PSYCHO-SOCIAL WELLBEING AND ITS RELATIONSHIP WITH PROSTHETIC MAINTENANCE IN PATIENTS WITH 1 AND 2 IMPLANT OVERDENTURES. A 5-YEAR FOLLOW-UP

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In The Faculty of Graduate and Postdoctoral Studies (Craniofacial Science)

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Abstract

Aim:

To study the effect of implant overdenture maintenance events on psychosocial outcomes using existing Visual Analogue Scale (VAS) and Oral Health Impact Profile (OHIP-49) measures, and to assess the association between VAS overall satisfaction and OHIP scores.

Materials and methods:

The data for this study were obtained from the charts of 86 edentulous patients who began implant overdenture treatment in a randomized clinical trial at the University of British Colombia between 2003 and 2006, and were followed for 5 years. Participants had been randomly assigned to receive either one or two implants to retain their mandibular dentures. Each participant had completed two patient-based outcome questionnaires at baseline before implant treatment, two months, one, three and five years after treatment. The questionnaires were the OHIP-49 and VAS assessing the following denture related variables for mandibular and maxillary dentures separately (pain, comfort, appearance, function, stability, speech, hygiene, and overall satisfaction). All maintenance events related to implants, attachments and overdentures bases were recorded.

Results:

After 5 years, completed data were available for 62 participants. No significant differences in the mean value of VAS scores for all mandibular denture outcome variables and OHIP-49 scores between participants who received one and two implants allowed for pooling of all the participant data into one group to study the effects of mandibular overdenture maintenance on patient-based outcomes without specifying the number of implants they had received.

Participants were divided into three maintenance groups, low, medium and high, based on the number of maintenance events they experienced during the five years. No significant differences were found in the 5-year VAS scores or in total OHIP-49 scores between the three groups of patients (ANOVA and Kruskal Wallis, $p>.05$).

Except for the one year time point, there was a significant association at the baseline, 2 months and 5 years between the VAS overall satisfaction and total OHIP-49 scores.

Conclusions:

The number of maintenance events did not tend to affect patient-based outcomes. The lack of significant correlation between VAS overall satisfaction and OHIP-49 cores at the one-year interval suggests that these two questionnaires are not necessarily measuring the same outcomes.

Lay Summary

The primary aim of this study was to find if the number of maintenance events needed for implant dentures would affect patient satisfaction, and the second aim was to study if there was an agreement between two questionnaires used to measure subjective patient outcomes.

The data for the present study were obtained from the charts of 86 patients with upper and lower complete dentures who were enrolled in a clinical trial at University of British Colombia between 2003 and 2006. The patients received either one or two oral implants to help stabilize their lower dentures. The patients filled out two questionnaires to measure their level of satisfaction before receiving the implant, two months, one, three and five years after implant treatment. The maintenance events related to the implant, the implant attachment clip, and the lower dentures were recorded for the five years.

Our results showed that in general the majority of patients were highly satisfied with their implant overdentures, that there were no significant differences in the level of patient satisfaction between those who had a low, medium or high number of maintenance events, and that the two questionnaires used to measure patient satisfaction were in agreement at baseline, two months and five years but not at one year.

Preface

This study was supervised by Dr. Ross Bryant. The research committee members are Drs. Jolanta Aleksejuniene and Kavita Mathu-Muju.

The research questions were identified by Dr. Bryant and refined by Dr. Alfallaj with guidance from the supervisory committee, and the data were obtained from the charts of the patients who participated in an existing clinical study initiated in 2003 at UBC. The maintenance data had been collected previously from the participant charts by Dr. Bryant, whereas the VAS and OHIP data were collected from the participant charts by Dr. Alfallaj. Then they were analyzed by Dr. Alfallaj with guidance of Drs. Aleksejuniene and Bryant. The thesis was prepared by Dr. Alfallaj with content edited by Drs. Bryant, Aleksejuniene and Mathu-Muju.

The study was approved by University's Clinical Research Ethics Board (Certificate H02-70082), and funded by the ITI Foundation (grants 222 and 635- 2009), the Canadian Institutes of Health Research (grant 58954), and Straumann Canada Ltd.

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OHIP-49: Oral Health Impact Profile

OHIP-EDENT: Modified short version of oral health impact questionnaire for edentulous patients.

VAS: Visual analogue scale.

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My immense gratitude goes to my parents for their unconditional love and support throughout my life. Great thanks go to my siblings, Hadeel, Rasheed, Ibrahim and Hessa, and also to my lovely friends, Hajar and Samah for their listening, understanding and always believing in me

Finally, I must express my very profound gratitude to the government of Saudi Arabia for financially supporting my education for the past three years.

Dedication

I dedicate my thesis to my caring parents, Haifa and Abdullah Alfallaj,

Chapter 1: Introduction

Although patient satisfaction is reported to be high for most completely edentulous individuals using oral implants to stabilize their complete lower dentures, some patients are much less satisfied than the typical patient (1, 2). The underlying causes of low levels of satisfaction with mandibular implant overdentures are not well understood, but could hypothetically relate to the amount of maintenance treatment needed to sustain a functioning implant overdenture (3, 4). An implant overdenture is a removable denture prosthesis usually consisting of acrylic teeth and a pink acrylic denture base that is retained and partially supported by dental implants.(5) This prosthodontic treatment has been recommended for completely edentulous patients, those missing all of their teeth, who have been encountering problems adapting to unstable complete dentures, especially mandibular dentures, and also to help them to improve their chewing ability and to accept their edentulous state (6, 7).

Before the introduction of implants into dentistry, conventional compete dentures were the only treatment option for edentulous patients. Due to mobility of the floor of the mouth, and to a relatively small supporting area of resorbed residual ridge, mandibular complete dentures were a great disappointment to some edentulous patients, especially those who lost their teeth at a young age and had since suffered extensive alveolar bone resorption (8). However, the retention and stability of lower dentures, and the resulting patient satisfaction have been improved dramatically since the development of osseointegrated root form implants used to retain the lower denture (9, 10).

Various designs of implant overdenture have been described for edentulous mandibles, involving different numbers of implants ranging from one to four implants to support the overdentures, and

also involving different attachment systems used to stabilize the connection between implants and the denture base. The attachment systems can be divided into three main categories: stud, bar, and magnet attachments. Stud attachments are a mechanical device, connecting the denture to the implants, consisting of a patrix (male component) usually screwed into the implant and a matrix (female component) integrated into the denture base. Bar attachments are also mechanical devices consisting of a rigid bar, connected between 2 or more implants, and a clip that is again integrated into the denture base, connecting the denture to the bar. Magnet attachments on the other hand are non-mechanical types of attachments made most recently from rare earth element alloys sealed in small ferromagnetic metal containers. Magnet attachments appear to provide the least amount of retention when compared to mechanical attachments system, but with the possibility of a more durable usable life (11-13)

While studies focusing on the clinical outcomes of implant prostheses found that different implant overdenture designs do not affect the success and survival rate of the supporting implants (14), prosthetic maintenance and the cost required for such events seem to vary substantially between different attachment systems and different numbers of implants (15). Nevertheless, when comparing patient satisfaction between different implant overdenture designs, for example, varied attachment types and numbers of implants, none of them appeared to be superior to others (16, 17). In the literature, there are two studies (3, 4) that compared different implant overdenture designs and reported high levels of patient satisfaction among different designs in spite of presenting significant differences in the amount of maintenance events. However, those studies may still have had a lower than average level of satisfaction for some participants that could have been masked by high satisfaction among participants with less

frequent maintenance needs. Hence, it remains uncertain how the maintenance required for implant overdentures would affect patient satisfaction.

1.1 Patient-based outcomes measures

Patient-based outcome assessments are used to study patient responses to dental conditions and dental treatments, the latter either comparing their status before and after the treatment, or comparing the outcome of two or more treatment (or non-treatment) approaches. The need for studies that report patient-based outcomes cannot be overemphasized, as they can help clinicians and potential patients understand how different oral conditions and treatment options may affect social and psychological wellbeing, and also in understanding what could motivate individuals to seek or not to seek dental care. Overall, such studies could greatly influence the utilization of different resources to efficiently develop treatment approaches and dental care programs, for example, including dental insurance policies, for individuals most likely to benefit from specific treatments (18, 19). Patient-based outcome studies can range from qualitative studies, where researchers interviewed patients asking them about their treatment experience, to quantitative studies, where questionnaires (whether validated or not), are used to subjectively measure patient feelings or attitudes toward the condition or treatment (20). Different quantitative measures have been used in dentistry in order to quantify patient-based self-report outcomes, examples of these are: Visual Analogue Scale (VAS) (21) to assess Pain or Satisfaction, Oral Health Impact Profile (OHIP-49) (18), Social Impact of Dental Disease (22), General Oral Health Assessment Index (GOHAI) (23), and Dental Impact Profile (DIP) (24). In this chapter, two measures, denture outcomes based on a Visual Analogue Scale (VAS) and the Oral Health Impact Profile (OHIP-49) will be further discussed as they were used in the current study.

1.1.1 Visual Analogue Scale

The visual analog scale (VAS) is widely used as a psychosocial measure to assess subjective phenomena, such as pain or satisfaction. It was first described in 1969 by Aitken as a tool to measure feelings (21, 25), and then it was promoted to be used as an instrument to measure pain in medical and dental fields (26-28), and more recently to measure self-reported patient satisfaction (29). The visual analogue scale is ostensibly a continuous scale composed of a 100mm long horizontal or vertical line, with its boundaries defining the two extremes of any feeling, where subjects are asked to mark a point on the line that represents how they feel about the phenomenon (26). For example, a score of zero would indicate not experiencing the feeling at all while a score of 100 indicates the maximum state of the feeling. The distance from one end of the line to the subject's mark is measured, and the reading represents a quantitative measure of the subject's feeling that can be used in statistical analysis. The VAS can also be presented in different ways, including a 100-mm line with a middle point, a line with graduation marks or numbers, or as a box scale, or meter shaped scales, however, it has generally been recommended to avoid any numbering or grading along the line to avoid clustering of the data around preferred values (26, 30, 31).

The VAS is easy to administer, takes less than one minute to complete and has been shown to have good validity and reliability (26, 32). However, its validity could obviously be affected by many confounding factors such as the ability of a participant to understand the concept underlying the scale, the visual and motor coordination abilities of the participant which would allow the subject to place a mark where he intended to, and the relative ability of the subject to

recall their previous rating for a specific feeling that would be required to direct any valid estimation of changes of their feeling (32, 33).

1.1.2 The Oral Health Impact Profile (OHIP-49)

The Oral Health Impact Profile (OHIP-49) is one of the most common measures currently used to assess subjective oral health status or treatment outcomes among groups or populations, in this case the frequency of negative physical events and social impacts related to the mouth. The questionnaire was developed by Slade and Spencer in 1994, after interviewing 64 adult dental patients from private practice and dental hospital clinics with structured open-ended questions about their experience with dental diseases or disorders. A total of 535 statements were obtained, and then selectively reduced into 46 representative unique statements, each one having a single event associated with dental diseases or disorders. The statements were then sorted into seven domains (functional limitation, physical discomfort, psychological discomfort, physical disability, psychological disability, social disability and handicap) of an existing conceptual model (Locker's model 1988) of oral health and disability. Three statements about handicap (relating to the tendency for social exclusion due to the dental condition) were added (for a total of 49 items) from an existing generic health status measure since none of the patient statements related to handicap (18). During this development phase, the OHIP-49 questionnaire was also validated among another set of dental patients by comparing the mean score of the OHIP sub-scales between patients who perceived the need to visit a dentist and those who did not. The reliability of the responses for both internal consistency and stability over time were also verified, and all the sub-scales of the OHIP-49 showed good internal consistency in Cronbach's alpha except for the handicap subscale which showed only moderate consistency. The intra-class

correlation coefficient revealed good stability for all subscales except for social disability which had low correlation (18).

