Patient satisfaction after receiving dental implants with immediate loading in the edentulous atrophic maxilla – a prospective study using the OHIP 49 questionnaire, one year results

Maria Erkapers

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Abstract

Purpose: Ability in analyzing and understanding patient assessment is crucial in further development of implant technology.

This study evaluated patient satisfaction for patients receiving six implants in the upper jaw and an implant supported bridge delivered within twenty-four hours after surgery using the Oral Health Impact Profile 49 questionnaire.

Materials and Methods: 51 patients who were edentulous in the upper jaw were included in the study performed at two centres. Six implants were placed in the maxilla and loaded within twenty-four hours after installation with a temporary restoration. 20-24 weeks later the permanent restorations were delivered. Patients were asked to fill in the OHIP 49 questionnaire prior to implant surgery and at three occasions after treatment. Data was collected and analysed.

Results: Baseline satisfaction scores for the two different centres displayed no statistical differences. Treatment resulted in improved total OHIP 49 scores in both centres with no significant difference in-between centres. Furthermore, no significant differences were observed in any of the individual pre- and post-treatment OHIP 49 domains between centres. All seven subgroups showed a statistically significant improvement in their post OHIP score but centre 1 tended to have a larger improvement in the Psychological discomfort-subgroup compared to centre 2.

Conclusions: Measurement with the OHIP 49 questionnaire used displayed; patient satisfaction increases after treatment with a fixed restoration on implants loaded within 24 hours.

Handledare: Karl Ekstrand, Associate Professor, Institution Klinisk Odontologi. The University of Oslo
Examinator: Docent Inger Wårdh, Institutionen för Odontologi, Karolinska Institutet, Stockholm
Patientupplevelse hos patienter med atrofisk maxilla som behandlats med direktbelastade implantat – en prospektiv studie med OHIP 49 frågeformulär, ett års resultat

Sammanfattning

Syfte: Förmågan att analysera och förstå patientupplevelse är nödvändigt för att kunna utveckla implantatteknologin vidare.

Den här studien utvärderar patienters tillfredställelse efter att de behandlats med sex implantat i överkäken som belastades med en temporär bro inom tjugofyra timmer efter implantatoperationen. För utvärdering användes ett frågeformulär; Oral Health Impact Profile 49.

Material och Metoder: 51 patienter som var tandlösa i överkäken var inkluderade i studien som utfördes på två centrum. Sex implantat installerades i maxillan och belastades inom tjugofyra timmer efter operation med en temporär bro. 20-24 veckor senare levererades den slutgiltiga restorationen. Patienterna ombads att fylla i OHIP 49 formuläret innan implantatinstallationen samt tre gånger efter behandlingen. Data sammanställdes och analyserades.

Resultat: Utgångsvärde för de två olika centren visade ingen statistisk skillnad. Behandlingen resulterade i högre totalpoäng av OHIP 49 för båda centren utan någon statistisk signifikant skillnad mellan centren. Dessutom, ingen signifikant skillnad var observerad mellan de individuella OHIP 49 domänerna före och efter behandling mellan centren. Samtliga sju undergrupper av OHIP 49 uppvisade en signifikant förbättring i poäng efter behandling, center 1 tenderade dock att visa en större förbättring jämfört med center 2 avseende Psykologiskt obehag.

Slutsats: Mätningar med OHIP 49 frågeformulär visar att; patienters tillfredställelse ökar efter behandling med implantat som belastas inom 24 timmar.

Keywords: Dental Implant, Dental Prosthesis, Implant-Supported, Follow-Up Studies, Patient satisfaction, Treatment Outcome, Oral Health Related Quality of Life, Questionnaires
Introduction

Implant technology has become a more frequent solution when replacing missing teeth as peoples expectations have increased due to prosthodontics. They require a good result when it comes to aesthetics and function. More patients become edentulous at an older age, and are less able to adapt to the limitations of dentures.

The implantology industry has continuous new actors on the market and the development is continually. Implantology is a relatively new technique and should be viewed as a complement and not a substitute to dentures and bridges.

Implant systems might vary in shape/implant body design (long, short, diameters, conical, cylindrical), surface (sandblasted, large grit or acid-etched, turned or machined), material and different way of applying the implants in place - one or two step surgery. In addition, different impression techniques, abutments variations and final restoration may vary, depending on implant system and how quickly the prosthodontics can be applied.

At all time there should be a clear indication for treatment regardless which prosthodontic treatment is planned and awareness regarding the indications and different advantages as well as disadvantages.

