

3.6. Summary of variables

- Demographic variables: age, gender.
- Clinical variables: number of replaced teeth, position of replaced teeth (anterior/posterior, upper/lower), treatment modality (implant-supported crown, implant-supported bridges or implant-supported overdentures).
- Oral Health Related Quality of Life, Self-anchored scale, Global Rating of Oral Health and Global Transition Judgement.

3.7. Measures

3.7.1. Treatment characteristics

Characteristics of the treatment were collected after obtaining signed consent on a dedicated consent form (Appendix B). Information regarding the number and position of replaced teeth (upper/lower, anterior/posterior) and treatment modality (implant-supported crowns, implant-supported bridges and implant-supported overdentures) was collected from patients' clinical records by the chief investigator.

3.7.2. Oral Health Related Quality of Life and perceived oral health measures

OHRQoL was assessed using the Oral Health Impact Profile- EDENT (OHIP-EDENT) and the perceived oral health with the self-anchored scale.

3.7.2.1. OHIP-Edent

This short form of the Oral Health Impact Profile is specific to edentulous people and aims to capture OHRQoL influenced by the clinical aspects of edentulousness and its treatment (Allen and Locker, 2002). The questionnaire has 19 questions on seven subscales: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. Participants are asked to rate their oral health problems for each item on a 5-point Likert scale coded as Never (0), Hardly ever (1), Occasionally (2), Fairly often (3), and Very often (4). A summary measure is calculated as the sum of the scores from the impact items for each participant (possible range 0-76). Higher scores indicate worse OHRQoL. The OHIP-Edent had better responsiveness (Effect Size=0.9) than the OHIP-14 (Effect Size=0.3) when used in individuals with DIT and the floor effects in measuring change were no worse than the full version (OHIP-49), indicating that the OHIP-Edent is better at detecting clinically relevant change in individuals with DIT (Allen and Locker, 2002, Allen and Steele, 2009). Moreover, this instrument is able to detect change in patients with prostheses and dental implants, with good internal consistency and validity (Awad et al., 2003b,

Sutton and McCord, 2007, Souza et al., 2007b, Zani et al., 2009, Stober et al., 2012, Montero et al., 2012, Albaker, 2013, Jofre et al., 2013b).

The questionnaire was administered to the complete sample at baseline and follow-up. At follow-up participants were also asked to retrospectively judge ('then') their OHRQoL at the time of the first interview using analogous items (Appendix D). For example:

- *Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures? Never (0), Hardly ever (1), Occasionally (2), Fairly often (3), Very often (4)*
- *How do you now think you were at the time of our last meeting? Never (0), Hardly ever (1), Occasionally (2), Fairly often (3), Very often (4)*

3.7.2.2. Self-anchored scale

An individualized variant of the ideal scale was used to assess perceived oral health and response shift. A self-anchored scale based on the "self-anchoring striving scale", also known as Cantril's ladder (Cantril, 1965) and similar to the anchor-recalibration approach was employed (Visser et al., 2005) (Figure 3.2 a and b).

Participants were first asked to provide a written description of the 'best' and 'worst' possible oral health state for them. Based on their own assumptions, the participants established these two extreme anchoring points.

At baseline participants were asked to specify where on the ladder they were and to provide the descriptors of the worst and best oral health conditions at the bottom and top of the ladder respectively (Figure 3.2 a).

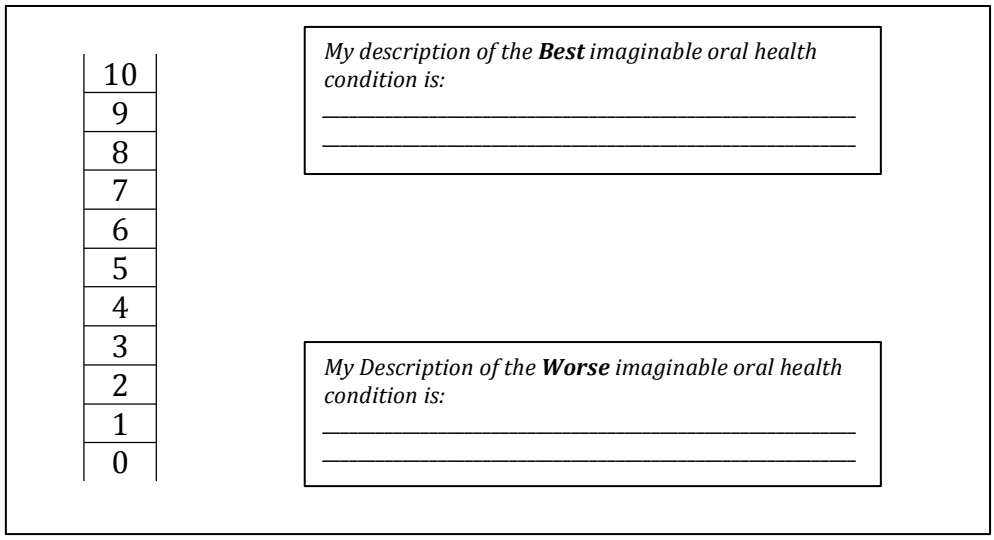


Figure 3.2.a. Self-anchored scale. The rating is presented as a ladder with the bottom marked with the number 0 symbolizing the worst and 10 the best. Each participant was asked to situate her or himself in the present.

At follow-up participants again described the best and the worst imaginable oral health and located themselves on the ladder. The new descriptors (if there were any) could be rated even worse, better or coinciding with the descriptions provided at baseline (Figure 3.2 b).

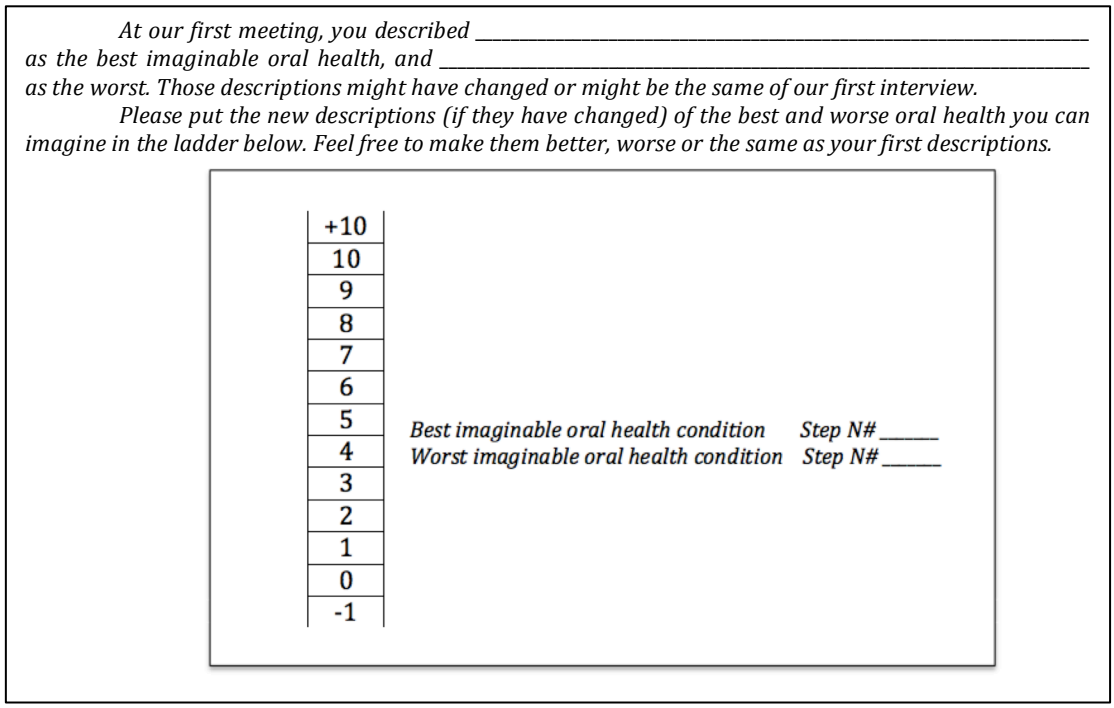


Figure 3.2.b. Self-anchored scale at follow-up.

3.7.3. Global ratings of oral health

Global ratings of oral health were used to assess participants' perceptions of their oral health. In addition, these questions assessed the extent to which patients perceive their oral health have changed since baseline.

These questions were formulated as follows:

- *"Overall, how would you rate the health of your mouth, teeth and gums?"* (5-point response scale ranging 5 (Excellent), 4 (Very good), 3 (Good), 2 (Poor) and 1 (Very poor) at baseline and follow-up) (Locker et al., 2005).
- *"Overall, how has your oral health changed since our last meeting?"* (5-point response scale ranging 5 (Much better), 4 (Better), 3 (About the same), 2 (Worse) and 1 (Much worse) at follow-up) (Locker, 1998).

The scores obtained were used as a criterion to assess the sensitivity of instruments to capture clinically meaningful changes (Liang et al., 2002). Thus, global oral health judgements can be used to triangulate the validity of questionnaires Guyatt et al. (2002) reported high correlations between global health changes scores and changes in HRQoL. Used retrospectively, global ratings of oral health change questions also defined groups of participants that their perceived oral health status improved after DIT, remained about the same or not improved at all.

3.8. Data analysis strategy

Data were analysed in 3 stages. First, the study sample was described. Secondly, the OHIP-Edent was validated. The third stage assessed change and response shift. Data were analysed using SPSS, version 23.0.0.0 (IBM Corp., Chicago, IL, USA). A p-value of 0.05 was selected as the level of significance for all statistical tests performed.

3.8.1.1. Stage 1: sample characteristics

The first stage of the analysis described the study sample at baseline and follow-up. The variables assessed in this stage were:

- Demographics (age, gender)
- Treatment characteristics (number and position of replaced teeth, treatment modality).
- OHRQoL measure scores (OHIP-Edent) and perceived oral health (self-anchored scale and global ratings of oral health).

Appropriated measures of central tendency and spread were used, supplemented by normality tests (Shapiro-Wilk test).

3.8.1.2. Stage 2: cross-sectional validation of the OHIP-Edent

The second stage was the cross-sectional validation of the OHIP-Edent. at baseline and follow-up, including its reliability and validity, as follows:

- Reliability
    - Internal consistency was assessed by calculating *Cronbach* alpha of the OHIP- Edent total and subscales.
    - Test-retest reliability was assessed as the intraclass correlation coefficient (ICC) between OHIP-Edent total baseline and the OHIP-Edent total follow-up.

- Validity
    - Convergent validity was assessed by calculating the Spearman Rank correlation between OHIP-Edent total score and the global oral health ratings.

3.8.1.3. Stage 3: assessing change and response shift

The third stage assessed change and response shift using approach separately as set out in the following sections.

3.8.1.3.1. The then-test

First, distributions of variables were calculated for the three assessments (baseline, follow-up and then-test).

The magnitude and direction of recalibration, unadjusted and adjusted change at group level were then computed (Table 3.1). Unadjusted change was calculated as the OHIP-Edent follow-up score minus the baseline score and adjusted scores as the difference between the OHIP-Edent follow-up score and the then-test score.

In the then-test, recalibration is calculated as the difference between the then-test and the baseline OHIP-Edent scores. A negative sign of recalibration suggests people retrospectively reassessed themselves as having fewer impacts than they thought at the actual baseline. Thus, such participants changed their internal standards downwards. A positive sign of recalibration indicates that people retrospectively assessed their status as worse than they thought at baseline, i.e. they changed their internal standards upwards.

Table 3.1. Approach to calculating unadjusted and adjusted change and recalibration for the then-test

OHIP-Edent unadjusted change	=	OHIP-Edent follow-up score - OHIP-Edent baseline score
OHIP-Edent adjusted change	=	OHIP-Edent follow-up score - OHIP-Edent then-test score
Recalibration response shift	=	OHIP-Edent then-test score - OHIP-Edent baseline score

As the data were not normally distributed, hypothesis tests for adjusted and unadjusted change and response shift were conducted with the Wilcoxon Signed-rank test for non-parametric samples.

A recalibration effect size (r) was calculated for the Wilcoxon Signed-rank test using the following formula:

$$r = \frac{Z}{\sqrt{N}}$$

Where Z is the z statistic and N is the number of observations.

Guidelines suggest that an effect size of $d < 0.3$ is small, 0.3-0.5 is medium, and > 0.5 is large (Field, 2013).

The predictor variables influencing the magnitude and direction of RS were investigated after normalization of the data, using multiple linear regressions with the recalibration RS as the outcome variable and gender, number and position of replaced teeth and treatment modality as independent variables.

The magnitude and direction of recalibration was also explored at the individual level. The minimal important difference (MID) was used as a threshold to classify participants who recalibrated upwards, downwards or not recalibrated at all. The MID is defined as the smallest change in score in the outcome of interest perceived as important by the participants

The MID of the OHIP-Edent was selected to act as a threshold to detect groups of participants that changed their internal standards upward, downwards or remained the same between baseline and follow-up. Allen et al (2009) reported a pre-post treatment difference of 9 points as a minimal important change when using the OHIP-Edent. Thus, participants were classified as changing internal

standards upward (retrospectively assessed as better than actual baseline) when recalibration was ≤ -9, downwards (retrospectively assessed as worse than actual baseline) when recalibration was ≥ 9 and values between -9 and 9 as no recalibration.

3.8.1.3.2. Self-anchored scale

When using the self-anchored scale scores, recalibration was calculated as the difference between baseline and transformed baseline scores, and true change as the difference between follow-up and transformed baseline scores (Visser et al., 2005). The transformed scores are a function of the baseline scores and the position of the best and worse new anchors in the Cantril's ladder at follow-up.

The magnitude of recalibration was calculated using the following equation (Visser et al., 2005):

$$X_{trans} = ((B_{new} - W_{new}) X_{baseline} + 10W_{new} - B_{new}) / 9$$

Where,

$X_{baseline}$ = Baseline self-anchor scale score

B_{new} = New best imaginable oral health anchor

W_{new} = New worse imaginable oral health anchor

Adjusted change and recalibration obtained with the self-anchored approach were calculated as follows (Table 3.2):

Table 3.2. Approach to calculating adjusted change and recalibration for the self-anchored scale.

Adjusted change	= *Follow-up - transformed baseline scores*
Recalibration	= *Baseline - transformed baseline scores*

The effect size for the self–anchored scale was calculated using recalibration as a function of the standard deviation using the following equation:

$$\text{Effect size of Recalibration} = \frac{\text{Adjusted change} - \text{Observed change}}{\text{SD Observed change}}$$

$$= \frac{(X_{\text{follow-up}} - X_{\text{trans}}) - (X_{\text{follow-up}} - X_{\text{baseline}})}{SD_{\text{follow-up - baseline}}}$$

According to Cohen's criteria, an effect size of $d < 0.3$ is small, 0.3-0.5 is medium, and > 0.5 is large (Field, 2013).

Recalibration with the self-anchored scale approach was quantified at the individual level to detect groups of participants that changed their internal standards upwards, downwards or remained the same between baseline and follow-up. As this instrument has not been validated, the MID has not yet been established. Therefore, downward recalibration was determined by a negative sign on the RS value (baseline-transformed baseline), upward recalibration by a positive sign and null value as no recalibration.

Ceiling and floor effects occur when many participants score the maximum or minimum scores. The proportion of participants who achieved each possible score of the self-anchored scale (within range 0-10) was analysed at baseline and follow-up. The ceiling and the floor effects were defined as 15% or above of participants achieving the maximum or minimum level of the score (Lim et al., 2015).

3.8.1.3.3. Classification and Regression Trees (CRT)

Classification and Regression Trees (CRT) are based on the method developed by Breiman and colleagues (1984). CRT creates a regression tree as a representation where each of the terminal nodes, or tree leaves represent a cell of a partition, and has a simple model attached which applies to that cell only, i.e. each member of the studied population is classified based on several dependant variables. The CRT trees were created using the OHIP-Edent unadjusted change total score (OHIP-Edent total score follow-up – OHIP Edent total score baseline) as the dependent variable and the unadjusted change of the 7 subscales as covariates. These covariates distinguished different patterns of change in the subscales scores.

Each node is split through the best variable, maximizing the purity of the resulting nodes; a node is considered 'pure' when all the cases have the same value for the dependant variable.

If the primary splitting variable is missing for an individual observation, this information is not discarded but instead, a surrogate variable that has the best similar pattern relative to the outcome variable is used, thereby enabling utilization of incomplete datasets.

As a result of the 'surrogates' in splitting the data, the contribution that a variable can make to the model is not only determined by the primary splits. A variable can be considered as highly important even when it does not appear as a node splitter. Variable importance is calculated with a variable importance score. The CRT method explores the improvement measure attributable to each variable in its role as either a primary or surrogate splitter. The values of all these improvements are summed over each node and totalled. Then, they are scaled relative to the best performing variable; the variable with the highest sum of improvement is scored 100 and all the other will have decreasing lower scores (Kajungu et al., 2012).

A 10-fold cross-validation was performed to evaluate the reliability of the tree. The dataset was divided into 10 randomly selected and roughly equal parts with each part containing a similar distribution of data. The first nine parts of the data (90%) were used to construct the largest possible tree, and the remaining 10% of the data to obtain initial estimates of the error rate of the selected sub-tree. The process was repeated 10 times using different combinations of the remaining nine subsets of data and a different 1/10 data subset to test the resulting tree. The results of the 10 tests were then combined to calculate error rates for trees of each possible size and are applied to prune the full tree.

The analysis was carried out following these criteria (Zhang and Singer, 1999):

- Minimum number of cases in the parent node corresponds to 10% of the sample
- Stopping rule for a terminal node corresponds to 5% of the sample
- Tenfold cross-validation to validate the tree

- Tree pruning to avoid over fitting with a maximum acceptable difference in risk between the pruned and the sub-tree of 1 standard error
- Missing data handled by surrogate splits

The model performance was investigated calculating the risk estimate. The risk estimated is a measure of within-node variance and can be used as a criterion of model fit. Lower values indicate a better model. Thus, the model fit is calculated following this formula:

$$S^2_e = \frac{\text{Risk value}}{S^2_y}$$

Where,

S^2_e = Error variance or proportion of variance due to error

Risk value = Variance within node

S^2_y= Dependent variable or root node variance or standard deviation of the root node squared

Operationalization of Response Shift in the CRT model

Response shift was operationalized as described in Table 3.3. Recalibration was inferred when the global rating of oral health change was inconsistent with the OHIP-Edent change score. The treatment was expected to improve participants' OHRQoL. If participants reported better OHRQoL at follow-

up but their global rating of oral health remained unimproved, this was interpreted as upward recalibration. If participants reported worse OHRQoL at follow-up but rated their oral health as improved, then downward recalibration was inferred.

Table 3.3. Operationalization of Response Shift in the CRT model

Response Shift	Operationalization	Qualitative indicator	Interpretation
Recalibration	Changes in subscale scores over time	↓OHIP Edent scores at follow-up with global rating oral health unimproved	Upward recalibration At follow-up individuals state global oral health as unimproved but rated their QoL as better at follow-up (Follow-up-Baseline = (-))
		↑ OHIP Edent scores at follow-up with global rating oral health improved	Downward recalibration At follow-up individuals state global oral health as improved but rated their QoL as worse at follow-up (Follow-up-Baseline = (+))
		↓OHIP Edent scores at follow-up with global rating oral health improved	No recalibration At follow-up individuals state global oral health as improved and rated their health as better at follow-up (Follow-up-Baseline = (-))
Reprioritization	Changes in the relative importance of each subscale to the model over time		

As suggested by Li and Schwartz (2011), this study reports the full rather than the pruned tree because, especially in small samples, pruning is likely to omit small groups or participants with subtle changes.

The interpretation of changes was based on the minimal important difference (MID) for the OHIP-Edent (as described in the section 3.9.3.3.1) of 9

points. This threshold was used to identify clusters of participants potentially with RS.

3.9. Ethical considerations

Participants received an information sheet with details of the research (Appendix B). They were also informed that nobody on the Implantology team (GDP, dental nurses) would have access to the questionnaires (to avoid bias for social desirability or complaisance with the caregivers).

People who agreed to participate could withdraw from the study at any time.

All paperwork compiled was filed confidentially in a safely locked place. Likewise, questionnaires did not contain any personal information such as name or contact details. The data obtained were collected only by CM and entered into the selected software. Only the researcher CM managed the data sets.

3.10. Conduct

3.10.1. Training and Calibration

To promote the commitment of the Dental Team, meetings were conducted to provide with the information about the study. Documents describing the study, ethical approval letter, research passport, protocol and questionnaires, were provided and available at the clinics throughout the investigation.

3.10.2. Procedure

3.10.2.1. Data collection

- Recruitment of potential participants was implemented as described earlier. On the day of the first approach, potential patients were asked to participate. The principal investigator (CM) gave them the information sheet and consent form (Appendix B). Participants voluntarily provided contact details to send reminders about the study follow-up via post mail and SMS.
- On the day of the treatment appointment, participants were asked to complete the questionnaires. The instruments were self-reported, but participants were assisted by the researcher, dentist or dental nurse when requested.
- After completion of the questionnaires, patients continued their treatment as planned with the dentist and were informed about the dates of their next appointments.

- Three to 6 months after treatment, participants were invited during a regular check-up appointment, to complete the follow-up questionnaire. Those participants who missed their appointment, were mailed a questionnaire to their preferred address.
- Data were compiled by CM, entered into software and filed confidentially.

3.10.2.2. Personnel

CM provided the questionnaires, collected data, filed the documents and entered data.

Dentists and/or Dental nurses helped with the recruitment of participants.

Administrative staff collaborated with the schedule and appointments.

3.10.2.3. Pilot Study

Pre-tests of the information sheet, the consent form and the full instrument (OHIP-EDENT + self–anchored scale) were conducted at the CCDH and the University of Sheffield with a convenience sample of 10 members of staff and PhD students.

This pilot study tested the understanding of the documents and determined the time required to complete the process. The test confirmed the feasibility of the OHIP-Edent and the self-anchored scale. The pilot study participants were able to respond without difficulty and the time required to complete both questionnaires was on average 8 minutes.

Feedback was provided verbally to participants who made suggestions and/or asked questions.

3.10.2.4. Data Transfer

CM transferred all data obtained into SPSS, version 23.0.0.0 (IBM Corporation, Chicago, IL, USA) and Microsoft Excel 2011, version 14.5.1 (Microsoft Corporation, 2008).

Personal details were coded and the datasets encrypted to preserve confidentiality.

Paperwork was stored in a safety locked place at the University of Sheffield premises.

4. RESULTS

4.1. Introduction

A total of 140 partially or total edentulous adults aged 16 years and above were invited to participate. Of these, 127 enrolled for the study at baseline between March 2015 and June 2016. The study was completed by 100 participants (Figure 4.1). The baseline assessment was before the definitive restorative treatment started and follow-up was 3 to 6 months after completion of treatment. Participants' failing to attend for the last review was the only reason for loss to follow-up. Those lost to follow-up shared similar characteristics to the rest of the sample. Nonetheless, not all the data are complete and each analysis is reported with the number of data available.

The results are presented in the three main sections described in the analytical strategy:

Section 1 describes the sample distribution at baseline in terms of demographic (age, gender) and treatment characteristics (number and position of replaced teeth, treatment modality), oral health related quality of life (OHIP-Edent and self-anchored scale) and global ratings of oral health.

