STUDIES ON MAXILLARY OVERDENTURES: IMPLANT- AND PROSTHESIS SURVIVAL, COST ANALYSIS AND PATIENT-REPORTED OUTCOMES

Studies on Maxillary Overdentures: Implant- and Prosthesis Survival, Cost Analysis and Patient-Reported Outcomes

Thesis for Doctoral Degree (Ph.D)

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The thesis will be defended in public

Fredag 16 december klockan 09:15, Aulafoajén på Odontologiska fakulteten

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ISBN 978-91-7877-322-0 (print)

ISBN 978-91-7877-321-3 (pdf)

DOI 10.24834/isbn.9789178773213

Print: Media-Tryck, Lund university, 2022

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MADE IN SWEDEN

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STUDIES ON MAXILLARY OVERDENTURES: IMPLANT- AND PROSTHESIS SURVIVAL, COST ANALYSIS AND PATIENT-REPORTED OUTCOMES

Malmö university, 2022
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To my beloved wife and daughter

For their infinite patience

"A hair divides what is false and true."

Omar Khayyam

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LIST OF PAPERS

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

I. Ghiasi P, Ahlgren C, Larsson C, Chrcanovic BR. Implant and prosthesis failure rates with implant-supported maxillary overdentures: a systematic review. Int J Prosthodont. 2021 July/August;34(4):482–491. doi: 10.11607/ijp.6905. Epub 2021 Feb 23. PMID: 33625390.

II. Chrcanovic BR, Ghiasi P, Kisch J, Lindh L, Larsson C. Retrospective study comparing the clinical outcomes of bar-clip and ball attachment implant-supported overdentures. J Oral Sci. 2020 Sep 26;62(4):397-401. doi: 10.2334/josnusd.19-0412. Epub 2020 Aug 26. PMID: 32848099.

III. Ghiasi P, Petrén S, Chrcanovic B, Larsson C. Comparative cost analysis of different prosthetic rehabilitations for the edentulous maxilla: early results from a randomized clinical pilot study. BDJ Open. 2022 Mar 22;8(1):8. doi: 10.1038/s41405-022-00100-0. PMID: 35318307; PMCID: PMC8940901.

IV. Comparison of patient-reported outcomes between different prosthetic rehabilitations for the edentulous maxilla. Early results from a randomized clinical pilot study.

THESIS AT A GLANCE

STUDY	AIM	KEY FINDINGS
(I) Implant and prosthesis failure rates with implant-supported maxillary overdentures: a systematic review.	To assess the clinical outcomes of maxillary overdentures supported by dental implants based on a literature review.	Most of the prosthesis failure was due to loss of implants, and the first year is the most critical period for failures. The number of dental implants placed per patient seemed to have an impact on the occurrence of overdenture failure.
(II) Retrospective study comparing the clinical outcomes of bar-clip and ball attachment implant-supported overdentures.	To compare the clinical outcomes of implant-supported overdentures (ODs) with either bar-clip or ball attachments. The implant, prosthesis failure, and technical complications were the outcomes analysed in this retrospective clinical study conducted in a specialist clinic.	None of the factors (sex, age, jaw, bruxism, smoking status, implant surface, number of implants, attachment, and opposing arch) showed a significant effect on prosthesis failure. Patients with ODs needed constant maintenance follow-ups to address technical complications and perform prosthodontic maintenance regardless of the attachment system used.
(III) Comparative cost analysis of different prosthetic rehabilitations for the edentulous maxilla: early results from a randomised clinical pilot study.	To compare the cost of different prosthetic rehabilitations for the edentulous maxilla.	The lack of difference in cost for maintenance and repair over the first year suggests that implant-supported overdentures will remain the least costly treatment option for the edentulous maxilla, at least in a short-term perspective.
(IV) Comparison of patient-reported outcomes between different prosthetic rehabilitations for the edentulous maxilla. Early results from a randomised clinical pilot study.	To compare patient-reported outcomes between patients rehabilitated with different prosthetic treatments for the edentulous maxilla.	Edentulous patients experience equal positive treatment outcomes with implant-supported restorations in a short-term perspective, regardless of whether the prosthetic superstructure is fixed or removable.

ABBREVATIONS

OD	Overdenture
ISOD	Implant-supported overdenture
ISFAFDP	Implant-supported full-arch fixed dental prosthesis
PROM	Patient reported outcome measure
CSR	Cumulative survival rate
JFLS	Jaw Functional Limitation Scale
OAS	Orofacial Aesthetic Scale
OHIP	Oral Health Impact Profile
WHO	World Health Organization
QoL	Quality of life
OHRQoL	Oral Health Related Quality of Life
CD	Complete denture
FPD	Fixed partial denture
SEK	Swedish crown
EUR	Euro
SD	Standard deviation

ABSTRACT

Edentulism is a debilitating condition which may negatively affect quality of life, particularly in relation to nutritional and social health, speech, and poor facial appearance. Prosthetic options available range from conventional complete dentures to implant-supported overdentures (ISODs) and implant-supported full-arch fixed partial dentures (ISFAFDPs). The choice of treatment is connected to the patient's general health, oral status, preferences and financial means. From the point of view of the treatment provider, there is a lack of evidence to support choice of treatment, as information from randomised clinical trials is sparse. This is particularly true when it comes to cost analysis and patient-reported outcome measures (PROMs). There is consensus today that an implant-supported overdenture is a valid treatment option for the edentulous mandible, but the same recommendation cannot be made for maxillary overdentures due to a lack of evidence.

The present study investigates implant-supported maxillary overdentures regarding implant and prosthesis survival, costs and PROMs in comparison to fixed implant-supported prostheses.

The thesis comprises four studies.

Study I analysed implant and prosthesis failure rates with implant-supported maxillary overdentures in a systematic review. The cumulative survival rate (CSR) for the implants and the prostheses was 70.4% and 79.8%, respectively. The main finding was that patients with few implants presented higher prosthesis failure rates than patients with more implants per prosthesis.

Of the most commonly used attachment systems, the ball/O-ring and the Ceka were the ones with the highest rates of patients with at least one implant failure. Most of the failures happened within the first year after installation for both implants (52.1%) and prostheses (41.8%).

Study II, a retrospective analysis, compared the clinical outcomes of implant-supported overdentures (ISODs) with either bar-clip or ball attachments. The results showed that all ISOD failures resulted from loss of implants. The bar-clip system resulted in more complications than the ball attachment system, suggesting that ISODs with the bar-clip system may necessitate a greater number of appointments and chair time for adjustments, thus increasing the maintenance costs for the patient.