Indications for prosthodontics

Prosthetic rehabilitation has several functions such as, the improvement of dysfunctional masticatory function, opportunity to improve aesthetic situations, improvement of the patients’ phonetics and prevention of further destruction in the masticatory system.
Several factors ought to be considered when choosing the most suitable prosthetic construction regarding rehabilitation of a dysfunctional bite. There should also be clear indications for treatment.

Currently, no specific research has been presented regarding partial dentures vs. implants, thus some guidelines are available; conventional removable dentures are associated with increased risk of caries, periodontitis and low acceptance, (Wostmann et al. 2005) which favors implant supported restorations. But even if implant treatment is superior, the economic factors (which is often the most crucial element in the decision-making-process) play a crucial role resulting in frequent selection of removable denatures. When a partial denture is replacing several occlusal units the patient satisfaction is increasing (van Waas et al. 1994). Thus, when merely a few teeth are being replaced, the discomfort of wearing the denture is larger than the satisfaction which therefore favors a bridge or an implant solution.

It is clear that patients are more satisfied with implant supported prosthodontic rehabilitation in terms of comfort, stability and aesthetics in comparison with conventional prostheses (Awad and Feine 1998). Patients consider implant-supported prostheses as an integral part of their body that clearly enhance their daily lives (Blomberg 1985). At the same time it has been observed that patients wearing a denture with a two-ball attachment system have just as high patient satisfaction as implant supported denture users (Thomason et al. 2003).

Patients with temporomandibular disorders (TMD) are complicated to treat due to TMD’s complex and unexplored causes of problems. As the etiology of TMD remains unsolved, the current treatment is not uniform. TMD’s major symptom is pain, accompanied by a restricted mandibular motion. Therefore, pain control is the primary
goal for TMD management, and upon achievement, improvement of function is possible.

A reason for replacing missing teeth in short dental arches is the risk of TMD. Some studies suggest a correlation between missing molars and TMD (Tallents et al. 2002), but available evidence is scarce (Turp and Strub 1996). In addition a poorly maintained partial denture may cause parafunctional jaw movements in the long term (Witter et al. 1994), which could also be an indication that implant treatment ought be the first choice in short dental arches if the patient suffers from TMD problems. Fixed restorations should be considered as first choice, as they demonstrate better survival (Vult von Steyern et al. 2005), but when only a few teeth are missing and the patient has no functional complaint, the best alternative is to leave it.

Aesthetics problems can be an indication for prosthodontics. Missing teeth is a common reason why people do not feel satisfied with their appearances, especially in the western world where missing front teeth is associated with a lower social class.

The reasons for missing teeth can be caries, periodontitis, aplasi or trauma.

Other aesthetic problems are tooth wear or different kind of malocclusions that can’t be corrected with orthodontic treatment.

Malnutrition is a controversial indication for prosthodontic treatment. Tooth loss might be associated with a poor diet, malnutrition and even influence the general health, (Osterberg and Steen 1982). In addition, there are many other components that compromise a patient’s health status such as systemic health, socio-economic status, and dietary habits.

A primary goal for dental treatment is to restore oral function, especially masticatory ability. Masticatory function is determined by the number of functional tooth units and
the bite force. The ability to chew is age-related because of tooth loss, decline in muscle mass and fragility. It has been shown that a patient’s subjective assessment of chewing is more influenced by age than dental and prosthodontic status (Lappalainen and Nyystssonen 1987).

Masticatory performance improves after prosthodontic treatment independent of the design and type of denture (implant supported or regular dentures)(Kapur et al. 1997), (Kapur 1991). Unless the patient has less than three occluding pairs of posterior teeth, there seems to be no sociofunctional benefit to be gained from replacing missing teeth (Locker et al. 2000). Thus, masticatory performance is an important factor which influences the quality of life (Ikebe et al. 2007).

Social and sexual activities are important aspects, regarding a person's well being, and a loose fitting denture can understandably cause problems in intimate situations. Heydecke et al.(2005) compared pre and post results for patients receiving implant supported dentures vs. regular mandibular full dentures. The results showed that the edentulous patient has a negative impact on social and sexual life and that mandibular over- dentures provide greater improvement in unease regarding intimate activities in comparison to new conventional mandibular dentures.