Section 2 reports the psychometric properties of the OHIP-Edent including its reliability and validity.

Section 3 investigates response shift analysing the then-test, self-anchored scale and the classification and regression trees.

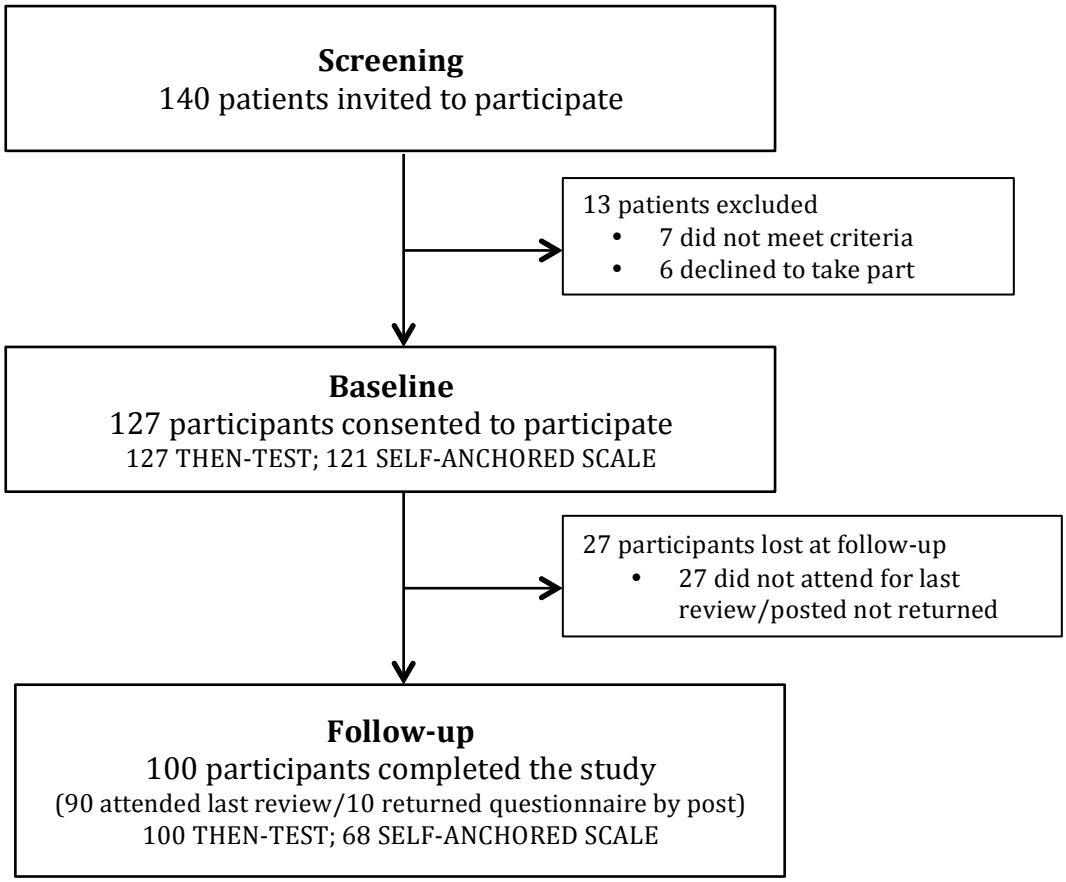


Figure 4.1. Study profile

4.2. Description of the sample

This section presents the first stage of the analytic strategy, describing the demographic (age and gender) and treatment characteristics (number and position of replaced teeth, treatment modality), oral health related quality of life (OHIP-Edent), perceived oral health (self-anchored scale) and global ratings of oral health of the sample at baseline.

4.2.1. Demographic and treatment characteristics

The baseline sample comprised 127 participants of which 100 completed the study (Table 4.1). The mean age was 37.5 (SD $\pm$ 16.9) years and 57.5% were female.

Participants were treated with 3 different types of restoration: implant-supported crowns (ISC), implant-supported bridges (ISB) and implant-supported overdentures (OD). Seventy-eight participants (62.2%) were treated with single upper anterior implant supported crowns (Table 4.1).

Table 4.1. Participants' clinical characteristics at baseline

Variable	All participants (n=127)	
	n	%
Treatment characteristics		
Number patients by number of replaced teeth		
1	73	57.5
2	25	19.7
≥3	29	22.8
Arch of replaced teeth (U/L)		
Upper	106	83.5
Lower	19	15.0
Both	2	1.6
Position of replaced teeth (A/P)		
Anterior	84	66.1
Posterior	21	16.5
Both	22	17.3
Treatment modality		
Implant supported crown	99	78.0
Implant supported bridge	13	10.2
Implant supported overdenture	15	11.8

4.2.2. Oral health related quality of life, perceived oral health and global ratings of oral health

OHRQoL was recorded using the OHIP-Edent. Total and subscales scores of OHIP-Edent were computed at baseline and follow-up to assess levels of impact on participants' oral health. Higher scores indicate worse OHRQoL. Overall, participants rated their oral health as having fewer impacts at follow-up (Table 4.1)

The self-anchored scale was used to measure participants' perceived oral health using their own best and worse imaginable oral health as benchmarks (Table 4.2).

The attrition or non-response rate was 21.2% for the OHIP-Edent and 43.8% for the self-anchored scale.

Table 4.2. Participants' oral health-related quality of life (OHIP-Edent total and subscale scores) and perceived oral health (self-anchored scale) at baseline and follow-up

	Baseline			Follow-up		
	n	Mean (SD)	Range	n	Mean (SD)	Range
OHIP-Edent						
Functional limitations	127	6.4 (3.4)	0-12	100	2.3 (2.4)	0-11
Physical pain	126	6.3 (4.5)	0-16	100	2.5 (3.0)	0-14
Psychological discomfort	127	5.2 (2.2)	0-8	100	2.5 (2.4)	0-8
Physical disability	125	5.3 (3.9)	0-12	101	1.7 (2.6)	0-12
Psychological disability	125	4.7 (2.7)	0-8	100	1.6 (2.0)	0-8
Social disability	145	3.5 (3.7)	0-12	100	1.1 (2.3)	0-10
Handicap	125	3.1 (2.6)	0-8	100	0.8 (1.7)	0-8
Total	124	34.8 (19.6)	2-75	100	12.5 (13.8)	0-71
Self-anchored scale score	121	6.2 (2.3)	0-10	68	7.7 (1.5)	2-10

The test for normality indicated the OHIP-Edent data were non- normally distributed with skewness of 0.380 (SE= 0.22) and Shapiro-Wilk test of 0.958 (p=0.01).

Global ratings of oral health were assessed. Overall at baseline, 83.3% of participants rated their oral health as 'good' or 'very good' (Table 4.3).

Table 4.3. Participants' global ratings of oral health at baseline and follow-up

	Baseline (n=127)	Follow-up (n=100)
	%	
Excellent	7.1	24.8
Very good	26.2	41.5
Good	57.1	29.7
Poor	7.9	4.0
Very poor	1.6	0

4.3. Cross-sectional validation of the OHIP-Edent

This second section describes the cross-sectional psychometric properties of the OHIP-Edent, assessed as reliability and validity.

4.3.1. Reliability

Internal consistency, assessed using Cronbach's α and by correlations between OHIP-Edent total score and each subscale all exceeded 0.7 and were significant at $p<0.05$ (Table 4.4).

Table 4.4. OHIP-Edent item-total correlation baseline and Cronbach' α if item deleted

OHIP-Edent (n=125)	Item-total correlation	Cronbach' α if item deleted
Functional limitations	0.853*	0.767
Physical pain	0.861*	0.754
Psychological discomfort	0.803*	0.785
Physical disability	0.918*	0.755
Psychological disability	0.855*	0.776
Social disability	0.814*	0.768
Handicap	0.832*	0.778

*Statistically significant at $p<0.05$

Cronbach's α for the baseline and the follow-up OHIP-Edent was 0.798, which indicates good internal consistency. When individual items were deleted the alphas remained stable.

The test-retest reliability, assessed by intra-class correlation coefficients

(ICC) for OHIP-Edent baseline and follow-up was 0.543 which indicates moderate reliability (Koo and Li, 2016).

4.3.2. Validity

Convergent validity was investigated through Spearman's rank-order correlations to determine the relationship between the OHIP-Edent total score and the global rating of oral health at baseline, follow-up and retrospectively. The relationships were small but non-significant for the baseline assessment, medium for the follow-up and large or strong effect for the retrospective, both significant (Table 4.5).

Table 4.5. OHIP-Edent construct validity

	Validity Global rating of oral health	
	Spearman correlation coefficient	*p* value
OHIP-Edent		
Baseline	0.13	0.14
Follow-up	0.30	<0.01*
Then-test	0.57	<0.01*

*Statistically significant at p<0.01

4.4. Measurement of response shift

The third section of the results reports the investigation of response shift using the three approaches: (i) the then-test, (ii) the self-anchored scale and (iii) classification and regression trees. This section describes the data for each method.

4.4.1. The then-test

As described in section 3.8.1.3, recalibration response shift was calculated as the difference between the then-test and baseline OHIP-Edent scores; observed change (unadjusted change) as follow-up minus baseline scores and true change (adjusted change) as the difference between the follow-up and the then-test scores.

4.4.1.1. Then-test magnitude and direction of recalibration

Overall, participants retrospectively assessed their OHRQoL as better (i.e lower OHIP-Edent scores) than they had at baseline (Figure 4.2). The negative sign of this recalibration suggests that, on average, participants recalibrated downwards. The overall magnitude of response shift was -4.0 $\pm$ 15.3 OHIP-Edent points with a small effect size (p<0.05; Wilcoxon Sign Rank test) (Table 6).

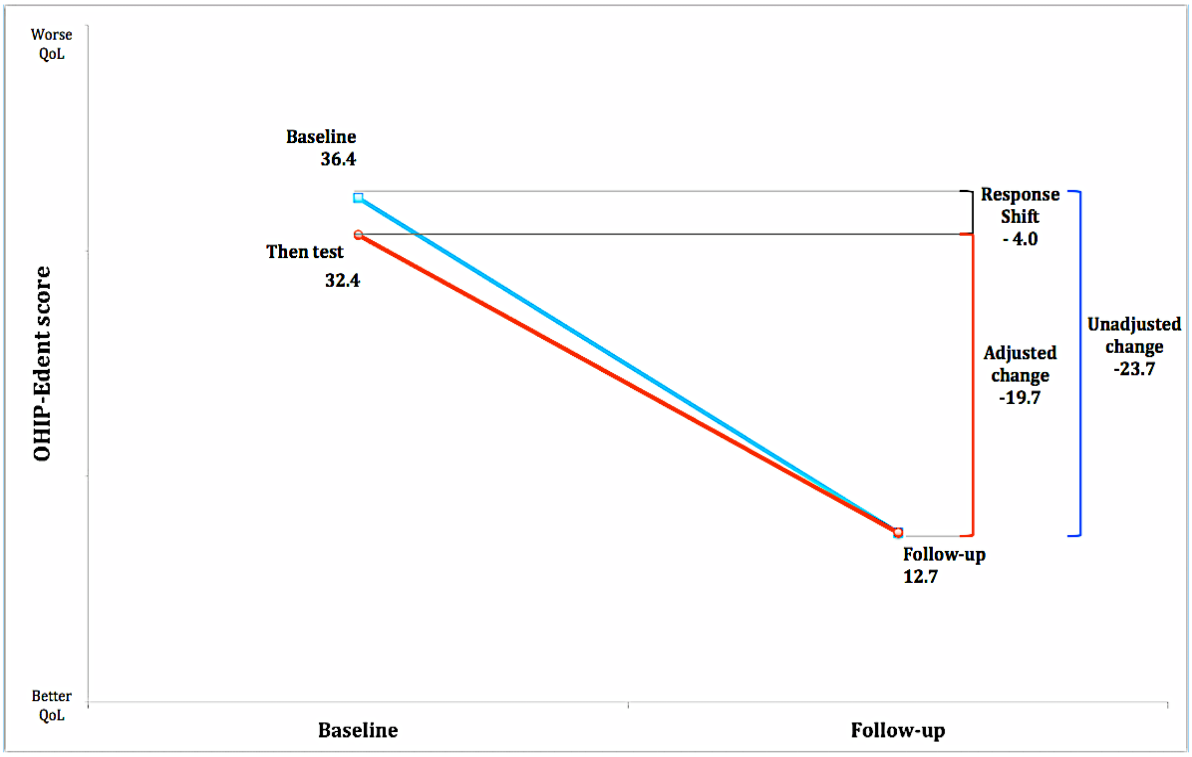


Figure 4.2. Recalibration in the then-test approach

The Wilcoxon signed-rank test showed that after treatment, on average participants retrospectively reassessed themselves as better at follow-up (downward recalibration). This was significant for the OHIP-Edent total score and the functional limitations and psychological discomfort, but non-significant among the physical pain, physical disability, social disability and handicap subscales.

Recalibration had a medium effect size for functional limitations and psychological discomfort. All the other subscales showed small effect sizes (Table 4.6).

Table 4.6. Magnitude and direction of recalibration response shift for OHIP-Edent

	Recalibration response shift Mean (SD)	z	Effect size	*p* value
OHIP-Edent				
Functional limitations	-1.0 (3.1)	-2.9	0.3	0.004*
Physical pain	-0.6 (3.9)	-0.8	0.1	0.430
Psychological discomfort	-0.6 (2.0)	-2.7	0.3	0.007*
Physical disability	-0.5 (3.1)	-1.1	0.1	0.266
Psychological disability	-0.4 (2.5)	-1.8	0.2	0.071
Social disability	-0.4 (2.9)	-0.9	0.1	0.391
Handicap	-0.5 (2.2)	-1.8	0.2	0.068
Total	-4.0 (15.3)	-2.2	0.2	0.028*

*Statistically significant at p<0.05 Wilcoxon Sign Rank test (two tailed)

Recalibration was also analysed according to treatment modality (Table 4.7). Whilst the overall, effect size was small, the effect size was large and significant for overdenture treatment, but small and non-significant for implant-supported crown and medium for implant-supported bridges treatments.

Table 4.7. Response Shift by treatment modality

Treatment modality	n	Baseline	Then-test	Recalibration	Effect size	*p* value
		Mean (SD)				
ISC	72	31.5 (19.2)	28.8 (20.1)	-2.7 (14.6)	0.2	0.150
ISB	12	41.6 (18.7)	35.8 (24.2)	-2.9 (10.1)	0.3	0.327
OD	14	56.9 (14.0)	45.3 (24.0)	-11.6 (21.2)	0.5	0.054*
Total	98	36.4 (20.5)	32.4 (22.8)	-4.0 (15.3)	0.2	0.022*

*Statistically significant at p<0.05 Wilcoxon Sign Rank test (two tailed)

4.4.1.2. Then-test observed change (unadjusted change)

Table 4.8 and figure 4.2 show the observed (unadjusted changes) by treatment modality. Results showed an overall improvement in the OHRQoL as indicated by a negative sign in the difference between follow-up minus baseline OHIP-Edent scores (-23.7 $\pm$ 19.6). The difference was significant for all three groups with a large effect size.

Table 4.8. Observed change (unadjusted change) by treatment modality

Treatment modality	n	Baseline	Follow-up	Unadjusted change	Effect size	*p* value
		Mean (SD)				
ISC	72	31.5 (19.3)	10.3 (10.5)	-21.2 (19.3)	0.8	0.001*
ISB	12	41.7 (18.7)	19.7 (17.8)	-22.0 (10.0)	0.8	0.002*
OD	14	56.9 (13.9)	18.7 (22.2)	-38.2 (22.1)	0.9	0.001*
Total	98	36.4 (20.5)	12.7 (14.1)	-23.7 (19.6)	0.8	0.001*

*Statistically significant at p<0.05 Wilcoxon Sign Rank test (two tailed)

4.4.1.3. Then-test true change (adjusted change)

Overall, adjusting for recalibration reduced the magnitude of change for all types of treatment (Table 4.9 and figure 4.2). The value of adjusted change was significantly reduced in the overdentures group with a difference of 12 OHIP-Edent points. The effect size for all treatments was still large and significant for all three groups.

Table 4.9. True change (adjusted change) by treatment modality

Treatment modality	n	Then-test	Follow-up	Adjusted change	Effect size	*p* value
		Mean (SD)				
ISC	72	28.8 (20.1)	10.3 (10.5)	-18.5 (19.8)	0.8	0.001*
ISB	12	38.8 (24.1)	19.7 (17.8)	-19.1 (17.4)	0.8	0.011*
OD	14	45.3 (24.0)	18.7 (22.2)	-26.6 (26.0)	0.9	0.007*
Total	98	32.4 (22.8)	12.7 (14.1)	-19.7 (20.6)	0.8	0.001*

*Statistically significant at p<0.05 Wilcoxon Sign Rank test (two tailed)

4.4.1.4. Then-test recalibration at the individual level

Recalibration response shift was explored at the individual level to detect groups of participants that changed their internal standards, downwards (people retrospectively reassessing themselves as having better OHRQoL than they thought at baseline), upward (people retrospectively reassessing themselves as worse OHRQoL than they thought at baseline) or remained the same between baseline and follow-up using a MID of 9 OHIP-Edent points. At this threshold, of the 98 participants who completed the then-test, 15 (15.3%) changed their internal standards downward, 25 (25.5%) upward and 60 (59.2%) did not recalibrate.

For explorative purposes only, changes in OHRQoL were also investigated by age (Table 4.10). Adjusted and unadjusted changes of younger participants were less than a half of the elderly group. The magnitude of recalibration was larger among older participants (Mean recalibration = -10.5 ± 21.1) with a large effect size.

Table 4.10. Unadjusted change, adjusted change and recalibration by age

Age group		Unadjusted change	Adjusted change	Recalibration	ES Recalibration	*p* value
	n	Mean (SD)				
18-25	28	-15.7 (10.1)	-11.2 (12.9)	-4.5 (10.8)	0.3	0.030*
26-59	54	-24.7 (20.8)	-22.8 (22.1)	-1.9 (15.2)	0.1	0.360
≥60	16	-34.6 (22.8)	-24.4 (22.4)	-10.5 (21.1)	0.5	0.060
Total	98	-23.7 (19.6)	-19.7 (20.6)	-4.0 (15.3)	0.2	0.020*

*Statistically significant at p<0.05 Wilcoxon Sign Rank test (two tailed)

4.4.1.5. Variables predicting the magnitude and direction of recalibration

The influence of the predictor variables gender, number and position of replaced teeth and treatment modality on the magnitude and direction of recalibration was explored using multiple linear regressions (Table 4.11). The standard regression coefficient (SRC) and the significance for each predictor are presented in Table 4.11. None significantly predicted recalibration (R^2 = 0.66; $F(5,89) = 1.25$, $p = 0.29$).

Table 4.11. Multiple Linear Regression analysis of predictors of RS

Predictor Variables	SRC	SE	*p* value
Gender (Female/Male)	0.049	3.38	0.641
Number Replaced Teeth	-0.362	1.03	0.298
Position Replaced Teeth (Upper/Lower/Both)	0.161	4.86	0.264
Position Replaced Teeth (Anterior/Posterior/Both)	-0.188	3.28	0.286
Treatment Modality (ISC/ISB/OD)	0.217	6.79	0.501

N = 98; R^2= 0.066
SRC, standard regression coefficient

4.4.2. Self-anchored scale

4.4.2.1. Self-anchored scale recalibration response shift

The second approach used to assess recalibration response shift was the self-anchored scale. Recalibration was calculated as difference between baseline and transformed baseline scores, and true change as the difference between follow-up and transformed baseline scores as described in section 3.8.1.3.2.

From the 121 participants that completed the baseline self-anchored scale, only 68 (56.2%) completed the follow-up, of whom 23 provided incomplete data.

The Wilcoxon signed-rank test showed that after the treatment on average participants perceived oral health improved ($z= -5.4$, $p<0.05$). The baseline and follow-up assessments were positively related (Spearman's rho: 0.34, $p<0.05$).

4.4.2.2. Self-anchored scale magnitude and direction of recalibration response shift

Table 4.12 presents means and standard deviations, effect sizes and significance levels of the observed change, recalibration response shift and true change for the self-anchor scale recalibration approach.

Table 4.12. Effect sizes and significance levels of the observed change, response shift and true change for the self-anchored scale recalibration

	n	Mean (SD)	Effect size	*p* value*
Self-anchored baseline score	121	6.2 (2.3)		
Self-anchored follow-up score	68	7.7 (1.5)		
Transformed baseline score	51	6.4 (2.4)		
Observed change *(follow-up-baseline)*	68	1.7 (2.3)	0.74	<0.001
Recalibration response shift *(baseline-transformed baseline)*	51	0.1 (1.2)	0.03	0.820
True change *(follow-up-transformed baseline)*	45	1.4 (2.0)	0.61	<0.001

* Wilcoxon Signed Rank Test

Overall, the observed change shows significant improvement in participants' perceived oral health (Figure 43.) with a large effect size. Using the self-anchored scale, recalibration was very small and non-significant. Thus, the true change was very similar to the observed change, with a strong and significant effect.

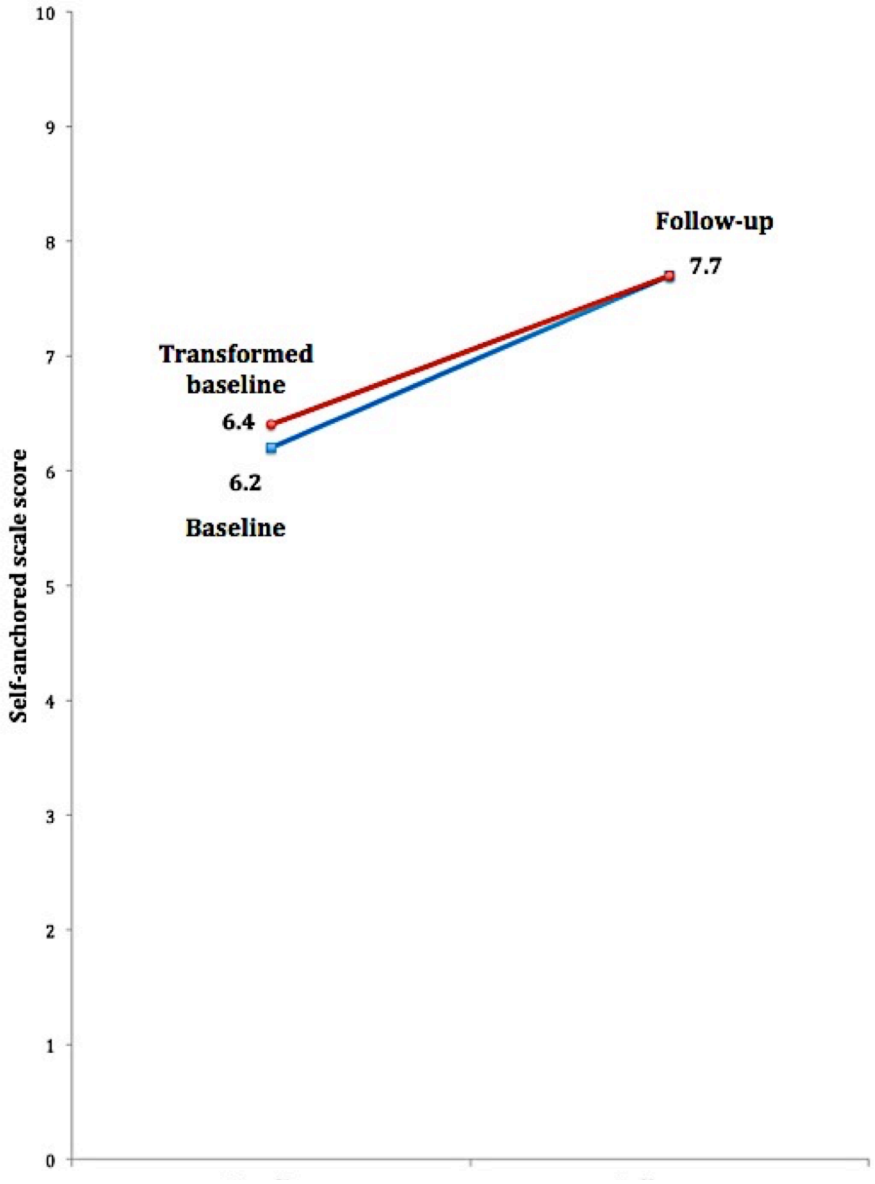


Figure 4.3. Self-anchored scale baseline, follow-up and transformed baseline scores

4.4.2.3. Self-anchored scale true change according to treatment modality

Considering the small sample size, this analysis was conducted for illustrative purposes only. Small differences were detected according to treatment modality (Table 4.13). Participants receiving overdentures showed a greater improvement on their perceived oral health than those implant-supported crowns and bridges.

