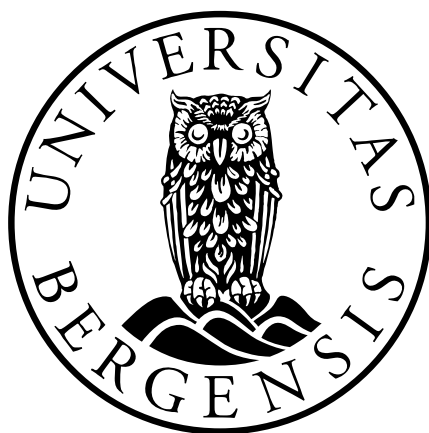


# **Prosthetic rehabilitation of the edentulous**

**A randomized controlled trial comparing  
implant-retained mandibular overdentures and  
conventionally relined mandibular dentures**

**Harald Gjengedal**



Dissertation for the degree philosophiae doctor (PhD)  
at the University of Bergen

2012

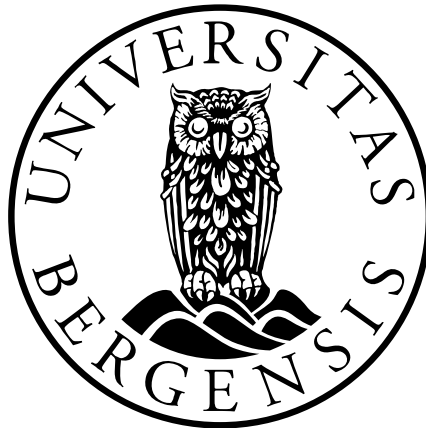


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Department of Clinical Dentistry  
University of Bergen



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And last but not least, my wife, Gudveig Cecilie; without you I would never have had the strength to finish this thesis. You have been the cornerstone of my life these years. Thank You!

## **ACRONYMS**

**BASQ:** Brief Approach/Avoidance Coping Questionnaire

**CD:** Conventional Denture

**ES:** Effect Size

**FIP:** Fixed Implant-retained Prosthesis

**HRQoL:** Health-Related Quality of Life

**IOD:** Implant OverDenture

**ITT:** Intention-to-treat

**OHIP-49:** Oral Health Impact Profile-49

**OHIP-20:** Oral Health Impact Profile-20

**OHRQoL:** Oral Health-Related Quality of Life

**QoL:** Quality of Life

**POM:** Patient-reported outcome measure

**RCD:** Reline Conventional Denture

**RCT:** Randomized Controlled Trial

**SF-36:** Short Form Health Survey -36

**WHO-Five:** World Health Organization-5 Well-Being Index

**24hRs:** 24-hours dietary Recalls

# **ABSTRACT**

## ***Purpose***

To investigate variables associated with satisfaction and self-perceived oral health among complete denture wearers. Subsequently, to assess the effect of two treatment modalities on masticatory ability, diet, self-perceived oral health and quality of life among denture wearers dissatisfied with their mandibular denture.

## ***Materials & Methods***

Patients treated with one or two complete dentures at the dental clinic, University of Bergen, were invited to an appointment to assess variables associated with satisfaction with their dentures and oral health. Of the 272 listed patients 176 responded and finally 172 constituted the study sample. Of these 16 were recruited to the RCT, a further 44 were recruited by advertisement in the Bergen area, compiling a study sample for the RCT of 60 participants. The RCT compared treatment of the mandibular denture with either conventionally relining or implant-retaining the denture.

## ***Results***

Most complete denture wearers (79%) reported satisfaction with their dentures as well as good or excellent oral health (65%). Denture wearers dissatisfied with their mandibular denture and who then got it turned into an implant-retained overdenture reported significantly improved chewing ability and less food avoidance, improved oral health and oral health related quality of life, persisting two years after treatment. However, dietary habits, nutrient intake, health related quality of life or overall quality of life did not change.

## ***Conclusions***

The modality of implant-retaining the mandibular denture in dissatisfied denture wearers significantly improves denture function and quality of life aspects related to this.

## LIST OF PAPERS

This thesis is based on the following papers, which in the text will be referred to by their Roman numerals:

- I **Harald Gjengedal, Einar Berg, Olav E Bøe & Tordis A Trovik.** Self-Reported Oral Health and Denture Satisfaction in Partially and Completely Edentulous Patients. *Int J Prosthodont* 2011;24:9-15.
  
- II **Harald Gjengedal, Lisbeth Dahl, Ågot Lavik, Tordis A Trovik, Olav E Bøe, Einar Berg & Marian K Malde.** Randomized Clinical Trial Comparing Dietary Intake in Patients with Implant-Retained Overdentures and Conventionally Relined Dentures. *Int J Prosthodont* 2012;25:xxx-xxx
  
- III **Harald Gjengedal, Einar Berg, Arne G Grønningsæter, Lisbeth Dahl, Marian K Malde, Olav E Bøe & Tordis A Trovik.** The influence on health-related quality of life of relining or implant retaining existing mandibular dentures. A two-year follow-up randomized clinical study of dissatisfied edentulous patients. *Int J Prosthodont*. Accepted for publication: April 14.2012.

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# 1 INTRODUCTION

## **Preface**

It has been elegantly stated: “the predicament of being both elderly and edentulous undermines life quality for both patient and dentist. The former suffer because of morphological and functional compromises, the latter because of a dearth of safe and predictably successful clinical techniques.”<sup>(1)</sup> The construction of complete dentures is, though theoretically fairly straightforward, often clinically challenging. Even dentures of optimal quality and with an optimal fit in relation to the supporting mucosa are sometimes not accepted by the patient. To have to tell these patients that there is no way to improve the dentures and thus make them more acceptable is quite depressing and gives a feeling of helplessness and even incompetence. In addition, the dissatisfied patient tells stories of denture-related problems in everyday life; like problems with eating, speaking, singing, well-being and self-esteem.

When this project started at the Centre for Clinical Dental Research it offered an opportunity to perform a clinical study concerning patients with a problem well known to dentists for many years. The present thesis is one of the results of this project.

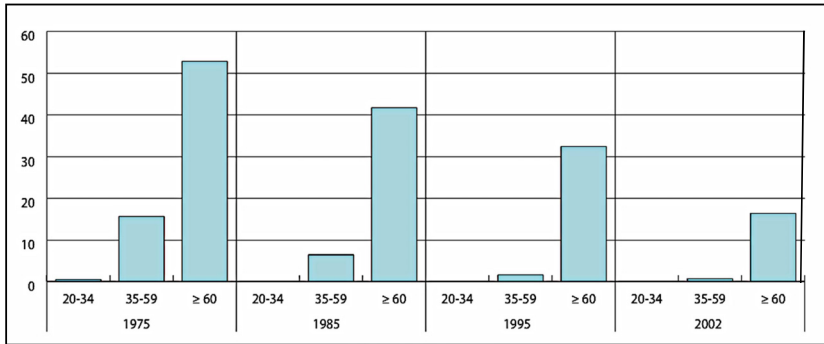
## **Edentulousness and complete dentures**

The loss of a tooth is definite. To lose all teeth and become completely edentulous is a chronic condition. This condition is incurable with all the characteristics of a chronic illness, and the provision of complete dentures can only to some degree compensate for the loss of natural teeth. The edentulous has to deal with functional, psychological and even social aspects of wearing removable dentures. These may have a substantial impact on a person’s life in general and should not be underestimated. In addition to treatment-related morbidity, treatment outcomes may not meet the physiological, psychological, or social needs of the individual.<sup>(2)</sup> The result is a reduction in oral function, health, self-esteem, well-being and social function.<sup>(3-7)</sup>

The prevalence of complete edentulism in Western society is declining, but with great differences between countries, between geographical regions within countries and between groups with various backgrounds.<sup>(8)</sup> However, the prevalence of edentulism changes fast and in a non-uniform rate within different cohorts. The use of different demographic cohorts regarding age, rural vs. urban, economic factors or education and even different survey methods, makes it complicated to assess and compare prevalences across countries. In addition, data are soon out-dated and surveys a few years apart are difficult to compare cross-sectionally. This is illustrated by surveys covering the period 1985 to 2000 among 35 countries; the prevalence varied from 0% to 72% for the age group of 65 to 74-year-olds.<sup>(9)</sup>

Even the Nordic countries, which are socially and economically comparable, show differences. Thus, in Norway in the late 1990s, it was estimated that approximately 30% of a national representative sample over 67 years wore complete dentures<sup>(10)</sup> whereas in the other Nordic countries Sweden, Denmark and Finland 27%, 45% and 58%, respectively, among 75-year-olds were edentulous.<sup>(11)</sup>

In Norway the proportion of edentulous in an adult population was reduced from 20% to 4.8% in the period 1975 to 2002 (Fig 1).<sup>(12, 13)</sup> Today's proportion is estimated to be 2.5% in the group 30 to 76 years old.<sup>(14)</sup> However, there are large geographical disparities with respect to denture status as only 11% in the most urban areas wore complete dentures versus 66% in the most rural areas.<sup>(10)</sup> In addition, there are differences between the general senior population and institutionalized elders. A recent survey from one of the largest institutions in Norway showed that in 1988 as much as 71% were edentulous and in 2004 still as much as 43% were edentulous.<sup>(15, 16)</sup>



**Fig 1.** Proportion of edentulous in three age groups in Norway from 1975 to 2002.

This general drop in rate of edentulism is so profound that even with the relative increase of the older population, the total number of edentulous will decrease.<sup>(17)</sup> Nevertheless, a review on complete denture treatment in oral rehabilitation concludes that; “it is likely that the need to rehabilitate edentulous patients will remain considerable for many more decades“ and further that “Complete dentures are and will remain the mainstay of treatment for the majority of edentulous patients; most are satisfied with their dentures but some others are unable to adapt.”<sup>(18)</sup> Some of the problems associated with wearing complete dentures are further elaborated in the following text.