Studies III and IV were based on a prospective clinical trial comparing different implant-supported prosthetic rehabilitations for the edentulous maxilla: implant-supported full-arch fixed partial dentures on 4 or 6 implants (ISFAFDP 4 or ISFAFDP 6) versus maxillary overdentures on 2 implants.

Study III is a comparative cost analysis, the results of which showed that all implants and restorations were in function at follow-up after the first year, i.e., the survival rate was 100%. Initial costs, i.e., cost of prostheses at delivery, were higher for ISFAFDP 6 and ISFAFDP 4 due to the higher number of implants and higher cost of materials and fees. There were no statistically significant differences in post-treatment costs between the groups.

In study IV, patient-reported outcomes regarding aesthetics and function were compared. The results showed that all patients, irrespective of group, showed improved patient-reported outcomes from before treatment to the one-year follow-up. There were no significant differences between groups regarding functional status of the masticatory system (Jaw Functional Limitation Scale - JFLS parameters) or how patients perceive their dental and Orofacial Aesthetic Scale (OAS), and only minor differences between the two groups with fixed restorations regarding patients' perception of the social impact of oral disorders on their well-being (Oral Health Impact Profile - OHIP).

POPULÄRVETENSKAPLIG SAMMANFATTNING

Tandlöshet är ett tillstånd som kan påverka livskvaliteten negativt, särskilt i relation till tuggfunktion, nutriton, tal, utseende, och social hälsa. Tandlöshet kan behandlas med hjälp av olika former av avtagbara eller fasta konstruktioner från konventionella avtagbara plattproteser till implantatstödda täckproteser (ISODs) och implantatstödda fasta broar (ISFAFDPs).

Val av behandlings hänger ofta ihop med patientens allmänna hälsa, orala status, preferenser och ekonomi. Ur vårdgivarens synvinkel saknas bra vetenskapligt underlag för val av behandling eftersom publicerade randomiserade kliniska studier är sällsynta. Detta gäller särskilt kostnadsanalyser och patientrapporterade utfall (PROM) om livskvalitet. Det råder konsensus idag om att en implantatstödd täckprotes är ett fullgott behandlingsalternativ för tandlös underkäke, men samma rekommendation kan inte ges för täckproteser i överkäken på grund av brist på kliniska studier.

Den föreliggande avhandlingen undersöker implantatstödda maxillära täckproteser avseende implantat- och protesöverlevnad, kostnader och PROMs jämfört med fasta implantatstödda broar.

Avhandlingen omfattar fyra delarbeten.

Studie I analyserade misslyckandefrekvens för både implantat och proteser bland implantatstödda överkäkstäckproteser i en systematisk översikt. Den kumulativa överlevnaden (CSR) för implantaten och proteserna var 70,4 % respektive 79,8 %. Huvudfynden var att patienter med få implantat visade fler proteskomplikationer r än patienter med fler implantat som stöd per protes. Av de vanligaste förankringssystemen var kulan/O'ringen och Ceka, de systemen med den högsta andelen patienter med minst en implantatförlust. De flesta av komplikationerna inträffade inom det första året, för både implantat (52,1%) och proteser (41,8%).

Studie II, en retrospektiv analys, jämförde kliniska utfall av implantatstödda täckproteser (ISODs) med antingen bar-clip eller kulfästen som förankringssystem. Resultaten visade att alla ISOD-misslyckanden berodde på förlust av implantat. Bar-clip-systemet resulterade i fler komplikationer än kulfästesystemet, vilket tyder på att ISODs med bar-clip-systemet kan kräva ett större antal kliniska timmar för justeringar, vilket ökar underhållskostnaderna för patienten.

Studie III och IV baserades på en prospektiv klinisk studie som jämförde olika implantatstödda täckproteser för tandlösa överkäken: implantatstödda fullbroar på 4 eller 6 implantat (ISFAFDP 4 eller ISFAFDP 6) respektive överkäksproteser kopplade på 2 implantat.

Studie III är en jämförande kostnadsanalys och resultaten visade att alla implantat och protetiska konstruktioner var i funktion vid uppföljningen efter det första året, dvs. överlevnaden var 100 %. De initiala kostnaderna, det vill säga kostnaden för proteser vid utlämning, var högre för ISFAFDP 6 och ISFAFDP 4 på grund av det högre antalet implantat samt högre kostnader för material och avgifter. Däremot fanns inga statistiskt signifikanta skillnader mellan grupperna i kostnader för underhåll och reparationer efter behandling. Detta antyder att det avtagbara alternativet kvarstår som det minst kostsamma behandlingsalternativet för den tandlösa käken över tid.

I studie IV jämfördes patientrapporterade utfall avseende estetik och funktion. Tre olika instrument för att mäta hälsomått och livskvalitet användes (Oral Health Impact Profile – OHIP, Jaw Functional Limitation Scale – JFLS, Orofacial Aesthetic Scale – OAS). Resultaten visade att alla patienter, oavsett grupp, visade förbättrade resultat från före behandlingen till ettårsuppföljningen. Det fanns inga signifikanta skillnader mellan grupper när det gäller funktionell status för tuggsystemet eller hur patienter uppfattar sitt utseende och endast mindre skillnader mellan de två grupperna med fasta restaureringar gällande patienters uppfattning om den sociala påverkan av orala störningar på deras välbefinnande. Detta antyder att patienter kan vara lika nöjda med rehabiliteringen av tandlöshet i överkäken oavsett om den protetiska konstruktionen är fast implantatstödd eller en avtagbar täckprotes.

INTRODUCTION

Edentulism: prevalence and consequence

Edentulism, the loss of all natural teeth, is a debilitating and irreversible condition which affects quality of life negatively due to compromised function and aesthetics, loss of social status, and diminished self-esteem (1).

The reasons for losing teeth are complex and may involve oral diseases and other health-related and socio-economic factors. Dental caries and severe periodontal disease are major contributors to the loss of natural teeth, according to the Global Burden of Disease Study (2). Caries is the number one global cause of chronic disease and injury, affecting more than 10% of the world's population in 2015 (3). According to the World Health Organisation (WHO), severe periodontal diseases are estimated to affect nearly 10% of the global population (4,5). Severe periodontal disease is found in 5–20% of middle-aged adults (35–44 years) in Europe, and up to 40% of older people (65–74 years). In addition, trauma and fracture of teeth and restorations may cause loss of teeth. Around 20% of people suffer from trauma to teeth at some point in their life (6). Furthermore, edentulism has been reported to be significantly associated with general health-related factors such as smoking, but also with age, education, and socioeconomic factors (7).