Table 4.13. Self-anchored scale by treatment modality

Treatment modality	n	Observed change *(follow-up-baseline)*	Response shift *(baseline-transformed baseline)*	True change *(follow-up-transformed baseline)*
			Mean (SD)	
ISC	39	1.5 (1.9)	0.2 (1.2)	1.2 (1.8)
ISB	2	1.7 (1.9)	0.1 (0.8)	1.4 (1.2)
OD	4	2.7 (4.1)	-1.1 (0.3)	3.2 (3.4)
Total	45	1.7 (2.3)	0.1 (1.2)	1.4 (2.0)

4.4.2.4. *Self-anchored scale recalibration at individual level*

Recalibration response shift was explored at the individual level to detect groups of participants that changed their internal standards upward, downwards or remained the same between baseline and follow-up. Of the 51 participants who completed the self-anchored scale, 29 (56.8%) changed their internal standards downward, 18 (35.3%) upward and 4 (7.8%) did not recalibrate.

4.4.2.5. Exploring floor and ceiling effects

Floor and ceiling effects were analysed by calculating the proportion of participants achieving the maximum and minimum scores of the self-anchored scale. There were no floor or ceiling effects for the self-anchored scale score at baseline and follow-up. The proportion of participants achieving the maximum and minimum was below the recommended cut-off of 15% (Terwee et al., 2007, Lim et al., 2015).

The mean self-anchored scale score at baseline was 6.2 and at follow-up increased to 7.7. At baseline, only 1.6% of participants achieved the worst score (0) and 8,2% the best (10). After treatment, none of the participants achieved the worst score (0) and 10.3% achieved the best score (10) (Figure 4.4)

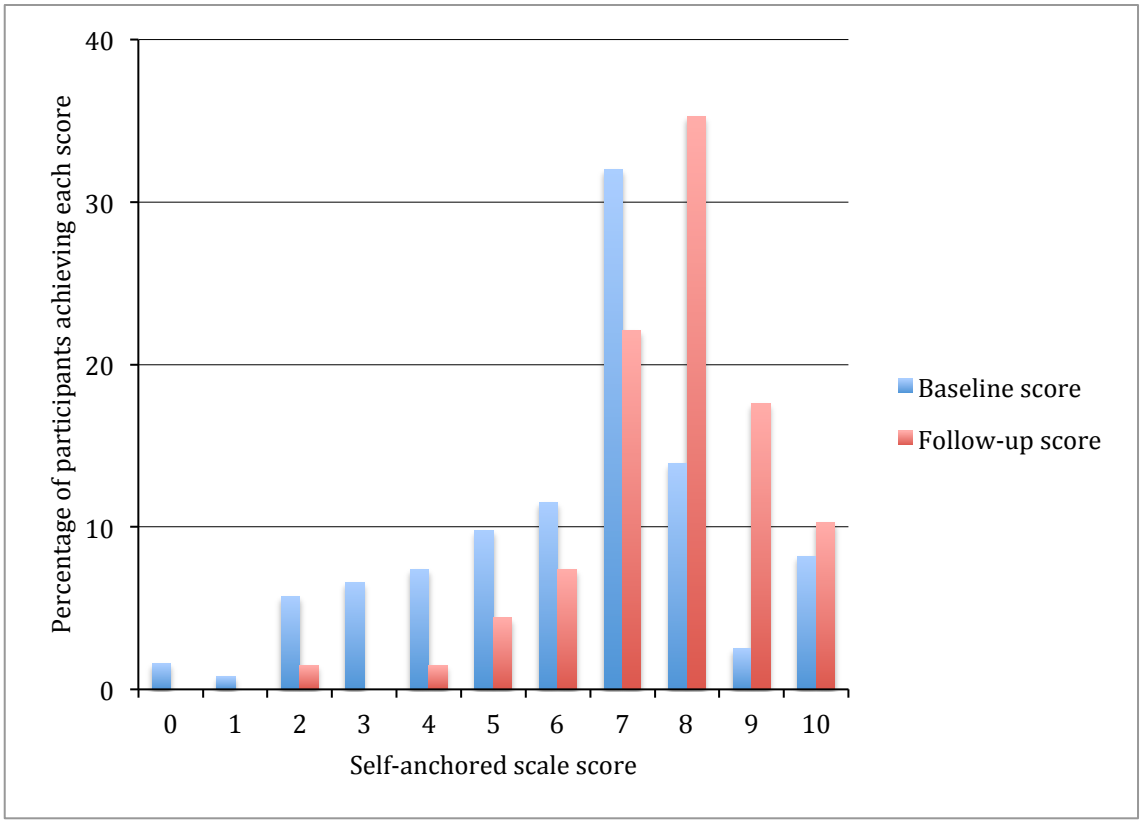


Figure 4.4. Distribution of scores of the self-anchored scale at baseline and follow-up

Nonetheless, there were floor and ceiling effects for the anchors of the self-anchored scale. Most participants rated the best and the worse descriptors of oral health as the endpoints of the scale. The mean self-anchored scale best descriptor score at baseline was 9.5 and the worst descriptor 0.6. At follow-up the mean of best descriptor score was 9.6 and the worst descriptor 0.9. At baseline, 57.9% of participants rated the worst descriptor with the worst score (0) and 76.8% rated the best descriptor with the best score (10). After treatment, 62.3% of participants rated the worst descriptor with the worst score (0) and 77.9% rated the best descriptor with the best score (10) (Figure 4.5)

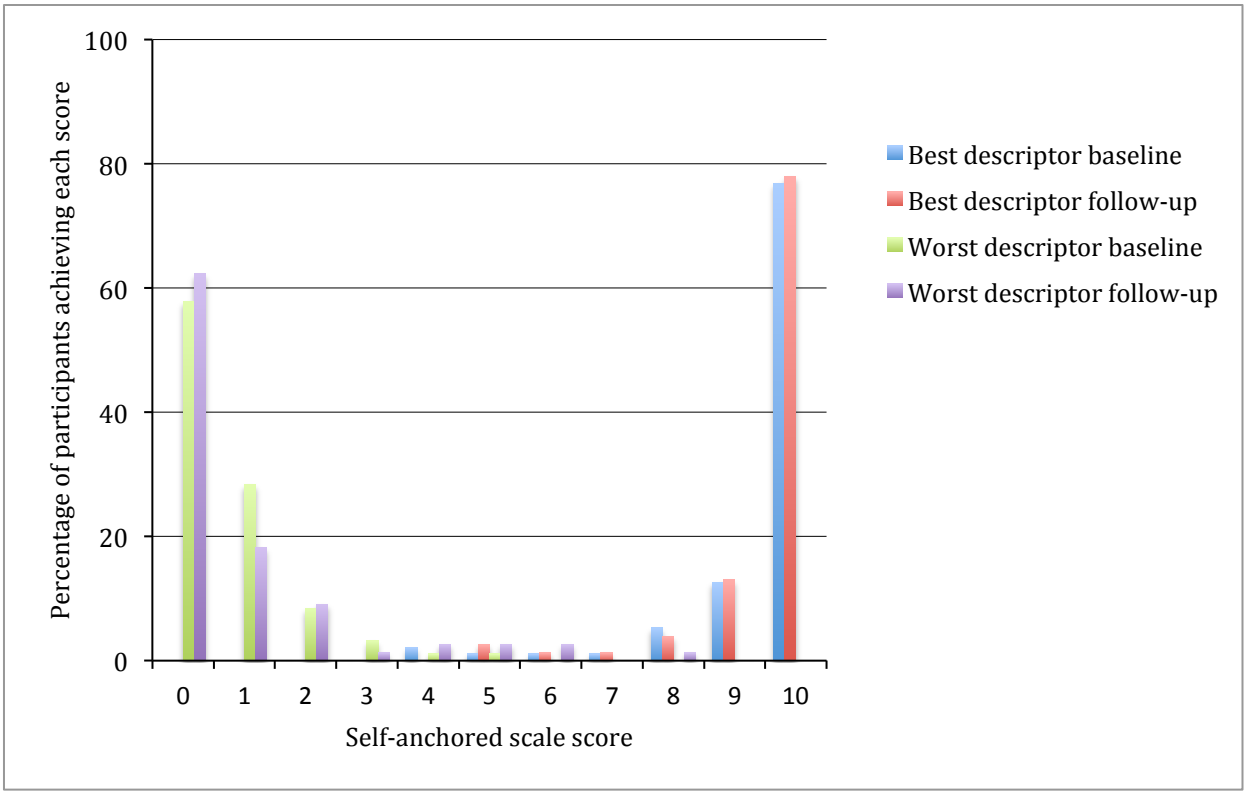


Figure 4.5. Distribution of the best and worse descriptors of oral health of the self-anchored scale at baseline and follow-up

4.4.3. Classification and regression trees

The third approach to assess response shift was the Classification and Regression Trees (CRT). CRT analysis was conducted with participants who completed the study (n=100). The sample was classified first using their global rating of oral health change. Thus, participants at the follow-up rating their global oral health as 'much better' and 'better' were categorized as reporting 'improvement' and those rating their global oral health as 'about the same', 'worse' and 'much worse' as 'no improvement'. The tree was fitted using OHIP-Edent total change score as the dependent variable and the change of the 7 subscales as independent variables.

The minimum number of cases in the parent node was set up to be 10% of the sample and the stopping rule for a terminal node to be 5%.

4.4.3.1. Model performance

The model performance was assessed by calculating the risk estimate. Figure 4.6 shows the risk value (44.160) and its standard error (12.567). The variance of the root node is calculated as the standard deviation of the root node squared. Thus,

$$S_y^2 = (19.453)^2 = 378.419$$

Thereby, the proportion of variance due to error is:

$$S^2_e = \frac{44.160}{378.419} = 0.12$$

The variation in the dependent variable explained by the model ($S^2_x S^2_x$) or explained variance is $S^2_x = 1 - S^2_e = 0.88$. Thus, 88% of the variation in OHIP-Edent total score was explained by the variation in subscales scores, which had a significant effect in forming the tree.

4.4.3.2. Tree analysis

The first split was defined by the global rating of oral health change (Figure 4.6). Participants rating their global oral health as 'much better' or better were classified as 'Improvement' (Node 1) and those who rated their global oral health as 'about the same', 'worse' or 'much worse' as 'No improvement' (Node 2). Overall, 70% (Node 2) of participants reported an improvement in their oral health after treatment.

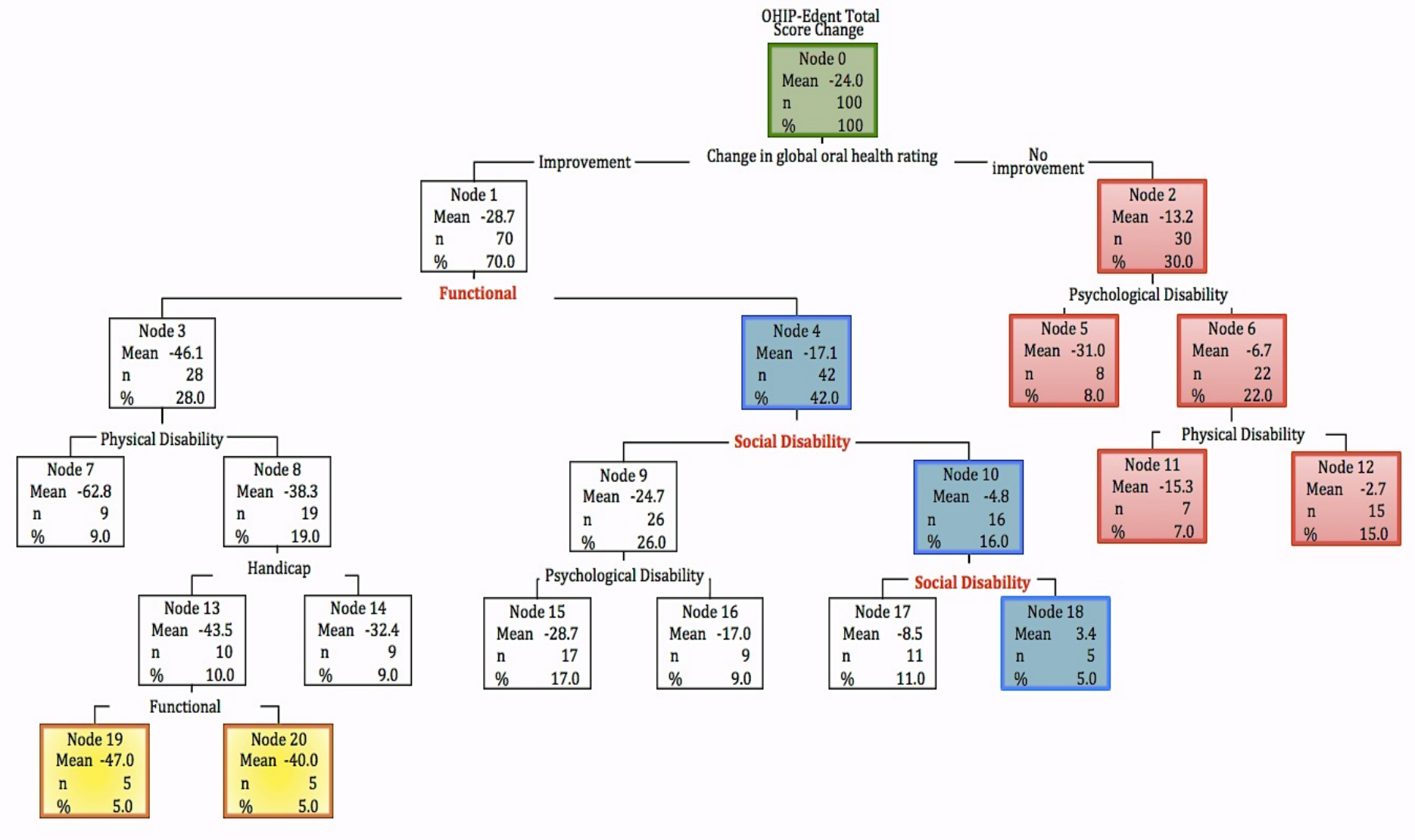
The model obtained determined that for those whose global rating of oral health indicated 'improvement', the second split was defined by changes on the functional limitations subscale of the OHIP-Edent (Nodes 3 and 4). Whereas for those whose global ratings of oral health did not improve, the second split was defined by changes on the psychological disability subscale of the OHIP-Edent (Nodes 5 and 6). Changes in the subscales for physical disability (Node 7, 8, 11 and 12), social disability (Nodes 9.10, 17 and 18), handicap (Nodes 13 and 14), functional disability (Nodes 19 and 20) and psychological disability (Nodes 16 and 16) defined the succeeding splits.

Recalibration was inferred when the global rating of oral health change was inconsistent with the OHIP-Edent change score. The treatment was expected to improve participants' OHRQoL. If participants reported better OHRQoL at follow-up but their global rating of oral health remained unimproved, this was interpreted as upward recalibration. If participants reported worse OHRQoL at follow-up but rated their oral health as improved, then downward recalibration was inferred.

Overall, participants reporting an improvement in their oral health after

treatment showed larger mean total scores for OHIP-Edent, but 5% of them (Node 18) rated their QoL as worse at follow-up. Node 18 indicates that this might be because social aspects of their oral health remained unimproved (downward recalibration).

The right side of the tree (Node 2) shows nearly one third of participants manifested no change in their global oral health rating even when they rated their QoL as better at follow-up, as indicated by the negative sign of the mean scores (upward recalibration). The 15 participants represented in the terminal Node 12 reached the MID of 9 points, which was used as the threshold to detect recalibration.



Risk value: 44.160 Standard Error: 12.567

Figure 4.6. Classification Tree amongst 100 participants receiving implant supported prostheses

4.4.3.3. Variable importance

The contribution of each independent variable to the model is termed 'variable importance'. The values of all these contributions are summed over each node and totalled. They are then scaled relative to the best performing variable where the highest contribution is scored 100% and all the others decrease sequentially. Reprioritization can be inferred by changes in the order of importance of the domains of OHIP-Edent before and after the treatment.

In this model, the social disability and psychological discomfort aspects of QoL increased in importance over time (Figure 4.7).

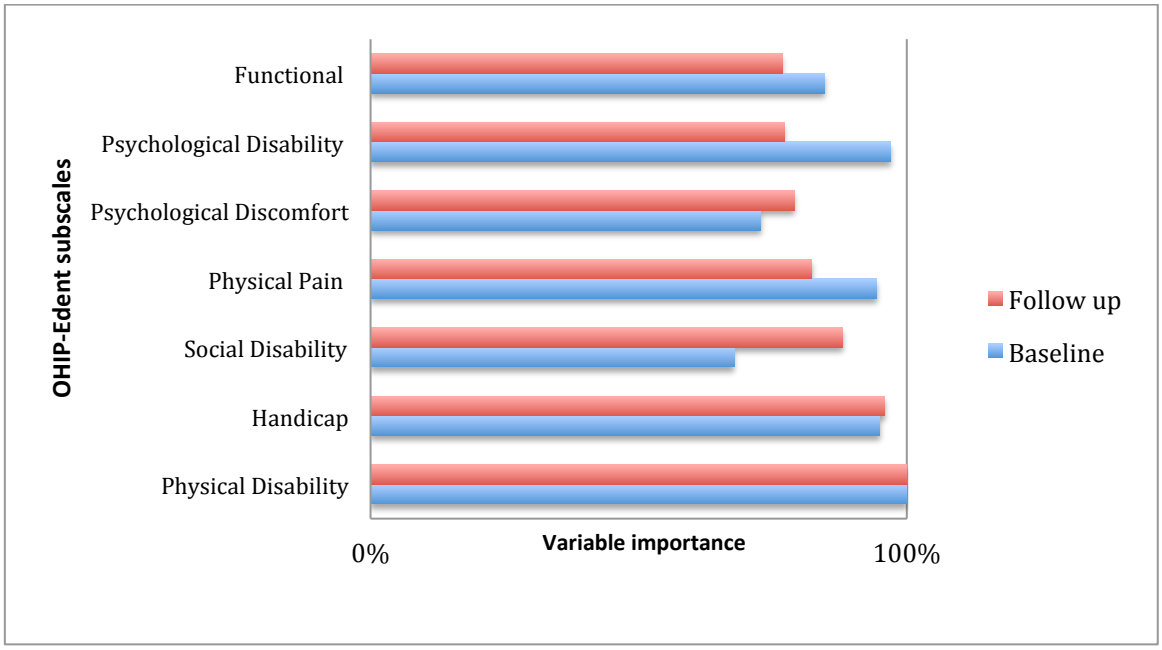


Figure 4.7. Variable importance at baseline and follow-up

4.4.4. Comparing methods

Apart from the low completion rates of the self-anchored scale (Section 4.4.2.1), the results of the three methods are comparable (Figure 4.8). Overall, the three approaches detected RS in participants. Using the then-test participants on average recalibrated downwards. Moreover, with the CRT downward recalibration can be inferred in participants in node 18 (Figure 4.6).

Adjusting for recalibration reduced the magnitude of change. Using the then-test, the magnitude of improvement on OHRQoL was reduced by 4.0 OHIP-Edent points and the magnitude of perceived oral health was reduced by 0.3 points using the self-anchored scale.

CRT demonstrates changes in the patterns of RS compatible with those obtained with the then-test and the self-anchored scale. The magnitude of improvement in OHRQoL is reduced among participants who rated their general oral health as not improved (Node 2) and is reduced when they recalibrated downwards (Node 18) (Figure 4.6).

The subscales where recalibration occurred were comparable between the then-test and the CRT. The then-test detected downward recalibration with a significant change on the functional limitations subscale. The CRT detected downward recalibration influenced by functional changes as observed in the first split of the tree differentiating those participants with improvement of their QoL (Node 1) with the highest (Node 3) and the lowest ratings of QoL (Node 4) (Figure 4.6).

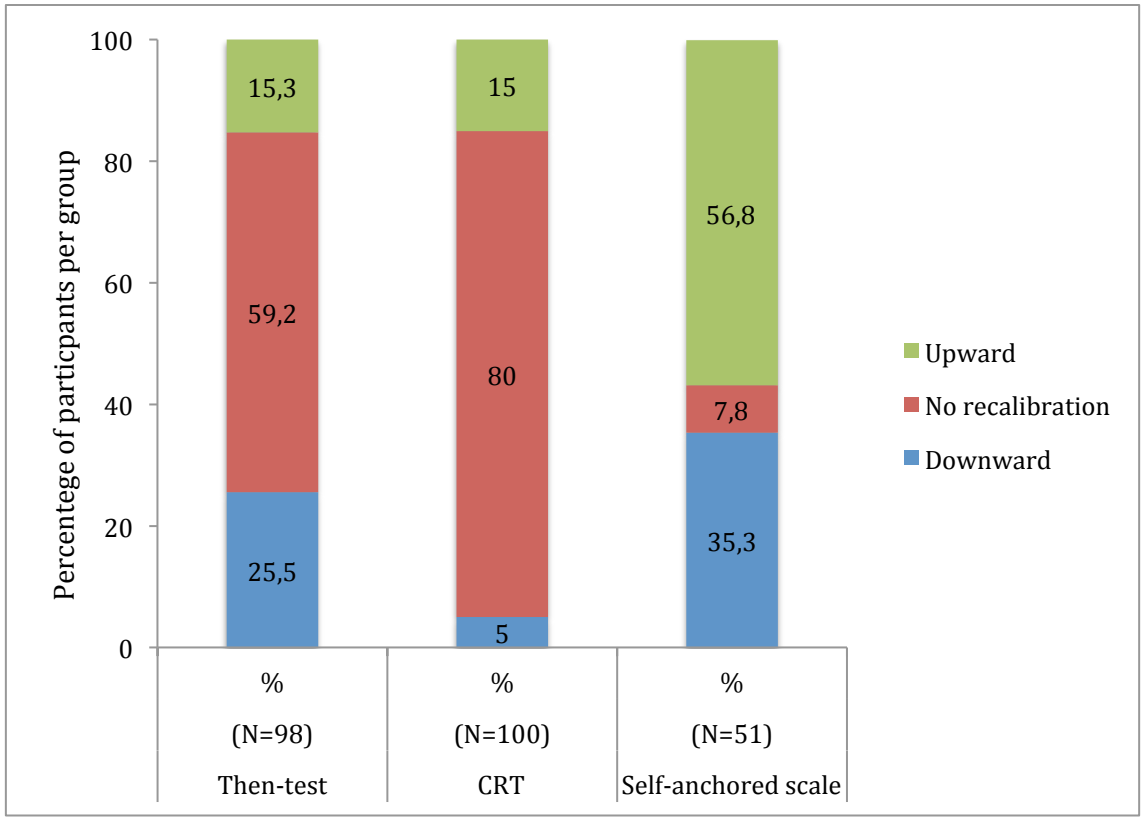


Figure 4.8. Recalibration for the then-test, CRT and self-anchored scale

5. DISCUSSION

5.1. Introduction

The purpose of this study was to assess response shift in individuals after treatment with dental implant supported prostheses. This study also explored the convergent validity of three approaches to detect response shift: the then-test, the self-anchored scale and the classification and regression trees. Data were collected from participants attending for definitive restorative treatment after dental implant placement. OHRQoL was assessed using OHIP-Edent and perceived oral health with a self-anchored scale. Response shift was explored using the three approaches.