In addition, the sexual activities, defined as uneasiness when kissing as well as during sexual relations, the patients were also asked about social activities such as how often they avoided conversation, refused invitation, and avoided sports because of their prostheses. Correlations between affected social activities and instability in denture were also shown. Further, patient satisfaction regarding conventional dentures, tend to stabilize over time while patients receiving implant supported dentures show continued improvement (Thomason et al. 2003).
Similar negative effects have been reported from patients affected by oral cancer or head-and-neck cancer and chronic pain.

Patients’ expectations play a crucial roll when selecting dental treatment. It has been shown that patients who require implant treatment report that tooth loss and denture wearing problems have a much greater impact on their quality of life than patients seeking conventional dentures. Difficulties eating many foods, particularly those that are hard or tough are common complaints for denture wearers. Also patients who require implant treatment, or conventional dentures, experience a larger improvement in health-related quality of life compared to patients who require implant treatment but receive conventional dentures (Allen and McMillan 2003).

Other studies have compared the outcome between implant retained prostheses to conventional dentures, and it appears that oral health status in edentulous patients are improved with implant-retained prostheses (Vervoorn et al. 1991).

Allen et al. (2006) came to a different conclusion when they compared the satisfaction of patients who received implant-retained prostheses vs. conventional dentures. They showed no significant post-treatment differences between groups when measuring oral-health-related-quality.

In their study all the patients expected new conventional dentures but half of them received implant supported prosthdontics.

Quality of life is a major indicator for prosthodontic treatment. It is well known that the loss of teeth influence most people in a negative way. The loss of chewing ability, self esteem and self conscience are very important indicators for teeth replacement. Oral health-related quality of life (OHRQ) appears to be enhanced when masticatory function is improved through dental treatment. Previous studies have shown the relationship
between self-assessed oral function and OHRQ, (Awad et al. 2003), (Locker et al. 2001), (Locker et al. 2002). In a previous study it was established that dentate subjects experience a higher health related quality of life compared to patients who had dentures (Allen and McMillan 2003). Another study reported that edentulous patient experienced severe psychological complications which were reduced by implant-supported prostheses (Blomberg and Lindquist 1983).

**Restrictions for prosthodontic treatment**

A restriction for partial dentures and full dentures is diabetes (Roumanas Ed el al. 2003). Diabetics are at higher risk of developing periodontitis and infection as well as wearing denture compare to healthy people. Dry mouth problem can make denture wearing impossible because of the mechanical trauma that can damage the already fragile mucosa (Arslan et al. 2008).

Regarding denture adaptation problems such as pronunciation difficulties, chewing and feeling comfortable wearing a denture takes time. As a consequence, some people never accept their dentures. Also some people feel nausea wearing a denture and can not adapt swallowing with their denture - especially upper dentures.

A denture might not always satisfy patient’s aesthetics demands (Reeve et al. 1982). Reasons for not proceeding with implant therapy might be that significant improvement can be possible using conventional prosthodontics, if the patient is unwilling to undergo the proposed procedure or if the patient is medically or psychiatrically unfit for this form of treatment (Abu Hantash RO et al 2005).

For patients with severe heart problems the surgical procedure itself can be a risk for the patient. Further, temporary exclusion of warfarin could be more negative than the
benefit of receiving implants (Obrenović-Kirćanski B and Subotić S 2006). Patients who have received jawbone radiation or have experienced surgery for head- and neck cancer have an increased risk of osteoradionecrosis, but at the same time they are the patients who best need the treatment (Ferguson and Stevens 2007).

Smoking is another negative parameter as there is a statistically significant difference between smokers and non-smokers in the failure rates of dental implants (Baig and Rajan 2007). Smoking causes more complications after receiving implants, it causes more marginal bone loss after implant placement and the risk of peri-implanted is higher. Furthermore, smoking affects the success rates for bone graft (Baig and Rajan 2007).

Periodontitis can successfully be rehabilitated with osseointegrated implants. However, the bone and attachment loss at the implants are higher than in periodontally healthy subjects.

Patients with psychological problems should also be handled with care, as implant treatment is an extensive treatment that might cause stress to a psychologically unstable person who might not be predictable when it comes to being able to adapt or accept the new dental construction (Abu Hantash RO et al. 2005).

Occasionally there is not enough bone left to install the fixtures, but those cases have become rarer due to improved surgical procedures and the availability to bone grafts. Another restriction is when the patients expect a treatment that is quick and painless, or have to high expectations of the final result. An implant treatment may not be as highly beneficial or worth the financial costs to all patients (Allen et al. 2006). Finally, young patients who are still growing should wait with implant surgery until they stop their
growth considering the risk of interfering with the growth of the jaw-bone (Carmichael and Sandor 2008).