1.2 Effect of different numbers of implants on patient-based outcomes

In May 2002, a meeting was held at McGill University in Montreal, during which experts presented 15 papers on the effectiveness of mandibular implant overdentures for the treatment of completely edentulous patients (34). Most of these presented papers were randomized clinical trials comparing implant overdenture treatment (primarily using 2-implants) and conventional complete dentures, and their results showed the superiority of the implant overdenture treatment. Hence, the consensus conclusion was that the two-implant supported overdenture should be "the first-choice of treatment for the edentulous mandible". Since then, many dentists consider conventional complete denture treatment as inadequate treatment based on what had been reported in the consensus. However, the patients who enrolled in such clinical trials to compare between conventional and implant denture treatments would have tended to be interested in the implant treatment, therefore, it would be expected that many patients would be disappointed if they received the conventional denture treatment, and that would be reflected in their satisfaction level (35). More recently the Annual Conference of the BSSPD (British Society for the Study of Prosthetic Dentistry) discussed the efficacy of the implant-supported overdenture in the edentulous mandible. Again the consensus conclusion was that the two implant-supported mandibular overdenture should be the minimum treatment offered to edentulous patients (10). However, neither of these consensus meetings offered whether it may be more reasonable to start treatment with a conventional complete denture and evaluate patient function and satisfaction prior to deciding on any possible need for implant treatment. Nor did they appear to openly

question if it would be advantageous to add more than two implants to retain the mandibular denture, or if the patient was unable to receive two implants due to anatomical or financial restrictions, would it be acceptable to provide a single symphyseal implant to retain the denture.

Perhaps in anticipation that more implants could offer better stability and higher satisfaction, a few studies have aimed specifically to compare patient satisfaction based on the number of implants used to retain the denture. Among the highest quality studies was a randomized clinical trial done in the Netherlands to study the effect of the number of dental implants on the outcome of the mandibular implant denture. Sixty edentulous patients with a severely resorbed mandible were randomized into two groups. Half of the patients received a 4-implant bar-retained mandibular overdenture, the others received a mandibular denture retained by a bar on two implants. Patient satisfaction was evaluated after 1, 5 and 10 years using a 54-item questionnaire and no differences were observed between the two groups throughout the study (36, 37). Another high-quality study was a randomized clinical trial (BIOS - Breda Implant Overdenture Study), conducted to compare clinical outcomes and patient satisfaction with complete implant overdentures using different numbers of implants and different attachment systems. Among 110 patients with atrophic mandibles, 36 received two implants with a ball attachment design (Dalla Bona attachment), 37 received two implants interconnected with a bar (egg-shaped dolder bars), and 37 received 4 implants interconnected by a triple bar (egg-shaped dolder bars). After 18 months of function, a questionnaire was used to assess patient satisfaction with their prosthesis, and the results showed that all patients had more positive satisfaction scores in comparison to the baseline, and there was no difference in satisfaction between the three study groups (38). Subsequently, after 8 years of function, participant satisfaction had decreased significantly regarding retention and stability of the mandibular overdenture in the two-implant ball

attachment group, while the opinion of participants in the single and triple-bar groups was still at the same level as it was at the 18-month evaluation (39).

In recent years, likely due to the evidence of successful clinical outcomes and high patient satisfaction with 2-implant retained mandibular dentures, the majority of clinicians recommend this treatment modality as a treatment of choice for edentulous patients. However, it remains significant that a considerable number of patients cannot access this treatment at least for some because of the high cost of the implants and attachments or in some cases because of anatomical limitations such as inadequate bone in the mandibular canine region. For these reasons, a randomized clinical trial was conducted at the University of British Colombia, to study the overall satisfaction of 86 edentulous patients, of which half received a single-implant retained prosthesis and the other half received a two-implant retained prosthesis. The results showed that both groups of patients tended to be significantly more satisfied after implant placement than before, and there were no significant differences in patient satisfaction between the two groups after one, three and five years of function. Hence, it now appears that a single-implant option can also be offered to edentulous patients wanting to improve the stability of their lower denture, perhaps especially for those patients not able to have two implants due to some sort of anatomical or financial limitations (2, 29). Tavakolizadeh and colleagues also compared patient satisfaction between two groups of patients who received mandibular dentures over either single or two immediately loaded implants. They used visual analogue scales to evaluate the general satisfaction and social life of participants, as well as their denture fit, and the mastication of hard and soft food, and the results showed no significant differences between the two groups after 12

months of function, suggesting that one implant could be a standard approach for patients needing a mandibular implant denture (40).

1.3 Implant overdenture maintenance/complication

The terms "complication" and "maintenance" have often been used interchangeably in many studies reporting implant overdenture prosthetic outcomes. However, it has also been recommended to use "complication" in medical literature only when the number of the problems or the time or cost required to fix them becomes a burden, or when an intervention is required to fix an unexpected problem, whereas "maintenance" is recommended when the occurred problems are expected and when they happened with a reasonable frequency. For implant overdentures treatment, there are perhaps only a few unexpected problems (e.g. implant failure or denture fracture) and the majority of problems are anticipated and relatively easy to fix, therefore the term "maintenance" will be used more frequently throughout this paper (41, 42).

Not surprisingly a range of mechanical complications and maintenance needs have been reported for implant over-dentures, involving any of the three major components: the implant, the attachment system or the denture prosthesis itself (43). The types of mechanical complications that could affect the implant include: implant fracture, jaw fracture or early implant failure due to micro-movement (1, 43, 44). For the attachment system, the maintenance requirements include: abutment screw tightening, the need for matrix/patrix adjustment, the reattachment of detached matrix or patrix components, or the replacement of the entire matrix or patrix-type parts with either the original design or a different attachment system altogether. Finally, the maintenance required for the denture prosthesis itself include: adjusting the intaglio surface of the denture, contouring the polished surface for neutral zone or esthetic concerns, removing occlusal

interferences, relining or rebasing denture bases (typically if there is a significant denture base fit problem due to ridge resorption), or tooth reset or denture remake depending on the extent of compromise to the structural integrity or appearance of the denture.

Substantial variation in the amount of maintenance needs have been reported across implant overdenture studies which appears to have resulted at least in part from differences in the way each study reported its data, as there is no consensus on what to report in regards to implant overdenture maintenance needs (45). For example, some studies report denture flange adjustments, occlusal adjustments and/or matrix tightening as part of the maintenance needs for the implant overdentures, while others ignore these types of adjustments perhaps because they are difficult to quantify (2, 46). In addition to that, studies have differed substantially in the way they reported maintenance frequency data, as some studies reported the number of visits or the time needed to maintain the prostheses (46), whereas others reported the cost required for the maintenance (47). On the other hand, some studies would only count the number of maintenance events occurring, for example, if a clinician tightened the matrices of two attachments during one visit, he would count them as two events (2).

1.3.1 Factors affecting the frequency and the type of implant overdenture maintenance

In the literature, several factors have been linked to different types and frequencies of implant-overdenture maintenance requirements. These include; the design of the attachment system, the number of implants, the angulation of the implants, the technique used to pick-up the attachment into the denture base, and the thickness of the denture base.

Attachment system and implant overdenture maintenance

As noted, the most commonly used attachment types with implant overdentures are bars, studs and magnets (17). The selection of a particular attachment system or design appears to be based mainly on the clinician's preference, but also on a clinical assessment of the available inter-arch prosthetic space as it interacts with the patients functional and esthetic needs. While bar attachment systems (physically connecting the implants with a bar as part of the attachment system) appear to provide greater direct retention of the prosthesis, a lot of clinicians now prefer to use independent stud implant attachments (with no connection between the implants) since they tend to require less three-dimensional space within a denture base, they are also less costly and easier overall in terms of routine maintenance compared to the bar type, and they seem to be easier for patients to maintain cleanliness compared to the bar type (48). Magnet attachments (also usually independent, but can also be integrated into a bar design) have been recommended to be used with older frail patients and for those who are physically less able to attach and detach their dentures using the more retentive mechanical attachment systems. Although magnet systems appear to have the most frequent prosthetic maintenance among the attachment systems, reportedly caused mainly by wear and corrosion of the alloys leading to loss of the magnetism, there are newer magnetic attachment systems made from rare earth elements- samarium and neodymium- that have shown to provide good durability (11, 17).

The most common prosthetic maintenance for bar and ball attachments with a metal matrix were the need to reactivate the clip and or retighten the matrix for bar and ball attachments respectively or the need to replace the attachment components due to wear or fracture of retention elements in the attachment system (17, 43). Clinical studies have reported conflicting results when comparing the rate of prosthetic maintenance for bar and ball attachments. For

example, significantly more maintenance was needed for the ball attachment group in a randomized clinical trial reporting prosthodontic complications and maintenance required for mandibular implant overdentures attached by either bar-clip or ball-spring matrices (49). On the other hand, in another randomized clinical trial, Gotfredsen and colleagues reported more prosthetic maintenance needs with a bar overdenture compared to ball attachments (Dalla Bona) after five years of function (50). However, in these two studies, different ball attachment systems were used which could explain why different rates of maintenance were reported. The ball-spring attachments that were used in the first study consisted of non-adjustable three-piece matrices (a small C shaped stainless-steel spring within a titanium-alloy cap) that were more prone to abrasion and fracture in comparison to the gold-alloy adjustable matrices (Dalla Bona) that were used in the second study (49, 50).

Locator® attachments are a stud system that has become popular these days due to its simplicity, resiliency and the ability to compensate for up to 40 degrees of angulation between implants. However, due to its relatively recent popularity, there are only a few clinical studies comparing outcomes of the locator-type design with other attachment systems. Again, the results have been conflicting on the relative rate of maintenance needs one may anticipate comparing the locator-type to other designs. Cristache and coauthors found in a randomized clinical trial that after 5 years of function, implant overdentures with Locator® attachments had significantly fewer prosthetic maintenance requirements and consequently lower maintenance costs compared to overdentures with ball attachments and a gold matrix design (51). In contrast, Kleis and colleagues compared three types of attachments (Locator®, Dal-Ro®, TG-O-Ring®) on 2-implant overdentures, and found more maintenance required for the locator-type compared to the

other two groups, in this case most of these maintenance needs being changing the nylon patrix (52).

Number of implants and implant overdenture maintenance

Another factor linked to implant-overdenture maintenance is the number of implants used to retain the prosthesis. This has been in the form of studies comparing two or more implants, or more recently comparing two implants to the single implant overdenture. In a randomized study where clinical and patient-based outcomes were compared for two groups of patients receiving 2 or 4 implants, after 5 years more prosthetic maintenance was needed for the 2-implant group (36). In contrast, the 10-year results of the same study population showed more prosthetic complications and surgical intervention, mainly to correct tissue hyperplasia around the implant, were recorded for the 4-implant group, which could be caused by the difficulty in maintaining good oral hygiene due to close proximity of the implants (36, 37). Also reported previously, was the UBC study which compared 1 and 2 implant retained overdentures, and found no statistical difference in prosthetic maintenance requirements between the groups, although perhaps a slight non-significant tendency to more frequent maintenance for the single-implant group (2, 53). Another study reported no significant difference in the number of implant failures and maintenance needs of one and two implant-overdentures loaded immediately (54).

Acrylic resin thickness and implant overdenture maintenance

The reduced thickness of acrylic resin around the matrix could increase the risk of denture fracture. As aging adults are tending in recent years to maintain teeth for more years, edentulism has started to happen later in life, meaning less severe bone resorption is expected to have occurred among edentulous patients compared to previous generations of patients. On average,

less severe alveolar bone resorption will result in dentures with thinner acrylic bases which could be more vulnerable to fracture especially near the implant and attachment where the denture base will tend to be thinnest (45). Some authors have recommended the use of a metal framework to reduce the incidence of acrylic factures and the resulting maintenance and costs (55, 56), though MacEntee and colleagues in a randomized clinical trial, found that the incorporation of a cast metal framework in the design of bar and ball overdentures did not reduce the maintenance needs during three years of evaluation (49).

Technique used to attach the matrices to denture base and implant overdenture maintenance

It has been reported that more frequent maintenance was required for the matrices that were attached in the lab (indirect) in comparison to those attached in the patient's mouth (direct) probably due to impression discrepancies or inaccurate mounting of the casts in centric position (57).