The prevalence of edentulism varies greatly between countries as well as between regions within countries and between rural areas and cities (8). The global rate of edentulism is suggested to be around 4% (8). In Europe, edentulism rates are in decline, but great differences are found between each country (8–10). A review estimates the worldwide edentulous population to be around 300-800 million (11). Other studies have found considerably lower rates of edentulism and a significant decrease over time (12).

Prevalence however increases gradually with age, showing a steep increase around the seventh decade of life, with a peak in incidence at 65 years. Despite an overall gradual decline in incidence and prevalence of edentulism, these age patterns did not change during the two-decade observation period, suggesting that edentulism may remain an issue among the elderly population for the foreseeable future. The low use of dental services even in developed countries, the lack of financial support from government and/or third-party payment systems, and the absence of relevant oral health policies are some of the key issues that may explain poorer oral health status among the elderly (12). Furthermore, a reduced prevalence and incidence of edentulism may be somewhat offset by increased life expectancy (13,14).

The prevalence of missing teeth in different generations and its effect on physical health has sometimes been overlooked. Comorbidity has been demonstrated between edentulism and obesity, cardiovascular disease and diabetes (15). Poor oral health has also been suggested to be a cause for pneumonia among the elderly, particularly those living in care facilities, and for people with disabilities (16). Available information suggests that decline in jaw muscle function could be responsible for the fact that elderly people consume mostly soft and easy-to-chew food. It seems that with noticeable tooth loss, there is a similar decline in jaw muscle function, and significant changes can occur in certain perceptual and sensory measurements (17). Older people with compromised dentitions, both with and without prostheses, may select certain diets, which can compromise their nutritional status and eventually pose health risks (17).

When normal functions such as speech, smiling and laughter are negatively affected, missing teeth can have negative consequences on self-image, social interaction and psychological health. In fact, losing teeth has been compared to amputation (1). Thus, tooth loss can be very traumatic and upsetting for the patient and is regarded as a serious life event that may require significant social and psychological readjustment (18). Edentulism affects patients' overall quality of life (QoL) (19). Oral Health-Related Quality of Life (OHRQoL) is defined as "a multidimensional construct that reflects, among other things, people's comfort when eating, sleeping and engaging in social interaction, their self-esteem and their satisfaction with respect to their oral health" (20). OHRQoL is associated with psychological, functional and social factors, as well as experience of pain or discomfort. Treatment of edentulousness is justified in order to alleviate functional, psychological and social impairment.

Treatment options for edentulism

For many patients, oral rehabilitation signifies a return to a normal lifestyle and considerably improved quality of life: enjoying food, participating in conversation and laughing with others, without the constant anxiety of disclosure (1).

Edentulism may be treated using removable or fixed restorations (**Table 2**), which are dependent either on adhesion directly on the oral mucosa or on anchorage of dental implants as either an overdenture or a fixed dental prosthesis. The choice of treatment is connected to the patient's general health, oral status, economy and expectations.

Before the introduction of dental implants, the complete denture (CD) was the only treatment option available. It is a simple and affordable treatment (21), but satisfaction with CD treatment is related to denture quality, which in turn seems directly linked to the corresponding denture-bearing area, existing denture experience, the quality of the dentist–patient interaction and the patient's expectations, in conjunction with overall personality and psychological well-being (22). To wear removable dentures involves concern about being exposed and anxiety regarding, for instance, the possibility of uncontrolled dropping of the prosthesis during chewing, coughing or laughing in the company of others (23–25). According to the current literature, denture satisfaction is affected by several factors and is not yet accurately predictable (26).

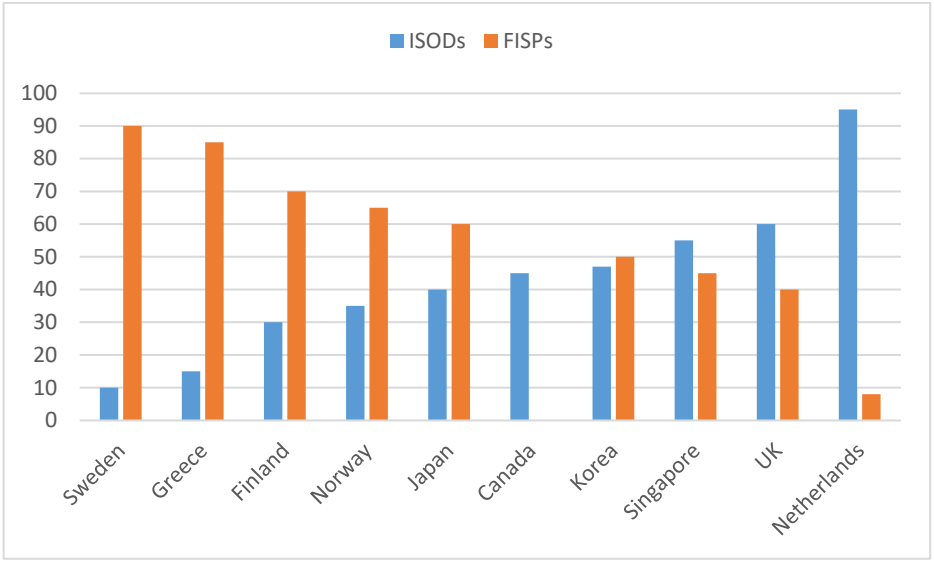
With osseointegrated dental implants, a full-arch fixed dental restoration can provide the patient with fixed restorations for a stable, aesthetic, long-term solution with improved stability and retention while usually covering less tissue compared to the CD for increased comfort for the patient (27). Fixed implant-supported restorations have been associated with increased patient satisfaction and overall quality of life as a result of improved masticatory function and aesthetics (28,29). There are however situations where the full-arch fixed dental prosthesis is not a feasible option. The quantity and quality of available bone determines the number and location of implants. Generally, six implants are needed in the upper and four in the lower jaw for a fixed restoration. Maxilla-mandibular relationships, whether or not facial tissues such as the lips and cheeks need support, the nature of the opposing occlusion and not least the expense that a patient is willing to bear are some of the factors that need to be considered (30,31).