The restrictions regarding bridges are the risks of future caries and periodontitis which might affect the construction. There might also be too few supporting teeth left to fit a bridge correctly as well as the remaining teeth might be in a poor condition resulting in detached or broken bridge. The relatively high costs are another restriction. A bridge preparation has also a negative impact of consuming healthy tooth or the risk of damaging the tooth during the bridge preparation (Wisithphrom K et al. 2006).

It is also important that the patient is capable of keeping the new construction clean, as an unattended construction can cause caries in bridge supported teeth, periodontitis or peri-implantitis (implants), (Roos Jansåker AM 2007).

**Methods of measuring prosthodontic outcome**

Current implant studies are based on evaluating survival rate and functionality, using radiology and clinical examination. The patients degree of satisfaction is often based on a subjective evaluation by the treating dentist and therefore biased to a certain level. Outcome of the prosthodontic procedures are variable and may not be assessed by clinical measures alone.

Few studies have been performed with focus on the patients experiences of implant treatment on oral health quality of life (OHQOL) (Vervoorn et al. 1991). The research area is still evolving as it has been shown that the correlation between clinical measures and ratings of treatment success by the patient are often inadequate or not significant (Carlsson et al. 1967), (van Waas 1990).
It has been shown that oral disorders have a much broader impact on daily life than previously suggested. The consequences of oral disease or treatment may include work loss, reduction in social interaction, and disruption of family life and severe change of dietary habits (Allen et al. 1999), (Reisine and Miller 1985), (Mojon et al. 1999).

Social impact approach to measuring disease outcome has been commonly used in general medicine, but surprisingly not been adapted to oral health outcome (Slade 1998), (Reisine et al. 1989). Previous oral studies have measured tissue pathology by utilizing different clinical indicators with minimal impact of the pathology of social and psychological function.

Outcome of prosthodontic procedures are variable and are not reliable when merely assessed by clinical measures.

Patients assessments have an impact on the treatment (Geertman et al. 1996) and evidently shows to be very important when considering satisfying final results of dental implant treatment.

It may also help regarding improvement of treatment impact (Geertman et al. 1996), (Awad and Feine 1998), (Boerrigter et al. 1995), (Wismeijer et al. 1992).

Previous studies (Wilson and Cleary 1995), (Davis et al. 2001) showed that in chronic conditions, where reduction in handicap rather than cure is the outcome, it is often found that objective measures of function do not necessarily reflect the way a patient feels or functions.

Dental implants is a major change for patients oral status and will never fully replace the feeling of a patients own teeth, even though satisfaction with implant treatment is generally high. Other studies compared patients reactions before and after prostheses placement of: the majority of the patients reported improvement in quality of life, self-
confidence, and acceptance of the prosthesis as a part of themselves (Blomberg and Lindquist 1983), (Hoogstraten and Lamers 1987). It is also known that implant-supported dentures give better oral health quality of life compared to conventional dentures (Awad et al. 2000).

Obtaining a new set of teeth might influence appearances, speech, chewing function, temper, and self-esteem which have an impact on patients quality of life (Reisine et al. 1989), (Awad et al. 2000).

When assessing health status and quality of life, it has been suggested that both specific and generic, i.e. general, instruments should be utilized.

To evaluate patient assessment and change in quality of life after receiving dental implant treatment, the Oral Health Impact Profile (OHIP) has been presented which offers a reliable and valid instrument for detailed measurement of the social impact of oral disorders and has potential benefits for clinical decision-making and research (Allen et al. 1999), (Slade and Spencer 1994).

Many other indices has also been designed to measure the subjective impact of oral health on quality of life (Slade 1998) but most of the traditionally, longitudinal studies of oral health have measured merely disease progression and ignored improvements in health (Slade 1998).

Different measurements have varied between studies. The consensus in available literature is that the assessment of quality of life in chronic disease states should include measurements of well-being, physical symptoms and social functioning and the selection of measures should be guided by the nature of the studied condition.

Some of the most common generic instruments used are Sickness Impact Profile (SIP), the SF-36 health survey and the Geriatric Oral Health Assessment Index (GOHAI),
which are well documented generic instruments designed to measure health status (Heydecke et al. 2003).

The SIP contains 136 questions and has been used to measure periodontal disease, denture wearing problems and TMD problems (Reisine et al. 1989).