Implants angulation and implant overdenture maintenance

The angulation of the implants that support the overdenture may also contribute to more overdenture maintenance. Walton and colleagues (58) studied if the angulation of the implants would contribute to more implant overdentures maintenance. In their study, they measured the angles of implant analogues in the sagittal and frontal planes of 44 dental casts of patients. They found that the inter-implant angulation did not affect prosthesis maintenance, however, individual implants with a lingual angulation of six or more degrees and a facial angulation less than 6.5 degrees (both in the sagittal plane) were associated with significantly more prosthetic

maintenance mainly for the attachment matrices, presumably because of the increase in non-axial forces on the attachment systems with lingually positioned implants.

Other factors and implant overdenture maintenance

Parafunctional habits, the nature of the opposing dentition, and denture quality in terms of occlusal and ridge adaptation are all potential factors that have been mentioned in the literature as potentially contributing to the risk of prosthetic complications. Nevertheless, none of them have been studied intensively in any of the clinical trials to examine if they have a direct effect on the implant overdenture maintenance needs (41, 45, 56, 59, 60).

1.4 Rationale for the study

With current trends to increased retention of teeth and a continued substantial decline in the prevalence of the edentulism in most of developed countries(61-65), as well as concurrently that edentulism is increasingly occurring at older ages, in the later stages of life, in comparison to years ago (61-65), more edentate patients now and in the future are expected to be less satisfied with their oral status and less capable to adapt to a traditional lower complete denture prosthesis (65). The implant overdenture has been demonstrated to increase patient satisfaction and quality of life. However, this approach has also resulted in higher initial financial costs and ongoing maintenance required to adjust and repair the prosthesis in addition to the periodic need to replace dentures, all of which comes with additional financial costs and sometimes a need for the patient to stay for short periods without their dentures (66).

The primary focus of most clinical trials on mandibular implant overdentures has been either to report different clinical parameters related to implant and prosthesis outcomes, including the number and types of maintenance events, or to compare patient-based outcomes between different implant overdenture designs, for example, designs with differing attachment mechanisms. However, although it seems likely that patient-based outcomes will relate to the extent of maintenance needs, there remains a lack of studies that clearly examined the relationship between implant-overdenture maintenance and patient-based outcomes.

1.5 Study aims

- To study the possible effect of implant overdenture maintenance events on psychological and social outcomes using the Visual Analogue Scale (VAS) and Oral Health Impact Profile (OHIP-49) measures.
- To examine the association between VAS overall satisfaction and OHIP-49 scores.

1.6 Research hypotheses:

- Mandibular implant overdenture maintenance events negatively affect the psychological and social outcomes of edentulous patients.
- There is a predictable association between VAS overall satisfaction scores and OHIP scores among edentulous patients with mandibular implant overdentures.

Chapter 2: Materials and Methods

The data for this study were obtained from the charts of 86 edentulous patients who began implant overdenture treatment in a randomized control trial at the University of British Colombia between 2003 and 2006, and were followed for 5 years as previously reported (2, 29). The trial was approved by the University's Clinical Research Ethics Board (Certificate H02-70082) and funded by the ITI Foundation (grants 222 and 635- 2009), the Canadian Institutes of Health Research (grant 58954) and Straumann Canada Ltd.

The primary aim of the trial was to compare the participants' overall satisfaction with their mandibular implant overdenture, using a visual analogue scale, between two groups of edentulous patients, one group having received a single implant and the other having received two implants to retain their mandibular overdentures, all by random allocation stratified to help distribute sex and ridge resorption patterns. The results of the primary aim were published previously in two articles (2, 29). However, additional patient-based outcomes data were also collected from the patients during the follow-up appointments, but not yet analyzed.

2.1 Participant sample

86 participants (43 female and 43 male) with existing maxillary and mandibular conventional dentures were accepted for the original study after the screening of 220 patients by a prosthodontist and oral surgeon based on specific inclusion and exclusion criteria (Table 2-1).

Table 2-1 Inclusion and exclusion criteria* (29)

Inclusion criteria

- Functional in English or accompanied by a responsible adult who can provide translation services.
- Able to consent to and participate in the treatment provided.
- Available for the duration of the study.
- Edentulous, and with at least 6 months experience with conventional complete dentures.
- Currently wearing conventional complete dentures that are esthetically satisfactory to the patient and technically acceptable in the judgment of the study prosthodontist(s).
- Medically/psychologically suitable for implant surgery in the judgment of the study clinicians.

Exclusion criteria

- Insufficient alveolar bone height for implant(s) (< 6 mm)
- History of head and neck radiation.
- Systemic or neurologic disease, including:

o ASA class 3 with recently diagnosed severe systemic disease, e.g. recent (within 6 months) myocardial infarction or stroke.
o Risks associated with bacteremia, (e.g. immune compromise, steroids, in-dwelling catheters, stents, prosthetic heart valves).
o Type 1 diabetes, pituitary and adrenal insufficiency, and untreated hypothyroidism.
o Chronic granulomatous disease (e.g. tuberculosis and sarcoidosis).
o Bone disease (e.g. histiocytosis X, Paget's disease, fibrous dysplasia).
o History of congenital or acquired uncontrolled bleeding

- Previous oral implant treatment.
- Need for additional pre-prosthetic surgery.
- Need for new complete dentures.
- Medically/psychologically unsuitable for surgery in the opinion of the study clinicians.

* (Adapted from Walton and colleagues, 2009)

Existing dentures were examined and considered acceptable if they were both esthetically acceptable to the patient and if they were technically acceptable according to standard quality criteria (Table 2-2).

Table 2-2 Denture criteria for inclusion in the clinical trial* (29)

Technically acceptable dentures (29)
• Hard densely processed acrylic resin bases without missing parts, fractures, visible porosity, or other structural defects.
• Periphery of denture bases within usual anatomical parameters.
• Maxillary denture retentive when denture-wearer opens the mouth to 15 mm between incisors.
• Mandibular incisors within the anatomical boundaries of the ridge crest and the labial vestibule.
• Posterior teeth on mandibular denture no higher than 3 mm above the retromolar pad. and within the triangular zone outlined by the width of the retromolar pad and the tip of the canine.
• Comfortable interocclusal rest space for the denture-wearer.
• Centric occlusal contacts within 2 mm of centric relation.
• No cheek biting.

* (Adapted from Walton and colleagues, 2009)

Participants were stratified based on sex and the severity of bone resorption at the time of being randomly assigned to the two types of treatments (to have either 1 or 2 implants to retain their existing denture). The severity of bone resorption was determined based on the position of the mental foramina in relation to the ridge crest when viewed on a panoramic radiograph. Bone resorption was classified as severe when the mental foramina was at or below the ridge on either side of the mandible.

Each participant also completed a background questionnaire collecting information on participant sex, marital status, occupation, income, use of tobacco, dental history and use of dentures when sleeping, self-awareness of bruxism, and self-assessed general health) in addition to two patient-based outcome questionnaires, the VAS and OHIP-49 scales described below.

2.2 Implant and prosthetic procedure

Depending on the group allocation, patients received an implant (Solid Screw, SLA surface; Straumann Canada, Burlington, ON, Canada) either in the mandibular midline or bilaterally in

the canine area. The mandibular dentures were relined approximately 10 to 14 days after implant placement with a soft reline material (Coe Comfort; GC Corporation, Tokyo, Japan). After 6 weeks, a 2.25-mm ball patrix (Straumann-ITI Spherical Stud Retentive Anchor; Straumann Canada) was attached to the implants, and a retentive matrix (Straumann-ITI Gold Matrix; Straumann Canada) was integrated into the denture using a laboratory-processed hard acrylic resin reline procedure (Ivoclar Vivadent, Mississauga, Canada). During all visits, clinicians were instructed to avoid commenting on the assigned treatment outcome and they were not present when the participants completed the questionnaires.

2.3 Follow-up procedures and outcome measures

Patients were examined at the baseline before the implant placement, as well as at 2 months, 1 year, 3 years and 5 years after the implant overdenture insertion to assess the implant, attachment system, and denture status. All maintenance events were recorded in the participant file.

Furthermore, patients were asked to complete two patient-based outcome questionnaires at 2 months, 1 year, 3 years and 5 years after implant overdenture insertion. The first patient satisfaction questionnaire used a Visual Analogue Scale (VAS) consisting of the following denture-related variables: pain, comfort, appearance, function (chewing), stability, hygiene, speech, and overall satisfaction, with all except speech being assessed separately for both the maxillary and mandibular dentures. For each one of these variables, the participants placed an "X" mark to indicate the level of patient response to that particular item (e.g. the level of satisfaction or pain) on an uninterrupted 100-mm line, where placement at 0 indicated the worst possible outcome (for example, not satisfied or the worst pain) and placement at 100 indicated (for example, totally satisfied or no pain). A clear ruler was used to measure the distance from

the zero point to the X mark which indicated the level of patient satisfaction. Any missing data in any of the variables was given a middle value of 50.

The second questionnaire was the Oral Health Impact Profile-49 (OHIP-49) which has been commonly used to assess the frequency of negative physical events or social impacts related to the mouth. The OHIP questionnaire consists of 49 questions which assess 7 domains (functional limitation, pain, psychological discomfort, social disability, physical disability, psychological disability, and handicap). Three questions from the OHIP 49 questionnaire were not related to edentulous patients, therefore, they were omitted from the analysis and only 46 questions were analyzed. Two methods were used to estimate the OHIP total scores (Table 2-3):

1. <u>Summative original OHIP score</u>

Responses to the OHIP questionnaire were given the following values:

- Never (= 1), hardly ever (=2), occasionally (= 3), fairly often (= 4) and very often (= 5).

Any OHIP question that was left by a patient without an answer was given a median value of 3. The total scores were calculated with a minimum for each questionnaire of 46 and with the highest being 230 (46 multiplied by 5).

2. <u>Summative severity (dichotomized) OHIP score</u>

Each response to the OHIP questionnaire item was dichotomized with the following values:

- Never, hardly ever, occasionally and any missing answer (code 0).
- Fairly often, and very often (code 1).

Essentially, the Summative severity OHIP score was calculated by counting the total number of questions that were answered with fairly often or very often (which are the two most severe categories). Therefore, the lowest total score was 0, while the highest total score was 46.

Table 2-3 Values given to the OHIP responses

Summative OHIP score	**Never**	**Hardly ever**	**Occasionally**	**Missing data**	**Fairly often**	**Very often**
Original	1	2	3	3	4	5
Severity	0	0	0	0	1	1

Table 2-4 OHIP domains and the number of questions in each domain. (18)

OHIP domain	Number of included questions
Functional limitation	9
Physical pain	7 *
Psychological discomfort	5
Physical disability	8 **
Psychological disability	6
Social disability	5
Handicap	6

* Two questions were removed from the OHIP-49 because they were not related to edentulous patients.
**A question was removed from the OHIP-49 because it was not related to edentulous patients.

2.5 Maintenance events

Maintenance events were recorded for 5 years, including events related to the implants (whether an implant survived or failed), the integrity of the mandibular overdenture (whether the denture was relined or rebased, or it was fractured or replaced for any reason). Also, all the maintenance events related to the attachment system were recorded for each implant (if the attachment was adjusted, or re-attached to the denture base, or was replaced with a new attachment using either the original design or a new design) (Table 2-5).

Table 2-5: Maintenance events recorded for implant, attachment system and overdenture

Implant
Failed.
Attachment system (matrix or patrix):
Replaced.
Reattached.
Adjusted.
Mandibular overdenture:
Fractured.
Replaced.
Relined or rebased.

2.6 Statistical analysis:

The SPSS version 25 was used to carry out the statistical analysis. The independent sample t-test was used to compare the mean total OHIP scores and the mean VAS scores for the eight denture-related variables between participants with one and two implants. Pearson and Spearman correlation tests were used to assess the statistical significance of the relationship between the number of maintenance events and VAS lower denture outcome variables. ANOVA and Kruskal Wallis tests were performed to compare patients-based outcomes (OHIP total scores and VAS lower denture outcomes) among the three maintenance frequency groups of patients based on the number of maintenance events they had (low, medium, high). Pearson and Spearman correlation tests were performed to study the association between VAS overall satisfaction and total original and dichotomized OHIP scores. Statistical significance for all the tests was set at $P<0.05$.