Using the then-test and self-anchored scale, participants on average recalibrated their internal standards downwards. Recalibration investigated with the then-test showed that participants retrospectively indicated their OHRQoL as better than at baseline. The magnitude of recalibration assessed with this method varied from small to medium. Assessed through the self-anchor sale, improvement in perceived oral health of participants was 0.3 points smaller when response shift was accounted for.

Likewise, the classification and regression tree approach showed that 5% of participants reported downward recalibration because, despite improvement in their global oral health, the OHRQoL after the treatment was rated as worse at follow-up. However, the CRT also demonstrated that 30% of participants indicated upward recalibration manifested as no change in global oral health rating with

OHIP-Edent ratings better at follow-up.

The discussion of the findings is divided into five parts. Section 5.2 discuses the distribution of the sample. Section 5.3 briefly discusses the cross-sectional validation of the OHIP-Edent. Then. Section 5.4 discusses the different approaches used to assess RS. The then-test, the self-anchored scale and the CRT are first discussed separately. Subsequently, the convergent validity of the three approaches is considered. Section 5.5 discusses the implications of the findings for the original Sprangers and Schwartz (1999) model of response shift. The implications of response shift for clinical research are discussed in Section 5.6. Finally, Section 5.7 considers the strengths and limitations of the study.

5.2. Distribution of the sample

This section discusses the sample characteristics. A total of 127 participants were enrolled at baseline, of which 100 completed the study. 57.5% were female and the mean age was 37.5 years.

The study sample was unequally distributed with respect to type of treatment. Most participants were treated with implant-supported single crowns (62.2%). Similarly, it was unequally distributed with regard to age. Older participants were 12.6% of the recruited sample. Although improvement in OHRQoL has been reported among all types of DIT and in all age groups, the findings of this study should be generalized with care. The relatively small size of each group will have affected the power of the performed tests to identify differences. That is, there is a risk of type II error.

5.3. Cross-sectional validation of the OHIP-Edent.

OHIP-Edent performed adequately in cross-sectional assessments. The mean scores (total and each subscales) of the OHIP-Edent are shown in table 4.1 (Results section 4.2.2). The internal consistency of the OHIP-Edent was good (Cronbach's $\alpha = 0.798$). This finding was in agreement with previous assessments of the instrument (Souza et al., 2007a, Sato et al., 2012, He and Wang, 2015).

However, the test-retest reliability suggested only moderate reliability (ICC = 0.543). It should be noted that the follow-up assessments of OHRQoL were collected several months after the baseline and in the meantime all participants had received definitive prosthodontic treatment. Moreover, there was variability

among participants because the follow-up assessment was between three to 6 months after the treatment. This may explain why the test-retest reliability appears less than reported by previous studies (Souza et al., 2007a, Sato et al., 2012, He and Wang, 2015).

The convergent validity showed that the association between the total score of the OHIP-Edent and the global rating of oral health was small for the baseline and medium for the follow-up. The low correlation may reflect little variation in global ratings in the sample.

It was expected that when the OHRQoL was high, the global rating of oral health would also be high. As participants in this study were in their final stage of treatment, most of them were caries free and periodontally healthy. Thus, the global ratings of oral health were good, but the OHRQoL low. Clinical aspects of treatment were not recorded in this study, but the baseline assessment might be reflecting that the participants rated their overall oral health from a biomedical rather than from a psychosocial perspective. That is, they may not relate their prosthodontic needs as an oral health problem.

5.4. Approaches used to assess response shift

5.4.1. The then-test

This section discusses the results of the then-test. Thus, the focus is on recalibration. Overall, participants reported improved OHRQoL after the treatment as indicated by the negative sign of the observed or unadjusted change (Results section 4.4.1.3, Table 4.8).

The then-test detected recalibration among participants. Retrospectively they reassessed their baseline OHRQoL as better than they did on the actual baseline. The difference between the then-test and baseline scores had negative sign suggesting that, on average, participants changed their internal standards downwards. The overall magnitude of response shift was -4.0 $\pm$ 15.3 OHIP-Edent points, with a small effect size (Results section 4.4.1.4, Table 4.9). Adjusting for recalibration, the magnitude of change after the treatment decreased (Results section 4.4.1.4, Table 4.9). Thus, the magnitude of improvement of OHRQoL was reduced if RS was accounted for. The discussion of these findings considers the direction and magnitude of recalibration, the selection of the OHIP-Edent as a measure of OHRQoL and the recalibration that occurred at the individual level.

5.4.1.1. Direction of recalibration

Overall, the negative sign of the recalibration score indicates that participants in this study retrospectively reassessed themselves as having less impact on their OHRQoL than they thought at baseline. This result may be interpreted as participants reducing their internal standards or downward recalibration and implies that the magnitude of improvement on OHRQoL is reduced adjusting for RS. This finding has not been reported in the literature or has been encountered only infrequently (Krasuska et al., 2014a).

Response shift has been defined as adaptation to changed health. From this perspective, if individuals have deteriorating conditions, they might decrease their internal standards to accommodate the illness and maintain acceptable QoL. This hypothesis had been corroborated in several studies where individuals with

declining health in such conditions as cancer or multiple sclerosis retrospectively assessed their QoL as better as a way of adapting to their status (Schwartz, 2004, Rees et al., 2005, Schwartz et al., 2006, Anota et al., 2014).

On the other hand, when the treatment has a positive impact on peoples' OHRQoL, as is the case of dental treatment, the retrospective assessments usually indicate more impact, i.e worse OHRQoL, than those provided initially at baseline. In this case, when accounting for RS, the improvement on OHRQoL apparently derived from treatment increases (Ring et al., 2005, Kimura et al., 2012, Reissmann et al., 2012).

Conversely, the results of this study show that despite the improved OHRQoL of participants derived from DIT, they retrospectively reassessed their OHQoL as better than they had at baseline.

There are several possible explanations for this finding. Participants may have overestimated the impact of DIT on OHRQoL at baseline. Then when they reassessed these impacts retrospectively made a more positive assessment of their previous OHRQoL. This explanation may be related to effort justification bias. Since participants have invested time and other resources, they might initially have overestimated their level of impacts to justify undergoing the treatment. Participants in this study spent at least one year on the waiting list for the definitive restoration. This might explain why they overrated their baseline impact.

Another explanation may be related to participants' expectations. Several studies have reported that patients have unrealistic expectations of DIT, (Allen et al., 1999, Rustemeyer and Bremerich, 2007, Andrade de Lima et al., 2012, Yao et al., 2014) which has been related to lack of information and the high cost of

implants. Dental implants are considered by some individuals as the solution to all their dental problems, restoring appearance, function and quality of life to absolute normality (Wang et al., 2015). The expectations of treatment success among participants in this study might have been extremely high, therefore in retrospect and based on their post-treatment state, they reassessed their OHRQoL better than at baseline because treatment had not fulfilled these expectations. Thus, due to their high expectations before treatment, overestimating the effects of DIT they evaluated their OHRQoL at baseline as poorer than it actually was. After treatment, expectations were reassessed and internal standards were readjusted. This finding may have broader implications. Currently, in dentistry, as in many other medical sciences, clinical decision-making must involve persons' preferences. As reported by Wang and colleagues' (2015) qualitative study about public perceptions of dental implants, individuals seeking DIT have diverse motivations and concerns, mainly influenced by dissatisfaction with conventional dentures and possibly biased by misinformation. Thus, understanding peoples' motivation and apprehensions may help practitioners to communicate more effectively the treatment options suitable for each individual, and simultaneously, help that person to make informed decisions. Individuals with high or unrealistic expectations of DIT may be disappointed if their expectations are unmet. Hence, good patient-dentist communication is essential.

One further factor merits special attention here: the patient flow at the Charles Clifford Dental Hospital (CCDH). The CCDH is a teaching hospital, with undergraduate students (dentists and hygienists), postgraduates and researchers, and as a consequence, each patient is seen, treated and cared for by multiple professionals for the duration of treatment. This makes it very difficult to establish

the doctor-patient relationship of trust that is critical in providing the full benefits of treatment and might explain why participants retrospectively made a more positive assessment of their OHRQoL than at baseline. Likewise, with the person subject to multiple professional interventions, a lack of engagement with the research at the time the questionnaire was completed may have created some random measurement error.

This observation of individuals retrospectively assessing their QoL as better before treatment in situations where QoL has improved after the intervention, is a counterintuitive finding. Evidence suggests that using the then-test, individuals reassessed their QoL in retrospect as better than before the intervention when the health status has deteriorated, such as cancer (Rees et al., 2005) and arthritis (Razmjou et al., 2006). Furthermore, in dentistry, it has been reported that when oral health status has improved due to treatment, participants reported retrospectively their OHRQoL as worse that they thought before the intervention (i.e upward recalibration) (Ring et al., 2005, Kimura et al., 2012). Publication bias may explain why most reports suggest upward recalibration. As the objective of any intervention is to improve health status and QoL, then downward recalibration would decrease the treatment effect. Thus, such contradictory results may not be reported.

Locker's conceptual model of oral health (Locker, 1988) proposes that as a consequence of the impairment caused by oral disease, functional limitations and psychological symptoms may arise (Section 2.2.3, Figure 1). In line with Locker's framework, functional limitations and psychological discomfort were outcomes of oral disease in this study, but also the OHIP-Edent subscales for these domains were recalibrated. Furthermore, functional limitations and psychological

discomfort are two subscales in the OHIP-Edent where scores on the latter subscale could be a logical consequence of the scores on the former. Recalibration may have occurred in the functional limitations and psychological discomfort subscales because at the time of the follow-up assessment, participants may have had functional problems as yet unmet. Thus, for example, if they have chewing problems, the score in the subscale psychological discomfort may be also high as a consequence of feeling worried about dental problems. Moreover, this finding may also indicate reprioritization among the subscales. Functional limitations and psychological discomfort aspects of oral health have become more important after the treatment and the effect of these subscales is larger than the others.

5.4.1.2. Magnitude of recalibration

The overall magnitude of recalibration response shift was -4.0 $\pm$ 15.3 OHIP-Edent points with a small effect size. Small effect sizes for recalibration when using the then-test have been reported in studies of serious (Visser et al., 2005) and mild health conditions (Krasuska et al., 2014a). However, RS should be considered when assessing change because even a small recalibration may result in a misrepresentation of the true change in QoL (Schwartz et al., 2006).

Participants in this study waited a long time between their implant placement and their final restoration (at least one year). Therefore, even if DIT improved their OHRQoL, only modest recalibration may have occurred or the change was not enough to catalyse clinically relevant recalibration. Moreover, it has also been proposed that RS occurs merely with the passage of time (Sprangers and Schwartz, 1999). Therefore, time might be considered as affecting changes in

the internal standards in these participants. However, accounting for recalibration is clinically important, regardless of its magnitude. Participants with objective improvement (for example, assessed clinically) may report no increase in OHRQoL due to recalibration. Considering recalibration may make such an improvement appreciable.

Because this study was conducted in a very specific point in the treatment (before the definitive restoration but long after the implant was placed) there may be some unmeasured catalysts. The change in OHRQoL immediately after the implant surgery and placement of the temporary restoration may be larger to detect clinically significant RS. Likewise, if the placement of the definitive restoration is temporally closer to the provisional, then clinically significant RS may be detected. However, as participants spent at least one year with the temporary restoration and another year in treatment for the final restoration, RS may have been attenuated to almost clinically negligible by this time. A longer-term cohort study from beginning to end of DIT with several data collection points, may show changes in OHRQoL and RS. Cohort studies have investigated OHRQoL in oral surgery (McGrath et al., 2003), dental implants (John et al., 2004) and periodontal treatment (Saito et al., 2010), but not over many months of care.

5.4.1.3. Selection of the measure

This study used a variant of OHIP as the most common instrument to assess QoL in dentistry, specifically the OHIP-Edent that is a condition-specific questionnaire for edentulous individuals to assess OHRQoL. Specific measures are

more sensitive to recalibration because individuals remember specific situations related to their health status. Furthermore, condition-specific measures also have less random variation (Robinson et al., 2003a), so highlighting treatment effects and RS. Nonetheless, if the specific items measured do not change, then the magnitude of RS might be small or not detected (Boucekine et al., 2013).

In life threatening conditions such as cancer, generic measures may detect recalibration RS (Korfage et al., 2007, Jakola et al., 2017). This might be explained by severe health conditions causing impacts on general aspects of health, whereas in mild health conditions, RS is better detected using condition-specific measures (Joore et al., 2002, Krasuska et al., 2014a).

Another aspect to be considered is that the current analysis is focused on variations between subscales and the total scores, but not on the individual items. RS can also occur at the item level and may not be revealed if, for example, the recalibration in different items within the same subscale cancels each other out. For the same reason, reprioritization may not be detected.

One problem of some QoL measures is that they often include both subjective and objective measures. For example, the SF-36, an instrument developed to assess QoL in the general population (Ware and Kosinski, 2001), confounds function with health by asking participants about their ability to walk up a flight of stairs. The problem with this instrument is that it discriminates levels of physical health effectively among different levels of impairment, but it has low correlation between psychosocial components of QoL and physical impairment (Schwartz et al., 2007). Likewise, including physical functioning questions in a HRQoL measure, confuses individuals with disability as they may answer with respect to their functional disability using assistive devices or rating their

disability when they are unaided (Horner-Johnson et al., 2010). The same concerns may be applied to the OHIP-Edent. Participants are asked about the emotional impacts of oral health (which may be considered more subjective) and at the same time, they are asked if they have had chewing difficulties (which may be more objective), and both subscales are included in the same global score. Thus, participants with few or no problems in functional limitations (as is the case of participants with single dental implants) may think that all the questions are related to the functionality of the mouth, discarding any other impacts of oral health on daily life. Similarly, when answering the questionnaire, some participants may have been confused by whether questions are related to the prosthesis itself or their OHRQoL regardless of treatment.

Arguably, the inclusion of objective and subjective questions creates confusion. If emotional aspects are considered subjective, then changes in responses over time may be considered as changes in internal standards, but if chewing ability is considered a more objective measure of how the treatment is affecting the daily life, then no changes in chewing ability after the treatment (which objectively improved participants' QoL) may be considered as measurement error. Further research is necessary to confirm these findings.

5.4.1.4. Recalibration at the individual level

Recalibration response shift was explored at the individual level using an MID of 9 OHIP-Edent points as a threshold. Whilst the average direction of recalibration in the total sample was downwards, at the individual level, the

results were heterogeneous. Of the 98 participants who completed the then-test, 15 (15.3%) changed their internal standards downward, 25 (25.5%) upward and 58 (59.2%) did not recalibrate. This finding indicates that, although the treatment improved the OHRQoL (Adjusted change total sample= -19.7 ± 20.5) with a large and significant change (ES=0.8; p=0.01), recalibration did not occur in all participants.

Similar results have been described previously (Visser et al., 2005, Mayo et al., 2008, Visser et al., 2013, Krasuska et al., 2014a). Visser et al (2013) reported that among 220 patients undergoing surgery for cancer, even when the change in health was large and treatment invasive, there was no recalibration in a substantial subgroup (n=91). Among those patients who reported recalibration subgroups were found recalibrating in opposite directions; downwards (n=71) and upwards (n=40). Likewise, Mayo et al 's (2008) longitudinal analysis of HRQoL in people after stroke, identified groups of individuals who rated their health differently over time independent of the impact of their stroke on their function; 67% showed no RS, 15% negative and 13% positive RS over time.

A likely explanation for finding subgroups of participants recalibrating upwards and downwards is that people respond differently to the same catalyst (Krasuska et al., 2014a) because other factors may have influenced RS. Schwartz and Sprangers (2009) proposed that only some individuals undergo RS because they have an innate capacity to accommodate changes in health by changing internal standards, values or conceptualizations. Individual factors such as age may influence their self-rated health (Harris et al., 1992) and therefore RS. For example, younger participants in this study showed recalibration (Recalibration Mean = -11.2) of half of the magnitude of middle-aged participants (Recalibration

Mean = -22.8) and less than a half of the magnitude of elderly participants (Recalibration Mean = -24.4) (Table 4.10).

Another explanation for both finding groups of participants recalibrating in different directions and for why people react differently to the same catalyst is the appraisal process underlying the assessment of QoL. The appraisal process can change in response to HRQoL and can also be influenced by experiences, coping and adaptation to new circumstances (Schwartz et al., 2007).

The OHIP-Edent MID was used as a threshold to identify different groups of participants, but recalibration larger or smaller than this MID could also account for change in OHRQoL. Furthermore, this threshold may not be reached for some participants due to downward recalibration. Accordingly, individual recalibration based on MID must be interpreted carefully. MID is the smallest change in the QoL that is clinically meaningful. Consequently, recalibrations equal or larger than the MID would influence changes on QoL over time.

5.4.1.5. Alternative explanations for recalibration in retrospective assessments

Although the then-test is a popular method for assessing RS, it has been widely criticized. It is subject, among others, to recall and effort justification bias. Recall bias occurs when participants are not able to accurately recall their health (or health ratings) if they had adopted new standards. Hence, recall bias potentially invalidates the change measured using retrospective instruments. Recall bias has been found to affect the retrospective ratings of quality of life of hospitalised older adults (McPhail and Haines, 2010b) and post stroke (Ahmed et

al., 2004). In this study, recall bias may explain the discrepancy between the baseline assessment of OHRQoL and the then-test, with the baseline assessment significantly worse.

Effort justification bias affects prospective measurements when individuals choose a response at follow-up that justify the effort invested during the intervention, particularly if the treatment has been unpleasant or has serious side effects (Schwartz et al., 2005). In this sense, the person may overestimate the improvement or retrospectively assess him or herself as worse off at baseline to justify undergoing the treatment. Effort justification bias has been found as alternative explanation to recalibration in patients undergoing lumbar spinal surgery (Finkelstein, 2010). As discussed previously (Discussion section 5.4.1.1), effort justification bias may explain why participants in this study retrospectively assessed their OHRQoL as better that the actual baseline, to justify time and effort invested during the treatment.

5.4.2. Self-anchored scale

The second approach used to assess recalibration was the self-anchored scale. This is a novel method to assess response shift based on the approach developed by Visser and colleagues (2005). Participants are asked to provide self-ratings that described their best and worst imaginable oral health. Those ratings were then used as anchors to transform the follow-up assessment to obtain recalibration and true change scores.

Only sixty-eight (56.2%) of the 121 participants completed both assessments of the self-anchored scale, of whom 23 had incomplete or missing

information. Therefore, the analysis was conducted using data from 45 participants, which is less than a half of the sample.

The mode of administration was slightly different to the previous section of the questionnaire. The self-anchored scale contains open-ended questions, thus the effort required to complete the task is higher than only ticking boxes as is the case of the OHIP-Edent. The cognitive burden of defining the anchors was a difficult task for some participants, which may also explain the high attrition rate. There were several practical problems when this instrument was administered. The questionnaire was completed in the waiting room before the dental appointment. On busy days, participants struggled to complete the form on time. In addition, the self-anchor scale instrument was on the last page of the questionnaire booklet, thus information might have been omitted involuntarily, either because participants missed it, or through fatigue. Cumulatively, this response rate questions the feasibility of using self-anchored scales.

Despite these drawbacks, the results obtained from the 45 participants with complete data are intuitive. They show a significant improvement in perceived oral health with a large effect size. The large change was as expected as it was anticipated that DIT would have a profound effect improving the oral health of participants as reflected in the results of this study.

This finding may suggest another possible explanation on how catalyst, antecedents, mechanisms and RS interact to change assessments of health. The original model of Schwartz and Sprangers (1999) proposes that RS is the result of a catalyst and the interaction of antecedents and mechanisms. Findings using the self-anchored scale may indicate that the catalyst may cause changes in oral health without changes in internal standards, values or conceptualizations of oral health.

Although there was no recalibration, the perceived health of participants improved significantly with a large effect size.

Another possible, and perhaps more important explanation arises from the self-anchored scales (and another ideals measures): floor and ceiling effects. Although, the self-anchored scale total score showed no floor or ceiling effects, when indicating their worse and best imaginable oral health, there were such effects when participants indicated the endpoints of the scale (0 and 10, respectively) at both baseline and follow-up. When participants rate the endpoints of the scale it may be difficult to obtain significant differences between scores, thus recalibration cannot be detected because there is not a numerical difference between the baseline and follow-up assessments (Terborg et al., 1980). Therefore, assessments of change in the self-anchored scale are difficult and cannot be ruled out that the results were obtained by mere chance (Schmitt et al., 1984).

The ratings of perceived oral health among participants wearing conventional full dentures before the treatment were very low and it was expected that the DIT could improve their health. Participants receiving overdentures showed greater improvement than those receiving single and partial treatments. The true change was 3.2 points better after adjusting for RS compared to 1.2 and 1.4 points in the single crowns and implant-supported bridges groups respectively. It is noteworthy the mean age of participants with OD was 65.7 years old, while for the SDI the mean age was 32.6. Evidence suggests that compared with conventional dentures, OD are better improving oral health in elderly people (Heydecke et al., 2005b). Furthermore, the impact of oral disease decreases with age (Heydecke et al., 2003b).

Recalibration RS with the self-anchored scale was explored at the

individual level. Of the 51 participants who completed the self-anchored scale, 29 (56.8%) changed their internal standards downward, 18 (35.3%) upward and 4 (7.8%) did not recalibrate. One possible explanation for this finding is that rating the anchors was already difficult for the participants and then asking them to determine if the anchors changed or not, exacerbated this difficulty. However, a lack of gold standard in this measure resulted in arbitrary cut-off points to classify upward, downward or no recalibration. Moreover, the validity of this measure is questionable due to the low completion rate. It should also be noted that more participants appear to recalibrate with the self-anchored scale than with the then-test because the latter used a threshold MID to determine RS at the individual level. No such threshold was available for the self-anchored scale, and any movement of the end points was regarded as recalibration.