The SF-36 is a shorter version of SIP with 36 questions and was originally developed and validated for the medical outcome studies (Ware and Sherbourne 1992).

Correlations between the OHIP and SF-36 have not been significant, which suggests that oral health status is largely independent from general health status (Ware and Sherbourne 1992).

Obviously, the majority of the SF-36 domains are not sensitive to change in oral health and exhibit very limited construct validity for oral health applications.

GOHAI contains questions more specifically referring to oral conditions which were not included in the SIP. The GOHAI can be regarded as an inventory which adds together a range of adverse effects ranging from functional disorders to social consequences of those disorders.

In this study we have chosen not to include a generic test.

**OHIP**

OHIP was developed to describe the social impact of oral disorders (Slade and Spencer 1994).

OHIP is a questionnaire with 49 unique questions that have been extracted from 535 statements and is regarded as the most qualified when it come to describing the consequences of oral disorders. The statements were obtained from interviews with 64 patients. The questions can be sub grouped into seven domains drawn from Lockers
model (Slade and Spencer 1994) Figure 1. The domains are: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap to describe the negative impacts of oral health conditions (Awad et al. 2000), (Slade and Spencer 1994), (Allen and Locker 2002).

There are five categories of choice per question; never, hardly ever, sometimes, fairly often, or very often. Also if the question is not applicable on the patient they are given an option to say so. The categories are graded from 0-4 based on the Likert scale, were 0 is never and 4 is very often. Internal reliable, test/re-test reliability, and validity were previously established (Slade 1998) (Allen et al. 1999).

Oral health-related quality of life measures capture both improvements and deterioration in health status (Slade 1998), which enables new opportunities to conceptualize and analyze change in longitudinal studies.

The Oral Health Impact Profile has several short forms ranging from 30 to 5 items. The 14-item version is widely used in population-based and clinical research, when developed statements relevant to denture wearing were excluded. Therefore, OHIP-14 may not be suitable for measuring change following prosthodontic procedures (Finbarr and Locker 2002).

OHIP-EDENT is a shorter version of OHIP 49, which has been suggested to be more appropriate for use in edentulous patients (Allen and Locker 2002).

A shorter version is less time-consuming, less costly, more adapted for elderly, and less prone to non-response. Thus, OHIP 49 is more comprehensive and precise (Baba K el al. 2008).
Figure 1. The seven sub group according to Lockers model (Slade and Spencer 1994)
The benefits of OHIP data

The OHIP is the most sophisticated and comprehensive generic instrument, currently available and offers a reliable and valid instrument for detailed measurements of social impact and disorders and has potential benefits for clinical decisions and research (Allen et al. 1999).

Because OHIP includes seven domains it covers a wide range of possible oral health problems that have an impact on quality of life, and is suitable for use as an outcome measure in a clinical trial in which different treatments are compared. The possibility to report changes in subscales than merely overall scores make the results more meaningful for a patient who has to select a specific form of treatment. For example, the physiological improvement (problem with chewing, trouble pronouncing words, food catching) is increased for implant patients, compared to conventional dentures wearers.

The benefits obtained from the OHIP information are many; analyzing and understanding patient assessment is crucial for further implant technology development, enabling identification of priorities of care and improvement possibilities.

Also, because OHIP handle with economic, social and psychological consequences of dental disease and dental treatment, it provides justification for allocation of health care recourses.

The assessment of priorities for care can be improved. By combining the social impact with clinical data for individuals or groups, it may be possible to formulate dental care programs directly towards the most dysfunctional conditions, or a tailor made dental implant program suited for individual needs.
It has been suggested that rational treatment planning, particularly in the field of geriatric dentistry, ought to include assessments of the functional and social benefits associated with alternative treatment plans (Ettinger 1984).

It is also shown that personality profiles might play a significant role in shaping patients satisfaction with dental implants. Certain personality profiles has been found to be associated with higher levels of patients dissatisfaction with implant therapy (Abu Hantash et al. 2006) Neuroticism might be associated with lower levels of total satisfaction with dental status and implant-supported prostheses as well as satisfaction with appearance, oral comfort and general performance.

The assessment of personality characters might be useful in predicting patient behavior and have an effect on provided therapy.

These measures might also help us understand oral health related behaviors. The ways a patient apprehend his or her condition has been identified as motive for preventive and care-seeking behavior. Ability to identify such perceptions ought to offer an opportunity to promote appropriate behaviors more effectively. It has been described in literature how the social impact of disease is a determinant of health seeking behavior. Possibilities to anticipate how a patient will handle the treatment might be also be predictable (Guckes et al. 1996).