### **Satisfaction with dentures**

Studies published over several decades have reported that 65 to 90% of complete denture wearers are satisfied with their dentures.<sup>(19, 20)</sup> These diverging results are probably caused by the fact that satisfaction in general is relative, and that patients most likely emphasize different aspects of satisfaction.

It has for many years been a longstanding assumption that some patients may not adapt to denture use, irrespective of the technique used or quality of the denture.<sup>(21, 22)</sup> According to some studies this may concern between 7 and 21 % of denture wearers and is mainly manifest for the mandibular denture.<sup>(23-25)</sup>

It seems that patient demographics,<sup>(19, 25-28)</sup> psychological factors<sup>(29-33)</sup> and age<sup>(19, 23, 26, 34, 35)</sup> only play a minor role in patients' satisfaction with dentures. However, older subjects with poorly fitting dentures are reported to be more satisfied than younger with dentures of similar quality, and to a lesser extent express a treatment need.<sup>(36)</sup>

Expectations of treatment outcome and of the treatment process logically influence satisfaction with actual treatment outcome.<sup>(37)</sup> The same can be argued regarding the relationship and communication between the patient and dentist during the treatment process,<sup>(25, 27, 38)</sup> as well as trust in the dentist's clinical skills. Also, a low-authoritarian behavior by the dentist appears to augment the rate of acceptance of the dentures. As many as 80% of participants in one study reported this to be of importance.<sup>(39)</sup>

A study by Berg showed that other peoples' view of a person's new dentures was the only significant factor predictive of satisfaction with the dentures.<sup>(28)</sup> But also in this respect, the patients' own attitudes towards dentures may be of importance. Denture wearers, who express a negative view of dentures or even feel ashamed and have lowered self-esteem because of their condition, report less satisfaction with dentures.<sup>(25, 40)</sup>

Regarding influence of years of edentulousness the available data show contradictory results,<sup>(41, 42)</sup> and the same can be said concerning esthetics.<sup>(28, 34, 37, 43)</sup>

Even 50 years ago findings were published that indicated no correlations between dentists' assessments of denture quality and patients' satisfaction with the same,<sup>(44)</sup> and this is still valid.<sup>(23, 45-49)</sup> Likewise, there is no strong correlation between the quality of the denture-supporting tissues and patients' satisfaction with complete denture treatment.<sup>(23, 50)</sup> On the other hand, dissatisfaction with the mandibular denture appears to be dependent on comfort, stability, ability to speak and to eat.<sup>(51)</sup> The patients' acceptance and satisfaction with dentures thus seem to be complex considerations.



## **Mastication**

During mastication, solid food is reduced in size to make it easier to swallow and digest. A well-functioning dentition plays a major role in this process, and complete dentures are by no means a perfect replacement of a natural dentition. The lack of retention and stability of the dentures, and the mandibular denture in particular, are reported to affect mastication negatively.<sup>(52)</sup> This effect on mastication can be measured objectively as masticatory efficiency or subjectively reported by the patient as masticatory ability.<sup>(53)</sup> Several methods exist to measure masticatory efficiency, varying from the very basic to the sophisticated. This includes methods like chewing a known weight of test foods a specific number of times and then measure the size of the food particles, or to counting the number of chewing strokes before swallowing a test food. More sophisticated methods, like electromyography, have also been used to test chewing force.<sup>(54)</sup>

One of the reasons for the loss of masticatory efficiency is a reduction in chewing force in the complete denture wearer by 50 to 75 %.<sup>(55, 56)</sup> Because of this the edentulous use between four and eight times more chewing strokes to comminute test food as compared to dentate persons.<sup>(57)</sup> This results in prolonged time of mastication or maybe even in swallowing coarser food particles.<sup>(58-60)</sup> However, the results of these methods are not necessarily related to a patient's perceived masticatory ability. There is in fact only a weak correlation between objective measures of masticatory efficiency and a patient's perceived masticatory ability.<sup>(49, 61)</sup> Hence, the most appropriate method to measure mastication in clinical trials is the patient-reported outcome of masticatory ability.<sup>(53)</sup> Nevertheless, and maybe contradictory, even though the complete denture wearer must be recognized as handicapped in terms of masticatory function, most denture wearers consider their self-assessed masticatory ability to be good.<sup>(62, 63)</sup>

## **Diet and nutrient intake**

Most edentulous have difficulties chewing various food groups <sup>(64, 65)</sup> and have a preference for food items that are easy to chew.<sup>(66, 67)</sup> Complete denture wearers thus seem to adjust their diet towards food items less coarse, softer, and they generally consume less fruits and vegetables.<sup>(68, 69)</sup> This may result in a suboptimal diet and

consequently a risk of having nutrient deficiencies.<sup>(70)</sup> Accordingly, the dietary intake and nutritional status of complete denture wearers are reported to be inferior to dentate individuals of comparable age.<sup>(71)</sup>

This change in diet results in a lower energy intake in complete denture wearers as compared to the dentate. The intakes of macronutrients like protein and fiber are lower and the intakes of fat and sugar are higher than in the dentate.<sup>(72)</sup> Furthermore, the intakes of micronutrients like vitamins C, E, A, folate as well as calcium are often low in this group of older adults.<sup>(73-75)</sup>

However, the evidence for a causal relationship between chewing ability and dietary intake is still equivocal.<sup>(76)</sup> In contrast to previously mentioned studies <sup>(65, 66, 69, 70)</sup>, it has been reported that although edentulous subjects were more likely to claim that they had trouble chewing their food, they were not more likely to choose easy-to-chew foods.<sup>(77)</sup> Masticatory ability seems to have little impact on intakes of fruit and vegetables, energy and nutrients, or on risk of malnutrition in older adults.<sup>(78, 79)</sup>

These somewhat contradictory findings must be viewed upon in a model of food choices. Diet is a matter of food choices that are developed through the years and are influenced both by masticatory ability and other factors like habits, preferences, cultural customs, financial and traditional aspects.<sup>(80-82)</sup> Older people are at a risk of inadequate diet and malnutrition for a variety of reasons; being edentulous and wearing complete dentures is only one of them.<sup>(83)</sup>

In this context, the denture wearers adjust to their dentures in order to manage mastication and even after improvements of poorly fitting dentures and also after receiving new dentures, only a gradual improvement of masticatory performance takes place.<sup>(84)</sup> Regardless, denture improvements or even new dentures resulting in better chewing ability do not seem to improve nutritional status<sup>(80, 85)</sup> nor a change in dietary habits.<sup>(86)</sup> On the other hand, there is some evidence to suggest that edentulous adults having functional problems with their mandibular denture experience even further changes in dietary intake than do denture wearers with well-functioning mandibular dentures.<sup>(87, 88)</sup>

## **Dietary assessment**

To assess dietary intake a variety of methods are at hand. Prospective methods register the present intake and include food record by menu, weighing or household measures and duplicated portions.<sup>(89)</sup> These methods require considerable cooperation from the participants and may be time consuming. Retrospective methods like dietary history, 24-hours recall or Food Frequency Questionnaires, on the other hand, rely on memory of the participants and may also be time consuming.

The 24-hours dietary Recalls (24hRs) is based on an in-depth interview conducted by a trained interviewer.<sup>(90)</sup> The interviewer follows a chronological approach asking about type and amount of eaten food the previous day. The interview usually takes about 30 minutes and is of little burden for the respondent. However, the validity of the interview is dependent on the memory of the respondent, but a trained interviewer can guide the respondent through the day.