Chapter 3: Results

Of the 86 patients that were treated with implant overdentures in the original study, 62 patients retuned for the 5-year follow-up so their records were available for analysis in the present study (see Table 3-1 and 3-2). The completed records available to be included for the data analysis in the present study included the following:

1. Maintenance events throughout the 5 years.
2. VAS data at baseline, and outcomes at 2 months, one year and five years after treatment.
3. OHIP data at baseline, and outcomes at 2 months, one year and five years after treatment.

Three-year follow-up data could not be analyzed due to a high number of missing data (at this follow-up only 23 patients completed the OHIP questionnaires).

Table 3-1 Patients included in the analysis

	1 implant group	**2 implant group**
n=62 patients	29 (14 male, 15 female)	33 (19 male*, 14 female)

* One of the male patients with 2 implants did not complete the 5-year OHIP questionnaire, therefore, only 61 patients were included in the 5-year OHIP analysis.

Table 3-2 Patients excluded and the reasons for their exclusion

	1 implant group (n=13 patients)	**2 implants group (n=11 patients)**
Deceased	8	6
Lost to follow-up for unknown reason	5	4
Withdrew from study	0	1
Total	13	11

Preparatory statistics:

The aim of the preparatory statistics was to explore if there were any significant differences in the patient-based outcomes (OHIP and VAS) between the two original groups of patients (one- vs. two-implants). Given that the aim of the current study was not to detect differences between the 1 and 2 implant groups, testing for an absence of significant differences in psychosocial outcomes between the two groups would allow pooling both groups data together for the present analysis, to maximize the pool of data available for studying the potential effect of maintenance events on patient based outcomes for all the patients who participated in this study without specifying the number of implants they had received.

Oral Health Impact Profile (OHIP-49)

The independent samples t test was used to compare means of the total original OHIP scores between participants in the 1-implant and 2-implant groups at the various time points. The results showed that there were no significant differences ($p>0.05$) in mean OHIP scores between the two groups before the implant treatment, at two months, one and five years after treatment (Table 3-3).

Table 3-3 Comparing means of total original OHIP scores between 1 and 2 implant groups at the baseline, 2 months, 1 year and 5 years after treatment

Timeline		N	Mean (sd)	Sig (2-tailed) *
Baseline	1 implant	29	97.2 (31.2)	0.729
	2 implants	33	100.3 (38.6)	
2 months	1 implant	29	65.1 (16.0)	0.809
	2 implants	33	62.9 (20.0)	
1 year	1 implant	29	67.5 (14.9)	0.893
	2 implants	33	67.0 (18.5)	
5 years	1 implant	29	78.5 (24.3)	0.164
	2 implants	32^{+}	70.6 (19.6)	

* Independent t test. $^{+}$ One patient failed to complete the five years OHIP questionnaire

Visual Analogue Scale

The average value of the 15 VAS subscales was calculated for each participant, then the VAS averages of all patients with 1 and 2 implants were calculated. The independent t-test was used to compare the means between the two groups of participants. The results showed that there were no significant differences ($p>0.05$) in the average VAS scores between the two groups before the implant treatment, at two months, one and five years after the treatment (Table 3-4).

Table 3-4 Comparing mean total scores of VAS denture related variables between 1 and 2 implant groups at the baseline, 2 months, 1 year and 5 years after treatment.

Timeline		N	Mean (sd)	Sig (2-Tailed) *
Baseline	1 implant	29	68.6 (13.9)	0.630
	2 implants	33	70.4 (15.9)	
2 months	1 implant	29	90.4 (4.9)	0.172
	2 implants	33	87.9 (8.2)	
1 year	1 implant	29	85.7 (8.3)	0.976
	2 implants	33	85.6 (9.9)	
5 years	1 implant	29	78.9 (15.4)	0.097
	2 implants	33	84.4 (9.1)	

* Independent t test

As there were no significant differences in mean denture satisfaction scores or in mean of total OHIP scores between the patients with 1- and 2-implants, the subsequent analyses combined information from both groups, i.e. the effect of implant overdenture maintenance events on the patient-based outcomes was analyzed without specifying the number of implants.

Aim 1: To study the possible effect of implant overdenture maintenance events on psychological and social outcomes using existing Visual Analogue Scale (VAS) and Oral Health Impact Profile (OHIP) measures.

To study the effect of the maintenance events on the VAS and OHIP scores, we calculated the total number of maintenance events related to the implants, attachment systems (matrices and patrices) and overdenture bases (Table 3-5).

Table 3-5 Sample distribution according to the five years total cumulative number of maintenance events

Number of complication events	Number of patients	Percent	Cumulative Percent
0	3	4.7	4.7
1	4	6.5	11.3
2	4	6.5	17.7
3	7	11.3	29.0
4	9	14.5	43.5
5	3	4.7	48.4
6	4	6.3	54.8
7	7	10.9	66.1
8	4	6.5	72.6
9	4	6.5	79.0
10	2	3.2	82.3
11	1	1.6	83.9
12	1	1.6	85.5
13	1	1.6	87.1
14	1	1.6	88.7
15	1	1.6	90.3
17	1	1.6	91.9
19	1	1.6	93.5
20	1	1.6	95.2
21	1	1.6	96.8

Number of complication events	Number of patients	Percent	Cumulative Percent
22	1	1.6	98.4
27	1	1.6	100.0
Total	62	100.0	

To study the effect of the maintenance events on patient satisfaction, patients were divided into 3 groups based on the frequency of maintenance events (Table 3-6).

Table 3-6 Three groups of patients based on the number of maintenance events

Groups	Number of maintenance events	Number of patients	Percentage of patients
Low	0-3	18	29.1%
Medium	4-7	23	37.1%
High	8-27	21	33.8%

No significant correlation (Pearson and Spearman $p>0.05$) was found between the 5-year VAS lower denture outcome variables and the cumulative number of maintenance events, and all the correlations were consistently found to be close to zero.

Table 3-7: Relationships between 5-year VAS scores for the lower denture variable and the 5-year cumulative number of maintenance events

Lower denture variables		5-year cumulative maintenance events	
		Pearson correlation	**Spearman correlation**
Pain	Coefficient	-.067	-.101
	P value	.605	.437
Comfort	Coefficient	-.047	-.175
	P value	.719	.175
Appearance	Coefficient	-.014	-.065
	P value	.914	.615
Function	Coefficient	-.112	-.243
	P value	.388	.069
Stability	Coefficient	.081	-.024
	P value	.533	.854
Cleaning	Coefficient	.025	.021
	P value	.848	.869
Speech	Coefficient	.021	.027
	P value	.869	.834
Overall satisfaction	Coefficient	.039	-.040
	P value	.761	.757

No significant differences were found among the various scales of lower denture outcomes at 5 years comparing the groups with a low, medium and high number of maintenance events (ANOVA and Kruskal Wallis p>0.05) (Table 3-8).

Table 3-8: Different aspects of denture outcomes (VAS) with a mandibular implant retained overdenture among patients with different numbers of maintenance events #

VAS Denture Outcome Subscales	Low ≤ 3 maintenances n=18	Medium 5-7 maintenances n=23	High 8-27 maintenances n=21	Significance	
				P value ANOVA	P value Kruskal Wallis
	mean ± sd %	mean ± sd %	mean ± sd %		
Pain	88.2 ± 16.4	81.0 ± 25.0	84.2 ± 22.1	0.574	0.632
Comfort	83.6 ± 18.5	68.5 ± 32.5	72.2 ± 31.4	0.242	0.264
Appearance	82.1 ± 24.1	81.3 ± 25.1	83.6 ± 18.9	0.944	0.749
Function	77.3 ± 24.0	67.3 ± 30.4	65.3 ± 27.6	0.365	0.261
Stability	64.4 ± 30.1	63.1 ± 34.1	62.7 ± 29.5	0.985	0.859
Speech	80.6 ± 23.4	86.7 ± 13.9	81.0 ± 26.2	0.586	0.609
Cleaning	85.5 ± 18.9	87.5 ± 12.3	87.3 ± 13.5	0.897	0.991
Overall Satisfaction	72.9 ± 30.8	70.6 ± 32.9	70.6 ± 29.4	0.964	0.776

Denture outcomes measured with Visual Analog Scale (0-100%). Comparisons among maintenance groups analyzed with One-Way ANOVA and Kruskal Wallis tests.

Graphically representing the same denture satisfaction data as in Table 3-8 using box-plots (Figures 3-1 to 3-8) shows that after 5 years of function, participants in all three of the maintenance groups (low medium and high) tended to be relatively highly satisfied in their overall satisfaction with the mandibular denture, exceeding a median VAS score of 80, as well as tending to high scores with the various specific aspects of denture outcome relating to the mandibular overdenture, again exceeding a median score of 80 for the absence of pain, and for comfort, appearance, cleaning and speech, and exceeding a median score of 70 for both function and stability. Nonetheless, there was still a wide range of outcomes reported for the denture outcome variables for all three of the maintenance event groups, evidently being due to small

numbers of outlier data from participants who reported relatively much lower VAS scores than more typical participants.

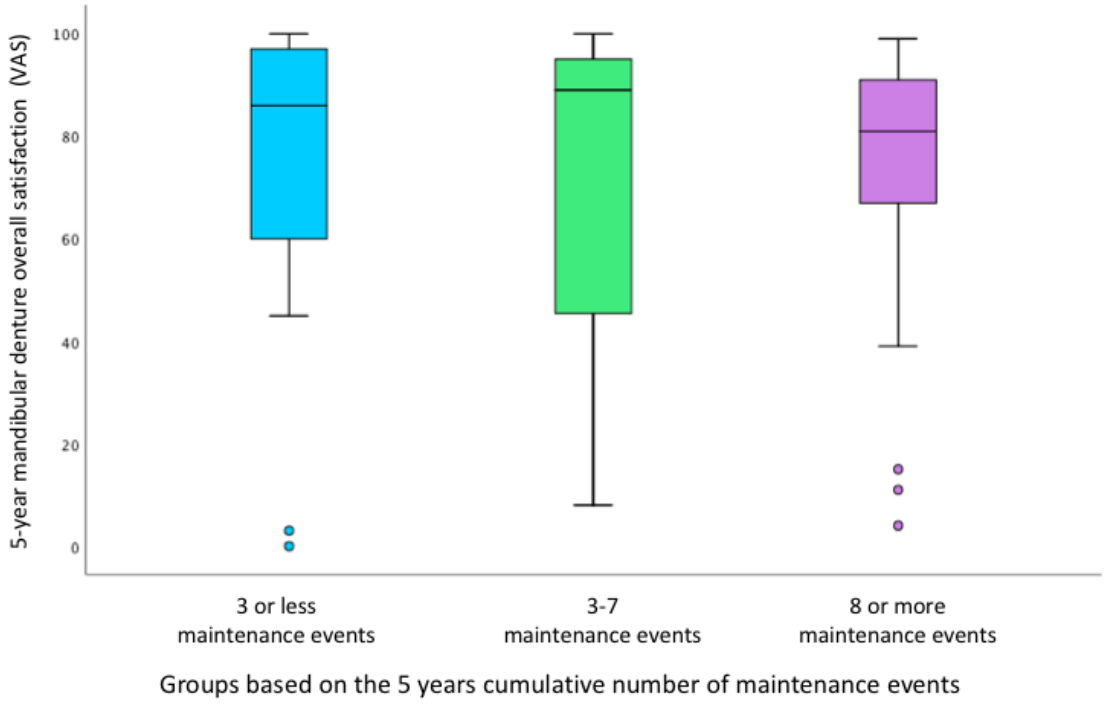

Figure 3-1 A 5-year lower implant overdentures overall satisfaction on VAS. Comparisons among patients with different number of maintenance events