A randomized trial involving subjects affected by rheumatoid arthritis showed that tooth restorations, utilizing gold (metal porcelain crowns) was cost-effective and beneficial in terms of OHQOL53. Such a study that indicates that OHQOL measures may influence clinical decision making when several numbers of oral treatments options are possible for disease affected patients.
Another benefit is the promotion of the importance of oral health. These generic
descriptions of health outcome draw attention to the importance of oral disease as part
of general health. For example ((Reisine and Miller 1985)) utilized population survey
data to demonstrate the extent of reduced activity and days of disability associated with
oral disease, in comparison to respiratory disease, genitourinary disorders and cancers.
Future studies in implant technology must to be able to show that the treatment works
from the patients point of view, as it is in everyone’s interest (patient, dentist and
fabricator). Oral health-related quality of life measurements capture both improvement
and deterioration in health status, creating new complexities and analyzing change in
longitudinal studies (Slade 1998).

The aim of this study was to evaluate patient satisfaction with the Oral Health Impact
Profile 49 before and after treatment with implants and implant-supported bridges in the
maxilla. Six implants were placed in the maxilla and loaded within 24 hours after
installation with a temporary restoration. 20-24 weeks later the permanent restoration
were delivered. The hypothesis was that patient satisfaction and oral health-related
quality of life according to OHIP 49 will increase after treatment with implants
immediate loaded with a temporary bridge.
Materials and Methods

Implants

Patients received implants in the maxilla using the fixture Osseo Speed™ (ASTRA TECH AB, Mölndal, Sweden). This is a screw-shaped and self-tapping implant with diameters of 3.5, 4.0, 4.5 and 5.0 mm. Implants are available in lengths of 8 to 17 mm.

Subjects

A total of fifty-one patients scheduled for implant treatment in the edentulous atrophic maxilla fulfilling all inclusion criteria and none of the exclusion criteria, were included and gave signed consent to participate in the study at the two centres. Of the 27 female and 24 male subjects the age range was between 47 to 83 years with a mean age of nearly 66 years (Table 1).

Power analysis for determination of the sample size in the study was performed with data from previous work by Jaffin et al. (Jaffin et al. 2004) and Friberg et al. (Friberg et al. 2003). The data was used for estimates of standard deviations and clinically relevant affects for OHIP-SC and OHIP-ADD. The standard deviations for change over time for OHIP-SC and OHIP-ADD for the implant group in this study were 11.5 and 50.6 respectively, and the effects were 9.7 and 37.8 respectively for OHIP total. It was concluded that a sample size of 50 or more subjects would give a 100% power at significance level of 5%.

Inclusion criteria were as follows:

- provision of informed consent
• age of 20 years or older
• history of totally edentulous maxilla of at least three months
• radiographic finding indicating bone status of Lekholm and Zarb class 3 or 4 (quality) and class C, D or E quantity in the maxilla, (Lekholm and Zarb 1985)
• presence of occluding natural teeth, partial prosthesis and/or implants within position 35-45 (according to the FDI digit system) in the mandible
• deemed by the investigator as likely to present an initially stable implant situation at placement surgery suitable for immediate loading.

Patients were excluded if:

• unlikely to be able to comply with study procedures as judged by the investigator
• uncontrolled pathological processes were found in the oral cavity
• showing known or suspected current malignancy
• history of radiation in the head and neck region was present
• history of chemotherapy was present
• found systemic or local disease or condition would compromise post-operative healing and/or osseointegration
• having uncontrolled Diabetes Mellitus
• use of corticosteroids or any other medication that would compromise post-operative healing and/or osseointegration
• bone augmentation had been performed in the maxilla within 6 month prior to surgery
• known pregnancy at time of enrolment
• presence of alcohol and/drug abuse
• current tobacco use or history of tobacco use within 6 month prior surgery
• need for interpreter was necessary

If treatment failed patients were offered retreatment but economic compensation was not to expect.