The feasibility of the self-anchored scale was limited and in this format should not be used. More attention should have been given during the piloting phase by testing the questionnaire with patients attending to the clinics. This might have contributed to provide a clearer guidance for participants. Likewise, it is worth to consider that not all the participants applied the same effort to respond this questionnaire. Thus, the self-anchored scale may show better response rate if administered through an interview.

5.4.3. Classification and regression trees

The third approach to assess response shift was the CRT. The tree was fitted using data from 100 participants who completed the OHIP-Edent at baseline and after their definitive restorative treatment. First, the sample was classified according to whether participants reported improvement or no improvement in self-perception of health using the global rating of oral health. In the CRT model, the OHIP-Edent total change score was the dependent variable and the changes on the 7 subscales were used as independent variables. The model obtained was a good fit as it explained the 88% of the variance in the total OHIP-Edent score change.

CRT may be a useful method to investigate patterns of recalibration because of its graphical representation of the data (Figure 4.6). Overall, participants reported better OHRQoL at follow-up (OHIP-EDENT $_{\text{post-pre}}$= -24 points) and as expected, most of them (70%) reported improved oral health after treatment as would be expected. The left side of the tree shows that the improvement in OHRQoL for most of the sample is even larger than the mean total change score for the OHIP-Edent (Node 1). Nonetheless, when exploring the tree, it can be observed that 5% of the sample (Node 18) reported worse OHRQoL after the treatment. Apparently, and observing the subscales trajectories across the tree, if functional changes remained unimproved (Node 1), then participants reported worse OHRQoL due to changes in social aspects of oral health (Nodes 4,10,18). However, these participants rated their perceived oral health as improved after the treatment (left side of the tree), thus it might be inferred that they recalibrated downwards. This explanation is consistent with the relationships predicted in

Locker's model of oral health (Section 2.2.3. Figure 1), which predicts that functional aspects of oral health determine levels of social handicap as a consequence of oral health problems (Locker, 1988). Likewise, this may reflect the importance that the individual gives to the treatment itself, rather than the influence that the treatment has on his/her daily life. It seems reasonable to consider that if the functional (or aesthetic aspects) of the treatment have not been fulfilled, this inevitably will restrict improvements on the social aspects of OHRQoL.

However, other explanations for this finding lie in the fact that people may have recalibrated their self-assessments of health based on recent health problems (Daltroy et al., 1999). Thus, for individuals with good overall oral health seeking for dental care because of problems with their dentures, measures of oral health focused on function may yield on a deteriorating status (as the OHIP-Edent functional limitations subscale), though the global assessments of oral health are more likely to be good (improvement of global ratings of oral health) (Schwartz et al., 2007).

The right side of the tree shows that 30% of participants (Node 2) indicated no change in perceived oral health but rated their OHRQoL as better after the treatment and from them, 15 reached the MID of 9 OHIP-Edent points (Node 12). According to the operationalization proposed, this corresponds to upward recalibration. Here, psychological (Node 5 and 6) and physical disability (Node 11 and 12) aspects of oral health might be playing a predominant role. For example, before the treatment an individual might have self-rated his/her perceived oral health as 'good'; after the treatment, this status might not have changed, but the psychological disability (for example, feeling 'embarrassed'

because oral health problems) caused by wearing dentures was improved by the DIT. Thus, this person rated his/her oral health as 'about the same' but with an improvement in OHRQoL. This finding might indicate two possible explanations: First, the individual actually recalibrated his/her internal standards and this is a new perspective on measuring oral health, in other words, the OHRQoL effectively improved with the treatment in participants with good self-perception of oral health. Second, this individual did not recalibrate, but the DIT had a little or no influence in his/her appreciation of general oral health.

Similar findings have been discussed in previous studies (Wyrwich and Tardino, 2006, Schwartz et al., 2007). Wyrwich and Tardino (2006) analysed interviews among participants with asthma, COPD or heart disease and compared qualitative findings with responses on OHRQoL. Many participants scores failed to observe any change over time in their emotions even when some effects of their treatment may cause depression or excitement. This may explain changes in scores of specific subscales of the questionnaire (such as emotional impacts) although the corresponding global oral health self-assessment may reflect no variations.

Nonetheless, this interpretation should be viewed cautiously. Statistical analysis such as CRT can identify predictors but not meanings of oral health to the participants, and self-ratings of oral health may measure different things in different populations. Studies suggest that, predicting ratings of global oral health, functional limitations and psychological aspects of the OHIP are more important for younger individuals and for older subjects, respectively. Moreover, people with lower levels of education apparently associated self-ratings of oral health based on actual factors as functional limitations and mean periodontal attachment loss than more holistic and contextual factors (Locker et al., 2005).

CRT additionally allows the investigation of reprioritization by exploring the importance of each variable to the model. At baseline and follow-up, the variable physical disability was the most important in the model, but the variable physical pain decreased. As might be expected, the treatment improved the OHRQoL of participants by reducing in 'painful aching' and 'sore spots' caused by the old dentures. However, the variable physical disability remained important, possibly because individuals are still not coping with their new dentures, manifesting as problems with their ability to eat.

In this particular CRT model, the social disability and psychological discomfort aspects of QoL increased in importance over time. After the treatment, participants might be more aware of the psychological impacts of dental problems on their everyday life. Thus, psychological aspects such as 'feeling worried' about dental problems might be rated as more prominent. And the same applies to the social aspects, they are more important after the treatment but as described previously, related to the functional aspects of OHRQoL. Nonetheless, the increased importance between the baseline and follow-up assessments of one variable necessarily implies a decline on the other. That is, these domains may have increased in importance simply because pain diminished. Thus, the interpretation of the model must be careful. Changes on variable importance may be reprioritization, but also a mathematical artefact.

This is the first time that classification and regression trees have been used to assess RS in people with dental implants or in relation to oral health. Dental implant treatment is considered as an optimal solution to replace tooth loss. Therefore, it is expected to cause great effects on the OHRQoL. CRT showed patterns consistent with recalibration and reprioritization of participants that

might explain why the overall improvement on OHRQoL was less than expected.

One of the advantages of the CRT is the graphically representation of the data. Clusters of participants with certain characteristics can be easily identified with this method and this is important when the analyses are performed in large data sets. Nonetheless, trees are subjects of large variance and slight changes in data might result in different trees.

Based on these data, CRT is recommended as an effective approach to assess RS. CRT revealed patterns of RS in participants after DIT. This method does not require retrospective assessments, thus it has the advantage that is not susceptible to recall bias, nor does it increase the burden on participants.

5.4.4. The three approaches compared

The results of the then-test, the self-anchored and the CRT approaches are compatible. Overall, the three approaches detected RS in all treatment groups and showed similar patterns of direction.

The improvement in OHRQoL associated with DIT was reduced when incorporating RS assessed through the then-test, the self-anchored scale and the CRT. Using the then-test, the treatment effect was reduced by 4.0 OHIP-Edent points and in 0.3 points by using the self-anchored scale. With the CRT the magnitude of RS cannot be directly assessed, but can be inferred through qualitative interpretations of the numerical findings of the model. Therefore, CRT demonstrates changes in patterns of RS similar to those obtained with the then-test and self-anchored scale approaches. The magnitude of improvement in

OHRQoL was almost halved among participants who rated their general oral health as not improved (Node 2) and deteriorated further reaching only 3.4 points when recalibration downwards was observed (Node 18).

The then-test was validated by the self-anchored scale because both showed similar recalibration patterns, i.e participants changed their internal standards downwards. Nonetheless, it is not possible to compare different areas as represented by the OHIP-Edent subscales as these are not represented in the self-anchored scale, which measures perceived oral health.

As CRT is not susceptible to recall bias, findings of this study suggest that both, CRT and the then-test measure the same concept. Similarly, areas susceptible to recalibration are comparable between the then-test and the CRT. By definition, the observed change (follow-up minus baseline scores) is the same for both approaches. Functional limitation apparently is most susceptible to recalibration as shown by the then-test and the CRT. The then-test indicated that the change in the functional limitations subscale was statistically significant with a medium effect size. In the CRT analysis, functional limitation (along with social disability) was the variable responsible for the first split of the data (indicating its importance) among those participants who, despite improved self-rated oral health, rated their OHRQoL as worse at follow-up. A possible explanation is that individuals when asked to assess QoL in a clinical context (as the waiting room) may tend to assess the functionality of the prosthesis or the quality of the treatment itself, rather than the perceived impact that oral health has on their daily life. Thus the functional aspects appear to be more important. From this point of view, the functional limitation subscale is recalibrated, manifested as a change in the then-test score but also, reprioritized because is now more relevant, and this is

corroborated through the exploration of the tree in CRT analysis. Likewise, the dental treatment among the participants of this study has been long and complex. Frequently, they had uncomfortable dentures or provisional restorations meeting some aesthetic requirements, thus the most important aspects to assess for their OHRQoL were the functional rather that the social or psychological aspects. Furthermore, is likely that assessing these individuals over time, other aspects of oral health may come to light if they are satisfied with the treatment.

As can be seen, the comparison of approaches to assess RS is complex. The different methods assess different aspects of RS and the operationalization may differ. The then-test, which is the most frequently used approach, assesses only recalibration. The self-anchored scale focuses on perceived oral health and requires the participant to describe anchors using a cognitive process it shares characteristics of the individualized approaches. Thus, it may be able to detect more accurately not only recalibration, but also reconceptualization of oral health if the anchors are compared qualitatively before and after the intervention. Similarly, the CRT is able to detect recalibration (on changes in subscales scores) and reprioritization (changes in the variable importance), and importantly, the CRT allows the assessment of patterns of change by observing trajectories of the subscales within the tree.

Another complexity is that the different types of RS are likely to occur together and may cancel each other out (Schwartz et al., 2013). The then-test used in this study detected recalibration, but is susceptible to recall bias. CRT detected recalibration and reprioritization, but is susceptible to large variance. Therefore, it is important to explore the convergent validity of complementary methods using several at once for this purpose and a more comprehensive assessment of RS. Only

three studies have explored convergence between methods. Visser et al (2005) compared the ability of the then-test, the anchor-recalibration scale and the SEM to detect RS in patients with cancer and found convergent validity in the results of the then-test and the SEM. Krasuska (2014a) explored the results of the then-test and ideals approach, detecting recalibration, and her results were divergent (then-test found downward recalibration and ideals upward). Mayo et al (2008) validated residual analysis against the then-test using data in a longitudinal study with participants post stroke and found convergence between the two methods in their ability to detect RS. Thus, the triangulation is essential to validate different methods used to assess RS.

In terms of feasibility, the then-test was easily implemented and clearly understood by participants, but the self-anchored scale required an additional cognitive effort, which apparently caused a large amount of participant loss. This disadvantage severely limits the feasibility of this approach. Moreover, the self-anchored scale may be assessing another concept than RS.

Alternatively, the then-test carried a participant burden because the number of items is doubled at follow-up assessments. The CRT does not increase the burden on participants and is not subject to recall bias, as it does not require retrospective assessment. Thus, this approach is a good approach to assess RS.

Therefore, results of this study suggest that the then-test and CRT have good convergent validity because they show similar patterns of RS. This might indicate that both approaches measure the same concept. This similarity might also indicate that the then-test was not subject to recall bias, as both methods use statistically different operationalization of RS leading to the same result. Thus, when using together both approaches are adequate to assess RS. In this regard, the

then-test and the CRT can be seen as complementary, offering different perspectives on RS to yield a more comprehensive understanding of how the phenomenon manifests.

5.5. Application of the findings to the Sprangers and Schwartz model of response shift

These data triangulate to demonstrate that RS occurs in individuals receiving dental implants. RS has been defined as a change in the meaning of peoples' QoL as a result of recalibration, reprioritization and reconceptualization. The theoretical model proposed by Sprangers and Schwartz (1999) posits that RS is the result of a catalyst and the interaction of antecedents and mechanisms (Section 2.2.4.1, Figure 2.3). Antecedents are stable characteristics of the individual and mechanisms are behavioural, cognitive and affective processes that adjust to change health state (Schwartz, 2010).

The Sprangers and Schwartz model may help to detect possible explanatory variables influencing changes in HRQoL due to an intervention. Many of the effects described by Sprangers and Schwartz (1999) can be found in the results of this study. RS was detected in people receiving DIT. Overall, participants recalibrated their scales of measurement downwards. Therefore, the magnitude of improvement of OHRQoL decreased after adjustment of RS. Accordingly, assessments of change in OHRQoL are influenced by recalibration, reprioritization and reconceptualization of oral health.

However, another possible pathways explaining the relationships among catalysts, antecedents, mechanisms and RS may influence changes in perceived

OHRQoL and not explored in the original model are proposed from the results of this study. Figure 4.9 depicts in bold the original Sprangers and Schwartz model of RS. The new relationships evident in these data are depicted in red and are detailed below:

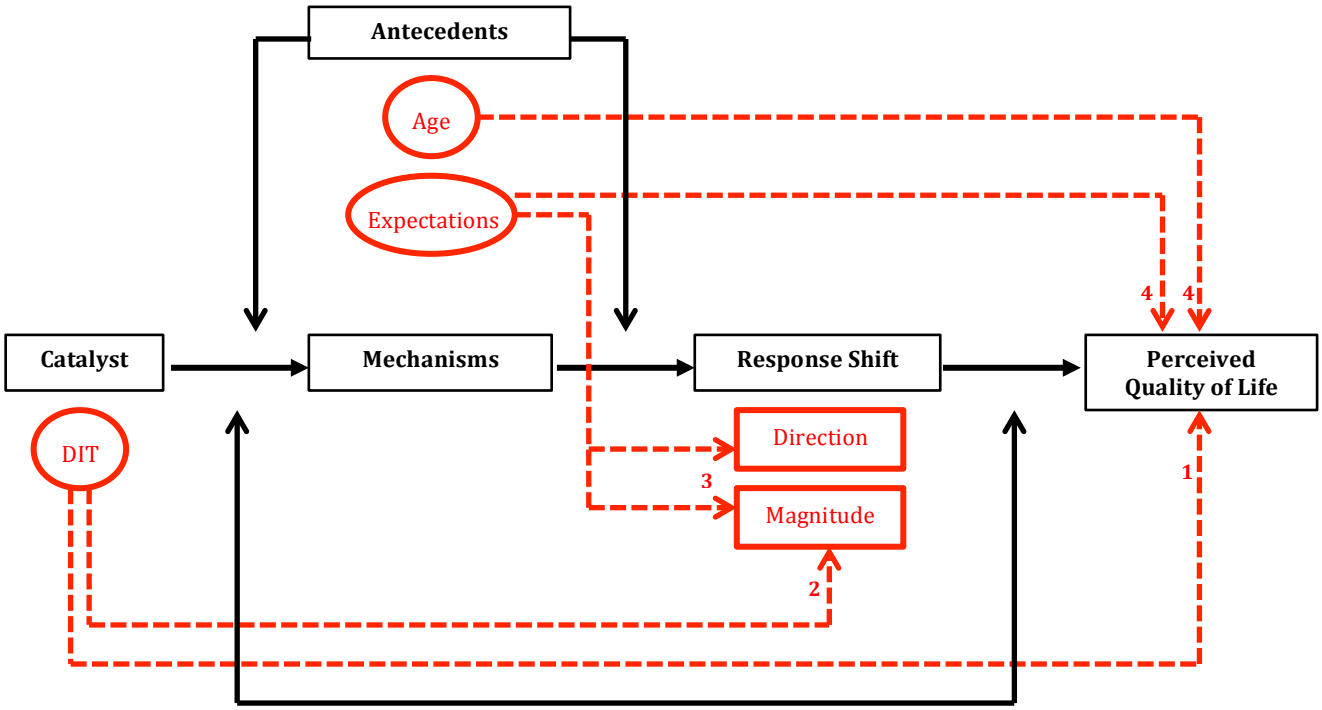


Figure 4.9. Application of the findings to the Sprangers and Schwartz (1999) model of response shift. The original model of response shift is depicted in bold black. RS is the result of a catalyst and the interaction of antecedents and mechanisms. The new pathways proposed are depicted in red dashed arrows.

1. Catalyst influencing the assessment of OHRQoL.
2. Catalyst influencing the magnitude of recalibration.
3. Antecedents influencing magnitude and direction of RS
4. Effect of antecedents in quality of life.

1. Catalyst influencing the assessment of OHRQoL.

Improvement in OHRQoL after DIT is expected and the benefits of DIT have been widely reported (Allen and McMillan, 2002, Awad et al., 2003b, Heydecke et al., 2005a, Emami et al., 2009, Bilhan et al., 2011, Furuyama et al., 2012, Guillaume, 2016a, Raes et al., 2017). Thus, the catalyst (in this case DIT) may cause changes in OHRQoL without changes in internal standards, values or the conceptualization of oral health. This could be inferred from the findings of the self-anchored scale: despite the negligible RS effect, there was a significant improvement of the QoL catalysed by the treatment itself. Thereby, RS is not inevitable and only happens in some individuals.

2. Catalyst influencing the magnitude of recalibration.

Allen et al. (2006) demonstrated that improvements in OHRQoL were significantly greater for individuals receiving overdentures than those who refused them. Results in the present study indicated that recalibration was large and statistically significant among patients receiving overdentures, but not for the implant-supported single crowns and bridges treatments (Results section 4.4.1.2, table 4.7). Thus, the type of treatment may be considered as a predictor of the magnitude of recalibration. The improvement in OHRQoL among completely edentulous individuals receiving overdentures is large, but in individuals treated with single crowns, the improvement is significant in the anterior but not in the molar areas (Ponsi et al., 2011)

3. Antecedents influencing the magnitude and direction of RS

Although some participants recalibrated their internal standards upwards, the recalibration did not succeed improving OHRQoL. This can be observed in the node 12 of the CRT (Figure 4.6). Fifteen participants manifesting no improvement in OHRQoL, recalibrated upwards to cope with changes in psychological and physical disabilities dimension of oral health. However, the improvement was as little as 2 points of the OHIP-Edent, which is not clinically relevant.

One possible explanation is that expectations (antecedent) affected recalibration. High expectations are frequently found in individuals seeking DIT (Allen et al., 2006) and may influence the magnitude and/or direction of RS without mechanisms involved if these expectations are unmet. People have different expectations of the results of their treatment, but also the value of their expectation may change over time (Carr et al., 2001) influencing the magnitude and direction of RS into different extents.

4. Effect of antecedents on quality of life.

Antecedents may predict changes in OHRQoL. Studies have demonstrated that elderly people report better QoL than younger people with similar treatment characteristics (Awad et al., 2000a, Heydecke et al., 2003b). Thus, antecedents such as age may account for the change of QoL without changing internal standards, values or concepts of oral health.

Similarly, the high expectations of individuals seeking for DIT have been widely reported (Allen et al., 1999, Rustemeyer and Bremerich, 2007, Yao et al.,

2014). Therefore, persons with high expectations may have overestimated the effects of DIT at baseline and evaluated their QoL as poorer than actually was. Unmet expectations may influence direct and negatively the assessment of QoL after the treatment.

Further investigation of these possible new relationships within the Sprangers and Schwartz model is essential. Structural equation model (SEM) could be used to verify if these findings are replicable.

In summary, whist these data largely confirm and support the Sprangers and Schwartz model, several modifications of it seem appropriate. Those changes are (Figure 4.9):

1. Catalyst influencing the assessment of OHRQoL.
2. Catalyst influencing the magnitude of recalibration.
3. Antecedents influencing magnitude and direction of RS
4. Effect of antecedents in quality of life.

5.6. Implications of response shift for clinical research

Despite the benefits of using patient-reported outcomes and their wide recognition for providing important information in health care, their use in dentistry is not as frequent as it could be. Furthermore, when assessments of OHQoL are included, they are frequently reported as simple before-after scores with comparisons that do not reflect improvements in oral health that may have been different if response shift had been considered.

The results of this study showed that RS occurred in people with DIT. When using the then-test, the magnitude of the OHIP-Edent change scores were reduced if recalibration was accounted for, reflecting that participants changed their internal standards downwards over time. This is supported with the classification and regression trees analysis, which also demonstrate downward recalibration among many participants. The results of a simple comparison of mean OHIP-Edent scores at baseline and at follow-up (unadjusted change) might reflect improvement in OHRQoL, but accounting for RS, the benefits of the treatment perceived by the individual were lower. This information might be useful in the clinical field. Adequate information provided during the treatment, might regulate patient's expectations and maximize the treatment gains.

One of the major advantages of using assessments of quality of life is the evaluation of the benefits of the treatment from the individual perspective. Thus, their incorporation in clinical research is recommended. However, there is limited knowledge on how to interpret change scores. For example, some participants in this study may have had difficulties eating because of their dental problems. After the treatment they may have been able to eat better, but may still have had

problems eating hard food. If they were asked to rate their OHRQoL after the treatment, the improvement may be small. These differences may be attributable to changes in internal standards, so the simple comparison before-after treatment does not reflect the true change in the health status if RS is not accounted for.

Discrepancies between clinical measures and people's subjective assessments are common. Moreover, changes in the meaning of QoL may vary within and between individuals. Currently, instruments used to assess OHRQoL are not designed to account for RS. Instead they assume that people respond consistently on measurement scales and are directly comparable within and across individuals over time. Thus, individual differences in response have been considered as a measurement error (Ring et al., 2005). The theory of response shift proposes that to assess changes in QoL, individual differences in cognitive appraisal process should also be accounted for, not as sources of error, but as an intrinsic property to the QoL measure (Rapkin and Schwartz, 2004). Thus, studies incorporating clinical and quality of life assessments can benefit from including response shift in their ability to distinguish real changes resulting from the treatment from those changes caused by adaptation.

Response shift has important implications for comparisons within different groups exposed to the same catalyst, inducing an RS effect. In the present study, for example, dental implant treatment was the catalyst for people of different ages and types of treatment. The size of the RS effects varied from large (ES=0.5) on the elderly group to moderate (ES=0.3) on the younger participants when using the then-test. On average, the magnitude of recalibration was small, becoming more difficult to observe the treatment effect. It may be that as older participants received overdentures, their improvement was higher than those

younger participants receiving single crowns. However, another possible explanation is that younger individuals recalibrated to a larger extent to the upward side. Thus, the magnitude of RS was also lower than the elderly group. Therefore, RS may reveal the true change in the OHRQoL that is needed to evaluate the efficacy of dental implant treatment, that otherwise would remain unnoticed.

5.7. Strengths and Limitations of the study

There are several advantages in the design of this study. Its longitudinal nature allowed detailed investigation of changes in oral health during DIT and enabled precise interpretations of those changes, revealing complexities previously unidentified. This research allowed the study of RS using three different approaches including two design-based and one statistical approach and the results were largely comparable. The convergent results obtained corroborated the detection of RS in people with dental implants and provided complementary perspectives.

Moreover, incorporating the then-test in OHRQoL measures such as the OHIP-Edent may yield new insights in evaluations of the benefits of the dental treatment. Likewise, the classification and regression trees approach proved to be an effective method to assess RS without increasing the burden on participants and or the risk of recall bias. This is the first study to use CRT in relation to dental implant treatment.