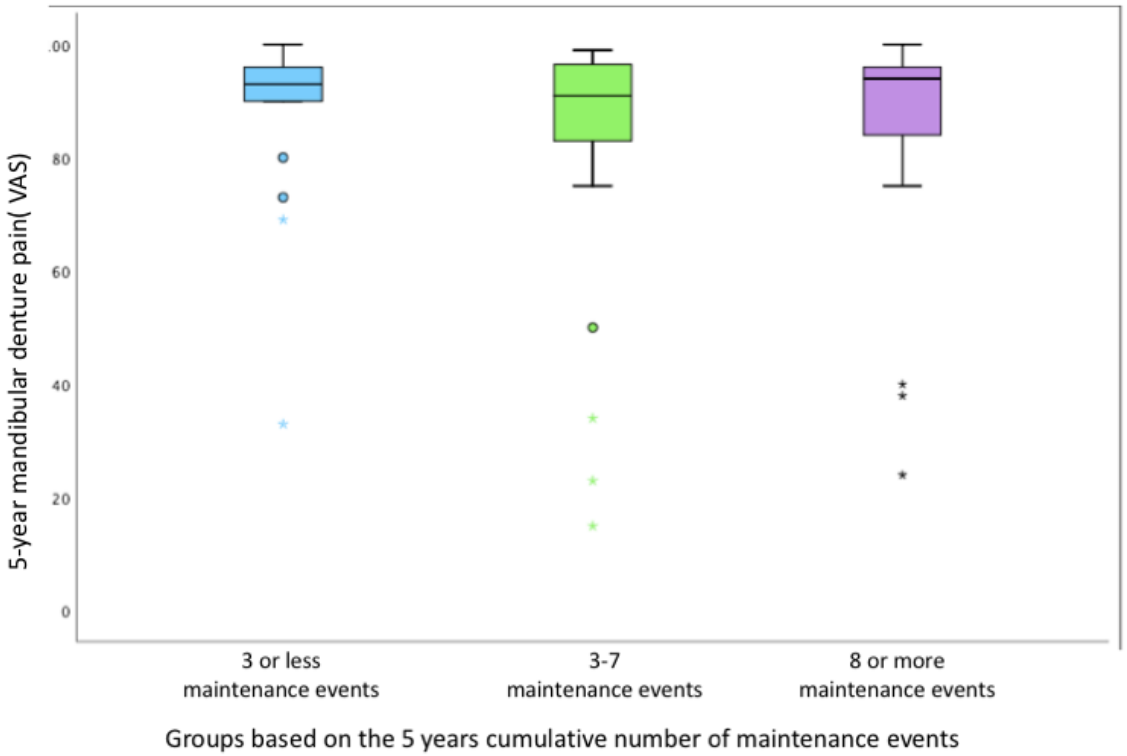

Figure 3-2 5-year lower implant overdenture pain on VAS. comparisons among patients with different number of maintenance events

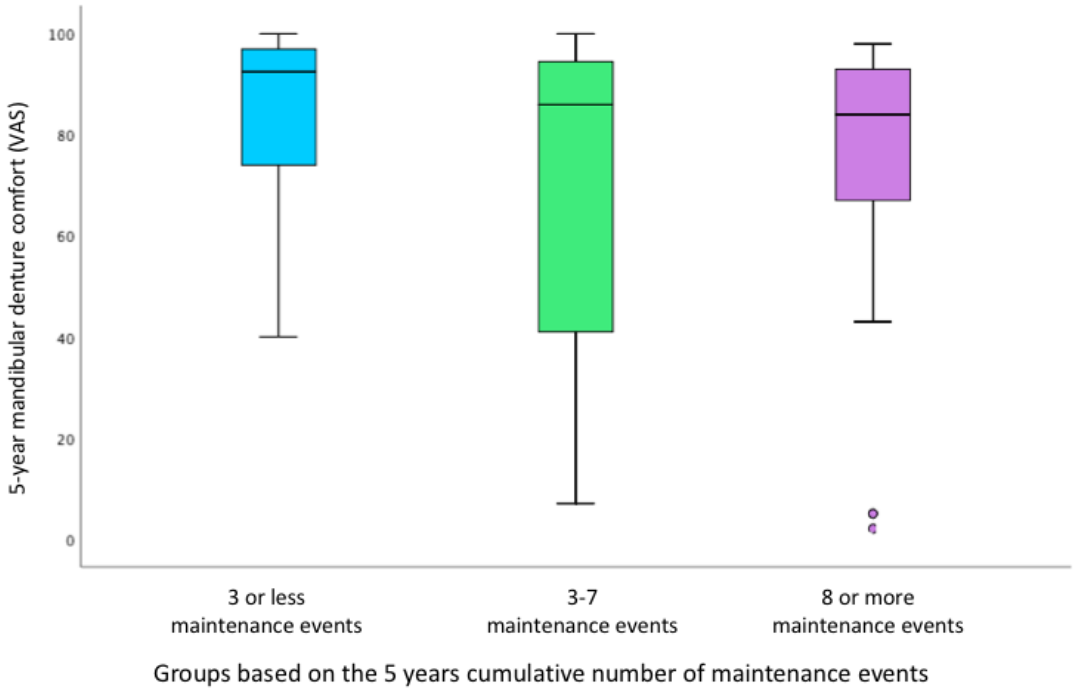

Figure 3-3 A 5-year lower implant overdenture comfort on VAS. Comparisons among patients with different number of maintenance events

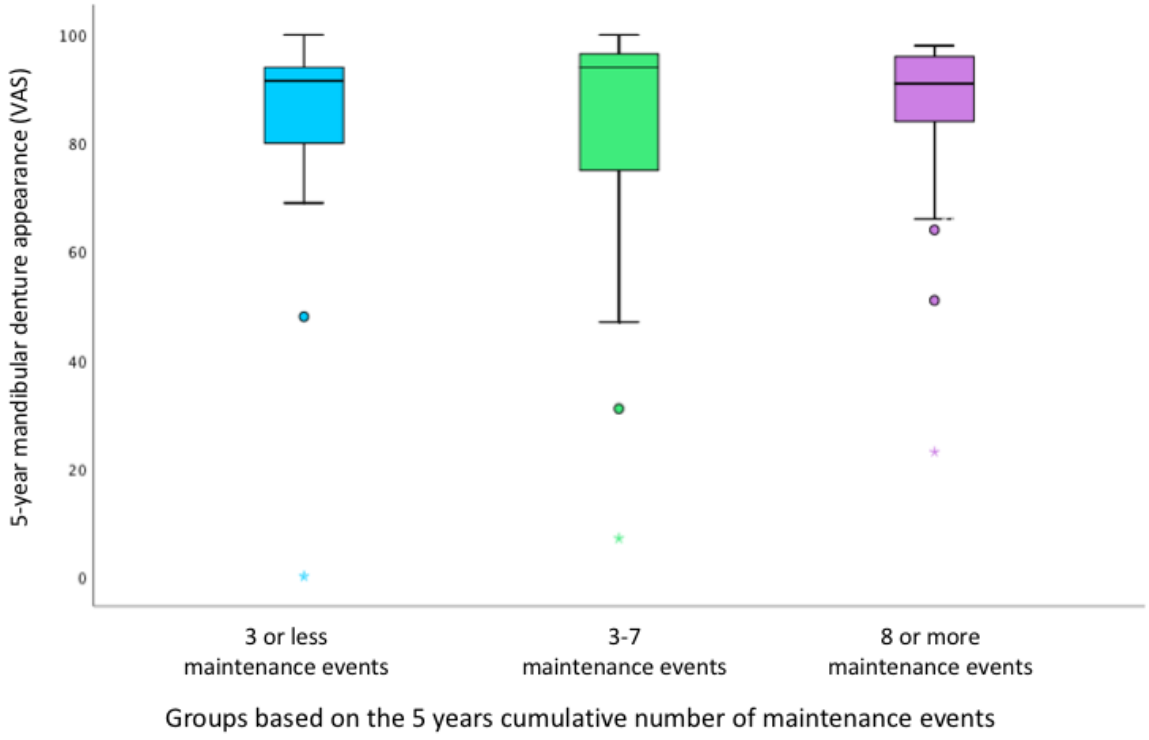

Figure 3-4 5-year lower implant overdentures appearance on VAS. Comparisons among patients with different number of maintenance events.

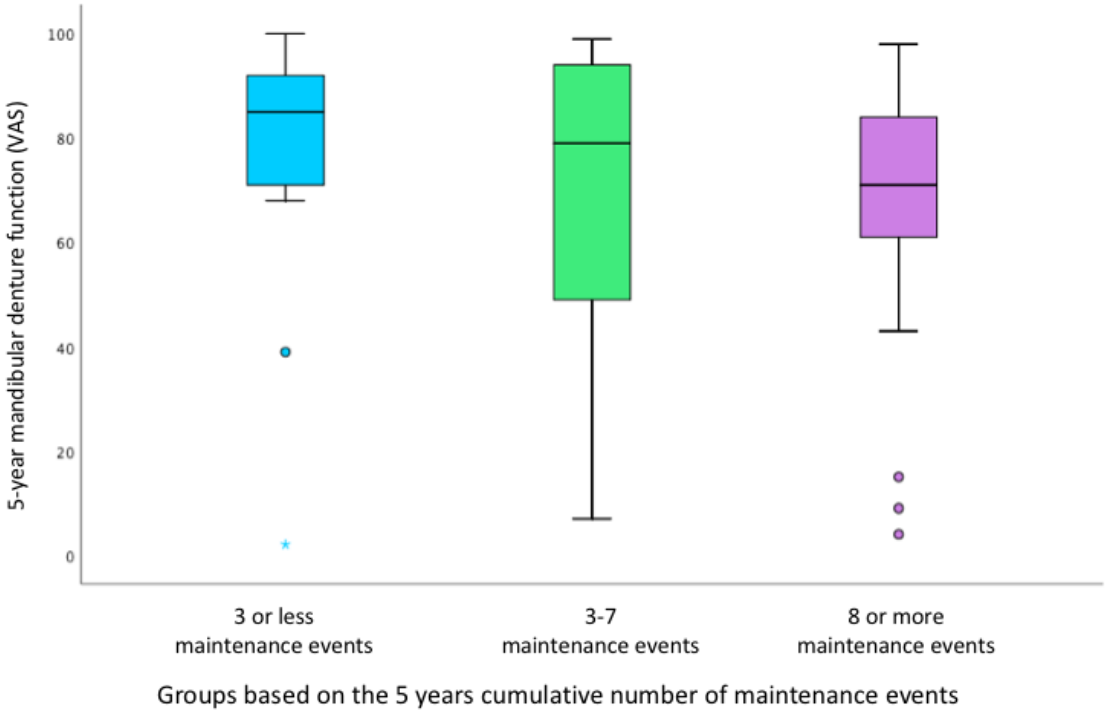

Figure 3-5 A 5-year lower implant overdentures function on VAS. Comparisons among patients with different number of maintenance events.