Table 1. Characteristics of the study sample at baseline

<table>
<thead>
<tr>
<th>Variable</th>
<th>Centre 1</th>
<th>Centre 2</th>
<th>Centre 1+2</th>
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<td>7</td>
<td>24</td>
<td>S¹</td>
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<tr>
<td>Female</td>
<td>9</td>
<td>18</td>
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<td>16</td>
<td>10</td>
<td>26</td>
<td>NS³</td>
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</tbody>
</table>

¹Fisher’s exact test. Two-side p-value.
²Wilcoxon rank sum test. Two-sided p-value.
³Fisher’s exact test. Two-side p-value.
S=Significant NS=Not significant

Clinical Procedures and protocols

The implants were placed under local anaesthetic of one surgeon at each centre with long (> 10 years) clinical experience of the implant system. Six implants were placed in the maxilla of each patient with maximum possible anterior - posterior spread in accordance with bone quantity and quality. A surgical guide for optimal positioning of the implants was used in all cases. One experienced prosthodontist at each centre
performed loading within 24 hours after surgery with a temporary bridge. Impression for final restorations was made twelve weeks after implant placement and permanent restorations were fitted twenty to twenty-four weeks after surgery.

Follow up visits and completion of the OHIP questionnaire were made at visit 1, 5, 7-12 following flow-chart displayed in Table 2.

This study reports the one-year follow up results from visit 1-8.

Oral health quality of life was measured using the original version of OHIP questionnaire with 49 questions developed by Slade and Spencer (Slade and Spencer 1994). The 49 statements are organised into seven conceptual domains, namely, functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The question format is “how often have you had... because of problems with your teeth, mouth or dentures?”, and a Likert response format is used. Response possibilities are 0=never, 1=hardly ever, 2=occasionally, 3=fairly often and 4=very often. Also if the question is not applicable on the patient they are given an option to say so. Each statement also has a weight, derived using Thurston’s method of paired comparisons. Higher OHIP scores indicating poorer oral health.

**Data Acquisition and Subject Follow-Up**

The OHIP 49 was used to establish the outcome of the treatment.

The 51 participants were asked to fill in the OHIP 49 questionnaire at four occasions: prior to implant surgery, twelve weeks, six and twelve months after receiving the implants. Solely the subjects completed the questionnaires at the study centres excluding the risk of completing the form with influence of others.
Statistical Analysis

The statistical analysis used in this study included a non-parametric approach.

Comparing the centres, the Wilcoxon Rank Sum test was used for continuous variables and the Fisher’s exact test for categorical variables. The hypothesis that the change over time for OHIP is equal to zero was tested by means of the Wilcoxon Signed Rank test. All reported p-values are two-sided. Missing values in OHIP has been imputed by the mean value for the non-missing items for that patient. No adjustment for multiplicity has been conducted. Collected data from the two centres was evaluated in total, but a comparison between centres was also made. Total OHIP-scores was followed over time as well as individual data from the seven different domains. Variables like gender, age and status of the dentition in the mandible were evaluated regarding possible influence on results from the two centres.
Results

Implants

Table 2 displays the baseline characteristics of study participants according to treatment assignment. Statistical differences between the two centres were found for distributions between gender and age differences, but no differences were found in status in the lower jaw, see Table 1.

306 implants were installed in the maxilla of the fifty-one subjects; 26 patients at centre 1 and 25 patients at centre 2. The clinical surgical and prosthodontic protocol were followed in all patients and the follow-up at one-year concluded that 12 implants were lost (two implants in two patients at centre 1 and ten implants in three patients at centre 2). Four patients were then excluded from the one year follow-up and one patient had not yet reached the one year follow up visit. Three of the four excluded patients were excluded due to loss of implants, one patient was lost to follow up. Out of the initial fifty-one subjects 46 patients were examined at the one-year control. A major cause for implant failures in two of three patients excluded at centre 2 may have been failure of the temporary supra-structure. As of today, two of the excluded patients have received new implants and fixed restorations. One patient declined further treatment and uses a denture today. The fourth patient excluded had other reasons for not proceeding. All four patients declined further participation in the study.
**Table 2.** Schedule for follow up visits and completed the OHIP questioner at visit 1, 5, 7-12

<table>
<thead>
<tr>
<th>Visit</th>
<th>Visit 2 Implant Placement (IP) + delivery of temp. restoration BASE LINE</th>
<th>Visit 3 Post-op visit</th>
<th>Visit 4 Post-op visit</th>
<th>Visit 5 Impression</th>
<th>Visit 6 Perm. restoration</th>
<th>Visit 7-12 Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Informed consent</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Patient demographics</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Medical / Surgical history</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Inclusion/exclusion criteria</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Oral examination</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Radiographic examination</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Status of soft tissue</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>OHIP</td>
<td>X</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>AE / ADE&lt;sup&gt;1&lt;/sup&gt;</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>9</td>
<td>Implant Stability</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>10</td>
<td>Clinical photography</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<sup>1</sup>Safety by recording of adverse events (AE) and adverse device effect (ADE)
OHIP

Baseline satisfaction OHIP-scores were similar (no statistical differences) for the two different centres, indicating that both groups were equally satisfied with their oral status prior to implant treatment. The total satisfaction with the performed therapy was significantly improved after treatment comparing OHIP scores for both centres, and also with no significant difference found between the two sites. Figure 2 displays the change in OHIP score over time, measuring the change at four different occasions for centre 1, 2 and the two centres together.