However, this study also has limitations. The study sample was unequally distributed regarding DIT modalities. For example, participants receiving OD comprised only a 12.6% of the whole sample. However they experienced

significant improvements in OHRQoL. Thus, repeating this study in a population receiving this or other treatments may validate these findings further or detect different patterns of response shift.

The self-anchored scale was an approach with limited application. It apparently introduced excessive cognitive efforts for some participants resulting in a large amount of missing data, which may have resulted in a loss of power and attrition bias. It is advisable the development of a guideline for participants to complete this instrument.

With the absence of a gold standard for the duration of studies investigating response shift, the follow-up period for this participants varied from 3 to 6 months. Thus, these findings need to be tested in studies with shorter and longer follow-up. Nonetheless, as this is the first study assessing the convergent validity of three RS methods, can serve as the basis for future research.

6. CONCLUSIONS AND RECOMMENDATIONS

6.1. Summary of the findings

This study explored response shift in participants receiving dental implant treatment and investigated the convergent validity of three approaches to assess RS: the then-test, the self-anchored scale and the classification and regression trees. Data were collected before and after the definitive restorative treatment in patients previously given dental implants.

Overall, the OHQoL of participants on this study improved. RS affected evaluations of this improvement. RS was detected by all three approaches. Overall, adjusting for recalibration reduced the magnitude of the benefit of treatment. Using the then-test and the self-anchored scale, participants on average recalibrated their internal standards downwards. The classification and regression tree approach showed upward and downward recalibration and reprioritization toward social and psychological aspects of QoL.

This thesis has contributed to current knowledge by identifying RS in people receiving DIT and detailing how the OHRQoL of people changed after receiving implant-supported dental prosthesis in a number of ways.

This chapter summarizes the findings and recommendations arising from this study.

6.2. Conclusions

1. Response shift was found in participants receiving DIT.
2. Using the OHIP-Edent with the then-test and the self-anchored scale, the OHRQoL and self-perceived oral health improved after the treatment, but response shift reduced the magnitude of change.
3. Participants on average recalibrated their internal standards downwards when the then-test and the self-anchored scale were used.
4. CRT detected recalibration and reprioritization response shift.
5. Recalibration detected by CRT shows groups of participants recalibrating upwards, downwards and no recalibration.
6. The magnitude of recalibration was related to age. Recalibration was smaller in younger participants.
7. CRT is recommended to assess RS because it is not susceptible to recall bias, nor does it increase the burden on participants.
8. The convergent results of these approaches support the validity of the then-test and the CRT, especially because they use statistically independent operationalizations of RS.
9. The convergence between the then-test and the CRT indicated that the then-test was not susceptible to recall bias in this study.
10. Using several methods to assess RS allows the view complementary perspectives that enhance its interpretation.
11. The self-anchored scale had limited feasibility due to loss data. The results suggest that defining anchors required additional cognitive efforts. Therefore, this method cannot be recommended for the

assessment of RS.

12. Three approaches to assess RS showed that at the individual level, recalibration occurs upward, downward and no recalibration.
13. These data largely support the Sprangers and Schwartz model of RS.
14. New relationships among the components of the original model of response shift are proposed: catalysts influencing the assessment of OHRQoL, catalysts influencing the magnitude of recalibration, antecedents influencing magnitude and direction of RS and the effect of antecedents in quality of life.
15. Including RS regularly assessments may improve OHRQoL measures in their ability to detect the real benefits of the treatment.

6.3. Recommendations

This thesis investigated the methodology of research evaluating dental implant treatment longitudinally. Consequently most recommendations are for research, which are detailed below:

1. RS should be accounted for when changes in OHRQoL are assessed in individuals with DIT.
2. The incorporation of the then-test as part of the assessment of OHRQoL is recommended.
3. CRT as a statistical approach is recommended to assess RS in OHRQoL, especially in dental implant treatments.
4. Triangulation of different approaches to evaluate RS is recommended. The

convergent results of the then-test and the CRT indicate that they should be used together to assess RS to give complementary perspectives.

5. Based on the result of this study and previous evidence, the role of expectations on DIT should be further investigated.
6. The new relationships proposed to the original model of RS should be validated.
7. These data support the practice of carefully managing patients' expectations of DIT.

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8. APPENDICES

Appendix A:

Approval Letter from National Ethics Research Committee

Research passport

Appendix B:

Study protocol

Appendix C:

Information Sheet

Participant Consent Form

Participant follow-up letter

Appendix D:

Questionnaires booklet

Appendix A:

Approval Letter from National Ethics Research Committee

Research passport

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - South Yorkshire
Unit 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0191 4283563

24 December 2014

Mrs Carolina Machuca
University of Sheffield
Academic Unit of Dental Public Health
School of Clinical Dentistry
19 Claremont Crescent
Sheffield
S10 2TA

Dear Mrs Machuca

Study title:	**How peoples' ratings of dental implant treatment change over time: Response Shift in patients with dental implants.**
REC reference:	**14/YH/1320**
IRAS project ID:	**166740**

The Proportionate Review Sub-committee of the NRES Committee Yorkshire & The Humber - South Yorkshire reviewed the above application via correspondence.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager Mrs Helen Wilson, nrescommittee.yorkandhumber-southyorks@nhs.net.

Ethical opinion

On behalf of the Committee, the sub-committee gave a **favourable ethical opinion** of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations.

Registration of Clinical Trials

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

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

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

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

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

Ethical review of research sites

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

Summary of discussion at the meeting

Social or scientific value; scientific design and conduct of the study

Members queried how the follow up questionnaire would be distributed and returned.

You explained that once the restorative treatment had been completed, a review was conducted by Clinical team three months after the placement of the final restoration. During this review, the second wave of questionnaires would be given to the participants. Participants would complete the questionnaires whilst they wait. Those participants who do not attend their review would be mailed the questionnaire by post with a pre-paid envelope enclosed to send it back to the University of Sheffield.

Informed consent process and the adequacy and completeness of participant information

Members queried in the consent form, the point relating to consenting for data to be used in future research was unclear, did it mean that they would send out the second questionnaire, or something else. An explanation was requested.

You explained that the data collected would be used in this research only. There was no intention to use this data in future research. This statement was an oversight and would be removed of the Consent Form. An updated version of the Consent Form was submitted.

Other general comments

Members requested an explanation of the technical term edentulous in A13.

You explained that "Edentulous adults" refer to people with one or more missing teeth.

Suitability of research summary

Members requested that the Summary in A6-1 be rewritten, along with typographical errors in the first word "Loosing" should be "Losing".

Members explained that the description of people's meaning of quality of life was difficult to understand and requested it was rewritten in lay language.

The applicant resubmitted the summary of the research.

The Committee was satisfied with the responses given to the issues raised and that the IRAS form has been amended with the revised summary.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Covering letter on headed paper [STH18703-Covering letter]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors		

only) [STH18703-Evidence of Sponsor insurance]		
IRAS Checklist XML [Checklist_16122014]		16 December 2014
Non-validated questionnaire [STH18703-Non Validated questionnaire baseline]	Version 1	26 November 2014
Non-validated questionnaire [STH18703-Non Validated questionnaire Follow up]	Version 1	26 November 2014
Participant consent form [STH18703-Participant consent form]	Version 2	22 December 2014
Participant information sheet (PIS) [STH18703-Participant information sheet]	Version 1	01 December 2014
REC Application Form [REC_Form_16122014]		16 December 2014
Research protocol or project proposal [STH18703-Research Protocol]	Version 1	26 November 2014
Summary CV for Chief Investigator (CI) [STH18703-CV for Chief Investigator]		
Summary CV for student [STH18703-CV for Student Carolina Machuca]		
Summary CV for supervisor (student research) [STH18703-CV Academic Supervisor Peter G. Robinson]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [STH18703-Flowchart of protocol]	Version 1	01 December 2014
Validated questionnaire [STH18703-Validated questionnaire baseline]		
Validated questionnaire [STH18703-Validated questionnaire Follow up]		

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of

changes in reporting requirements or procedures.

User Feedback

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

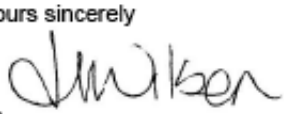
HRA Training

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

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

14/YH/1320	**Please quote this number on all correspondence**

Yours sincerely



pp

Dr Ian Woollands
Chair

Email: nrescommittee.yorkandhumber-southyorks@nhs.net

Enclosures:	*List of names and professions of members who took part in the review*
	"After ethical review – guidance for researchers"
Copy to:	Ms Samantha Heaton, Sheffield Teaching Hospital NHS Foundation Trust

NRES Committee Yorkshire & The Humber - South Yorkshire

Attendance at PRS Sub-Committee of the REC meeting via correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Ahmed H Abdelhafiz	Consultant Physician, Elderly Medicine	Yes	
Dr Duane Mellor	Assistant Professor in Dietetics	Yes	
Dr Ian Woollands (Chair)	Retired Clinical Director, Occupational Health	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kerry Dunbar	REC Assistant
Mrs Helen Wilson	REC Manager

Ref: STH18703 SH/DP

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

03 March 2015

Prof Peter Robinson
Academic Unit of Dental Public Health
School of Clinical Dentistry
19 Claremont Crescent
Sheffield S10 2TA

Dear Mr Robinson,

Project Authorisation
NHS Permission for Research to Commence

STH ref:	STH18703	
NIHR CSP ref:	N/A	
REC ref:	14/YH/1320	
MHRA ref:	CTA No: N/A	EudraCT No: N/A
Clinical Trial reg no:	N/A	
Study title:	Response Shift in patients with Dental Implants Treatment	
Chief Investigator:	C Machuca Vargas, University of Sheffield	
Principal Investigator:	P Robinson, University of Sheffield	
Sponsor:	Sheffield Teaching Hospital NHS Foundation Trust	
Funder:	N/A Unfunded	
NIHR TARGET FPFV RECRUITMENT DATE	12 May 2015	

MANDATORY REPORTING OF RECRUITMENT
The Research Department is obliged to report study set up and recruitment performance for the Trust to NIHR and to report research activity for all studies to Trust Board. In order to meet these reporting requirements please be advised that it is now a ***mandatory*** condition of STH project authorisation that recruitment to ***all*** research studies* at STH is reported into EDGE (the Accrual Collation and Reporting Database). It is essential that recruitment is entered into EDGE ***real-time*** to enable directorates to accurately monitor performance. Please see item 2 of the 'Conditions of R&D Authorisation' for further details.

Please be informed that failure to report recruitment to EDGE may result in loss or delay in funding to the Trust and to the Directorate.

*Information regarding EDGE eligibility for reporting is detailed in the 'Conditions of R&D Authorisation'

The Research Department has received the required documentation as listed below:

1.	**Sponsorship Agreement** **Clinical Trial Agreement** **Material Transfer Agreement** **Funding Award Letter**	N/A N/A N/A N/A
2.	**Monitoring Arrangements**	N/A
3.	**STH registration document**	REC Form, 16 Dec 14
4.	**Evidence of favourable scientific review**	UoS, 21 Nov 14
5.	**Protocol – final version**	Version 1, 26 Nov 14
6.	**Participant Information sheet**	Version 1, 01 Dec 14
7.	**Consent form**	Version 2, 22 Dec 14
8.	**Letter of indemnity arrangements**	UoS, 27 Nov 14
9.	**ARSAC certificate / IRMER assessment**	N/A
10.	**Ethical review- Letter of approval from NHS REC**	South Yorkshire REC 24 Dec 14
11.	**Site Specific Assessment**	SSI Form, 03 Mar 15
12.	**Clinical Trial Authorisation from MHRA**	N/A
13.	**Evidence of hosting approvals** - STH Principal Investigator - Clinical Director - Directorate Accountant - General Manager - Research Finance - Data Protection Officer	 P Robinson, 23 Dec 14 A Loescher, 24 Dec 14 A Lowe, 23 Dec 14 J Eustace, 24 Dec 14 E Fraser, 18 Dec 14 P Wilson, 12 Dec 14
14.	**Honorary Contract/Letter of Access**	Carolina Vargas, 25 Feb 15
15.	**Associated documents** - Non validated OHIPEDENT questionnaire baseline - Non validated OHIPEDENT questionnaire follow up - Validated questionnaire baseline - Validated questionnaire follow up - Flowchart	 Version 1, 26 Nov 14 Version 1, 26 Nov 14 Version 1, 26 Nov 14 Version 1, 26 Nov 14 Version 1, 01 Dec 14

This project has been reviewed by the Research Department. NHS permission for the above research to commence has been granted on the basis described in the application form, protocol and supporting documentation on the understanding that the study is conducted in accordance with the Research Governance Framework, GCP and Sheffield Teaching Hospitals policies and procedures (see attached appendix).

Yours sincerely

Professor S Heller
Director of R&D, Sheffield Teaching Hospitals NHS Foundation Trust
Telephone +44 (0) 114 2265934, Fax +44 (0) 114 2265937

Sheffield Teaching Hospitals NHS Foundation Trust

Conditions of R&D Authorisation

Please note the following requirements that must be adhered to by the investigator when embarking on a research project at Sheffield Teaching Hospitals NHS Foundation Trust (STH). The investigator must update the Research Department of the following:

1. Safety reporting

Investigators should ensure that they elicit information regarding adverse events from participants at each study visit. If a Serious Adverse Event (SAE) is discovered the Investigator must alert the Sponsor immediately (within 24 hours) and must comply with sponsor requests for further information to ensure that events are reported to ethics and regulatory bodies within the timelines laid down in the Medicines for Human Use (Clinical Trials) Regulations 2004. Investigators should refer to the STH Research Department SOPs available by request or on the Department website http://www.sheffieldclinicalresearch.org for further guidance.

2. Recruitment reporting in EDGE

It is now a *mandatory* requirement of STH NHS Permission that recruitment to research studies at STH is reported using the EDGE and essential that recruitment is entered into EDGE *real-time.*

EDGE Exempt Studies

Not all studies are required to use the EDGE Accrual Collation and Reporting Database. Your CRO Research Coordinator will confirm during the set-up phase of your study whether you are required to record recruitment into EDGE.

Those studies which are EDGE exempt:

Studies conducted in a STH Clinical Research Facility (CRF)* - These studies will be under the management of the CRF where accrual will be captured in the CRF Manager database.

*Recruitment for CRF Link studies (where the CRF provides the research environment for the PI and their team) will require reporting into EDGE as data for these studies are not captured in CRF Manager.

Definition of Recruited Participant: Eligible participant recruited onto the trial.

Note: Screen failures do not count as a recruited participant.

Once you have been issued with a login for EDGE, please refer to the training materials at the link below to use the system:
http://www.sheffieldclinicalresearch.org/clinical-research-office/setting-up-running-your-study

For further information regarding the use of EDGE or training provision please contact your local STH EDGE Administrator Gaurika Kapoor (gaurika.kapoor@sth.nhs.uk).

3. Protocol Amendments

Investigators should alert the Research Department if there is a protocol amendment subsequent to initial Trust Research Governance authorisation. An amendment includes any changes which affect the conduct of the study. This may include for example any changes to study documentation e.g. a patient information sheet, a decision to use advertising, changes to staff or revisions to study timelines. Where studies are sponsored by STH, changes to the protocol and/or other study documents must be submitted to the Research Department for review prior to ethics submission to ensure that they are appropriately categorised as substantial or non-substantial amendments and that appropriate scientific review is carried out.
Where studies are not sponsored by STH, the revised documentation accompanied by a REC approval letter should be submitted to your Research Coordinator in order for Trust Authorisation to be issued before implementation of the amendment.

4. Training

In accordance with the principle of Good Clinical Practice, investigators should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial related duties and functions. The investigator is responsible for ensuring that the research team have the requisite study-specific/GCP training. If anyone joins the team after authorisation has been granted, their GCP status should be checked by the Principal Investigator and notified to the Research Department who will arrange access to our on-line GCP training programme if required.

5. Study status

Under the Research Governance Framework, STH has a responsibility to maintain an accurate record of all research undertaken within the organisation or involving participants, organ, tissue or data obtained through the organisation. A requirement of Research Governance authorisation is that the Investigator provides ongoing information on study progress. The investigator should inform their Research Coordinator on an ongoing basis of the dates where major milestones are reached as defined below. Equally an investigator should inform their Research Coordinator of any revisions to timelines for example, if the study fails to recruit as originally forecast.

Milestone	Definition
Registered	Project is registered with STH Research Department
Withdrawn (before authorisation)	PI has withdrawn the study application before Research Governance Authorisation
Authorised	Project has received STH Research Governance Authorisation
Open to recruitment	Research team are actively identifying/screening/recruiting participants and/or collecting data
First patient First visit (FPFV)	Date of first visit at which data (e.g., medical history) is collected from the first study subject to determine eligibility to participate in a given clinical study
Abandoned (after authorisation)	Study previously given Research Governance Authorisation has been abandoned by the PI prior to recruitment
On hold	Study is delayed/not active but plans to continue at some point. This delay could be resource issues such as finance, research team personnel etc or a decision of Sponsor for safety concerns, business issues etc.
Recruitment ended	All participants/data sources identified. Participants are currently actively involved in research process. Questionnaires/interviews/interventions are being undertaken. Data collection from identified sources is ongoing
Last patient Last visit (LPLV)	For IMP studies, if not otherwise defined in protocol, this is the end of trial and MHRA can be informed of end of study at this point as per clinical trials toolkit advice http://www.ct-toolkit.ac.uk/_db/_documents/Protocol.pdf. For STH sponsored studies we expect safety data to be collected for a minimum of 30 days post last patient last dose.
Long-term follow up	For studies where last on-site patient visit has occurred and patients are followed to final outcome e.g. mortality/morbidity at X years post project
Database Lock	All data collected and cleaned. No further changes of data expected/allowed
Close out at site	No further research project activity expected at site. All study material has been removed/disposed.
Published	Research project results have been published (May occur after archiving)
Archived	All research documentation has been archived (on or off site). Project results may not have been published at this stage.

PI: Principal investigator.

6. Standard Operating Procedures (SOPs)

Investigators should familiarise themselves with any STH SOPs which are relevant to the study they are undertaking. Evidence of training in these SOPs should be recorded in your individual SOP training log, a template log can be found at http://www.sheffieldclinicalresearch.org/clinical-research-office/useful-documents. Investigators may also wish to develop study specific SOPs, if appropriate. Copies should be kept in the Investigator Site File. Investigators should ensure that they use the most current SOPs or file note why this is not the case. A full list of STH Research Department SOPs can be found on the departmental website http://www.sheffieldclinicalresearch.org

7. Progress reports

A copy of all interim, annual or final reports sent to the Research Ethics Committee, Regulatory Authority or Sponsor must be sent to your Research Coordinator in the Research Department. This may include annual progress, end of study, expedited SUSAR or safety reports.

8. Archiving of Essential Documentation at the End of a Study

The lead investigator is responsible, according to the principles of Good Clinical Practice, for arranging for the archiving of their research data whether they are taking part in a commercial trial, a non-commercial trial or one that is funded from their own account. The UK Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 cover the maintenance of a trial master file and the archiving of essential documentation. Investigators must adhere to these Regulations and ensure that facilities used to archive essential documents are compliant with the requirements of the Regulations. The Sponsor of a study will advise the investigator as to when documents may be destroyed.

9. Audit & Inspection

It is a requirement of STH Healthcare Governance that an investigator alerts their Research Coordinator within the Research Department as soon as they receive notification that an external body will be entering STH premises to carry out an audit or inspection of any aspect of their research.

10. The Use of Human Tissue Samples in Research

Investigators should familiarise themselves with the provisions of the Human Tissue Act 2004, a framework for regulating the storage and use of human organs and tissue from the living, and the removal storage and use of tissue and organs from the deceased for specified purposes. All investigators intending to collect/use human tissue samples in the course of their study must advise the Research Department of this intention upon registering the study. Similarly, the intention to create and maintain a tissue bank must be registered with the Research Department as the storage of tissue for unspecified research purposes is licensable under the HT Act.

Sheffield Teaching Hospitals NHS
NHS Foundation Trust
Research Department

Letter of access for researchers who do not require an honorary research contract

25 February 2015

Carolina Machuca
University of Sheffield
19 Claremont Crescent
Sheffield
S10 2TA

Dear Carolina,

STH ref: STH18703
Study title: Response Shift in patients with Dental Implants Treatment
Chief Investigator: Carolina Machuca
Principal Investigator: Peter Robinson

Letter of access for research
This letter confirms your right of access to conduct research through Sheffield Teaching Hospitals NHS Foundation Trust for the purpose and on the terms and conditions set out below. This right of access commences on **25 February 2015** and ends on **25 February 2018** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

The information supplied about your role in research at Sheffield Teaching Hospitals NHS Foundation Trust has been reviewed and you do not require an honorary research contract with this NHS organisation. We are satisfied that such pre-engagement checks as we consider necessary have been carried out.

Status
You are considered to be a legal visitor to Sheffield Teaching Hospitals NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by this NHS organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

Reporting Arrangements
While undertaking research through Sheffield Teaching Hospitals NHS Foundation Trust you will remain accountable to your place of study **University of Sheffield** but you are required to follow the reasonable instructions of **Peter Robinson** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Legal Claims
Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

Policies and Procedures
You must act in accordance with Sheffield Teaching Hospitals NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

You are required to co-operate with Sheffield Teaching Hospitals NHS Foundation Trust in discharging its duties under the Health and Safety at Work Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on Sheffield Teaching Hospitals NHS Foundation Trust premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and Sheffield Teaching Hospitals NHS Foundation Trust Occupational Health Department prior to commencing your research role at the Trust.

Confidentiality
You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

Duration and Termination
We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately. Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

Indemnity and Liability
Sheffield Teaching Hospitals NHS Foundation Trust will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

Change in Status
If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely,

Professor Simon Heller, Director of Research
Sheffield Teaching Hospitals NHS Foundation Trust

cc: Daniel Lambert, Dept. of Clinical Dentistry, University of Sheffield

Appendix B:

Study protocol

PROTOCOL OUTLINE

<table>
<tr><th></th><th colspan="2">Content</th></tr>
<tr><td rowspan="10">1</td><td>Project details
1. Investigator details</td><td>Name: Carolina Machuca
Post: PhD student. School of Clinical Dentistry
Qualifications: BDS, MSc
Employer: University of Sheffield
Work Address: Academic Unit of Dental Public Health
School of Clinical Dentistry
19 Claremont Crescent
S10 2TA
Work Email: camachucavargas1@sheffield.ac.uk</td></tr>
<tr><td>2. Sponsor details</td><td>Sheffield Teaching Hospital</td></tr>
<tr><td>3. Project title</td><td>How peoples' ratings of dental implant treatment change over time: Response Shift in patients with dental implants.</td></tr>
<tr><td>4. STH Project Reference number</td><td>STH18703</td></tr>
<tr><td>5. Protocol version number and date</td><td>Version 1</td></tr>
<tr><td>6. Signatures of Chief Investigator and Sponsor*</td><td></td></tr>
<tr><td>7. EUDRACT & CTA Number*</td><td></td></tr>
<tr><td>8. Phase of Trial*</td><td></td></tr>
<tr><td>9. STH Directorate affiliation</td><td>Oral and Dental</td></tr>
<tr><td></td><td></td></tr>
<tr><td>2</td><td colspan="2">Research question: clearly defined and answerable

How people’s ratings of Dental Implants treatments change over time?</td></tr>
<tr><td>3</td><td colspan="2">Abstract

Peoples’ quality of life changes due to illness and/or treatment. However, judgements of quality of life may also change independently of changes in their understanding of health. How peoples’ meanings of quality of life change over time is a question that might be addressed through the phenomenon of Response Shift.