This method is widely used and its reliability has been demonstrated although the predictive validity needs more testing.<sup>(91)</sup> Because the diet, on a personal level, changes from day to day several non-consecutive 24hRs are needed and for the same reason, the measures are only useful for analyses on the group level.<sup>(92)</sup> The 24hRs seem to underestimate the energy intake by approximately 15 % compared with observed intake.<sup>(93)</sup> In addition, the underreporting varies among individuals, but women seem to underreport more than men.<sup>(94, 95)</sup> The degree of misreporting of macro- and micronutrients are, however, inconclusive as assessed by this method,<sup>(93)</sup> but it seems that socially desirable food items were not underreported to the same extent as socially undesirable food items.<sup>(94)</sup> Whether it is a telephone interview or a face-to-face interview does not seem to influence the outcome.<sup>(96)</sup>

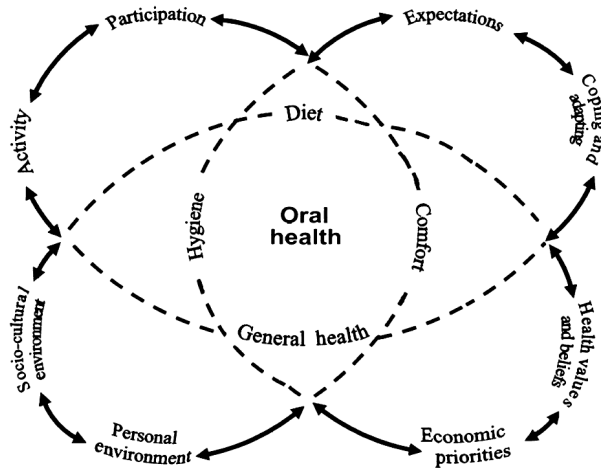
## **Oral health**

Oral health is part of the general health concept and as such it is a multidimensional concept. There is, however, not a generally accepted definition of health, and hence

neither of oral health, which is therefore elusive to date. Nevertheless, based on the World Health Organization (WHO) definition from 1948, health is recognized not only as the absence of disease but also as optimal functioning and social and psychological well-being.<sup>(97)</sup>

Even though this definition, and later classifications in 1980 and 2001, focus on health as opposed to disease, it still does not capture all the interactions of health domains.<sup>(98, 99)</sup> This is clearly demonstrated in the concept of oral health; it reflects the oral status of an individual at any point in time and is influenced by numerous factors such as history of oral diseases, tooth loss and prosthesis wear,<sup>(100, 101)</sup> age and additional cultural, psychological, social, educational, dietary and financial considerations.<sup>(102)</sup> It also tends to change over a lifetime.<sup>(103)</sup> In addition, and perhaps most importantly, oral health cannot be defined in exclusive clinical evaluation terms; subjective aspects such as self-perceived problems and oral related values define oral health for the individual.<sup>(103-105)</sup>

A model visualizing the interactions between principal components of oral health is illustrated in Fig 2.<sup>(106)</sup> In this model, oral health integrates four components, each of which affects peoples' social and personal lives: comfort, general health, hygiene and diet. The model illustrates the interactions between the domains and is a conceptual framework for exploring how people cope with, and adapt to, oral ill health and aim to maintain a positive perspective on life.<sup>(107)</sup>



**Fig 2.** *A model of oral health. (From Brondani et al,2007)<sup>(106)</sup>*

Oral health as such must be measured taking into account the individual's definition and perception of health in the oral cavity as well as adjusting, coping and adapting to predicaments of the oral milieu and social environment.<sup>(5, 108-110)</sup> To assimilate these individual judgments into a single rating the measure has to be simple: "how do you rate your oral health?" The response scale may be a graded Likert scale or a Visual Analog Scale. This measure of self-perceived oral health lets the individuals use different yardsticks in evaluating oral health and this is strengthening the measure as it permits the individual to decide which experiences or factors are most salient to their oral health.<sup>(111, 112)</sup>

The wearing of complete dentures has a profound effect on self-perceived oral health<sup>(101)</sup> and the edentulous report reduced oral health compared to the dentate with a nearly full dentition. Nevertheless, in spite of complete tooth loss, between 47 and 70% of the edentulous report good self-perceived oral health.<sup>(104, 113-115)</sup> In fact, even though the edentulous report reduced oral health compared to the completely dentate they report better self-perceived oral health than the dentate with less than 24 teeth.<sup>(116)</sup> This illustrates the complexity of oral health; being edentulous is worse than to have a

complete, well-functioning dentition, but better than to have a few, still troublesome, teeth. This way, the edentulous focus on different factors than the dentate in the understanding of oral health.<sup>(117)</sup>

Even though wearing complete dentures influence self-perceived oral health, no studies have been found that explore how the edentulous dissatisfied with their dentures, report self-perceived oral health.

## **Quality of Life**

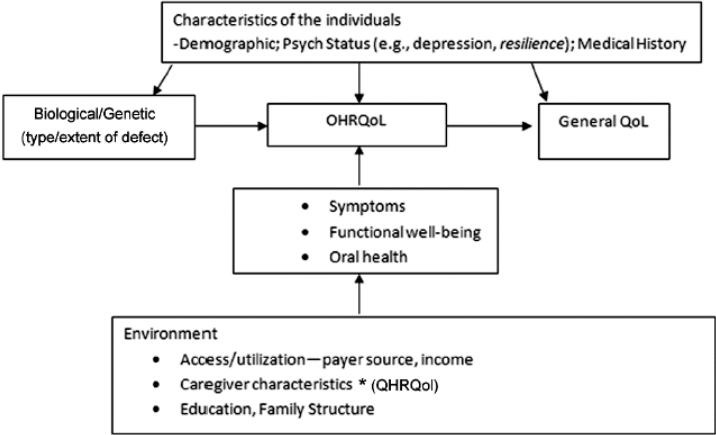
During the last decades the concept of Quality of Life (QoL) has evolved based on WHO's definition of health, and it is widely used as a patient outcome measure (POM) of medical and dental treatment. But despite an overwhelming amount of publications addressing QoL the concept is not clearly defined.<sup>(118)</sup> Nevertheless, it is accepted to be a multidimensional construct that includes aspects like physical health, psychological state and well-being, social functioning, economic situation, relationships and environment. It is a dynamic concept containing both positive and negative attributes and is influenced by individual and social aspects and takes on different meanings depending on the settings.<sup>(107)</sup> Thus the meaning of QoL is arguably dependent on the user of the term, their understanding of it, their position and agenda.<sup>(119)</sup>

Health is clearly associated with QoL, but the concept of health related quality of life (HRQoL) is an equally nebulous concept as QoL. It covers a range of components and refers to the individual's subjective assessment and perspective of his or her current general health condition as well as functional, social and emotional well-being.<sup>(120, 121)</sup> Thus HRQoL is an essential dimension in QoL, but the interrelation of these concepts is rather complex and not clearly defined.<sup>(108, 122)</sup>

Health problems may not necessarily affect QoL. Healthy persons who experience serious illness may report no change in QoL and persons with serious health problems have reported better QoL than healthy persons.<sup>(123, 124)</sup>

Most people regard oral health as important for QoL, and this is mediated through the concept of oral health related quality of life (OHRQoL),<sup>(125)</sup> which can be defined as

the part of QoL that is affected by a person’s oral health.<sup>(126)</sup> The concept is the interaction of different oral conditions, social and contextual factors, as well as the rest of the body (Fig 3).<sup>(109, 120)</sup>



**Fig 3.** A theoretical model of OHRQoL. From Sisco & Broder<sup>(120)</sup>

The interaction between OHRQoL, HRQoL and QoL is similarly complex as previously described, and the impact OHRQoL may have on QoL is not clearly conceptualized or defined.<sup>(107)</sup>

These complex interactions make it challenging to measure QoL and hence disclose possible treatment effects. As QoL is a multidimensional construct it may be meaningless to try to summarize individual multi-item measurements to form a single overall score for QoL.<sup>(127)</sup> Rather, a single-item global measure may be more valid on the individual level as it lets the person put all his or hers understanding, individual assessments and perception of the concept into a single measure. This measure is, however, impossible to use for scientific elaboration as it fails to give insight into factors that, on a group level, might influence QoL. In addition, it’s sensitivity to detect small or even moderate treatment effects in clinical trials is questioned.<sup>(128)</sup>

The need for meaningful measures for further analyses is thus obvious and has led to the construction of a plethora of different HRQoL and OHRQoL instruments.<sup>(129)</sup> These instruments are either generic or disease-specific.<sup>(130)</sup> Generic instruments are designed to assess HRQoL in populations irrespective of health status. However, these instruments may not be sensitive enough to detect changes in HRQoL in any specific illness, but are useful when comparing HRQoL in persons with different diseases or conditions as well as healthy people.<sup>(131)</sup>

A number of generic HRQoL instruments have been developed over the past decades, and The Short Form Health Survey (SF-36) is one of the most comprehensive ones.<sup>(132)</sup> It is a well-documented generic instrument designed to measure health status and is widely used and tested in range of conditions and settings as an HRQoL outcome measure.<sup>(132, 133)</sup> The instrument has been used in different settings in dental research in an attempt to measure a possible impact on HRQoL by oral conditions and treatment of oral problems. However, the occurrence of a number of oral conditions seems to have little impact on HRQoL as measured by SF-36.<sup>(134-136)</sup>

The disease specific instruments are designed to assess the impact of specific diseases or health conditions on QoL.<sup>(130)</sup> In this category several OHRQoL measurement instruments have been developed, each containing between three and 49 questions.<sup>(137)</sup> Instruments such as the Oral Health Impact Profile-49 (OHIP-49), have been developed from a model of oral health status,<sup>(138)</sup> based on perceived oral health problems and attempts to assess their impact on an individual's QoL.<sup>(110, 139)</sup> The instrument contains 49 questions covering seven domains of oral health. A denture-specific short form, the OHIP-20, containing the same seven domains but with only 20 questions has been developed and assesses specific oral health problems associated with wearing dentures.<sup>(140)</sup> It is validated as an OHRQoL outcome measure in clinical studies comparing different treatments for edentulous wearing complete dentures.<sup>(135, 141)</sup>