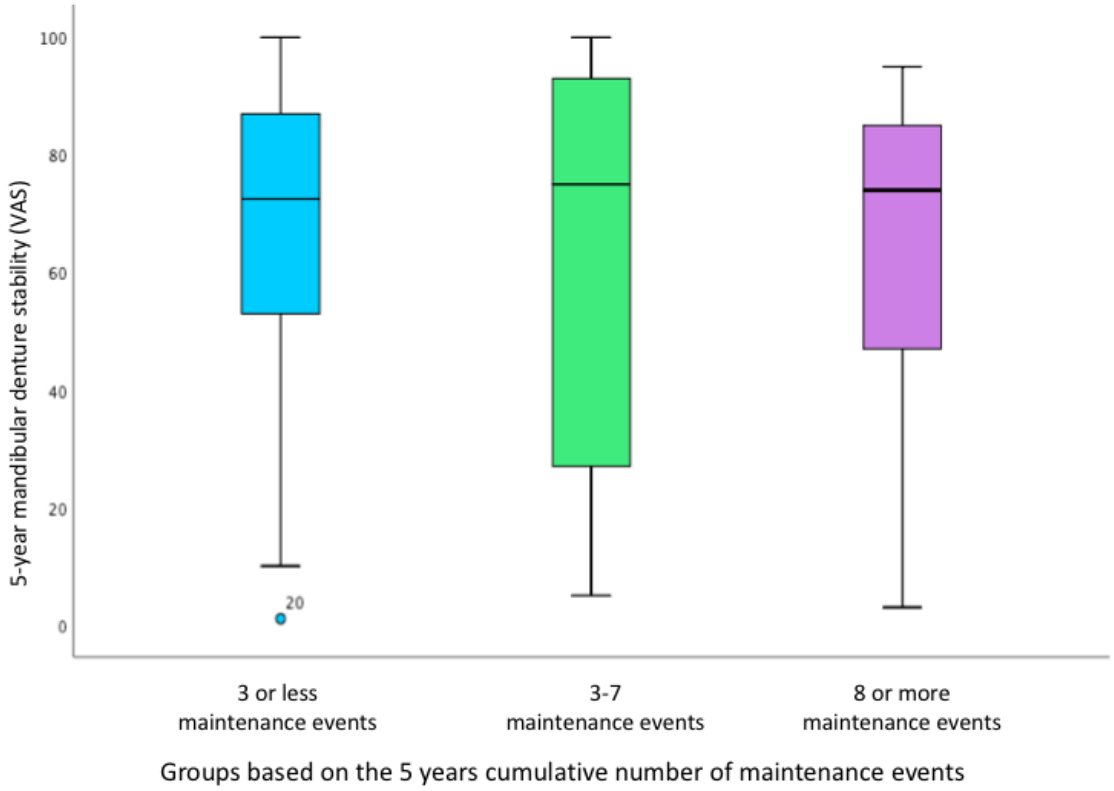

Figure 3-6 A 5-year lower implant overdentures stability on VAS. Comparisons among patients with different number of maintenance events.

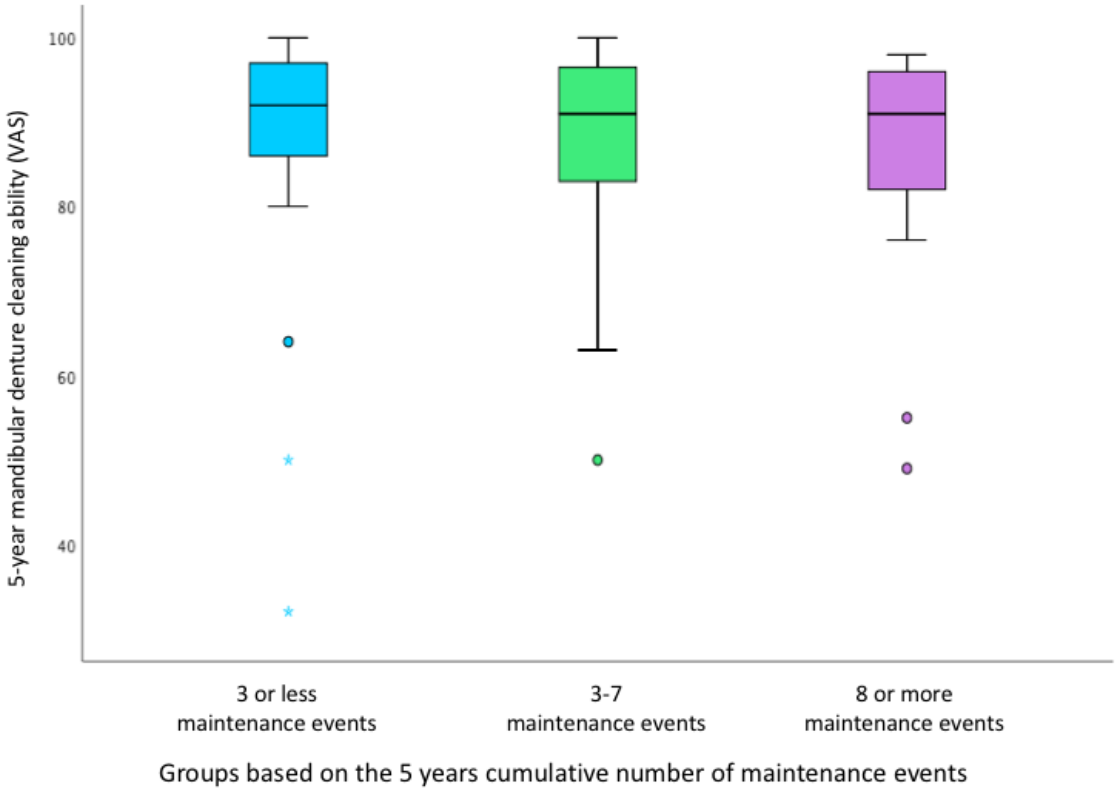

Figure 3-7 A 5-year lower implant overdentures ability to clean on VAS. Comparisons among patients with different number of maintenance events.

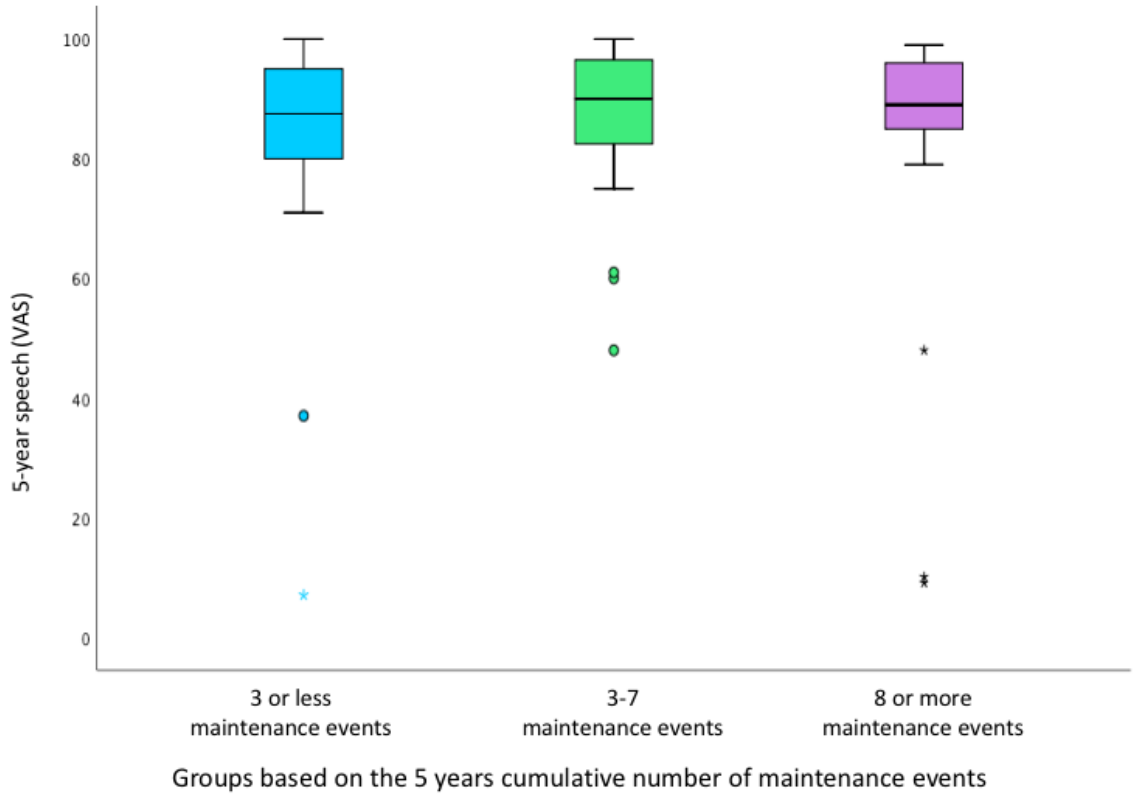

Figure 3-8 A 5-year lower implant overdentures speech on VAS. Comparisons among patients with different number of maintenance events.

Comparing the OHIP total scores calculated in two different ways (original and severity scores) at 5 years among groups with a low, medium and high number of maintenance events using parametric One-Way ANOVA and non-parametric Kruskal Wallis statistical tests. No significant differences were found (ANOVA and Kruskal Wallis $p>0.05$) (Table 3-9).

Table 3-9 Oral Health Impact Profile calculated in two different ways (original and severity scores) among patients with different numbers of maintenance events *

	Low ≤ 3 maintenances n=18	**Medium 5-7 maintenances n=23**	**High 8-27 maintenances n=21**	**Significance**	
				P value ANOVA	**P value Kruskal Wallis**
5 year OHIP original Scores (Theoretical range 46-230#)	mean ± sd	mean ± sd	mean ± sd		
	66.1 ± 12.1	74.5 ± 26.5	74.4 ± 22.2	0.115	.110
5 year OHIP severity scores (Theoretical range 0-46^)					
	0.8 ± 1.1	2.5 ± 4.1	2.1 ± 3.4	.249	.431

*Parametric One Way Anova and non-parametric Kruskal Wallis test. # Sum from 46 OHIP scale questions; ^Sum calculating only the OHIP questions that were answered with worst values.

Graphically representing the same OHIP total scores data calculated in two different ways (original and severity scores) using box-plots (Figures 3-9 and 3-10) showed that after 5 years of function, participants in all three of the maintenance groups (low medium and high) tended to have low numbers of negative OHIP events. Nonetheless, although the statistical analysis (parametric and non-parametric) consistently shows a lack of statistical significance between the 3 groups, the graphic box-plot representations show a tendency for a higher range of scores as the number of maintenance events increases across the 3 groups.

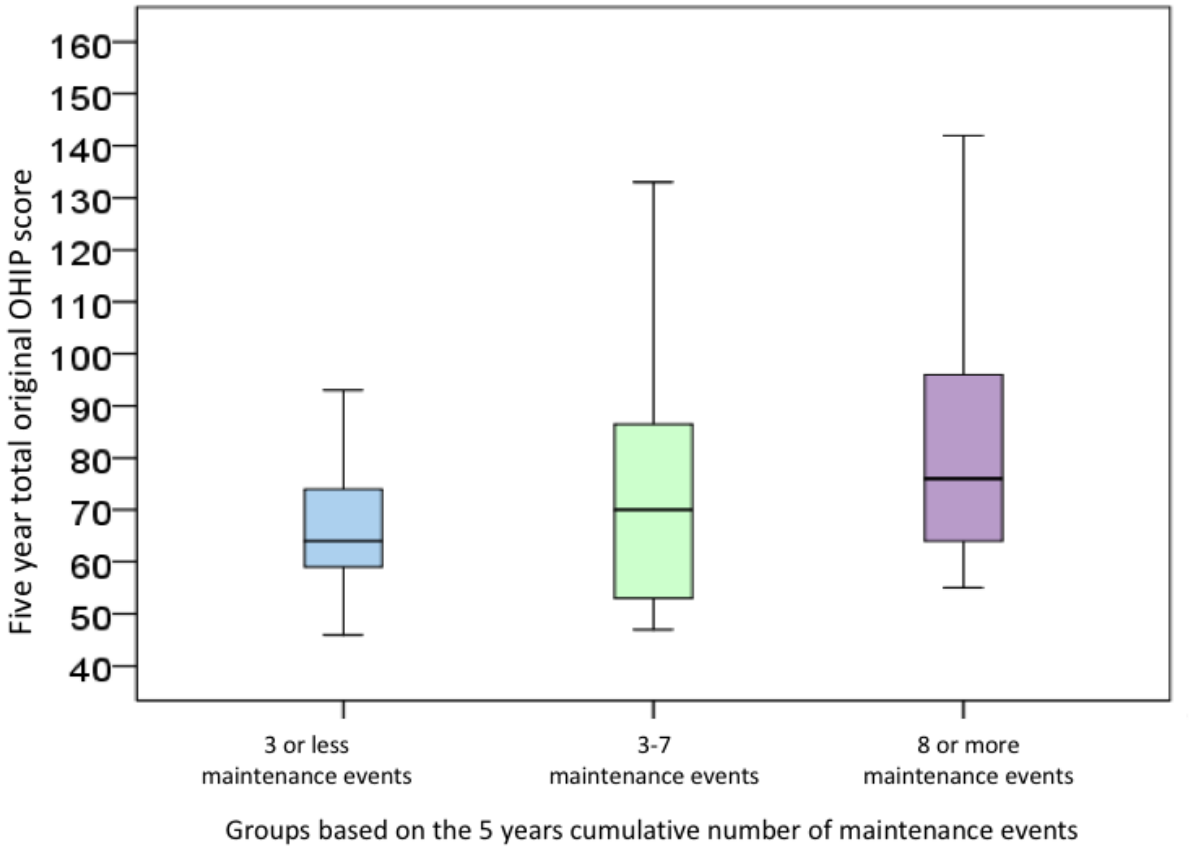

Figure 3-9 5-year summative original OHIP scores for mandibular implant overdenture among patients with different number of maintenance events.