If a full-arch implant-supported fixed partial denture is not feasible, optimal or desirable for the individual patient, a removable overdenture is another treatment option. The number of implants used varies between maxillary and mandibular

overdentures but they are generally significantly fewer than full-arch implant-supported fixed partial dentures (32,33). The design of an implant-supported overdenture (ISOD) also varies from full palatal coverage similar to the complete denture (CD), to a horse-shoe milled bar fixed-removable hybrid design (34,35).

Capability to speak, aesthetics, ease of cleaning and general satisfaction have been shown to be the factors with the greatest influence on the choice between an implant-supported fixed prosthesis and an ISOD in favour of the overdenture (35). For elderly patients, who may lack dexterity and/or have limited visual acuity, and for patients with poor oral hygiene, an overdenture may be preferable because it can be removed and is therefore easier to clean (36). Patients wearing ISODs find it easier to chew than those wearing CDs; consequently, they may change their diets to include foods that they could not previously eat (37,38). Furthermore, since fine motor skills decrease with age, this type of prosthetic rehabilitation can be easier to manage for the patient, compared to fixed prosthetic restorations on implants. Studies have shown high levels of patient satisfaction for mandibular ISODs, providing significantly improved function and comfort (38–44). Satisfaction and QoL among patients after receiving maxillary implant-supported prostheses is however uncertain, as this has been less investigated (45).

Numerous studies have evaluated clinical outcomes of ISODs in mandibles (39,42,46–48). Survival rates are high, varying between 97-100% (40,43,49,50). Complications occur and may be influenced by the number of implants and the type of attachment system (51). Knowledge about maxillary overdentures is, however, limited. Implant treatment in the maxilla is more challenging than in the mandible based on factors such as bone quality and quantity, the presence of the maxillary sinus, and accessibility problems (52). When choosing between a fixed or a removable restoration, the available bone quantity and quality, the number, location and distribution of implants, the available inter-arch distance and maxilla-mandibular relationship, and the nature of the opposing occlusion are all crucial factors to consider prior to treatment planning (30,31). Results obtained in the mandible cannot apply directly to the maxilla, which differs in bone morphology and loading circumstances. Further studies are thus needed.

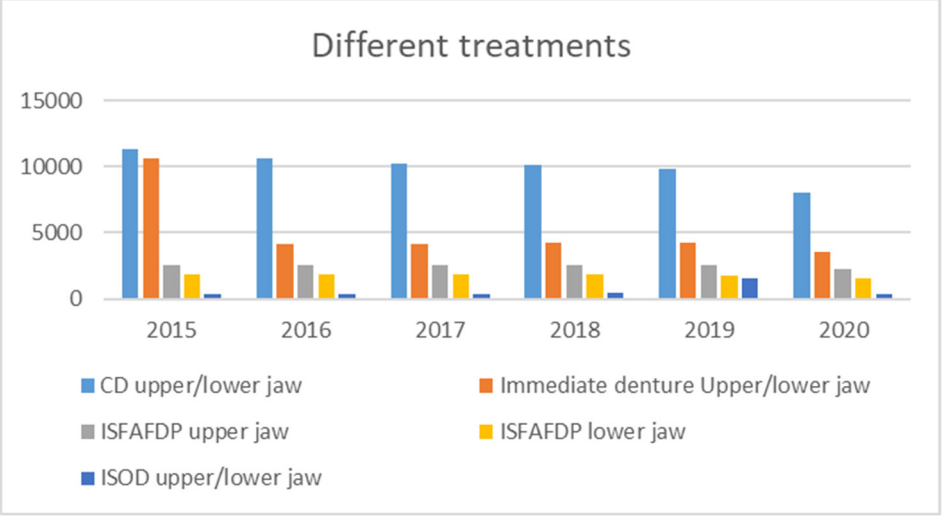


Tab 1. Ratio of implant overdentures and fixed implant-supported prostheses provided to patients with edentulous mandibles in 10 countries in 2001. The countries are arranged according to increasing ratios of implant overdentures. FISP = fixed implant-supported prosthesis; ISOD = implant-supported overdenture. Adapted from Carlsson GE, Kronström M, de Baat C, Cune M, Davis D, Garefis P, et al. A survey of the use of mandibular implant overdentures in 10 countries. Int J Prosthodont. 2004;17(2):211–7 (53).

In summary, implant treatment for the edentulous patient offers significant improvements in comparison to conventional dentures (54,55) and ISODs are today the preferred choice for oral rehabilitation over CDs (52). However, ISODs are a comparatively uncommon treatment alternative in Sweden, according to the Swedish Social Insurance Agency (Försäkringskassan) (56), where the full-arch fixed dental prosthesis is preferred (**Table 2.3**). Dental care in Sweden is part of the welfare system but is financed differently as compared to medical care. There is a high cost threshold for dental care procedures, whereby more extensive and complicated treatments such as CDs, fixed partial dentures (FPDs) and implants are subsidised by the government (57). Swedish patients today prefer to have fixed reconstructions instead of removable ones (58). The National Dental Care Insurance system in Sweden may thus have influenced the preference towards fixed dentures, since the insurance system gives high subsidies for more expensive treatments (19).

There are several factors that may influence treatment choice including patient preference, anatomical conditions, finance, but also knowledge and attitudes among dentists. While there is compelling evidence that implant-retained and/or

-supported prostheses are preferable to conventional removable prostheses and would represent the standard of care for edentulous individuals, a significant number cannot afford and may never be candidates for implant therapy (58). As the elderly population increases both in age and in numbers, it is of high importance for society to find ways to take care of them. This may become a problem if most edentulous patients are treated with complex fixed prosthetic restorations on implants. When these patients become frail and unable to take care of themselves, an overdenture on implants would presumably be easier to clean and facilitate maintenance of good oral health (35,41). To accommodate different needs among edentulous patients, dentists must have knowledge about various treatment options and adapt their treatment strategy to each individual patient and situation.



Tab 2 The table shows the number of treatments regarding complete dentures (CD), implant-supported full-arch fixed dental prostheses (ISFAFDP), and implant-supported overdentures (ISOD) in the upper or lower jaw performed between 2015-2020 in Sweden. Numbers retrieved from Swedish Social Insurance Agency (Försäkringskassan).