Oral health measures are more sensitive to oral health outcomes than generic health survey instruments.<sup>(142)</sup> The effect on overall QoL of either of them is nevertheless still



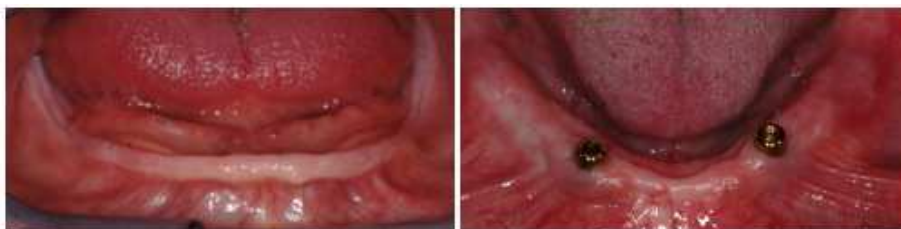
controversial, and therefore a combination of global, generic and disease specific measures are recommended.<sup>(143, 144)</sup>

The effect of tooth loss has been measured in a variety of ways, included the OHIP instrument. A clear association is found between tooth loss and reduced OHRQoL,<sup>(145-147)</sup> especially when it affects well-being, appearance, eating and social dimensions measured by a global question.<sup>(148)</sup>

On the other hand, conventional rehabilitation of the edentate improves OHRQoL and optimizes the patient's oral function.<sup>(149-151)</sup> In addition, dentures have an effect, though minor, on HRQoL, and this association is mediated by OHRQoL.<sup>(152)</sup>

### **Mandibular implant-retained overdentures**

Osseointegration, the physiological attachment between titanium and bone, makes it possible to retain prosthodontic constructions to an integrated implant in the edentulous jaw. During the 1970s, completely edentulous patients were treated with fixed implant-retained prostheses (FIP) in the mandible after installation of 6 to 8 implants. This treatment gave excellent results over a 20 years period.<sup>(153)</sup> However, the treatment protocol was rigorous and costly. Therefore, a less costly and less invasive treatment modality was developed: the mandibular denture retained by two implants (Fig 4), thus turning the denture into an implant-retained overdenture (IOD).<sup>(154)</sup>



**Fig 4.** *Two edentulous mandibular jaws, the one to the right with implants and Locator abutments installed. (Photography: H. Gjengedal).*

This treatment modality soon became implemented in clinical practice. Because the cost of treatment is the main reason for choosing a mandibular overdenture versus a

fixed bridge, the relative prevalence between IOD and FIB treatment varies considerably between different countries.<sup>(155)</sup> This is for the most part due to different health care systems regarding cost of treatment, but also because of different prosthetic traditions in the various countries.

As the IOD treatment for the impaired complete denture wearer became more attractive and thus more common, several clinical studies were implemented and reported excellent results regarding surgical and prosthetic outcome measures.<sup>(156-163)</sup>

In these clinical studies a variety of attachment system were applied; bar retention, ball and magnet attachment. The number of implants varied from two to six. The treatment outcome was generally positive. Nevertheless, the varying designs of these clinical studies were not sufficiently strict to satisfy the requirements of scientific evidence of the IOD treatment.

However, a series of RCTs have been published comparing IOD treatment and CD treatment.<sup>(135, 141, 164-176)</sup> In all RCTs reporting on the treatment outcome of implant-retaining the mandibular denture, the study participants received new maxillary and mandibular conventional dentures. Subsequently, one of the two randomized groups had their mandibular denture turned into an IOD. Even though some of these studies are difficult to compare due to different study designs and methodological limitations like lack of blinding, reporting of allocation concealment and statistical power,<sup>(177)</sup> some significant differences between these two treatment modalities were demonstrated.

Thus, patients receiving IOD reported significantly better satisfaction with the dentures than those treated with only CD.<sup>(168, 172-176)</sup> A meta-analysis including these six studies found a pooled effect size (ES) of 0.80 in favor of the IOD treatment.<sup>(177)</sup> As described by Kazis, an ES more than 0.80 is considered a large change while an ES lower than 0.20 is considered a small change.<sup>(178)</sup>

Even though one recent RCT reports no improvement in masticatory efficiency<sup>(179)</sup> most RCTs conclude that IODs are significantly superior to CDs in this regard.<sup>(57, 180-182)</sup> In addition, three prospective studies with within-subject evaluation report the

same superiority of the IOD treatment.<sup>(183-185)</sup> A ten year follow-up of a RCT concluded that the increased masticatory function following IOD treatment remained unaltered during the follow-up period.<sup>(186)</sup> Regarding chewing ability, the superiority of the IOD is acknowledged,<sup>(173, 175)</sup> but improvement in both treatment groups are reported.<sup>(187)</sup> One RCT even reported a decline in chewing ability regarding tough food items, and with the largest decline in the IOD group.<sup>(188)</sup>

As food choices are influenced in a negative manner by masticatory problems it might be expected that optimizing the masticatory ability will have a positive effect on food choices. As stated above, the results are divergent in this regard as some studies show a change in diet after IOD treatment while most do not.<sup>(187, 189-193)</sup> In these RTCs the patients receiving CD treatment reported the same diverging results in change in food choices. Hence, overall, there is no significant difference between the IOD and CD treatment in the effect on dietary intake.

Nutritional effects of IOD treatment are, as for food choices, not significantly different from the effects of CD treatment. One study reports inadequate nutrient intake post treatment in both groups,<sup>(194)</sup> while another reports a higher risk of malnutrition in the CD group.<sup>(195)</sup> To further illustrate the diverging results; two RCTs report on adequate and improved nutritional state in both study groups.<sup>(189, 190)</sup>

Oral health-related quality of life as measured by the OHIP-20 and OHIP-49 are reported in three studies, which had a pooled effects size of -0.41 in favor of the IOD treatment.<sup>(141, 167, 172)</sup> The effect-size changed to -0.71 when only studies with participants from the general population recruited via advertisement were included. Because of the statistical calculations a positive value is in favor of CD treatment, and a negative value is in favor of IOD treatment and an increase in absolute ES is indicative of a positive change.

Health-related quality of life as measured by the SF-36 is reported in one RCT, but no significant effect of IOD treatment as measured by this instrument was demonstrated.<sup>(135)</sup>

The global questions of QoL and overall self-perceived oral health are not reported in any of the RCTs.

### **Summary of status presence**

Based on the published studies, most of which are mentioned earlier in this paper, the McGill Consensus statement on overdentures<sup>(196)</sup> and later the York statement<sup>(197)</sup> recommended that an implant-retained overdenture should be the first choice of treatment for the edentulous mandible. The reason for this recommendation was the overwhelming body of evidence that demonstrates significantly improved patient satisfaction, OHRQoL, chewing efficiency and ability with implant-retained overdentures compared to conventional dentures.

However, in all the RCTs the patients received new complete maxillary and mandibular dentures before implant treatment. The previously reported treatment effects of new complete dentures on OHRQoL and chewing ability might confound the actual treatment effect of implant-retaining the mandibular denture. So far no RCTs have reported on the various treatment effects of implant-retaining the existing mandibular denture that is of satisfactory technical quality, thus avoiding the confounding effects of a preoperative new denture.

The literature search was ended February 29, 2012.

## **2 OBJECTIVES**

### **Overall aim**

To study QoL, oral health, satisfaction with dentures and diet as reported by patients wearing complete dentures.

### **Specific aims**

- Without intervention: to study oral health and satisfaction with dentures in patients wearing one or two complete dentures.
- With intervention: (implant-retaining as opposed to relining), to study the effects of implant-retaining the existing mandibular denture in patients dissatisfied with their mandibular denture in regard to dietary intake, nutritional status and long-time effect on oral health, OHRQoL, HRQoL and overall QoL.

### **Hypotheses**

Study without intervention: There are no significant differences between patients wearing one or two complete dentures regarding any of the outcome variables.

Studies with intervention: There are no significant differences during the 2-year follow-up between the IOD group and the RCD group regarding any of the outcome variables.

### **3 MATERIALS AND METHODS**

The materials and methods used in these studies (Paper I, II and III) are extensively described in the respective papers. Here follows a brief summary:

#### **The Survey Study (Paper I)**

##### **Study design**

This was designed as a survey study.

The study sample was recruited from all 294 patients, aged 76 years or younger, who had been treated with one or two complete dentures at the Department of Prosthodontics, Faculty of Dentistry, Bergen, Norway, in the period 1997 to 2005. All patients were invited by letter to participate in an interview and have a clinical examination, free of charge. The patients were thereafter contacted by telephone and 176 respondents (60%) accepted the invitation and had an appointment. Four respondents were excluded, one because he did not attempt to fill out the OHIP-20 questionnaire, and three because they had a single mandibular denture and therefore were regarded as outliers. The remaining 172 respondents constitute the study sample.

The aim of the study was to study patient-reported oral health and satisfaction with dentures and make inferences regarding variables associated with oral health and satisfaction.