Figure 2. Total OHIP scores over time

*Figure 2 displays the change in OHIP score over time, measuring the change at four different occasions for centre 1, 2 and the two centres together.*

In Figure 3 the mean OHIP scores at the four occasions for the 7 domains are presented. All seven subgroups showed a statistical improvement in their post OHIP scores. No
significant differences were observed in any of the individual pre-post treatment OHIP domains between centres but the patients at centre 1 tended to have a larger improvement in Psychological discomfort compared to centre 2 even though it was not statistical significant.

Figure 3.

The diagram shows the improvement in the seven domains for centre 1 and centre 2 as one group.
Discussion

This study support our hypothesis that patient satisfaction and oral health-related quality of life will increase after treatment with the described treatment protocol using implants and immediate load of a temporary bridge within 24 hours.

There are some limitations to this study, as allocation to centres was not randomized. It would therefore be inappropriate to infer that differences between groups could only be ascribed to the treatment intervention. Considering that the inclusion and exclusion criteria were very thorough and detailed in this study, it may be possible to look at the two centres as one unit. To get a substantial result we compared in between centres and we also looked at the result from both centres as a whole group.

No control group was used, since it has already been established in previous papers that dentate individuals have lower OHIP scores before and after a regular dentist visit compared to patients needing denture or implant treatment (Allen and McMillan 2003). It has also already been proven that patients receiving implants instead of dentures have a larger improvement in OHIP (Allen and McMillan 2003).

The age and gender distribution between centres was statistically different in our study. Earlier studies show that preference, interaction between baseline OHIP-20 scores and treatment assignment, age and gender are not significantly associated with overall OHIP-20 outcome (Heydecke et al. 2003) which might indicate that it should be the similar for OHIP 49.

Considering the fact that age or gender does not seem to affect the OHIP outcome when it comes to implant treatment it should be possible to say that no patient, man or women is too old to receive implants.
In this paper we report results after the 12-months follow-up, which may be considered a short period for evaluation. The length of the reference period used in studies of subjective oral health may have a marked influence on the responses obtained. However, population studies have established that a shorter reference period than 12 months does not appear to influence responses (Sutinen et al. 2007).

No differences were found between centres when comparing total OHIP change before and after treatment, supporting the fact that we should be able to look at the two centres’ as one group.

The reason why centre 1 tended to show a larger improvement in Psychological discomfort compared to centre 2 might be due to differences in socioeconomically status, or esthetical awareness.

Even though OHIP seems to be the most superior measurement when it comes to change in oral health it has some disadvantages. OHIP in its full version is unpractical in a clinical setting because of its length and the detailed questionnaire and can be inappropriate for some individuals (for example children or persons with reduced language or cognitive skills). To avoid people not finishing the questionnaire the OHIP were completed at the oral surgeon or the prosthodontics department and not at home, excluding the risk of the patient forgetting to complete the form and without the influence of relative’s opinion.

In this study two different centres (Chicago/USA and Uppsala/Sweden) were compared with OHIP. Because of the nature of OHIP we might risk a distortion in answers because of culture differences between countries. It is known that people in the USA deem their sickness problem higher compared to Swedish people. One of the reasons might be the possibility getting insurance benefits.
It has also been noticed that OHIP can give a false impression that no change has occurred when quantitative analyses cause improvements and deterioration to cancel and analysis of mean OHIP scores are analyzed. Changes in mean OHIP scores can be masked by regression to mean (Slade 1998), also called floor effect.

Future studies in implant technology must to be able to prove that the treatment works in the patient’s point of view since it is in everyone’s interest (patient, dentist and manufacturer). Creating an implant system that is not adapted to patient’s needs and wishes is not going to be acceptable on the implant market in the future.

An interesting follow-up study would be to use the same inclusion/exclusion criteria but different implant systems or fixtures to see if there are any differences in patient satisfaction depending on the type of implant.
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References