Number of procedures performed within the national dental care in Sweden

	2015	2016	2017	2018	2019	2020
CD upper/lower jaw	11333	10602	10269	10090	9821	7993
Immediate denture Upper/lower jaw	4348	4124	4157	4221	4246	3560
ISFAFDP upper jaw	2588	2551	2526	2516	2578	2235
ISFAFDP lower jaw	1860	1825	1825	1832	1734	1524
ISOD upper/lower jaw	362	334	385	406	385	344

Table 3. Number of treatments performed in Sweden between 2015-2020. CD = complete denture; ISFAFDP = implant-supported full-arch fixed dental prosthesis; ISOD = implant-supported overdenture.

Cost of treatment

Dental treatments carry costs for both the patient and society. Economic evaluation has become an integral component of health service research in recent years and is likely to assume increasing importance for decision-making in dental services in the future (59). The main reason is that resources within the health sector (personnel, time, facilities, equipment and knowledge) are limited (60).

Health economics in public health

According to The Public Health Agency of Sweden, health economics is a discipline within economics that seeks to analyse and assess the costs and impact of the use of resources within the health and social care services, and to prioritise alternative treatments and preventive measures in a variety of subject areas. Failure to analyse the economic aspects of dental health services may result in unsustainable over-expenditure or withdrawal or reduction of services and/or resources in other areas of healthcare (61). Economic analysis is thus an important tool in deciding how to portion out often tight public health resources; however, there is currently a shortage of such analysis by public health researchers (62).

Economic Evaluation (EE) may be defined as a comparative analysis of alternative courses of action in terms of both their costs and consequences (63). Economic evaluation is the process of systematic identification, measurement and valuation of the inputs and outcomes of two alternative activities, and the subsequent comparative analysis of these. It is an essential element in the process of decision-making about health programmes.

An important concern for patients, clinicians and policy makers is whether it is possible to control costs while maintaining the quality of health care services and providing care (64).

Two aspects of a treatment to be considered, when choosing between competing alternatives, are outcome and cost (65). A prosthodontic treatment has an economic cost that should be balanced between the initial cost, such as the cost of labour, and maintenance and/or repair costs. The economic cost of any treatment may be particularly significant for the ageing population, whose income may be decreasing or limited (66–69). The dental profession needs data on both costs and outcomes for different available treatment methods for the purposes of establishing consensus for specific treatments (60,61).

Prosthodontic treatment can carry high costs for patients. Dental care in Sweden is subsidised by the government. The dental care benefits comprise a general dental care grant, a specific dental care grant (for certain groups of patients) and a high-cost protection scheme. The general dental care grant is intended to encourage adults to regularly visit their dentist for check-ups and preventative care. The specific dental care grant is intended to provide additional support to patients having a higher risk of developing dental problems due to certain diseases or disabilities. The government regulates the high-cost protection scheme, and decides which dental procedures are reimbursable. A reference price is set as the maximum compensation payable for an individual dental procedure. If the dentist charges a higher price than the reference price for a dental procedure, the exceeding cost is paid by the patient. Furthermore, not all costs are fully covered, which means that prosthodontic treatment may still be costly for the individual patient, especially for implant-supported restorations. There is also a significant difference in cost between ODs and fixed restorations, as the number of implants differs. The lack of evidence on the cost of dental implant treatments makes it difficult to identify clearly the most cost-effective course of action without a sound analysis of all relevant costs and the prognosis of treatments (70–72).

Patient-reported outcomes

Besides analysing data on survival and complication rates, well-designed clinical trials should also aim to include patient-reported outcome measures (PROMs). PROMs are the tools and/or instruments that have been developed to ensure both a valid and a reliable measurement of these patient-reported outcomes, such as quality of life (QoL) measures. They typically consist of questionnaires, which can be completed by an individual about themselves or by others on their behalf (73,74). PROMs can be applied to obtain data from the patient's perspective in a range of areas. Some characteristics of PROMs are: health-related quality of life (HRQoL), functional status, health behaviours, symptoms and symptom burden, and patient experience. Data obtained from PROMs can ease decision-making among clinicians. It can also provide a baseline assessment of patients' health status, QoL, satisfaction/wellbeing, etc. PROMs can also be routinely administered in clinical settings for audit and quality assurance such as in the assessment of the effectiveness of different procedures (74).

Routine use of PROMs in clinical practice has been shown to improve patient satisfaction with care, symptom management, QoL and survival rates (75,76). Some routinely used PROM instruments in dentistry are the Oral Health Impact Profile (OHIP), the Jaw Functional Limitation Scale (JFLS) and the Orofacial Aesthetic Scale (OAS). They are validated for use in research and are considered well-suited as clinical outcome measures in patients with functional and aesthetic concerns, such as prosthodontic patients (77).

Knowledge gaps

Even though ISODs represent a reliable treatment option for the mandible, there is a lack of evidence for ISODs in the maxilla regarding patient satisfaction, implant and prosthesis survival rates, and analysis of biological and technical complications (34,38,52,78).

Furthermore, there is a lack of knowledge about the cost-effectiveness of maxillary ISODs. Our group performed a systematic review with the aim to assess evidence regarding cost-effectiveness of implant-supported maxillary overdentures compared to fixed implant-supported restorations. Only two included studies, presenting results from a randomised clinical trial on the same study population of 20 patients, were identified, and it was concluded that the evidence for the cost-effectiveness of ISODs is very weak (79).

In summary, there is an insufficient scientific basis on which to determine which of these treatment methods gives the best results in terms of aesthetics and function, or is the most cost-effective (80).

Rationale for thesis

Despite a gradual decline in incidence and prevalence of edentulousness, this condition will remain an issue for the foreseeable future, especially for the elderly population. Considering the significant negative effects of edentulousness on physical health and normal functions, social interaction and overall quality of life, restorative treatment is indispensable.

Treatment choice should be based on sound evidence that includes knowledge about survival rates, potential complications, patient-reported outcomes, and the cost of different treatments. This thesis aimed to increase knowledge about maxillary ISODs, taking all the above-mentioned variables into account, and compare this treatment to the commonly used fixed options for the edentulous maxilla.

Furthermore, improved understanding of the outcome of a treatment may aid preventive measures to avoid complications. Comparison of the cost-effectiveness of different treatments not only helps patients and caregivers in deciding on treatment, but can also help public health officials in developing policies.