Response Shift explores how quality of life changes independent of health status and has been defined by Sprangers and Schwartz (1999) as a “change in the meaning of one’s self evaluation of quality of life as a result of change in the person’s</td></tr>
</table>

	internal standards (recalibration), change in the person's values of the components of quality of life (reprioritization) or redefinition of quality of life (reconceptualization). These changes act as a mediator of adaptation processes. Response Shift has been proposed as an explanation for several paradoxes when quality of life is evaluated. For example, when individuals with severe chronic illness report equal or better Quality of Life than healthy people, when patients tend to rate their health better than their caregivers or care providers' assessment and when discrepancies arise between objective measures and self-assessments of health. In addition, Response Shift may allow people to adapt to any benefits of treatment, so they may no longer realize their health has improved. Thus, understanding the influence of response shift in self-reported outcomes is crucial in evaluation of treatments where response shift might under or overestimate important treatment effects. The purpose of this study is to find out more about how patients' ratings of dental implant treatments change over time. A longitudinal questionnaire cohort study in patients undergoing Restorative treatment after Dental Implant placement will be conducted in the Charles Clifford Dental Hospital (CCDH). Partially or total edentulous adults aged 16 years old and above will complete a version of the Oral Health Impact Profile appropriate for use in edentulous patients, the OHIP-EDENT and variants of the Ideal scale and a self-anchored scale methods of detecting Response Shift. Questionnaires will be administered at baseline (pre treatment) and 3 months post treatment. Response Shift will be analysed through three methods: then-test, self-anchoring scales and Recursive Partitioning and Regression Trees (RPART). The then-test approach measures Response Shift using a retrospective judgement of the pre-test quality of life levels. In the self-anchoring scales Response Shift is measured assessing shifts in patients' individual definitions of the scale-anchors over time and in the RPART, Response Shift is operationalized as changes in the observed trajectories of the domains in the OHIP-EDENT scores.
4	**Aim of the study**: State the objectives and purpose of the study. Is the research original or is it intended to fulfil taught course requirements? Will it make a useful contribution to the field? Student projects, specify: Undergraduate/ Masters by dissertation/ Masters by thesis/ Doctoral **Aim**: To describe changes in internal standards (recalibration), values (reprioritization), and conceptualization (reconceptualization) in quality of life in patients receiving restorative treatment after dental implants. This original project is being undertaken in part fulfilment of a PhD and will advance understanding of the benefits of dental implant treatment and of the field of Response Shift in the use of Patient-reported outcomes in health care evaluation.
5	**Background**: clinical and scientific justification

To include evidence of whether the research:

1. Is of clinical significance
2. Has previously been undertaken, and whether all sources of evidence, especially systematic reviews, have been fully considered
3. Fits in with the strategy of the directorate to which it belongs

Behavioural, cognitive and affective processes can change an individual's appreciation of health and influence their perceived quality of life (QoL), hence yielding counterintuitive research findings. For example, individuals with severe chronic illness report equal or better quality of life than healthy people or people with less severe illness (Breetvelt and Van Dam, 1991, Lacey et al., 2008, Finkelstein et al., 2014). In addition, conventional methods to assess treatment effectiveness through simple comparison between pre and post treatment outcomes show ambiguous results (Ring et al., 2005, Kimura et al., 2012, Finkelstein et al., 2014). A potential inaccuracy of assessing Health Related Quality of Life (HRQoL) emerges: people not only change their health status due a disease and/or treatment, but also change their perception, appreciation or meaning of QoL.

Response Shift theory explains this phenomenon as a result of changes in internal standards of measurement (scale recalibration), values (importance of the component domains constituting the target construct) or a redefinition of the target construct (reconceptualization) (Sprangers and Schwartz, 1999).

Sprangers and Schwartz (1999) proposed a theoretical model of Response Shift that has five major components: catalyst, antecedents, mechanisms, response shift and perceived quality of life (Figure 1).

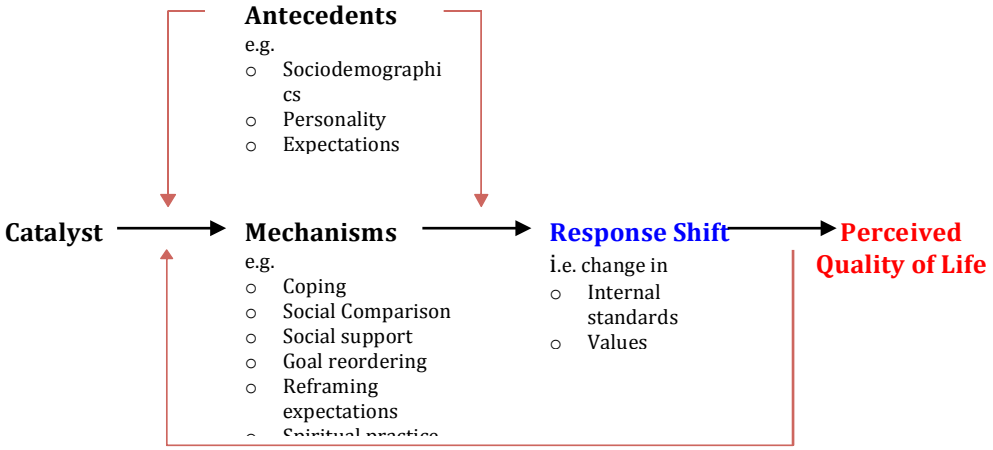


Figure 1: The Sprangers and Schwartz theoretical model of response shift model and quality of life

A catalyst may induce mechanisms to accommodate this change. The mechanisms depend on the specific change and on stable and inherent characteristics of the individual, namely antecedents (sociodemographics, personality, etc). The catalysts, mechanisms and antecedents may induce response shift that in turn affects the perceived quality of life. The process is dynamic and iterative.

Edentulism, although is not a life-threating condition, has considerable impact on people's life and is susceptible of response shift. Has been observed as masking important results in dental treatment (Ring et al., 2005, Kimura et al., 2012, Krasuska et al., 2014b), but there is still little knowledge about.

Dental implant treatment is one method to replace missing teeth; is a process starting with the insertion of the implant with a surgery. Depending on the technique used, fitting the final restorative treatment (i.e. crowns, bridges or prostheses) might be done in the same procedure or differed several months after the surgery. Once the restoration or prostheses are fitted, usually are required check-ups over time to make sure that their function is adequate. Several studies have reported that Dental Implant treatments improve Oral Health Related Quality of Life (Vieira et al., 2014, Bramanti et al., 2013, Dolz et al., 2014, Fillion et al., 2013, Kim et al., 2014, Nickenig et al., 2008, Persic et al., 2014, Petricevic et al., 2012a, Schropp et al., 2004, Swelem et al., 2014, Farzad et al., 2004, Kapur, 1991, Kuboki et al., 1999, Pjetursson et al., 2005, Vermylen et al., 2003). This improvement has been reported to be better in older patients (Petricevic et al., 2012a) and significant in anterior and premolar region but not in molar areas (Ponsi et al., 2011). Differences might be explained by the greater impact of missing an anterior tooth but if response shift is not accounted for in the assessment of this change, important benefits might be masked. For example, Kimura et al (2012) assessed Response Shift as influencing apparent treatment efficacy in patients with Dental Implants as retrospective assessments. Treatment efficacy of dental implants was four times higher than the conventional pre-post treatment effect. Thus, in studies that reported change in QoL in people with Dental Implants as small or moderate, response shift might have masked the benefit. Therefore, it is important to take response shift into account when QoL is assessed as an outcome of treatment efficacy. Patients being treated with dental implants provide a good participant base for studying Response Shift because the effect of implant-retained prostheses on QoL is marked.

Numerous methods have been proposed to assess response shift, but there is a lack of evidence comparing different approaches. The most common method is the then-test (Razmjou et al., 2009, Finkelstein et al., 2014, Rees et al., 2005, Nolte et al., 2012, Sprangers et al., 1999), which constitutes a retrospective judgement of pre-test quality of life levels at the time of the post-test. The then-test assesses response shift by comparing then-test scores with baseline to estimate changes in internal standards, i.e. recalibration. Thus, numerically speaking, then-test-minus-pretest difference score represents a recalibration response shift effect and the post test-minus-then-test represents the adjusted treatment or time effect (Schwartz and Sprangers, 2010). However this method is prone to bias (Krasuska et al., 2014b).

The Ideals Scale Approach has been used to assess response shift with interesting results (Visser et al., 2005, Krasuska et al., 2014b). This method asks the participant to complete a questionnaire in reference to their actual status to describe their ideal status (e.g. how they would like their QoL ideally to be). Administrating this this types of questions at different points in time, allows estimating changes in internal standards from changes in ideal scores over time. Furthermore, if the participant is asked to identify domains and indicates relative importance in QoL, the data could indicate reconceptualization (Schwartz and Sprangers, 1999).

Visser et al. (2005) applied a similar anchor-recalibration approach to assess recalibration response shift in patients with cancer. Participants were asked to rate their current QoL (1 to 10 points) from the 'best´ to 'worst' imaginable. Then they described what they imagined to be the worst and best imaginable QoL, i.e the anchors at baseline and follow up. At follow up participants were shown their previous descriptions of the anchors and asked whether these first anchors meant the same to them as the second description or meant something worse or better. Recalibration may be estimated using the quantitative information about the position of the first and second anchors and reconceptualization may be assessed as

changes in the concepts.

Statistical methods to assess response shift include the Recursive Partitioning and Regression Trees (RPART), which has successfully analysed complex interactions between variables (Li and Rapkin, 2009, Li and Schwartz, 2011, Schwartz et al., 2011). The method splits the participants into increasingly homogeneous groups, growing a complex tree and then pruning the tree back by cross-validation. The multiple pathways created allow analysis of how similar QoL response shift patterns are influenced by different variables depending on the context.

In summary, several methods have been proposed to assess response shift. Further, one single method may not be enough to assess the different forms of response shift, but there is a lack of evidence comparing the different approaches. Triangulation of several methods has been discussed as effective (Schwartz and Sprangers, 2010). For example, the then-test has been compared with structural equation modelling (Visser et al., 2005) and with the patient generated index (Ahmed et al., 2005b). Both studies support the validity of the then-test, the patient generated index and the SEM to assess Response Shift but more comparisons between approaches are needed.

This research proposes to assess Response Shift in patients treated with Dental Implants and to analyse the convergent validity of three methods to evaluate it: then-test, self-anchoring scale and RPART and to identify the extent to which they are valid to detect response shift.

6

Plan of the investigation

1. Methodology

Longitudinal questionnaire cohort study in patients receiving Dental Implant treatments

2. Design: type of study design and justification

Edentulous (partial or total) adults undergoing Restorative treatment after Dental Implant placement will complete a shortened version of the Oral Health Impact Profile appropriate for use in edentulous patients, the OHIP-EDENT, a variant of the Ideal scale method and a self-anchored scale. As this study will describe changes in people's ratings of dental implant treatments over time, we will investigate changes before and after the most positive stages of treatment. Therefore, the assessments will be conducted before placement of the final restorative treatment and 3 months post treatment.

3. Setting

Charles Clifford Dental Hospital (CCDH). Department of Restorative Dentistry.

4. Participants

Partially or total edentulous adults aged 16 years and above referred to the CCDH for Restorative treatment after Dental Implant placement.

Exclusion criteria:

- Patients below 16 years old.
- People not eligible for Implant and Restorative treatment.
- People who decline to participate.
- Patients with cognitive limitations.

5. Sample size: Power of the study. Viability and representativeness of the sample

The statistical method selected to assess response shift in this research is the RPART. The recommended sample size is 10 participants per variable (Ahmed and Schwartz, 2010). The analysis will be conducted taking the 7 subscales of the OHIP-EDENT as the *independent* variables (7 variables). Three additional predictor variables were included to detect antecedents of the magnitude and direction of RS (number, position of replaced teeth and treatment modality). Thus the minimum sample size may be N= 100 participants. Patients for Dental Implant treatment are carefully selected and loss to follow-up is anticipated to be minimal. Therefore, and additional 20% of participants will be recruited. Thus, the incept cohort will be of 120 patients.

6. Recruitment: method used to identify, approach, recruit and consent

Potential participants will be approached on the day of their first appointment with the Restorative Dentistry Consultants and will be invited to participate. People expressing an interest will be informed about the study by the Chief Investigator and provided with the information sheet and consent form. During their second appointment, participants agreeing to join the study will be asked to provide consent and to complete the baseline questionnaires. After completion of the questionnaires patients will continue their treatment as planned.

It is expected that the first stage of recruitment will last approximately 6 months. Participants who enter in the study will be given a second set of questionnaires at their routine post restorative treatment check up approximately 3 months after the completion of the first assessment. If the participant misses the appointment, the questionnaires will be sent by post to the appropriate address.

7. Outcome measure(s)

Oral Health Related Quality of Life (OHRQoL)

OHRQoL will be measured using a short form of the Oral Health Impact Profile specific to edentulous patients. OHIP-EDENT is aimed to capture OHRQoL influenced by the clinical aspects of edentulousness and its treatment. The psychometric properties of the OHIP-EDENT in the UK are good (Allen and Locker, 2002). Maintaining the 7 subscales of the original instrument the OHIP-EDENT has 19 questions asking participants to rate their oral health problems on 5-point Likert scales (from Never to Very Often). Higher scores indicate worse OHRQoL.

8. Analysis including statistical methods, where appropriate

Descriptive statistics

Demographics of the sample, the number and position of replaced teeth, type of treatment and OHRQoL measures (OHIP-EDENT and self-anchored scores) at baseline and follow up will be analysed to describe the distribution of variables.

Then test

The questionnaire will be applied to the complete sample at baseline and follow-up. At follow up will also complete a retrospective judgement of their QoL at the time of the first interview.

Recalibration will be calculated as the difference between pre-test and then-test total scores and true change as the difference between post and then-test scores and tested with paired t-tests.

Patient-based transition scores at baseline, follow up and retrospectively will be correlated with the OHIP-EDENT total pre, post and then scores. Response shift is likely reflected when transition scores correlate more highly with the adjusted treatment effect (post-minus-then-test) than with the treatment effect (post-minus-pre-test scores) (Schwartz and Sprangers, 2010).

Effect size will be calculated using Cohen's d criteria reflecting the impact of response shift in relation with the standard deviation (SD).

$$\text{Effect size to Response Shift} = \frac{\text{Then test score} - \text{Pre test score}}{\text{SD Pre test}} \quad (1)$$

Self-anchored scale

Self-anchored scale will allow assessment of the difference between pre-test and transformed pre-test scores, and true change as the difference between post test and transformed pre-test scores (Visser et al., 2005). The transformed scores are a function of the pre-test scores and the position of the best and worse self-generated anchors in the Cantril's ladder.

Where Xpre is the pre-test score, W is the position of the Worse and B the best imaginable oral health anchor on the post-test.

$$X_{trans} = ((B-W)\, X_{pre} + 10W - B) / 9 \quad (2)$$

Effect size in the self–anchored scale will be calculated using Cohen's d criteria reflecting the impact of response shift in relation with the standard deviation.

$$\text{Effect size of Response Shift} = \frac{\text{True change} - \text{Observed change}}{\text{SD Observed change}} = \frac{(X_{\text{post test}} - X_{\text{trans}}) - (X_{\text{post test}} - X_{\text{pre test}})}{SD_{\text{post test} - \text{pre test}}} \quad (3)$$

Recursive Partitioning and Regression Trees (RPART)

The decision trees are based on subsequent binary splits of a dependent variable (here, OHIP-EDENT total score) according to cut-off values or classes of independent variables (Zhang and Singer, 1999, D'Alisa et al., 2006). In this case the independent variables (or covariates) will be each subscale score. Namely, the OHIP scores can be split on the basis of a cut-off score of each OHIP-EDENT subscale.

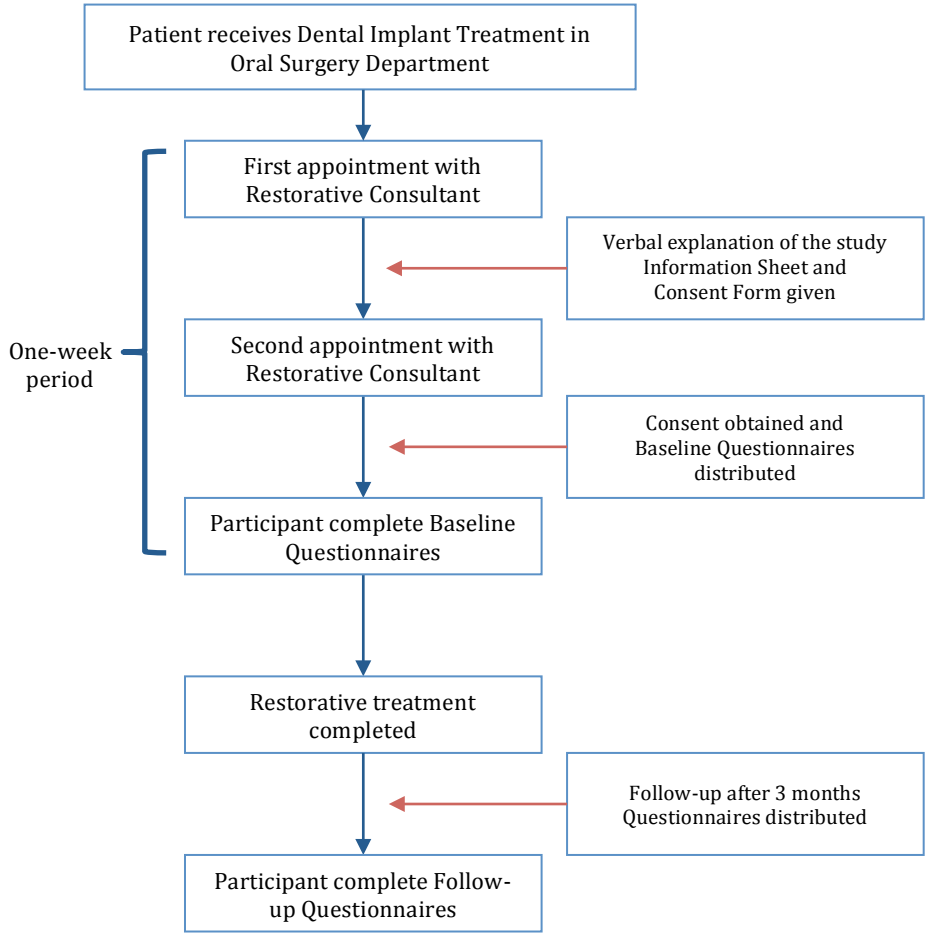
This partitioning process is recursive. The 'root' of the tree is made up of the un-split values of the independent variable (all of the OHIP-EDENT scores). Two sub-groups come from the first split. Either of these parent' branches can be further split into two more subgroups, according to optimal cut-off points or classes of different variables. In turn, these may become 'parent' branches of further sub-groups, etc. When the process stops, 'terminal' branches make up the final classification system.

The observed trajectories of changes in domains and scores in the OHIP-EDENT might indicate response shift in this proposed operationalization:

Response Shift is defined by changes in OHIP-EDENT subscales scores accompanied by 'stability' in overall OHIP-EDENT.

- *Recalibration: change in subscale scores*
- *Reconceptualization: changes within each subscale domains*
- *Reprioritization: changes in subscales order.*

9. Intervention: flow chart indicating participant's involvement throughout the course of the study



10. Safety assessment: safety parameters and adverse event reporting for interventional studies

None of the questionnaires contain sensitive questions. Nevertheless, the process will be stopped if participants feel uncomfortable completing them. The application of questionnaires will not involve any risk for the staff involved.

11. Subject withdrawal (withdrawal criteria and procedures), breaking the blind (circumstances and procedures) and trial stopping/discontinuation rules*

Participants can withdraw from the study at anytime by expressing their intention to do so.

12. Justification of use of screening tools/questionnaires, etc: include data collection tools, eg screening tools, questionnaires and Case Report Forms

Two questionnaires will be used to assess the Oral Health Related Quality of Life of the participants: the Oral Health Impact Profile for Edentulous people (OHIP-EDENT) and the Self-anchoring scale (see Appendix D)

Oral Health Impact Profile –EDENT

The OHIP-EDENT is a short form of a generic Oral Health Related Quality of Life (OHRQoL) measure (OHIP-49) specific to capture aspects of OHRQoL relevant to edentulous patients (Allen and Locker, 2002). This questionnaire has 19 questions with seven subscales: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. Participants are asked to rate their oral health problems on a 5-point Likert scale coded as Never (0), Hardly ever (1), Occasionally (2), Fairly often (3), and Very often (4). Higher scores indicate worse OHRQoL. This instrument has a better performance to detect change specifically in patients with prostheses and dental implants, with good internal consistency and validity (Awad et al., 2003b, Sutton and McCord, 2007, Souza et al., 2007b, Zani et al., 2009, Stober et al., 2012, Montero et al., 2012, Albaker, 2013, Jofre et al., 2013b)

Participants will complete the OHIP-EDENT questionnaire before restorative treatment (pre-test) and 3 months after treatment (post-test). Immediately after rate their post treatment OHRQoL, patients will be asked to rate their OHIP-EDENT as retrospective judgment of the pre treatment (then-test) without having access to their pre-test scores.

At baseline and follow-up:

"Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?" 5-point response scale ranging from 0 (Never) to 4 (Very often)

At follow-up as retrospective judgment:

"How do you *now* think you were three months ago?"
5-point response scale ranging from 0 (Never) to 4 (Very often)

Self-anchoring scale

An individualized variant of the Ideal scale to assess response shift will be implemented; a self-anchored scale based on the "self-anchoring striving scale", also known as Cantril's ladder (Cantril, 1965).

Participants first provide a written description of the 'best' and the 'worst' possible oral health condition for them. At baseline patients specify where they are in a picture of the ladder and place the descriptors of the worse oral health condition at the bottom and the best at the top of the ladder.

At follow up participants will again describe the best and the worst imaginable oral health and locate themselves on the ladder. The new descriptors can be located even worse, better or coinciding with the descriptions at baseline.

Global questions

Transition questions are used to assess global changes in oral health. One question will be used to measure global rating of oral health at the baseline and follow-up:

"Overall, how would you rate the health of your mouth, teeth and gums?"
5-point response scale ranging from 1 (very poor) to 5 (excellent)

In addition, at follow-up another question is formulated in terms of change:

"Overall, how has your oral health changed since our last meeting?"
5-point response scale ranging from 1 (much worse) to 5 (much better)

The transition scores obtained are used as referents to assess the sensitivity of instruments to capture clinically meaningful changes and as external measures to validate self-reported change (Liang et al., 2002). When they are used retrospectively, transition questions also define groups that have changed or not and to observe their trajectories (i.e if patients improve their oral health status after Dental Implant treatment) (Schwartz and Sprangers, 2010).