##### **Instruments used**

The participants completed a self-administered questionnaire containing items regarding demographics, denture status and experience, appetite, avoiding food items as a consequence of wearing dentures, perceived general and oral health, satisfaction with dentures, various aspects of wearing dentures and the OHIP-20 survey. The data were registered and dichotomized.

## **The Randomized Controlled Trial (Papers II and III)**

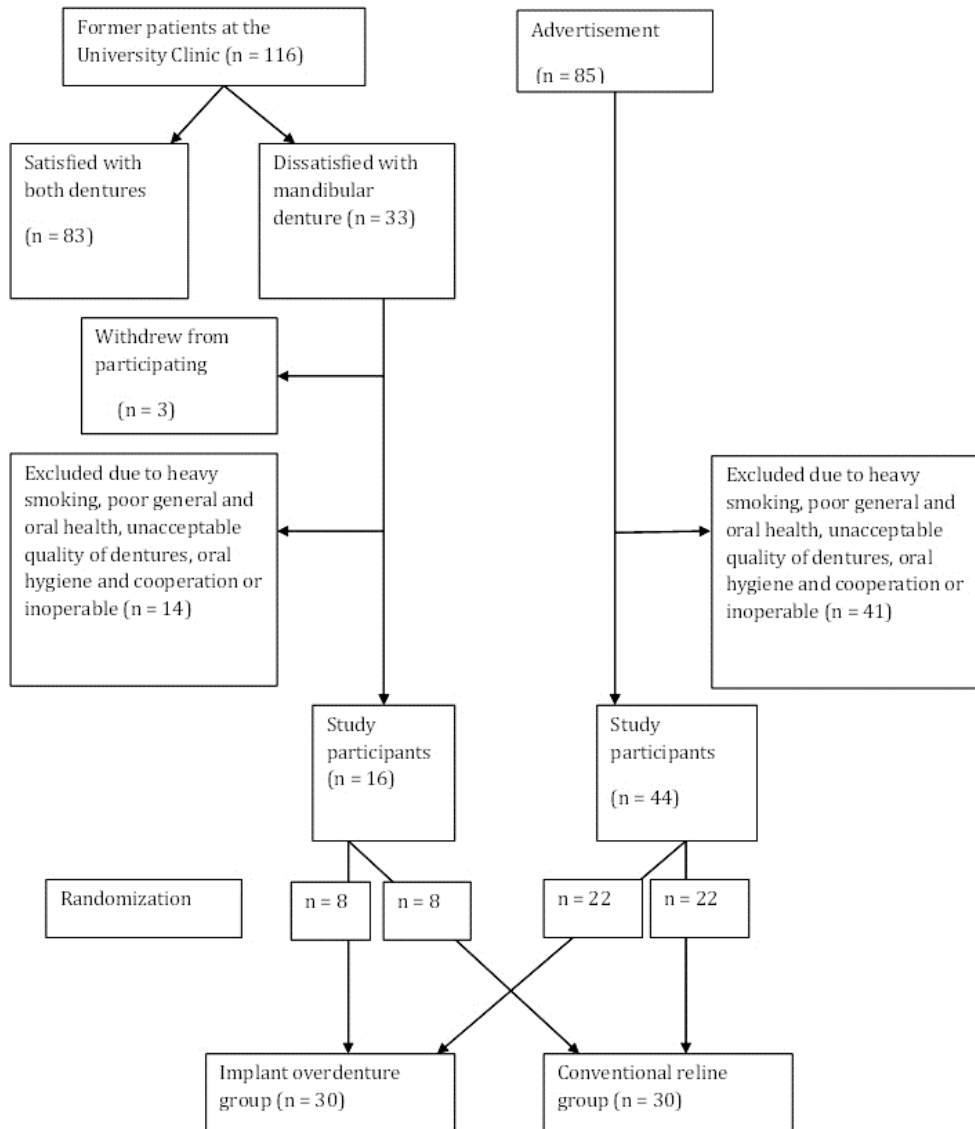
### **Study design**

The study was designed as a randomized, 2-year longitudinal clinical study in which the selected edentulous subjects were randomly allocated into one of two different treatment modalities for the mandible: implant-retained overdenture (IOD) and relined conventional denture (RCD).

Patients selected to participate in the study had to be wearing complete dentures in both jaws and specifically express dissatisfaction with their mandibular denture. In addition, the dentures should be of acceptable technical quality and the oral mucosa healthy. Four calibrated specialists in prosthodontics assessed these criteria. The patients should be  $\leq 76$  years, have acceptable general health, be cooperative and communicate easily, smoke less than 20 cigarettes per day, and with no general or local contraindications to inserting two mandibular intraosseous implants. A specialist in oral surgery and oral medicine assessed the latter criteria.

A convenience study sample was recruited during two periods between 2006 and 2008. The first recruitment was from the survey study (paper I), in which 116 were completely edentulous (batch 1). The second recruitment was made by advertising for participants in 7 newspapers in Bergen and nearby regions, and through referrals from dentists in Bergen. Eighty-five edentulous persons responded during this second recruitment period (batch 2) and were invited to a clinical examination.

Fig 5 shows the flow chart of the selecting process of participants. As a result of this process, 16 subjects from batch 1 and 44 from batch 2 constituted the final study sample. To ensure even treatment distribution in each of the two batches, the patients in batch 1 blindly drew a ticket with the treatment allocation from an original stack of 16, with 8 tickets of each of the two treatment modalities. The same procedure was followed for the patients in batch 2; each patient drew a ticket from an original stack of 44, with 22 of each treatment modality.



**Fig 5.** Recruitment flow of study participants

Before random allocation to treatment groups the patients were only generally informed about the aim of the study. After allocation they were informed in full, but only about the specific treatment they were allocated to. All treatment was offered at no cost, and the patients were guaranteed free treatment with the alternative treatment



modality after the study period of 2 years, if they should so wish. The patients could withdraw from the study at any time without consequences. An informed consent to join the study was signed.

In the IOD group two Astra OsseoSpeed implants (Astra Tech AB, Mölndal, Sweden) were installed using a standardized one-step surgical technique. Six weeks later Locator abutments (Zest Anchors, Escondido, CA, USA) were installed. Existing dentures were relined with Vertex<sup>TM</sup> self-curing acrylic (Vertex Dental B.V., Zeist, The Netherlands), during which Locator patrices were mounted. The mandibular dentures in the RCD group were indirectly relined using the same materials. All clinical procedures were performed by a specialist in oral surgery and by the first author.

### **Instruments used**

The participants completed a self-administered questionnaire at baseline, at three months, 6 months, one year and two years after completed prosthetic treatment. The questionnaires contained the same issues as the survey questionnaire, but in addition contained items regarding overall quality of life, health status (SF-36), general well-being (WHO-Five) and coping strategies (BACO).

Overall quality of life (QoL) was registered by responses to a global question on a 5-point Likert scale. The Medical Outcomes Study Short-Form 36-Item Health Survey (SF-36) is a generic multi-purpose health survey designed to measure subjective health status. The 36 items are divided into eight domains that again are collected in a physical and a mental dimension that each reflects physical and mental health symptoms. Calculations of the SF-36 scores were made with the Quality Metric Health Outcomes(tm) Scoring Software 4.0 transforming the scores of each domain and dimension into a 0-100 scale where 100 represents the most positive score.

The WHO-5 Well-Being Index (WHO-Five) is a five-item modification of the Positive General Well-Being Scale and measures positive well-being. Each item is registered on a six-point Likert scale and a greater sum score represents greater problems. The Brief Approach/Avoidance Coping Questionnaire (BACQ) is a 12-item index designed

to measure a general concept of approach versus avoidance-oriented coping of illness or problems. Responses are registered on a five-point Likert scale, where a lower sum score represents better coping ability.

### **Dietary assessments**

Three unannounced 24-hour dietary recalls (24hRs), Tuesdays through Fridays, were obtained by telephone approximately 4, 8 and 11 months after treatment. Trained personnel conducted the interviews and a structured template was used to collect detailed information on dietary intake during the previous 24 hours. These data were entered into a free computer program (“Food on data”) based on nutrient values from the Norwegian food composition table. The average dietary intake for the three 24hRs was used to calculate intakes of energy, fat, protein, carbohydrate, vitamins and minerals.

During the 24hR interviews the patients were additionally asked if the treatment they had received had made a difference in terms of chewing ability or in the amount of any food items consumed. They were also asked how many times per week they had fish at their main meal.

### **Methodological considerations**

The survey study was designed as a cross-sectional questionnaire study combined with a clinical examination for two reasons; first of all to explore the level of satisfaction and self-perceived oral health among patients treated with complete dentures at the university clinic, secondly to recruit participants for the RCT. The instruments chosen to assess the appropriate data were, except for the Norwegian version of OHIP-20, validated instruments. The Norwegian version of OHIP-20 was to be validated in our study by a test-retest procedure.

The intervention studies were designed as a randomized clinical trial (RCT) in order to fulfill, to the best possible extent, the principals of evidence-based medicine. A more complex intervention was to be compared to a standard intervention. The instruments used to assess the data were validated and appropriate for testing the hypothesis regarding the two interventions.