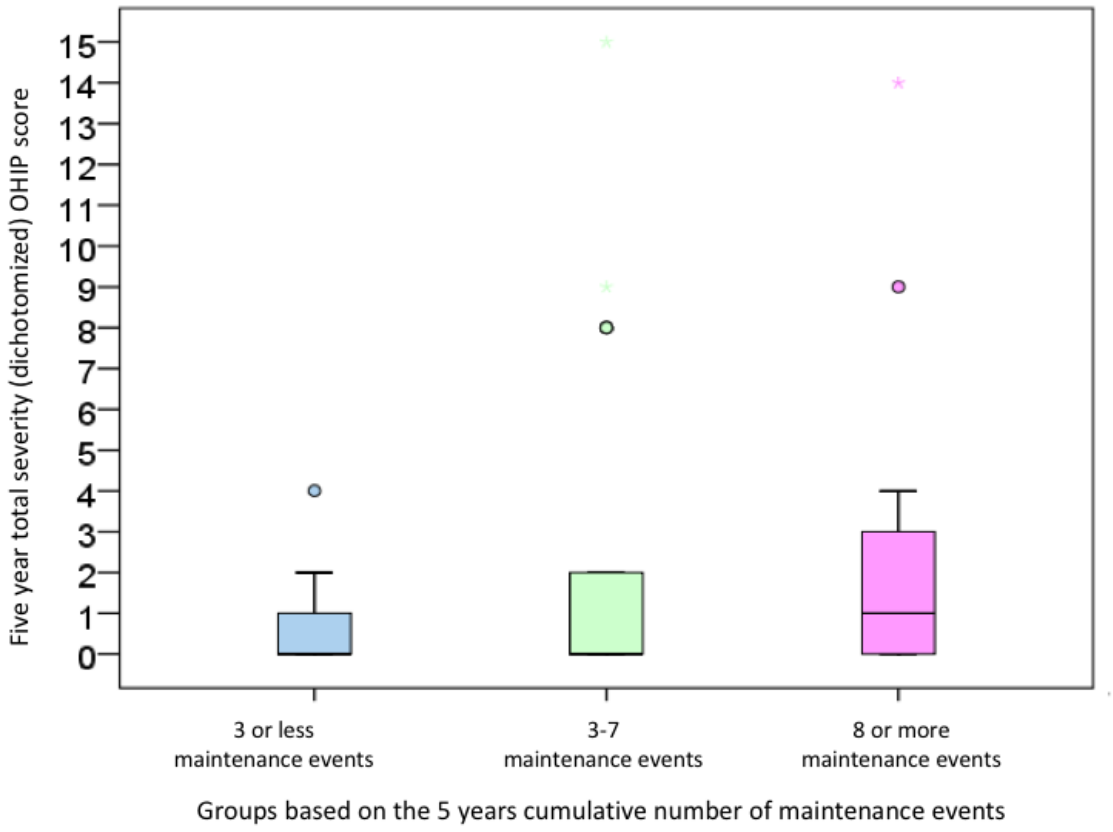

Figure 3-10 5-year severity OHIP scores for mandibular implant overdenture among patients with different number of maintenance events.

Also, except for the social disability sub-domain, no significant differences were found with the ANOVA and Kruskal Wallis tests comparing the 5-year total original scores of the OHIP sub-domains among the three maintenance frequency groups of patients (with low, medium and high numbers of maintenance events).

Table 3-10 Comparing mean total original scores of the seven OHIP sub-domains among the three groups#

OHIP Subscales	Low ≤ 3 maintenances n=18	Medium 5-7 maintenances n=23	High 8-27 maintenances n=21	Significance	
				ANOVA	Kruskal Wallis
	mean ± sd	mean ± sd	mean ± sd		
Functional limitation	15.7 ± 3.8	17.0 ± 5.9	18.9 ± 5.1	.166	.194
Physical pain	12.9 ± 3.6	14.5 ± 6.3	16.0 ± 4.0	.15	.127
Psychological discomfort	6.8 ± 2.0	8.3 ± 4.6	8.8 ± 3.5	.162	.142
Physical disability	12.3 ± 3.0	13.7 ± 6.0	14.4 ± 5.1	.432	.421
Psychological disability	7.3 ± 1.5	7.7 ± 3.2	8.4 ± 2.8	.452	.452
Social disability	5.1 ± .48	5.7 ± 1.6	6.2 ± 2.2	.127	.004
Handicap	6.6 ± 1.4	6.6 ± 1.2	7.6 ± 2.5	.118	.303

Comparisons among maintenance groups analyzed with One-Way Anova and Kruskal Wallis analysis.

AIM 2: To assess the possible association between VAS overall satisfaction and OHIP scores

To make the positively-focused VAS scores directly comparable to the negatively-focused OHIP scores, the average values of the upper and lower overall satisfaction scores were calculated and then the reverse values (reverse average overall satisfaction VAS scores) were calculated by subtracting these average values from one hundred (100 minus the average upper and lower overall satisfaction).

Then, the correlation comparison (Pearson and Spearman $p<0.05$) of the relationship between the reverse average values of upper and lower overall satisfaction and the total OHIP scores (calculated in the two different ways – the original total and the dichotomized severity scores) revealed that: (Table 3-11)

- With the exception of the one-year data, there were statistically significantly high levels of correlation between the OHIP total (original and severity) scores and the reverse average overall satisfaction VAS scores at the different time points.
- There were statistically significantly high levels of correlation between the two ways used to calculate OHIP total scores (original and severity).

Table 3-11 Correlation between reverse mean value of average upper and lower overall denture satisfaction VAS, OHIP original score and OHIP severity score #

	Reverse overall VASs vs original OHIP				Original OHIP vs severity OHIP				Reverse overall VASs vs severity OHIP			
	Spearman		Pearson		Spearman		Pearson		Spearman		Pearson	
	Correlation	P value	Correlation	P value	Correlation	P value	Correlation	P value	Correlation	P value	correlation	P value
Baseline	.75	<.001	.76	<.001	.88	<.001	.92	<.001	.73	<.001	.70	<.001
Two Months	.38	<.001	.59	<.001	.39	.002	.65	<.001	.44	<.001	.92	<.001
One year	.16	.214	.15	.217	.37	.003	.66	<.001	.05	.693	.18	.182
Five years	.63	<.001	.67	<.001	.77	<.001	.85	<.001	.77	<.001	.76	<.001

Chapter 4: Discussion

The first study hypothesis, on a possible relationship between subjective patient-based outcomes and mandibular implant overdenture maintenance, could not be accepted because there were no statistically significant differences in either the VAS satisfaction scores or in the total OHIP-49 scores among the three maintenance groups. Likewise, no significant correlations were found between the number of maintenance events and the VAS scores for any of the eight mandibular denture outcome variables, including overall satisfaction. The results also demonstrate that there was no identifiable trend, irrespective of statistical significance, towards lower VAS denture satisfaction scores as the number of maintenance events increased. Nevertheless, a slight, but non-statistically significant, tendency towards higher total OHIP original and severity scores at five-years was noticed as the number of maintenance events increased across the three maintenance groups, which could indicate that the OHIP scale was measuring a somewhat different aspect than the VAS scales, but possibly unable to detect differences in the OHIP response due to inadequate statistical power. However, a far simpler explanation is that the OHIP is only designed with the mouth as the unit of analysis whereas the VAS overall satisfaction and most of the VAS sub-scales used the maxillary and mandibular dentures separately as units of analysis, and since the frequency of maintenance events were available only for the mandibular denture, it is perhaps not so surprising that the OHIP differed slightly in its response. A more complicated alternative explanation could be that, unlike the VAS scales, the OHIP measures the frequency of various possibly negative experiences, an example being the frequency of food catching in the denture, consequently, it is not necessarily suited to detect how important such experiences are to a participant, or even whether some experiences are actually problematic for a person. It is perhaps not so surprising that the VAS overall satisfaction, may not always relate

closely to the OHIP score which demands the participant to report on experiences that may not actually be related to satisfaction.

Two previous studies (3, 4) reporting a high level of satisfaction among patients with different implant overdenture designs despite a significant difference in the amount of maintenance events, seem to imply that patient satisfaction was not affected by the extent of prosthetic maintenance similar to the present study. However, due to methodological differences between those studies and the current study, it is not possible to easily compare the results. This is because participants with high numbers of maintenance events in those previous studies may still have had a lower than average level of satisfaction that could have been masked by a high satisfaction among participants with less frequent maintenance needs. Hence, in the present study the participants were divided into three, approximately equal-sized, mandibular overdenture maintenance groups, demonstrating relatively high mean scores of patient satisfaction, and low mean total OHIP scores (i.e. relatively few negative impacts) among all three groups as well as the absence of significant differences in the various VAS denture outcome scores and in the total OHIP-49 scores comparing the three groups. Overall, this reflects that, in general, the patients were typically relatively satisfied with the implant overdenture treatment and that the number of maintenance events per se did not tend to affect patient-based outcomes as indicated by different measures. This could also indicate that the majority of patients appreciated the functional improvement they acquired with placement of one or two implants to an extent that they were willing to overcome the need in some cases for multiple maintenance events.

Both parametric and non-parametric tests were used in the present study to analyze comparisons involving either of the two psychosocial measures (VAS and OHIP), because of arguments about

using these measures as continuous interval data for statistical purposes. Although the face validity of the VAS indicates a continuous interval scale variable (67), some have argued that the VAS is an ordinal level scale with its numerical values not continuous in a mathematical sense (68, 69). In contrast, although the OHIP questionnaire scores are evidently compiled from ordinal Likert-scale responses, there is a long-standing debate defending the adequacy of using Likert-scale data involving at least 5 response categories as continuous interval numerical data (70-72).

The presence of outliers with very low levels of satisfaction (VAS scores being < 20) in the three groups may indicate that some patients were poorly adapted to their oral condition regardless of the frequency of the maintenance events. Although the present study did not detect the reason for their dissatisfaction, a further descriptive analysis of the study participants demonstrated approximately equal representation across the three maintenance frequency groups among the 7 participants who reported a VAS score of <20 in at least two of the lower denture variables. Among these, 3 participants were in the high maintenance group individually with 8, 11 and 13 maintenance events by 5 years, whereas 2 participants were in the medium maintenance group with 4 and 7 maintenance events each, and 2 participants were in the low maintenance group with 2 and 3 maintenance events each. This manifestation of the same patients as low-satisfaction outliers with more than one of the denture satisfaction variables and with seemingly reasonable maintenance needs over the 5-year period may indicate that even with implant treatment these patients had ongoing difficulty adapting to their edentulous state and removable prosthesis status, and may even have had unrealistic expectations with the overdenture treatment.

The second aim of our study was to explore if there was an association between one global question assessing overall satisfaction using VAS and the total OHIP scores calculated in the original or severity (dichotomized) modalities. Overall, both the Pearson and Spearman correlations showed that, except for the one year time point, there was a significant association between the two types of measures at the baseline, 2 months and 5 years. Therefore, the second study hypothesis was only partly accepted. For this portion of the study, the VAS questionnaire items assessed overall satisfaction for the maxillary and mandibular dentures separately so we decided to calculate the averages of these two VAS scores hence the VAS would be more comparable to the OHIP which uses the mouth as the level of analysis. We also calculated a reverse average overall satisfaction (with the lowest satisfaction being 100 instead of 0) to facilitate a positive correlation of the VAS overall satisfaction with the negative-based outcome of the OHIP questionnaire (with the highest numbers indicating greater negative impact).