When correlating transition questions scores and then-test, response shift is likely when transition ratings correlate more highly with post-minus-then-test scores than post-minus-pre-test scores (Broberger et al., 2006)

13. Quality control: Monitoring and audit procedures*

Not applicable.

14. Project plan with timescale and clearly delineated milestones

	2014											
	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	
Protocol submission for ethical approval												
Pilot Study												
Participants Recruitment												
Baseline data collection												
Follow up data collection												
Data transfer												
Data analysis												
Report												

7

Statistical opinion: recommended for quantitative studies; include evidence and discuss as applicable

Supervisor of the study, Dr Mario Vettore has expertise in statistical techniques required to develop this Project. The complete analysis will be conducted under his supervision.

8

Project management: describe what arrangements have been made

Overall project management will be the responsibility of Mrs Carolina Machuca.

Supervisors of the study, Professor Peter G. Robinson and Dr. Mario Vettore will participate and provide support during the complete process.

Dr. Kathryn Hurrell-Gillingham as Research Manager for Dentistry in the University of Sheffield will overview this study.

9

Expertise: of the researcher and associated team

Professor Peter G. Robinson, Professor in Dental Public Health is the Director of Research of the School of Clinical Dentistry, University of Sheffield. His experience and multiple publications in diverse areas of Dental Public Health support an impeccable academic career. He has an expertise in Quality of Life and Response Shift research.

	Dr Mario Vettore is Senior Lecturer in the School of Clinical Dentistry, University of Sheffield. He has extensive publications in oral health related quality of life and expertise in statistical techniques to support the current project. Dr Kathryn Hurrell-Gillingham has extensive experience in project management and her support is essential in this study. Mrs Carolina Machuca is a Dentist and gained her Masters Degree in Dental Public Health from the University of Sheffield in 2012. The proposed research will go towards the fulfilment of her PhD.
10	**Ethical issues:** description of issues and methods used to address them; include Subject Information Sheet(s) and Consent Form(s) where applicable Formal ethical approval will be obtained from a local NHS REC and Research Governance Committee prior to study commencement. *Informed Consent* Participants will be provided with an Information Sheet and Consent Form before joining the study. The Informed Consent will be signed with two copies, one for the research team and the other for participants. Participants will be informed that their participation is completely voluntary and if they chose to take part, they can withdraw at any point. It will be emphasized that their dental care will not in anyway be affected by whether they agree to take part in the research. All this information will be reinforced at each stage of the study. *Confidentiality* Information collected during the research will be kept strictly confidential. The questionnaires will not contain any personal information such as name or contact details. Questionnaires will be assigned with an identification number thus participants' answers are anonymous and not identifiable. All paperwork compiled will be filed with strict confidentiality in safety locked storage at the University of Sheffield. The data obtained will be collected only by the Chief Investigator and entered into selected software. Those will be recorded, archived and encrypted to ensure discretion. *Risks* None of questionnaires contain sensitive questions. Nevertheless, the process will be stopped if participants feel uncomfortable completing them. The application of questionnaires will not imply any risk for the staff involved. *Incentives*

	There are no incentives offered to the participants to be included in the research. *Complaints and concerns* Participants will be informed that any member of the research team will be able to answer any questions, concerns or complains regarding the study.
11	**Service users:** involvement during study design A pilot study will be conducted among 5 dental implant patients at CCDH to test the understanding of the questionnaires and how long it takes to complete them. The information sheets and the consent form have been reviewed by members of the public to check their understanding. Suggestions will be collected to improve both documents.
12	**Dissemination:** methods for dissemination of the research Dissemination will include a non-technical report outlining the key findings, which will be sent to all participants and relevant health professionals interested in the findings. The findings will be presented at scientific meetings. All the results will be disseminated through the submission of a PhD thesis. The production of peer-reviewed journal articles is planned.
13	**Taking the work forward:** describe the strategy for development if the research project is productive The Pharmaceutical Industry is interested in this evaluative methodology. Research is expected to produce interesting findings. As the application of questionnaires requires two assessments with an elapsed time of 3 months, it may be desirable to re-assess the same cohort after 6 months and 1 year.
14	**Intellectual Property:** describe what arrangements have been made The policy frameworks for the management of intellectual property within the NHS and the University of Sheffield will be adopted.
15	**Costing schedule:** specify the costs associated with the project The study will produce minimal costs. The main expense will be the production of the information sheet, consent forms and the questionnaires booklets.

16	**Funding arrangements:** If there is no funding associated with the project, explain the agreement with the host research team/ clinical area for the use of resources. The expenses will be covered by the Studentship award made to the chief investigator by her sponsor. The School of Clinical Dentistry will meet any additional costs relating to research dissemination.
17	
18	**Curriculum Vitae:** include brief CV
19	**Other:** Contact details*

[1] For additional guidance, see 'Guidance for writing protocols for the independent scientific review process':
http://www.sheffieldclinicalresearch.org/clientfiles/File/Protocol%20guidance%20notes_v1%205%2020nov12.pdf

* Sections marked with an asterisk are required for CTIMPs only

Appendix C:

Information Sheet

Participant Consent Form

Participant follow-up letter

How peoples' ratings of dental implant treatment change over time

INFORMATION SHEET

I would like to invite you to take part in a research project. This information sheet will tell you about why this research is being done and what it involves. It is important that you read this sheet carefully before you decide if you are happy to take part in this research. You can ask me for any more information if anything is not clear or if you have any questions. Thank you for taking time to read this information sheet.

What is the purpose of this research?

The purpose of this study is to find out more about how people with dental implants rate their quality of life and how these views change over time. From this we hope to know how your dental treatment affects your quality of life.

Why have I been invited to take part?

You have been chosen because you are registered at the Charles Clifford Dental Hospital and you have already received dental implants. You are about to have your final restoration placed. I will be asking around 120 adults like you who are registered at the clinic to join this study.

Do I have to take part?

It is totally up to you to decide. I will describe the study for you and after you have read this information sheet, if you decide to take part we will then ask you to sign a consent form. You are free to withdraw from the study at any point without having any reason. This decision will not affect your treatment in any form.

What will happen to me if I take part?

If you decide to take part, you will be asked to answer a series of questions in the booklets you have received, and will be asked to return it to me on the clinic. The questions will take you about 30 minutes to complete. If you agree, you will be given a similar set of questionnaires after your treatment is finished approximately within three months.

What are the possible benefits of taking part?

The study will not change the care or treatment you receive at Charles Clifford Dental Hospital. The study will not help you directly. It helps us to understand about how patient's ratings of dental implant treatment change over time. This information will be very useful to provide help to support patients' treatment in the future.

What are the possible disadvantages and risks of taking part?

There are no risks to you from taking part in this study. Your name will not be in any report we will write about the study, so you need not worry that other people will know about your answers. Everything you answer in the questionnaires will be entirely confidential.

What happens when the research project ends?

When the study has finished we will look at all the questionnaires and we will then write some reports on the findings and can send you a copy via email or post if you like me to. You will just continue your regular care with Charles Clifford Dental Hospital as normal.

What if there is a problem or something goes wrong?

We can't see anything going wrong during this piece of research as we are asking you to complete questionnaires alongside your usual care. But if you feel unhappy about anything to do with the project, I will be very happy to talk to you about your concerns at any time, my contact details are given below. You can also talk to the Patient Services Teams (PST or previously PALS). You can contact them on pst@sth.nhs.uk or telephone 0114 271 2400.

Will my taking part in the study be kept confidential?

All information that is collected about you during the course of the research will be kept confidential. You will not be asked to write your name on your questionnaires and the only people who will see the information will be me and other people in the research team. Nothing that identifies you will be kept on a computer. All the forms from the research will be kept in a locked cabinet at the University of Sheffield. The reports from this research will not mention any of the people personally who took part. The questionnaires will be stored safely and kept for three years before being destroyed.

Who is organizing and funding the research?

The research is organised by Carolina Machuca, who is currently a PhD student at the School of Clinical Dentistry at the University of Sheffield. The research is supported by a team of supervisors, Professor Peter G. Robinson, Director of Research of the School of Clinical Dentistry, University of Sheffield and Dr Mario

Vettore, Senior Lecturer in the School of Clinical Dentistry, University of Sheffield. The project is funded by the University of Sheffield.

Who has reviewed the study?

Before any research in the NHS goes ahead it is checked by an independent group of people called a Research Ethics Committee (REC). They make sure that the research is well conducted and it protects your interests.

Contacts details

If you have any further questions or want to find out more, please contact me by email: camachucavargas1@sheffield.ac.uk.

Thank you for taking the time to read this information sheet.
Please feel free to ask any questions if you need to.

PARTICIPANT CONSENT FORM

Title of Project: *How people's ratings of dental implants treatments change over time*
Name of Researcher: *Carolina Machuca*

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 22/12/2014 Version 2 for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

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

3. I understand that the research team will have access to my medical records in order to seek relevant information about my health. I give my permission for member of the research team to have access to my medical records with strict confidentiality. ☐

4. I understand that the research team will keep my responses strictly confidential. I give permission for members of the research team to have access to my anonymised responses. I understand that will not be identified or identifiable in the report or reports that result from the research. ☐

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

6. I would like to receive the study results and consent to my details being kept to this purpose. ☐

Name of Participant	Date	Signature
Name of Person	Date	Signature taking consent

Copies:
Please sign both copies of this consent form. You will need to keep **one copy** of this consent form for your own records and **return one copy** to the research team (details below).
Carolina Machuca. Academic Unit of Dental Public Health. School of Clinical Dentistry. Claremont Crescent. Sheffield. S10 2TA. Tel: 01142717877. Email: camachucavargas1@sheffield.ac.uk.

The University Of Sheffield.

Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Month, 20XX

Mr/Mrs
XXX

Dear XXX,

This letter is being sent to you as a participant in the study "How peoples' ratings of dental implant treatment change over time" conducted by the University of Sheffield. According to our records, your treatment was finished in June 2015 and it is now time to assess the impact that your treatment has had on your everyday life.

The follow up questionnaire is attached. Please, could you complete it according the instructions and return it in the pre-paid envelope enclosed.

YOUR NAME IS NOT INCLUDED ON THE FORM AND YOUR REPLY WILL BE TREATED IN CONFIDENCE.

If we do not receive your reply within 3 weeks we may send you another letter and/or contact you by phone.

If you have any further questions, please contact me by email: camachucavargas1@sheffield.ac.uk

Thank you for your participation in this project. Your time and consideration are really appreciated.

Yours sincerely,

Carolina Machuca
PhD Student
Oral Health and Development
University of Sheffield

Appendix D:

Questionnaires booklet

Oral Health Impact Profile- EDENT
Baseline

This questionnaire asks how troubles with your teeth, mouth or dentures may have caused problems in your daily life. We would like you to complete the questionnaire even if you have good dental health.

Each question on the left hand side of the page asks you about a particular dental problem. You should think about each question in turn, and mark the answer to the right of the question, to indicate how often you have had the problem during the last year.

There are no right or wrong answers, so please tell us what is true for you.

	Very often	Fairly often	Occasionally	Hardly ever	Never
1. Have you had difficulty *chewing* any foods because of problems with your teeth, mouth or dentures?	O	O	O	O	O
2. Have you had food *catching* in your teeth or dentures?	O	O	O	O	O
3. Have you felt that your dentures have not been *fitting* properly?	O	O	O	O	O
4. Have you had *painful aching* in your mouth?	O	O	O	O	O
5. Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
6. Have you had *sore spots* in your mouth?	O	O	O	O	O
7. Have you had *uncomfortable dentures*?	O	O	O	O	O
8. Have you been *worried* about dental problems?	O	O	O	O	O
9. Have you been *self-conscious* because of your teeth, mouth or dentures?	O	O	O	O	O

	Very often	Fairly often	Occasionally	Hardly ever	Never
10. Have you had to *avoid eating* some foods because of problems with your teeth, mouth or dentures?	O	O	O	O	O
11. Have you had to *interrupt meals* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
12. Have you been *unable to eat* with your dentures because of problems with them?	O	O	O	O	O
13. Have you been *upset* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
14. Have you been a bit *embarrassed* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
15.Have you been *less tolerant* of your spouse or family because of problems with your teeth, mouth or dentures?	O	O	O	O	O
16. Have you been a bit *irritable with other people* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
17. Have you *avoided going out* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
18. Have you been *unable to enjoy* other people's company as much because of problems with your teeth, mouth or dentures?	O	O	O	O	O

	Very often	Fairly often	Occasionally	Hardly ever	Never
19. Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth or dentures?	O	O	O	O	O

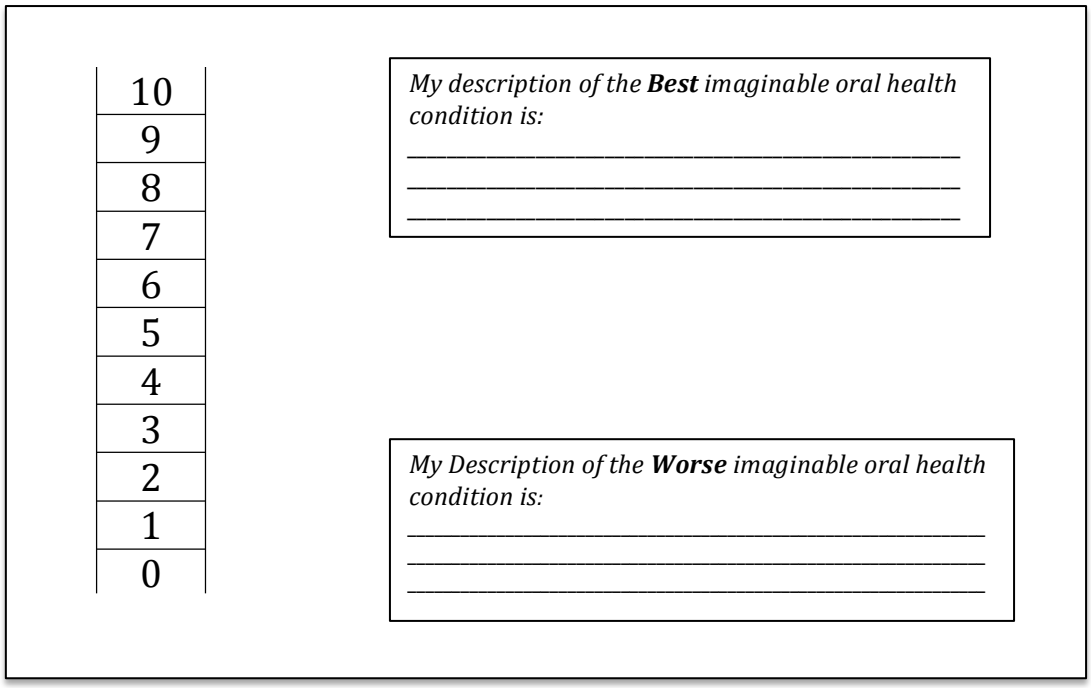
	Excellent	Very Good	Good	Poor	Very Poor
20. Overall, how would you rate the health of your mouth, teeth and gums	O	O	O	O	O

SELF-ANCHORING SCALE
Baseline

This section has two parts:

1. *A picture of a ladder*
2. *Description of the best and the worse oral health condition you can imagine.*

Suppose that the top of the ladder represents the best possible oral health you can imagine for yourself, i.e is the oral condition you would have if all your personal wishes, hopes and dreams were fulfilled. Then, suppose that the bottom of the ladder represents the worst possible oral health you can imagine for yourself, which represents all your fears and worries. Where on the ladder you feel you stand at the present time? Please select and mark only one step.



Now, in the two boxes on the right side of the diagram, please describe the best and the worst imaginable oral health you can imagine. Feel free to describe it in a single word, sentence or paragraph that represents the best for your mouth. Take all the time you need.

Where on the ladder you would locate these descriptions?

Best imaginable oral health condition Step N# _____
Worst imaginable oral health condition Step N# _____

Thank you for your time

Oral Health Impact Profile- EDENT
Follow up

The following questions are about your oral health and the impact it has on your everyday life.
For each question, there are two parts:

- ***Part a** asks about how things are NOW for you. Please give your answer by marking the number that comes closest to what is true for you.*
- ***Part b** asks how do you **now think** you were <u>three months ago</u>. When answering this part of the question please take a minute and think how you were in relation to that question when we first meet for the interview three months ago.*

There are no right or wrong answers, so please tell us what is true for you.

	Very often	Fairly often	Occasionally	Hardly ever	Never
1a. Have you had difficulty *chewing* any foods because of problems with your teeth, mouth or dentures?	O	O	O	O	O
1b. How do you *now* think you were three months ago?	O	O	O	O	O
2a. Have you had food *catching* in your teeth or dentures?	O	O	O	O	O
2b. How do you *now* think you were three months ago?	O	O	O	O	O
3a. Have you felt that your dentures have not been *fitting* properly?	O	O	O	O	O
3b. How do you *now* think you were three months ago?	O	O	O	O	O
4a. Have you had *painful aching* in your mouth?	O	O	O	O	O
4b. How do you *now* think you were three months ago?	O	O	O	O	O

	Very often	Fairly often	Occasionally	Hardly ever	Never
5a. Have you found it *uncomfortable to eat any foods* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
5b. How do you *now* think you were three months ago?	O	O	O	O	O
6a. Have you had *sore spots* in your mouth	O	O	O	O	O
6b. How do you *now* think you were three months ago?	O	O	O	O	O
7a. Have you had *uncomfortable dentures*?	O	O	O	O	O
7b. How do you *now* think you were three months ago?	O	O	O	O	O
8a. Have you been *worried* about dental problems?	O	O	O	O	O
8b. How do you *now* think you were three months ago?	O	O	O	O	O
9a. Have you been *self-conscious* because of your teeth, mouth or dentures?	O	O	O	O	O
9b. How do you *now* think you were three months ago?	O	O	O	O	O

	Very often	Fairly often	Occasionally	Hardly ever	Never
10a. Have you had to *avoid eating* some foods because of problems with your teeth, mouth or dentures?	O	O	O	O	O
10b. How do you *now* think you were three months ago?	O	O	O	O	O
11a. Have you had to *interrupt meals* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
11b. How do you *now* think you were three months ago?	O	O	O	O	O
12a. Have you been *unable to eat* with your dentures because of problems with them?	O	O	O	O	O
12b. How do you *now* think you were three months ago	O	O	O	O	O
13a. Have you been *upset* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
13b. How do you *now* think you were three months ago?	O	O	O	O	O
14a. Have you been a bit *embarrassed* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
14b. How do you *now* think you were three months ago?	O	O	O	O	O

	Very often	Fairly often	Occasionally	Hardly ever	Never
15a.Have you been *less tolerant* of your spouse or family because of problems with your teeth, mouth or dentures?	O	O	O	O	O
15b. How do you *now* think you were three months ago?	O	O	O	O	O
16a. Have you been a bit *irritable with other people* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
16b. How do you *now* think you were three months ago?	O	O	O	O	O
17a. Have you *avoided going out* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
17b. How do you *now* think you were three months ago?	O	O	O	O	O
18a. Have you been *unable to enjoy* other people's company as much because of problems with your teeth, mouth or dentures?	O	O	O	O	O
18b. How do you *now* think you were three months ago?	O	O	O	O	O
19a. Have you felt that life in general was *less satisfying* because of problems with your teeth, mouth or dentures?	O	O	O	O	O
19.b How do you *now* think you were three months ago?	O	O	O	O	O

	Excellent	Very Good	Good	Poor	Very Poor
20a. Overall, how would you rate the health of your mouth, teeth and gums	O	O	O	O	O
20b How do you *now* think you were three months ago?	O	O	O	O	O

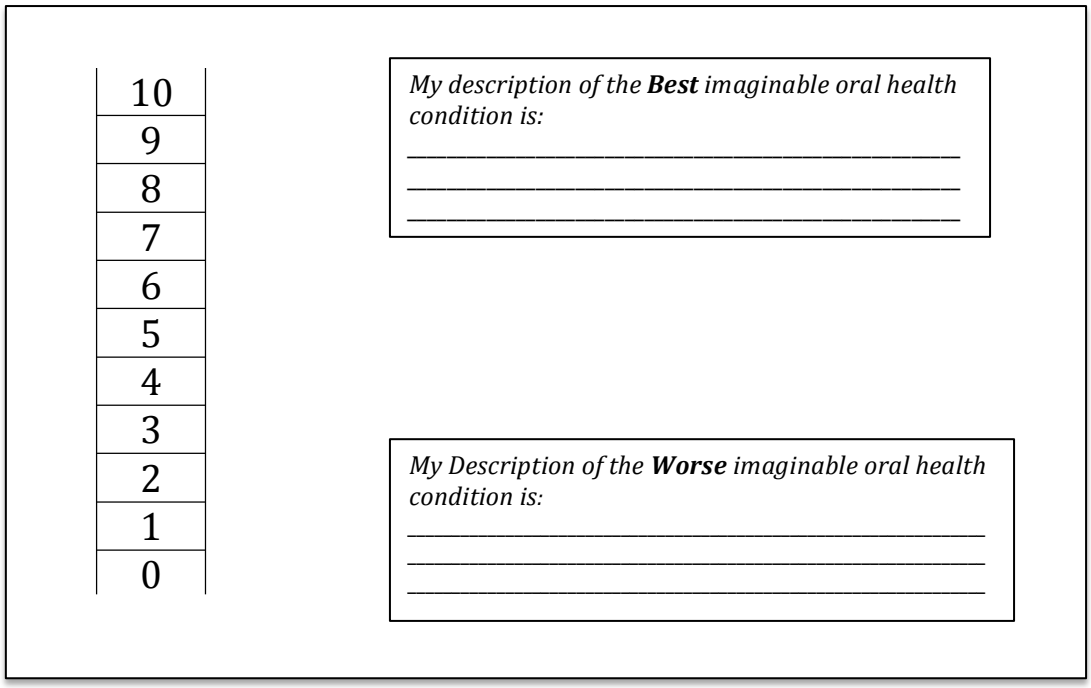
	Much Better	Better	About the same	Worse	Much worse
21. Overall, how has your oral health changed since our last meeting	O	O	O	O	O

SELF-ANCHORING SCALE
Follow up

This section has two parts:

1. *A picture of a ladder*
   3. *Description of the best and the worse oral health condition you can imagine.*

Suppose that the top of the ladder represents the best possible oral health you can imagine for yourself, i.e is the oral condition you would have if all your personal wishes, hopes and dreams were fulfilled. Then, suppose that the bottom of the ladder represents the worst possible oral health you can imagine for yourself, which represents all your fears and worries. Where on the ladder you feel you stand at the present time? Please select and mark only one step.



Now, in the two boxes on the right side of the diagram, please describe the best and the worst imaginable oral health you can imagine. Feel free to describe it in a single word, sentence or paragraph that represents the best for your mouth. Take all the time you need.

Where on the ladder you would locate these descriptions?

Best imaginable oral health condition Step N# _____
Worst imaginable oral health condition Step N# _____

At our first meeting, you described (X) as the best imaginable oral health, and (Y) as the worst. Those descriptions might have changed or might be the same of our first interview.

Please put the new descriptions (if they have changed) of the best and worse oral health you can imagine in the ladder below. Feel free to make them better, worse or the same as your first descriptions.

+10
10
9
8
7
6
5
4
3
2
1
0
-1

Best imaginable oral health condition *Step N#* _____
Worst imaginable oral health condition *Step N#* _____

Thank you for your time