## Ethical clearance

The study protocol, including the above procedures, was approved by The Regional Committee for Medical Research Ethics in Norway, Health Region West (ref nr 05/8161) and registered at the Norwegian Social Science Data Services (NSD).

## Statistical analyses

Several different statistical methods were used in the analyses (Fig 6). Data were analyzed using the Statistical Packages for the Social Sciences (SPSS), versions 15-18 (Chicago, Illinois, USA). The significance level was set at 0.05.

Statistical methods	Paper I	Paper II	Paper III
Descriptive statistics	•	•	•
Chi-square test	•	•	•
Fisher exact test		•	•
<i>t</i> -test		•	
Repeated measure analyses of variance			•
Effect size calculation			•
Mann-Whitney U test		•	•
Friedman test			•
Wilcoxon signed rank test			•
Logistic regression	•		•
Multiple linear regression			•
Power analysis			•

**Fig 6.** *Statistical methods used in the analyses*

## 4 RESULTS

### Paper I

Non-response was 40% (n = 118). The mean age of the 172 participants was 67 years and 52% (n = 89) were males. Sixty-seven percent (n = 116) had complete maxillary and mandibular dentures and 33% (n = 56) had a complete maxillary denture opposing a dentate mandible.

In the completely edentulous group the mean age was 68 years and the genders were equally represented (57 males and 59 females). A majority (82%, n = 95) reported satisfaction with their dentures. Good or very good oral health was reported by 67% (n = 78); 62% (n = 72) reported good or very good general health.

In the partially edentulous group the mean age was 66 years and 57% (n = 32) were men. In this group 66% (n = 37) reported satisfaction with their dentures. Good or very good oral health was reported by 46% (n = 26). Sixty-three per cent (n = 35) reported good or very good general health.

### *Bivariate relationships*

The complete denture wearers reported significantly better oral health and were more satisfied with their dentures than the partially edentulous were ( $P < .05$ ).

### *Multivariate relationships, oral health*

In the completely edentulous group the final model for global self-reported oral health contained three independent variables (Table 1): OHIP-20, speech and avoiding certain food items ( $P < .001$ ). In the partially edentulous group the final model contained two independent variables: denture retention and age group ( $P = .002$ ) with ORs of 5.1 and 4.2, respectively.

### ***Multivariate relationships, denture satisfaction***

In the completely edentulous group the final model contained two independent variables: OHIP-20 and maxillary denture aesthetics ( $P < .001$ ) recording ORs of 19.1 and 13.0, respectively. The final model for the partially edentulous included only one variable: Maxillary denture comfort with an OR of 22.5.

Fig 7 gives an overview of all statistically significant variables showing dissimilar responses to global self-reported oral health and global satisfaction with dentures for the partially and the completely edentulous groups, at the descriptive, bivariate (step I) and logistic regression levels (step II-III) of analyses.

**Fig 7.** Statistically significant variables with dissimilar responses to the two global outcome variables for the two groups.

Type of analyses	Outcome variable	Completely edentulous	Partially edentulous
Descriptive	Global <i>good</i> oral health	67 %	47 %
	Global <i>good</i> satisfaction with dentures	82 %	66 %
Cross-tabulations Explanatory variables	Global Oral health	Avoiding food items Denture satisfaction Chewing Speech Comfort (both jaws) Pain (both jaws) Fit (both jaws) Aesthetics (maxillary) Retention (mandibular)	Retention (maxillary) Age
	Global satisfaction with dentures	Oral health Comfort (mandibular) Fit (both jaws) Aesthetics (maxillary)	Retention (maxillary) Speech
Logistic regression Step III Predictive variables	Global Oral health (Tables 1 and 2)	OHIP-20 Speech	Retention (maxillary) Age
	Global satisfaction with dentures (Tables 3 and 4)	OHIP-20 Aesthetics (maxillary)	Comfort (maxillary)

## **Paper II**

In the follow-up after treatment, seven patients did not complete all the interviews and were excluded from the analyses. This left a study sample of 53 patients, 27 in the IOD group and 26 in the RCD group. The IOD group included 17 women and 10 men, with mean age 68 years (range 48-78), whereas the RCD group included 16 women and 10 men, with mean age 67 years (range 52-78).

The IOD group reported significantly lower prevalence of food avoidance at all controls than the RCD group did. Similarly, in the 24hRs, the IOD group reported improved chewing ability and improved capability to consume more of some food items.

There were no significant differences between the groups regarding reported consumption of the main food items. The intake of fish was rather high, but without significant difference between the groups. Equally, no significant differences were found in mean energy, fat, protein, carbohydrate or vitamin intake between the treatment groups, hence further analyses were made for the complete study sample.

Almost all the patients had an energy intake below the Nordic recommendations, as were the relative energy intake of macronutrients. Most of the patients had higher energy intake from fat, especially saturated fat, and protein, but a carbohydrate intake below the recommendations. The mean fiber intake was only half of the recommendations for almost all the patients. The total (dietary and supplements) mean daily intake of vitamin D was 16 µg and 62% of the patients had more than the recommended intake. The mean intake of folate was low and none of the patients had the recommended intake.

Men had a higher total energy and fat intake, especially saturated fat, compared with women, who, on the other hand, had a higher energy intake from carbohydrates.

## **Paper III**

### *Between group comparisons at baseline*

Six patients were lost to follow-up and were excluded from the analyses. This left a study sample of 54 patients: 28 in the IOD group (18 women and 10 men) and 26 in the RCD group (17 women and 9 men). The mean age in the IOD group was 68 years, and 67 years in the RCD group. There were no significant differences between the groups regarding gender, age or any of the other variables.

### *After three months*

Three months after prosthetic treatment the IOD group reported significantly better overall self-perceived oral health and lower OHIP-20 total score than the RCD group did. There were however no significant differences between the groups regarding the global question of Quality of life, the BACQ, WHO-Five or SF-36 summary components or any of the domains.

### *After two years*

Two years after treatment the IOD group reported significantly better self-perceived oral health and lower OHIP-20 total score than the RCD group. A comparison between the groups of the clinical impact of OHIP-20 at two years showed that the IOD group had a significant higher portion of responses indicating only small clinical problems for the OHIP-20 total score and for five of the domains.

### *Within group comparisons*

In the RCD group no significant changes occurred for any variable during the two-year follow-up period and in the IOD group there were no significant changes regarding the variables Quality of life, the BACQ or the WHO-Five indices.

In the IOD group significant improvement was registered for the OHIP-20 sum score and all seven domains from baseline to two years follow-up. An improvement was also



registered for self-perceived oral health. In fact, the significant changes had occurred at the three months control and remained stable until the two-year control. No further significant changes occurred in the period from three months to two years for these variables.

Analysis of the SF-36 measures in the IOD group showed that the Role physical and General health domains and the Physical component significantly decreased after two years, indicating a deteriorating situation.

Effect size calculations for OHIP-20 changes in the IOD group showed definite positive effects for the sum score and most of the domains with effect sizes over 1.0. For the SF-36 almost all effect sizes were negative and generally small.

Multiple linear regression analyses for OHIP-20 change (pre-treatment – two years post-treatment) were performed for both groups combined. The multiple linear regression analyses included nine baseline variables either showing significant correlations with OHIP-20 or were of clinical interest. In the final model, only Treatment was statistically significant, with a B value = 29.96,  $P < 0.001$ .

Multiple logistic regression analyses for oral health two years after prosthetic treatment were performed for both groups combined. In the forward stepwise logistic regression analysis the final model included five variables. IOD treatment had the highest OR with 6.4. This means that patients treated with implant-retained overdentures were 6.4 times as likely to report good oral health compared with those who were treated with a conventional relining.

## 5 DISCUSSION

### **Methodological considerations**

These studies have been designed, performed and reported, intentionally using the best possible methodology, according to principles for evidence-based medicine.<sup>(198)</sup> Still there are methodological considerations that must be taken into account when interpreting the findings.

### **Internal and external validity of the studies**

The internal and external validity of any study is of paramount importance for the interpretation of the outcome. Internal validity is the extent to which instruments used measure what they are intended to measure, whereas external validity is the extent to which the reported outcome can be reasonably applied to a definable group of patients in the general population in a similar clinical setting.<sup>(199)</sup>

In terms of internal validity RCTs represent the most scientifically rigorous method. When properly executed they will have strong internal validity as they are best able to control bias (systematic and/or random error). They serve as the gold standard of study design for evaluating treatment efficacy and are widely recognized as level-1-evidence for evidence-based practice.<sup>(198)</sup> Despite several guidelines, RCTs are reported to be somewhat inferior to recommendations,<sup>(200-202)</sup> particularly those pertaining to HRQoL in RCTs.<sup>(203)</sup> The different forms of bias in question are selection bias, performance bias, detection bias or attrition bias.