AIMS

The aims of this research plan were as follows:

- To review existing literature regarding the clinical outcomes of implant-supported overdentures supported by dental implants. (Study I)
- To retrospectively compare clinical outcomes of ISODs with different attachments and analyse the influence of different factors on implant and prosthesis complications and failure. (Study II)
- To study and evaluate implant survival as well as biological and technical complications in maxillary ISODs compared to implant-supported fixed dental prostheses is a randomised clinical pilot study. (Studies III, IV)
- To perform comparative cost analysis of different prosthetic rehabilitations for the edentulous maxilla, ISFADP 6, ISFADP 4 and ISOD 2. (Study III)
- To study patient satisfaction by analysing responses to the questionnaires OHIP, JFLS and OAS regarding functions and aesthetics among patients treated with maxillary implant-supported overdentures and implant-supported fixed dental prostheses (Study IV).

HYPOTHESES

Different patient- and OD-related factors influence the clinical outcomes of maxillary overdentures (Study I).

There are no differences in the clinical outcomes and the prevalence of technical complications between implant-supported ODs supported by bar-clip or ball attachments. Different factors such as bruxism and smoking status have an influence on implant and OD complications and survival (Study II).

Initial differences in cost at delivery between ISOD and ISFAFDP will be reduced over time due to the higher need for maintenance in the ISOD group (Study III).

There are no significant differences between the groups with respect to self-assessed oral function, oral comfort and aesthetics (Study IV).

MATERIALS AND METHODS

Study I assessed the clinical outcomes of maxillary ISODs in a literature review. The focused question was explored by using the PICO format (participants, interventions, comparisons, outcomes): What is the failure rate of dental implants and implant-supported overdentures used for the rehabilitation of patients with edentulous maxilla?

An electronic search without time restrictions was undertaken in the following databases: PubMed/Medline, Web of Science and Science Direct. The terms used in the search strategies were:(implant overdenture) AND (maxilla OR maxillary OR "upper jaw").

A manual search of all related prosthodontic, implantology, maxillofacial and specialist dental and oral journals was performed. The reference list of the identified studies and the relevant reviews on the subject were also checked for possible additional studies.

From the studies included in the final analysis, the following data were extracted: number of patients, patients' age and sex, implant healing period, number of supporting implants per overdenture, implant surface modification, number of attachments per overdenture, type of attachment used, presence of palatal coverage, use of a metal structure, grafting procedures, occurrence of implant and/or prosthesis failure, time from implant/prosthesis installation to failure, follow-up time.

Study II This retrospective study included patients who received dental implants during 1984-2014 at one specialist clinic (Clinic for Prosthodontics, Centre of Dental Specialist Care) in Malmö, Sweden. The study was based on collection of data from dental records.

The patients were treated by specialists in prosthodontics. Only ODs that were supported by dental implants using the ball or bar-clip attachment systems and followed for a minimum of six months after prosthesis installation were included.

Threaded cylindrical or conical-design implants were included, whereas zygomatic implants were excluded from the study.

Cox regression analysis was used to identify covariates possibly associated with prosthesis failure. An analysis of the prevalence of technical complications was performed at the prosthesis, implant and attachment level, according to the attachment system and to bruxism.

Studies III and IV were based on a randomised clinical trial. Subjects were recruited consecutively.

The inclusion criteria were the following:

1) patients of at least 18 years of age;
2) edentulous maxilla;
3) patients encountering problems with the existing dentures and in need or desire for dental implant treatment;
4) patients of good general health condition, without local or systemic contraindications for oral surgery;
5) patients having any ridge resorption pattern in the anterior maxilla provided that implants could be placed with primary stability mostly embedded in autologous bone;
6) patients willing to participate and having signed an informed consent.

The exclusion criteria consisted of:

1) patients with clinical signs of severe oral functional disorders;
2) patients with systemic diseases/conditions jeopardising successful implant therapy.

The allocation of patients to either test group, ISOD 2 implants or ISFAFDP 4 implants, was randomised at the stage of abutment connection surgery. A dental assistant drew a lot, i.e., an envelope containing a note with either “ISOD 2” or “ISFAFDP 4” written on it, successively for each patient. ISFAFDP 6 implants (control) were not randomised. This group consisted of patients who were not able to be included in the study due to insufficient bone quality to receive prostheses supported by less than six implants.

Implants (Deep Conical, Southern Implants, Irene, South Africa) were placed by one experienced oral and maxillofacial surgeon. Based on the group, the surgeon installed either four implants (ISOD and ISFAFDP 4), preferably in the canine area and second premolar, or six implants (ISFAFDP 6) in the edentulous maxilla

of the patient. In the ISOD group, two implants were to be used as support, and two implants left resting. The two dormant implants thus acted as a reserve in case the outcome showed that a two-implant anchorage was not sufficient, or the patient for some reason would rather have an ISFAFDP at the end of the study, or in case one of the two active implants was lost during healing or at a later stage.

Post-delivery check-ups were performed within a week after prosthesis delivery.

Patients in the two test groups were thereafter called back for 6- and 12-month follow-ups; control patients were called back for a 12-month follow-up.

Examinations included a clinical and radiological evaluation of implant and prosthesis stability and of the presence or not of any technical (component or material wear or fracture) or biological complications (peri-implant soft tissue bleeding and/or pocket depth), as well as any patient complaints (aesthetic or functional).

STUDY III

The cost of treatment and costs during follow-up were registered and compared.

All costs were based on 2021 prices and expressed in Euros. Costs in Swedish krona, SEK, were converted to Euros, EUR, using a web-based currency converter (www.xe.com). Calculations were performed at the time of preparing the manuscript (May 2021). The cost of 1 SEK equalled 0.0987 EUR which was rounded up to the nearest ten and expressed as 10 SEK = 1 Euro. Hourly rates were set at 3,000 SEK/hour = 300 Euro/hour, i.e., 5 Euro/minute according to the clinic's tariff.

STUDY IV

Three different instruments for patient-reported outcomes were used: OHIP, JFLS and OES.

OHIP was used to measure patients' perception of the social impact of oral disorders on their well-being, JFLS to assess functional status of the masticatory system, and OES to assess how patients perceived their dental and facial aesthetics.

Measurements were performed before treatment and at each follow-up, which was at six and twelve months for patients in the test groups (ISOD 2 and ISFAFDP 4) and at twelve months for patients in the control group (ISFAFDP 6).

RESULTS

The present thesis encompasses the results of four publications.

Study I

The electronic search in the databases resulted in 131 eligible publications, which altogether reported 1,478 maxillary ISODs, supported by 6,681 implants. The 1,478 patients consisted of 446 (43.7%) men and 575 (56.3%) women, with no available information on gender for 457 patients. The patients received a mean of 4.5 ± 1.3 (range, 2-10) implants. Grafts were placed in the site of 1,786 implants, and 29 patients were submitted to Le Fort I osteotomy, mainly for grafting procedures. The iliac crest was by far the main donor site.