Finding a significant association between the two different measures (satisfaction and OHIP measures) was in agreement with previous studies. A longitudinal study by Stober and his colleagues assessed the association between an OHIP-EDENT questionnaire and patient satisfaction evaluated on one global question, using a scale from one to ten, on 52 edentulous patients who received complete dentures. The patient-based outcomes were assessed at different time intervals, and they found a significant association between the two measures in all time intervals (73). Locker and colleagues also reported a significant correlation between a global oral satisfaction question on a 4-point Likert format ranging from ‘very satisfied’ to ‘very dissatisfied’ and (OHIP-14) total scores obtained from 766 geriatric patients (74).

Finding no significant association between the OHIP total scores and the average overall VAS scores at the one year follow-up was not necessarily an unexpected result in the present study, even though the related hypothesis was upheld at all the other time-points in this longitudinal study on the same patients. A similar tendency to an anomalous variation in the OHIP scores compared to VAS scores was also noticed when comparing the participants who received one and two implants which showed that the mean total OHIP score at the baseline for patients who received one implant was lower than the mean scores for those with 2 implants hence the 1 implant group were having less negative impacts (i.e. the OHIP indicated a tendency to better wellbeing for the 1-implant at baseline). In contrast, the mean VAS scores at the baseline showed that the 2-implant group tended to be more satisfied with their dentures, but with neither of the findings being statistically significant. This could indicate that these two questionnaires are not necessarily measuring the same outcomes. Although speculative, one of the possible explanations is that anomalies between the two measures may arise because the two questionnaires use different approaches in their questioning modality, the OHIP asking about the frequency of negative social impacts (negatively-oriented outcomes), while the global VAS indicating overall satisfaction with the prosthesis (positively-oriented outcomes). This has also been observed by Hobkirk and his colleagues (75) who found significant differences between satisfaction level (positively-oriented outcomes) between the two treatment groups, yet no significant differences between the same two groups in their denture-related complaints (negatively-oriented outcomes). Moreover, the frequency of negative impact measured with the OHIP instrument does not usually indicate the level of patients' overall satisfaction, so even while a patient may experience some unpleasantness, for example their denture is not retentive or tends to collect food, the incidence of such events will not necessarily adversely affect his or her

level of satisfaction (20). All of this supports the long-established observation (76) that two-thirds of survey participants identified dentist-mediated problems with their mouths but only about one-third of the same participants reported having a problem.

Although using more comprehensive measures such as the OHIP 49 questionnaire to assess patient-based outcomes may seem to give a more detailed view of how patients perceive their oral status, there may be some drawbacks associated with the use of such measures. One of these drawbacks is that the OHIP-49 questionnaire is somewhat lengthy and may make patients less inclined or even unwilling to respond thoughtfully to so many questions. Additionally, missing answers from the OHIP-49 questionnaire, perhaps related to the length of the instrument, represent a serious challenge for statistical analysis. In our analysis, it was decided to manage the missing answers by calculating the total scores in two different ways; by giving the missing answers a score of three then calculating the original total scores and by calculating dichotomized severity scores. Pearson and Spearman correlations in our analysis showed that both calculations were highly correlated to each other.

4.2 Limitations

The present study started with 86 edentulous patients, however, only 62 patients attended the 5-year recall-visit and filled out questionnaires resulting in a 28.0% drop-out rate. 14 (16.3%) of these drop-outs were deceased, thus if we consider that these patients were actually followed-up for as long as possible, we can consider the follow-up rate to be higher (2). Nonetheless, we tried to manage the relatively high number of drop-outs by pooling the results from patients who received one and two implants after confirming that there were no significant differences in their satisfaction levels and their OHIP total scores.

Another limitation that should be taken into account is that the original study assessed the possible effect of 5 years of cumulative maintenance events on patient-based outcomes, the latter being collected at a single time point, the 5-year follow-up appointment, rather than at multiple different time points throughout the 5-years. Thus, the patients' memory of the previous 5- years of cumulative maintenance events was a major resource used to assess the possible effect of maintenance on patient-based outcomes. Although the number of maintenance events were documented continuously and the patient-based outcome questionnaires were also collected at two months, and at the one and three year follow-ups, it was not possible to make statistical comparisons at the separate time intervals before 5 years because the number of maintenance events during the first year, and the number of patient-based questionnaires at the three year time point were too low in both cases to perform any meaningful statistical analysis. Therefore, we decided to analyze only the five-year results.

Moreover, interpreting the data and drawing appropriate conclusions regarding prosthetic maintenance is very difficult due to the lack of standardized criteria available across clinical

trials reporting on prosthetic outcomes. Essentially clinical trials, including the present study, have reported maintenance outcomes in a variety of different ways. For example, in our study, occlusal and denture base adjustments were not counted as maintenance events, even though the patients could have experienced enough discomfort to make them seek their dentist's intervention for relief. Other studies ignored counting matrix tightening or the reattachment of a separated attachment matrix as maintenance events (46, 77).

The main limitation for the second aim of the present study is a concern over the missing items on the OHIP-49 questionnaires, possibly related to the length of the instrument, and therefore, over the extent the comparison to the global VAS was compromised somewhat by interpolated data. Another limitation could be that the 2 measures (VAS and OHIP) use different units of analysis as noted, and that combining the upper and lower scores of the VAS overall may not actually be a valid representation of the overall satisfaction with the mouth as the unit of analysis. Although not available in the present set of data, a better assessment of OHIP comparison to VAS for implant overdenture patients might instead be to use a global overall VAS of satisfaction rather than averaging the individual upper and lower denture scores.

4.3 Future recommendations

- There is an evident need for standardizing the reporting of maintenance outcomes for implant overdenture studies.
- Although the present study showed that the number of maintenance events did not have a significant effect on the patient-based outcomes measured with two different self-report measures (VAS and OHIP-49), further clinical studies with larger sample sizes having adequate power for comparing patient-based outcomes and the maintenance requirements for implant overdentures may make it possible to distinguish the possible more subtle effect of different types of maintenance events.
- Given our inability to fully understand the underlying source of variation in patient-based outcomes, future research would likely also benefit from qualitative research approaches with open-ended questions that allow patients to describe their feelings and experiences with treatment using their own words. Having an open-ended format would widen our understanding of what factors affect the patient satisfaction.

Conclusions

- There were no significant differences in the various scales of mandibular implant overdenture satisfaction and total OHIP scores at 5 years among groups with a low, medium and high number of maintenance events, which implies that the number of maintenance events may not affect patient-based outcomes.
- Although statistically significantly strong correlations were found between a global VAS measure of overall satisfaction and OHIP-49 total scores at most time-points in an existing five-year mandibular implant overdenture study, the finding of no such significant correlation at the one-year interval suggests that the OHIP-49 may not consistently correlate inversely with measures of overall satisfaction with mandibular implant overdentures.

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Appendix A Denture outcomes measured with Visual Analog Scale

I.D# (office use only)

ASSESMENT OF DENTURE BY STUDY PARTICIPANTS

Name: Today's date:

(office use only) Stage [check one]:

1. Base line •
2. 2 months post-IP insertion •
3. 1 year post- IP insertion •
4. 3 years post-IP insertion •
5. 5 years post-IP insertion •

starting on the next page, we will ask you to evaluate a number of characteristics of your upper ("U") and lower ("L") dentures by placing an "X" on the scales shown

EXAMPLE: If you feel that your upper denture is very stable, but your lower denture is quite unstable, you might mark the scale as follow:

5 . Stability

"U" X
unstable _____ stable

"L" X
unstable _____ stable

Please turn over the page and begin marking the eight scales shown.

I.D# (office use only)

1. Pain

"U"
painful _____ not painful

"L"
painful _____ not painful

2. Comfort

"U" _____
uncomfortable comfortable

"L" _____
uncomfortable comfortable

3. Appearance

"U" _____
poor excellent

"L" _____
poor excellent

4. Function

"U" _____
difficult to chew easy to chew

"L" _____
difficult to chew easy to chew

5. Stability

"U" _____

loose/unstable stable

"L" _____

loose/unstable stable

6. Speech

_____

abnormal speech normal speech

7. Cleaning difficulty

"U" _____

very difficult easy

"L" _____

very difficult easy

8. Overall satisfaction

"U" _____

not satisfied satisfied

"L" _____

not satisfied satisfied

Appendix B Oral Health Impact Profile questionnaire

THE QUESTIONNAIRE.

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. We would like to know how often you have had each of the 49 listed problems during the last year.

How to answer the questions.

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 circle the answer to the right of the question, to indicate how often you have had the problem during the last year

examples *If you occasionally had sore spots in your mouth you would circle the answer as shown in this example*

Q 16. Have you had sore spots in your mouth?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER

If you have never the problem during the last year circle "NEVER" as follows.

Q 16. Have you had sore spots in your mouth?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER

WHAT IF THE QUESTION DOES NOT APPLY?

Question 3 applies only to people who have all or some of their own teeth. If the question does not apply to you then you would answer by checking the box as follow.

examples

Q13. Have you had a toothache?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER

Does not apply – I do not have my own teeth ☐

Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. Community dental health. 1994;11(1):3-11.

	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q1. Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?					
Q2. Have you had trouble pronouncing any words because of problems with your teeth, mouth or dentures?					
Q3. Have you noticed a tooth which doesn't look right?					
Q4. Have you felt that your appearance has been affected because of problems with your teeth, mouth or dentures?					
Q5. Have you felt that your breath has been stale because of problems with your teeth, mouth or dentures?					
Q6. Have you felt that your sense of taste has worsened because of problems with your teeth, mouth or dentures?					
Q7. Have you had food catching in your teeth or dentures?					
Q8. Have you felt that your digestion has worsened because of problems with your teeth, mouth or dentures?					
Q9. Have you had painful aching in your mouth?					
Q10. Have you had a sore jaw?					
Q11. Have you had headaches because of problems with your teeth, mouth or dentures?					

Q12. Have you had sensitive teeth, for example, due to hot or cold foods or drinks?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Does not apply – I do not have my own teeth ☐

Q13. Have you had toothache?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Does not apply – I do not have my own teeth ☐

Q14. Have you had painful gums?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Q15. Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Q16. Have you had sore spots in your mouth?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Q17. Have you felt that your dentures have not been fitting properly?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Does not apply – I do not have dentures ☐

Q18. Have you had uncomfortable dentures?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Does not apply – I do not have dentures ☐

Q19. Have you been worried by dental problems?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Q20. Have you been self-conscious because of your teeth, mouth or dentures?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Q2l.Have dental problems made you miserable?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Q22. Have you felt uncomfortable about the appearance of your teeth, mouth or dentures?

VERY OFTEN | FAIRLY OFTEN | OCCAS-IONALLY | HARDLY EVER | NEVER

Q23. Have you felt tense because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q25. Have people misunderstood some of your words because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q26. Have you felt that there has been less flavor in your food because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q27. Have you been unable to brush your teeth properly because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
	Does not apply – I do not have my own teeth ☐				
Q28. Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q29. Has your diet been unsatisfactory because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
30. Have you been unable to eat with your dentures because of problems with them?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q31.Have you avoided smiling because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER

Q32. Have you had to interrupt meals because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q33. Has your sleep been interrupted because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q34. Have you been upset because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q35.Have you found it difficult to relax because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q36. Have you felt depressed because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q37. Has your concentration been affected because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q38. Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q39. Have you avoided going out because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q40. Have you been less tolerant of your spouse or family because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q41. Have you had trouble getting on with other people because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER

Q42. Have you been a bit irritable with other people because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q43. Have you had difficulty doing your usual jobs because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q44. Have you felt that your general health has worsened because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q45. Have you suffered any financial loss because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q46. Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q47. Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q48. Have you been totally unable to function because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER
Q49. Have you been unable to work to your full capacity because of problems with your teeth, mouth or dentures?	VERY OFTEN	FAIRLY OFTEN	OCCAS-IONALLY	HARDLY EVER	NEVER

Please write today's date _____