Selection bias occurs when the randomizing process fails to ensure two balanced treatment groups.<sup>(199)</sup> Our randomizing procedure should comply with this requirement. Performance and detection bias occurs if the two treatment groups are not followed up and observed in a similar manner. Both our study groups also conformed to this condition. Attrition bias occurs when there are systematic differences between the treatment groups in the loss of study participants. This loss of participants may render the two treatment groups different in baseline values and hence an intention-to-treat principle should be applied. However, no such systematic differences between the

present treatment groups occurred. Random error is another aspect that might influence internal validity and occurs when variability of the measured data arise purely by chance.<sup>(199)</sup> The sample size in our study is considered large enough to reduce considerably this risk.

In the survey study the non-response was 40%, which may influence the validity of the results if these were significantly different from the respondents.<sup>(204)</sup> However, in a recently published paper, using the same sample as in the survey study, no significant differences could be discerned between the responders and non-responders on questions concerned with care<sup>(205)</sup> For that reason it might be argued that it is unlikely that such a bias should exist with regard to the questions of the survey study. Regardless, it has been reported that non-response up to 70% in oral health surveys is acceptable if the responses are evenly distributed.<sup>(206)</sup>

In our RCT the principles of intention-to treat are applied throughout the randomizing process, ensuring adherence to allocated treatment and similar follow up and assessments in the two groups. The loss of participants was very small and was not related to any of the inclusion or exclusion criteria for the study. Hence we did not do ITT analysis, but performed per protocol analysis although taking into consideration that this might produce an overestimation of clinical effectiveness.<sup>(207-209)</sup>

Single questions with global rating were used to assess oral health and satisfaction. These questions are valid as they comprise all the aspects each patient put into his or her evaluation of the concept. In addition, this is an instrument used as a gold standard for assessing the validity of multi-item OHRQOL instruments.<sup>(210, 211)</sup> The OHIP-20 questionnaire, which was applied to assess OHRQOL, is the most frequently used instrument for this purpose in the edentulous and is validated for this purpose.<sup>(135, 149, 212)</sup>

For all of the above reasons it would seem that the internal validity of our survey study as well as the RCT ones are of acceptable standards.

However, the most frequent criticism by clinicians of RCTs is lack of external validity, and it must be acknowledged that clinical judgments rather than statistical expertise

are required to evaluate this aspect.<sup>(213)</sup> Moreover, there are no accepted guidelines on how external validity should be assessed<sup>(214)</sup> although the latest version of the CONSORT-STATEMENT points to important aspects of external validity.<sup>(215)</sup>

As stated earlier, the external validity is a matter of generality and is dependent on the study sample in relation to a general population with a similar clinical situation.<sup>(198)</sup> Patients seeking treatment at a university clinic may do so for several reasons; cost of treatment is low, they live in nearby regions of the university, they want high quality treatment and they also accept longer treatment periods. Thus their expectations and acceptance of treatment outcome may not be equal to those of a population seeking treatment in general dental practice. However, 44 of the 60 patients in the RCT studies were recruited from general practice, reducing the risk of arguable external validity on that account.

Participants in the RCTs were specifically dissatisfied with their mandibular denture in addition to fulfilling all inclusion and exclusion criteria. Most complete denture wearers are not similarly dissatisfied.<sup>(19, 20, 23–25)</sup> Hence the findings and magnitude of treatment outcomes of these studies may not be applicable to all complete denture wearers.

The criterion of being dissatisfied with the mandibular denture may influence treatment preferences and hence influence the treatment effect size.<sup>(216)</sup> This clinical situation is well known to clinicians. Our findings and others from more pragmatic RCTs ought to enable clinicians to better decide whether or not a specific treatment will benefit a patient wearing complete dentures.

Reliability in the studies depends on the instruments used to assess the specific variables. The self-report instruments OHIP-20, SF-36, BACO and WHO-Five are widely used and their reliabilities are validated.<sup>(132, 138, 217, 218)</sup> The instrument to assess dietary intake, the 24hRs, has likewise been used for many years and with acceptable reliability and validity.<sup>(91)</sup>

## Results

In our studies an attempt was made to disclose the subjective views of complete denture wearers and how they experience their situation. To this end we have analysed results from patients without intervention, who were wearing one and two dentures (study I). We have also analysed the results from patients where two different interventions have been implemented. These approaches were made so that the influence of the different settings on the subjective experiences might be studied. Consequently, these are also comparison studies, where differences as well as likenesses are brought to light. Furthermore, in order to focus on those who have the most acute problems, and whose need for purposeful treatment is greatest, the latter studies were made on completely edentulous who expressed dissatisfaction with their mandibular dentures (studies II and III).

The main results of these studies consist of expected as well as less expected findings. As expected, patients with implant-retained mandibular overdentures reported significantly improved OHRQoL, physical function and oral health, improved masticatory ability and a lesser tendency to avoid certain food items (study II and III). Perhaps less expected was the finding that patients with two dentures were significantly more satisfied with their dentures and their self-perceived oral health compared with those who had only one denture (study I).

Somewhat less expected is also the finding that although patients with implant retained dentures claimed to have experienced all the above functional improvements – including better masticatory ability – their diet was unaffected and still seriously defective both in terms of energy, fibre, vitamins and minerals (study II). Also, the finding that older patients have a more positive attitude to their status than the younger ones is a paradox. Interestingly, the advantages experienced by patients with implant-retained overdentures did not translate into significant improvements in HRQOL, QOL or well-being indices (Study III).

The dissatisfied denture wearer thus depicts a complex situation. The individual reactions are obviously influenced by the physical and psychological challenges that exist, but equally by the ability to adapt and resign. Into this equation the unconscious comparing of the different function of the two jaws also appears to play a part. In terms of intervention the most important finding is that the positive effect of implant-retaining the mandibular denture makes a subjective significant difference lasting for at least two years.

The main objective effects of implant-retaining the mandibular denture are an increase in denture retention and stability. The effect this has on the patient reported outcomes is reflected in changes in the different measures applied in this study. Measures directly linked to denture function are sensitive to this change, while measures that include additional psychological, social, personal, and perhaps even habitual, weighting are less sensitive to improved denture retention and stability.

Improved OHRQoL in the IOD group, as measured by the OHIP-20, is in accordance with results from other RCTs.<sup>(135, 141, 167, 172, 219)</sup> However, the other studies reported improved OHRQoL in both the IOD and the CD group, although with greater improvement in the IOD group, except in the study by Allen et al that showed no difference between the groups<sup>(172)</sup> This is in contrast to the RCD group in this study, which reported no improvement at all and confirms that the present study design accentuate the true effect of implant-retaining the mandibular denture.

There are two aspects that clearly illustrate the effect of increased retention and stability; first of all, compared to the other RCTs, the ES in the IOD group regarding OHRQoL is larger, whereas the ES of 0.0 in the RCD group is much lower than in the CD groups. Secondly, only the domains directly linked to denture function (functional limitation, physical pain and physical disability) are significantly different in the IOD and RCD groups two years after treatment. In the other RCTs all patients received new complete dentures and both treatment groups reported improved OHRQoL. This implies that implant-retaining the denture in dissatisfied patients has a profound effect on OHRQoL, whereas relining the denture does not have any effect at all.

The ES in both groups in this study might be influenced by their baseline maladaptive denture function. The effect of implant retaining the mandibular denture might be increased in patients dissatisfied with their denture<sup>(220)</sup> whereas relining the denture, which is of acceptable quality as judged by the dentist, might be a disappointment and thus seems futile.

All RCTs reporting on OHRQoL, as measured with OHIP, report significant improvement in the IOD group, and this reduced negative impact of wearing dentures was significant in all subdomains of the OHIP. However, the difference between the groups on the domain level varied. Interestingly, in the present study, with no improvement in the RCD group, it was only in the three physical domains that the IOD group was significantly better than the RCD group. Again, this emphasizes the importance of actual denture function.

The ES is used as a measure of a clinically important difference. In this study the ES in the IOD group was larger than previously reported. In addition the ES in the RCD group was zero while the other studies reported ES between 0.4 and 0.8 in the CD group. This illustrates that conventional denture treatment does have an impact on OHRQoL whereas a conventional relining of a technically acceptable denture does not have any effect.

In all RCTs reporting ES the same two domains: social disability and handicap, had the smallest ES, indicating low to moderate effect of implant treatment. These domains are influenced by numerous individual factors in addition to denture function, and thus seem to be only moderately sensitive to implant-retaining the denture.

Implant-prosthetic treatment seems to have an immediate effect on OHRQoL. Other RCTs have reported on two and three month results concurrent with our three months results.<sup>(141, 167, 172)</sup> In terms of intervention the most important finding is, however, that the positive effect on OHRQoL of implant-retaining the mandibular denture makes a subjective significant difference lasting for at least two years. This is concurrent with a recent RCT study reporting that an improved OHRQoL was stable two years after treatment.<sup>(219)</sup> This study, however, reported that compared with the IOD group, a smaller, but significant improvement occurred in the RCD group, also lasting after two

years. Accordingly, the available evidence seems to indicate that in terms of OHRQoL the relative change of subjective evaluation is very small over time.