Regarding the antagonist jaw (mandible), most patients presented an overdenture (46.0%) in the mandible, followed by partial or total fixed prosthesis over teeth and/or implants, or natural teeth. Most of the ISODs did not present palatal coverage (82.1%) and had a metallic structure (81.9%). The mean number of attachments per overdenture was 3.8 ± 1.2 (range 1-9), and the bar-clip system was used in about half of the cases. A total of 401 implants failed (out of 6,681; 6.0%) in 219 patients (out of 1,478; 14.8%) after a mean period of 21.4 ± 26.0 (range, 0.5-247) months. Where the information was available, 41.9% of the implant failures were identified up to or at the abutment connection (second-stage surgery).

When the implant failure rates were compared between those reported in the case report and the case series articles, the difference was not statistically significant (6.1% versus 6.0%, respectively; $p = 0.379$, log-rank test). The difference in implant failure rates between irradiated and non-irradiated patients (in the head and neck region) was statistically significant ($p < 0.001$, log-rank test), as well as for the difference between implants placed in grafted or pristine sites ($p = 0.013$, log-rank test), but not concerning the presence or not of cleft palate ($p = 0.087$, log-rank test).

Concerning the prostheses, 55 (out of 1,478; 3.7%) failed. The failure of the overdentures happened at a mean of 40.2 ± 53.2 (6-240) months after prosthesis installation. Most of the prosthesis failure (92.7%) was due to loss of implants.

Overdentures with palatal coverage had a higher prosthesis failure rate (4.4%; 10/226) when compared to overdentures without palatal coverage (1.9%; 19/995), (p = 0.173, log-rank test). Prostheses with metallic structure/reinforcement presented a lower prosthesis failure rate (1.6%; 15/922) when compared to overdentures without it (4.2%; 9/212), (p = 0.238, log-rank test).

The difference in failure rates between overdentures reported in the case report and case series articles was not statistically significant (3.2% versus 3.7%, respectively; p = 0.679, log-rank test). No maxillary overdenture opposed to removable total prosthesis or overdentures in the mandible failed.

The implants were followed up for a mean of 51.7 ± 32.3 (range, 1-247) months, and the prostheses for a mean of 47.9 ± 32.8 (range 1-240) months.

The correlation between the survival rate of implants and the number of implants was very weak (r = 0.004, p = 0.867, Spearman correlation). Patients with fewer implants presented higher prosthesis failure rates than patients with more implants per prosthesis. Of the most commonly used attachment systems, the ball/O-ring and the Ceka were the ones with the highest rates of patients with at least one implant failure. If one considers the analysis until the 'interval start time' of 19 years (since there were so few entries at 20 years, and many of these failed, strongly decreasing the CSR), the CSR for the implants and the prostheses was 70.4% and 79.8%, respectively..

Most of the failures happened within the first year after installation, for both implants (52.1%) and prostheses (41.8%).

Study II

Ninety-one patients (37 men, 54 women) were identified as having been rehabilitated with implant-supported ISODs. Two patients received two subsequent ISODs in the same jaw; among them, one lost all four implants that supported the maxillary bar-clip OD and received two new implants for a second bar-clip OD, while the other patient was first rehabilitated with a mandibular OD and Locator attachments.

These attachments presented with many complications within a short period of time; therefore, the attachment system was changed to a framework (an alveolar bar) with clips. The prostheses that resulted in the subsequent use of different

attachment systems or were supported by a complete set of different implants were considered as distinct ISODs.

A total of 93 ISODs were used; 10 of these were followed up for periods of <6 months and excluded from further analyses. Six cases of ISODs using Locator attachments and one using magnet attachments were also excluded, due to the small number of cases with these attachment systems. Thus, the present study included a total of 76 ISODs (36 in the maxillae, 40 in the mandibles) in 75 patients (32 men, 43 women).

The mean ± SD age of these 75 patients was 65.6 ± 12.8 years (min- max, 34.6-90.2) at the time of prosthesis delivery, and was followed up for 88.8 ± 82.9 months (min-max, 7.2-403.9).

With regard to the rehabilitation in the opposite jaw, the ISODs were opposed by removable complete prostheses in 25 cases, either natural teeth or tooth- or implant-supported fixed prostheses in 35 cases, and a partially dentate arch with a removable partial prosthesis in five cases. It was not possible to retrieve the information in 11 cases.

Two hundred and forty-two implants (3.2 ± 1.3 implants per prosthesis; min-max, 1-6) were placed to support the 76 ODs. The majority of the ODs were supported by two (n = 26; 34.2%) or three implants (n = 21; 27.6%). There were 43 implant failures (43/242; 17.8%) in 17 prostheses (17/76; 22.4%). All the implant failures occurred with the Nobel Brånemark turned/ machined (35/153; 22.9%) or Nobel MK III TiUnite (8/83; 9.6%) implants. The turned implants did not have a statistically significant higher failure rate than moderately rough surface implants (37/153, 24.2% vs. 8/89, 9.0%; p = 0.064; clustered log-rank test). Most of the turned implants were installed in the maxilla (111/153, 72.5%), whereas most of the moderately rough implants were placed in the mandible (65/89, 73.0%).

Information about bruxism was available for patients who received a total of 214 implants, and bruxers presented with a significantly higher (p = 0.035) implant failure rate (5/14, 35.7%) than non-bruxers (26/200, 13.0%). Fourteen implants were placed in four patients who presented with bruxism; among them, two patients lost five implants. There was a statistically significant difference (p < 0.001; clustered log-rank test) in the number of failures between implants placed in the maxilla (39/135; 28.9%) and those placed in the mandible (6/107; 5.6%).

The majority of the implants were placed in the region between the canines. The implants were placed in the following positions (incisors/canine/premolars/molars; failure rate in %): maxilla (62/45/21/7; 25.8/33.3/33.3/14.3) and mandible (57/50/7/1; 1.9/6.7/28.6/0). The implants failed at 43.3 ± 41.0 months (min-max, 6.1-146.2). A total of 60 ISODs (78.9%)

using the bar-clip attachment system (Round bar, Cendres+Métaux, Biel/Bienne, Switzerland) and 16 cases (21.1%) using the ball attachment (Dalbo system, Cendres+Métaux, Biel/Bienne, Switzerland) were identified. The distribution of implant failure based on the attachment system was as follows: bar-clip (39/199; 19.6%) and ball (4/43; 9.3%).