Problems related to wearing dentures, as measured by OHIP-20, is predictive of oral health in the edentulous (Study I). The IOD group reported significantly improved oral health as well as improved OHRQoL (Study III). This is not reported in earlier RCTs, and hence the explanation is not straightforward. The single question of oral health contains all the patients' individual weighting of factors they find pertinent to their oral health. The fact that a reduced frequency of problems related to wearing dentures not only resulted in an almost immediate better rating of oral health, but that the rating indeed persisted two years after treatment, indicates the importance of denture function in oral health perception. It also indicates that the global measure of oral health is sensitive to this change in denture function. The global question of oral health therefore seems to be a valid outcome measure of implant-prosthetic treatment in the edentulous. This finding illustrates that oral health for the edentulous is highly dependent on denture function and includes other aspects than oral health for the dentate.

This is further illustrated in the finding that age was predictive for oral health in the partially dentate but not in the edentate (Study I). However, this somewhat paradoxical finding is in agreement with earlier reports in both dentate<sup>(221-223)</sup> and edentate.<sup>(117, 224)</sup>

The younger and the older have different attitudes and expectations to health status.<sup>(225)</sup> The younger, generally, have less health problems and higher expectations of a healthy life.<sup>(226)</sup> Oral health problems and especially the wearing of a removable denture appear to have a negative impact on self-perceived oral health.

Older dentate, on the other hand, are more positive regarding their health status. They probably tend to accept oral health problems as part of the aging process, not as real problems on which they should focus.<sup>(102, 227)</sup> Hence, in terms of oral health problems and objective oral health measures, the presumption that older people report more problems appears erroneous.



Furthermore, oral health in the dentate is predicted by oral health problems as measured by the OHIP-49, and the subjective need for dental treatment; both moderated by age.<sup>(117)</sup>

These findings illustrate some of the complexities of oral health; age is a predictor of oral health in the dentate but not in the edentate, denture function is a predictor of oral health in the edentate but not in the partially dentate. They also illustrate how focus changes when all teeth with all their problems are lost, and the function of the dentures then becomes the main center of attention.

The importance of denture function is further demonstrated in improved masticatory ability and less food avoidance in the IOD group. These findings are to be expected and most RCTs report the same effect of this treatment modality.<sup>(141, 168, 174, 175, 187, 193, 228-231)</sup> Interestingly, even though these studies assessed masticatory ability and food choices using listed food items of varying consistency, the outcomes were comparable to the responses to the open-ended questions applied in our study. That these various methods give comparable results emphasizes the effect of improved denture function on masticatory ability and has been shown to be persistent even after 5 years.<sup>(230)</sup>

In view of the fact that no changes in dietary intake was reported by the patients, the improved chewing ability and a reduction in food avoidance in the IOD group seems paradoxical. However, the literature on food choices portrays an overwhelming complexity of eating behaviours and factors that may influence this over the years.<sup>(81, 232)</sup> This complexity is confirmed in a recent paper; despite improved masticatory ability and a change in dietary intake towards more fruits and vegetables in the IOD group, 12 months after treatment there was no change in nutritional status.<sup>(233)</sup>

Only rarely is masticatory ability or OHRQoL a variable in the equation.<sup>(82, 234)</sup> As discussed earlier, and confirmed in this study, the dietary intake in the edentulous is inferior to recommendations. Unfortunately, from a prosthetic rehabilitation point of view, chewing ability in complete denture wearers only account for 4 to 8% of the input factors in dietary habits and food choices.<sup>(78)</sup>

In conclusion, better chewing ability does not automatically lead to a change in food choices. Through the years they have adjusted their diet and eating scenarios but not recognized that their dietary intake had gradually deteriorated.

Despite a significant improvement of OHRQoL the measures of HRQoL, QoL and general well-being were not significantly influenced. The generic questionnaire of HRQoL, the SF-36, did not capture any possible changes after the prosthetic intervention. Neither did the single global question regarding QoL nor the well-being indices. Few studies have reported on these variables, but the findings of those that do, are in agreement with the findings in this study.<sup>(135, 164, 165)</sup>

It would thus appear that the measures of HRQoL, QoL and well-being are not sensitive to the impact of prosthetic treatment. If the measures and the intervention are not logically, medically or mentally connected, the different measures must be looked upon as separate constructs. A measure of health status, like SF-36, is not necessarily a measure of how the patients evaluate this in a QoL aspect, and oral health, general health status and QoL are different constructs mostly unrelated in a seemingly healthy population.<sup>(235)</sup> Actually, a relationship between oral health and HRQoL are only found when the persons had specific health conditions.<sup>(236)</sup> Nevertheless, the impact of oral health on a person's perceptions of overall health is not yet fully captured by HRQoL measures.<sup>(237)</sup>

The lack of impact on QoL is illustrated in a study by Locker et al where the participants were asked to what extent oral problems affected their QoL.<sup>(144)</sup> Of the participants reporting oral problems (29%) only a small portion (2%) reported an impact on QoL. In addition, the OHIP-20 measures frequency of oral problems, not the patients' evaluation of impact on OHRQoL. This offers the most likely explanation why the IOD and the RCD group report different oral health and frequencies of oral problems after treatment, but still report no difference in their perception of QoL.

The same line of reasoning can be applied to the various concepts of psychological well-being. Most instruments used to assess well-being perform adequately for survey research, but we know less about their validity for use in evaluating health care

interventions. There is an ongoing debate on how adequately the questions included, portray the theoretical definition of well-being on which they are based.<sup>(238)</sup>

The WHO definition of health includes positive aspects, and the concept of QoL is basically a concept of positive constructs. However, most measures of QoL associated measures focus on negative aspects.<sup>(121, 125)</sup> The positive aspects are pointed out as important aspects of oral health, thus focus should be on possibilities and instead of on limitations and restrictions.<sup>(106)</sup> Oral problems are not necessarily associated with restriction, dysfunction or illness and concerns about these negative associations are expressed in recent years.<sup>(239)</sup>

The lack of a definite definition of QoL leads to the use of the concept with a lack of conceptual precision. Thus the use of the term “quality of life” as a universal suffix may eventually render it meaningless.<sup>(240)</sup> As a construct, QoL may be too broad and nonspecific as a treatment outcome, and eventually should be replaced by a more treatment specific outcome measure.<sup>(241)</sup>

This study differs from other RCTs in one important aspect; no patient received new dentures. Most likely for that reason, the significant improvement reported by the CD groups in other RCTs was not corroborated. On the other hand, in our study the IOD group reported significant improvements with a higher ES for OHRQoL than previously reported, without the confounding effect of new dentures.

## 6 GENERAL SUMMARY AND CONCLUSION

Most complete denture wearers are satisfied with their dentures and report good oral health. The partially edentulous wearing a maxillary denture report significantly less satisfaction with their denture and oral health.

The study hypothesis of no differences between the two groups of denture wearers regarding satisfaction and self-reported oral health is rejected.

Complete denture wearers dissatisfied with their mandibular denture, and having their denture retained to two implants, report significant improvement regarding the following outcome variables:

- Masticatory ability
- Food avoidance
- Ability to eat certain food items
- Oral health
- Oral health related quality of life (OHRQoL)

Complete denture wearers having their mandibular dentures relined report no significant changes regarding these outcome variables.

The study hypothesis of no differences between the two treatment groups regarding these outcome variables is rejected.

Both treatment groups report no significant changes regarding the following outcome variables:

- Dietary habits
- Nutrient intake
- Health related quality of life (HRQoL)
- Overall quality of life (QoL)

The study hypothesis of no differences between the two treatment groups regarding these outcome variables is not rejected.

This study shows that improvement of mandibular denture retention and stability has a positive impact on denture function, oral health and oral health related quality of life in the edentulous. However, other aspects of wearing complete dentures that in addition depend on habits, individual preferences or individual values in quality of life are not significantly influenced by the treatment intervention.

## **7 FUTURE PERSPECTIVES**

### **The scientific approach**

The treatment of implant-retaining the mandibular denture is the prosthodontic treatment with the most patient-reported outcome measures. Still, as this thesis suggests, measurements of several aspects of oral health and QoL need to be further elaborated and conceptualized in order to specify treatment effects that are effective and valuable to patients with various clinical conditions.

Furthermore, the lack of impact on dietary intake by implant-retained dentures should be addressed. The documented insufficient nutritional status of edentulous is conspicuous and research should focus on the interactions between prosthetic interventions and nutrition in order to optimize dietary intake.

### **The clinical approach**

The treatment modality of implant-retaining dentures should be implemented in both education and general practice. The actual treatment procedure is known to most dentists and should not be a hindrance against offering this to those who are in need of the treatment.

Dietary counseling in combination with prosthetic treatment significantly tends to change the diet <sup>(242)</sup> and should be implemented along with the prosthetic treatment of the edentulous.

### **The patient-centered approach**

The edentulous should not have to accept a conventional denture with which they are dissatisfied or with which they cannot function in everyday life. The treatment modality of retaining the mandibular denture to implants must be recognized and made available to those in need of a better functioning mandibular complete denture.

Several issues must be pointed out in this regard:

- The treatment modality should be advertised. This is necessary because dissatisfied, and probably resigned, complete denture wearers do not stand in line for treatment.
- The treatment modality should be made available to complete denture wearers.
- The government should make such treatment affordable to the edentulous, since these patients are in fact functionally, psychologically and sociably handicapped.

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