Fixed full-arch prostheses were initially planned in 15 patients included in the present study; however, these patients lost 28 implants before the prosthetic stage of the rehabilitation. The choice of ISODs in these patients came with the patients' refusal to be subjected to further implant surgeries together with the fact that they were offered another type of rehabilitation with the remaining implants, i.e., ISODs.

Ten patients were supposed to receive ISODs from the beginning of treatment and had lost 14 implants before the prosthetic stage. These losses, however, did not compromise continued rehabilitation with ISODs. Six out of 15 (40%) patients who received ISODs and were initially supposed to receive a fixed full-arch prosthesis presented with additional implant failures compared to 11 out of 61 patients (18%) who were initially supposed to receive an implant-supported ISOD ($p = 0.073$, Fisher's exact test). Three out of the aforementioned 15 patients (20%) eventually lost their ISODs compared to 7 out of 61 (11.5%) patients who were to receive an OD at the beginning ($p = 0.309$, Fisher's exact test).

Fractures of the acrylic teeth or parts were more prevalent in bar-clip ODs, whereas the prevalence of poor retention was similar between both attachment systems. Prosthetic and abutment screws were only used in the bar-clip system, thereby limiting the occurrence of screw complications. The bar-clip system usually presented with more complications in the attachment parts compared with the ball attachment system.

A total of 10 ISODs (13.2%) had failed due to the loss of supporting implants. Among them, three were supported by two implants, two by three implants, four by four implants, and one by five implants. All the supporting implants were lost in eight out of the 10 ISODs; one ball ISOD with two implants presented with a loss of one implant, and one bar-clip OD with four implants presented with a loss of three implants.

The failure of these ISODs occurred after 44.0 ± 45.5 months (min-max, 7.2-130.4). The 66 ISODs that did not fail were followed up for 95.6 ± 85.4 months (min-max, 7.8-403.9). Nine (11.8%) patients who were initially rehabilitated with implant-supported ISODs received additional implants for fixed full-arch prostheses, which were provided after 44.5 ± 35.5 months (min-max, 16.8-118.1).

According to the Cox proportional hazards model, no factor appeared to affect the probability of prosthesis failure. No multivariable Cox regression model was performed because only one variable was moderately associated ($p < 0.10$) with prosthesis failure in the univariate models.

Studies III and IV

Twenty-four patients were included, seven women and 17 men, mean age 64.9 and 67.5 respectively. Six patients received ISOD 2 treatment (two women, mean age 62.5, and four men, mean age 63.5). Eight patients received ISFADP 4 treatment (eight men, mean age 67.9). Ten patients received ISFADP 6 (five women, mean age 65.8, and five men, mean age 70.0).

Study III

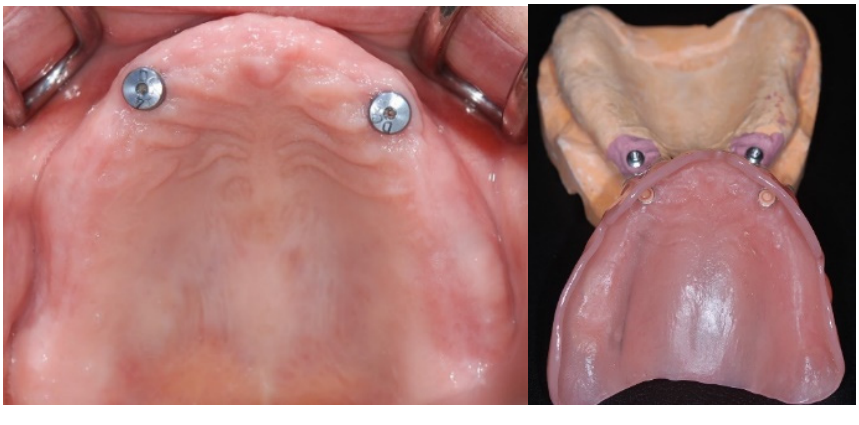
All implants and all restorations were in function at the latest follow-up, i.e., the survival rate was 100%. Initial costs, i.e., cost of prostheses at delivery, for ISFAFDP 6 were higher than costs for ISFAFDP 4 and ISOD 2 due to the higher number of implants and higher cost of materials and fees.

Three complications occurred in the ISOD 2 group, two in the ISFAFDP 4 group, and three in the ISFAFDP 6 group. There were no statistically significant differences between groups in post-treatment costs ($p > 0.05$).

There were significant differences between groups regarding total costs, i.e., costs of prostheses at delivery plus post-treatment costs. Total costs for ISFAFDP 6 were significantly higher than total costs for ISFAFDP 4 ($p < 0.001$) and ISOD 2 ($p < 0.001$). Total costs for ISFAFDP 4 were significantly higher than total costs for ISOD 2 ($p = 0.001$).

ISFAFDP 6

ISFAFDP 4



ISOD 2

Figure 1 photographs of the three different treatments in study III-IV

Study IV

All patients, irrespective of group, showed improved patient-reported outcomes from before treatment to the one-year follow-up. The improvement was statistically significant in most cases. For the OES scale, all improvements were statistically significant for all three treatment groups. In the ISOD2 group, however, the improvement was not statistically significant regarding 'Mastication', 'Verbal and non-verbal communication' or total JFLS score, nor for 'Oro-facial Pain/Psychosocial Impact' in OHIP. Likewise, the improvement in 'Psychosocial impact' for the patients in the ISFAFDP 6 group was not statistically significant.

There were no significant differences between groups regarding functional status of the masticatory system (JFLS parameters). Regarding patients' perception of the social impact of oral disorders on their well-being (OHIP), there were significant differences regarding the 'Oro-facial appearance' domain, where ISFAFDP 4 patients reported significantly higher satisfaction ($p = 0.015$) compared to ISFAFDP 6 patients. Regarding how patients perceive their dental and facial aesthetics (OES), there was an initial difference between ISOD 2 and ISFAFDP 4 before treatment, where ISFAFDP 4 patients reported higher satisfaction ($p = 0.038$). This difference was not present after treatment.

DISCUSSION

In a recent consensus paper from the 2019 Oral Reconstruction Foundation Conference on the Edentulous Patient, Robert A. Sader writes, "Even if the incidence of edentulism is on the decline in some parts of the world, there are many patients who suffer from insufficient dental rehabilitation. In these cases, it is important to offer solutions that are functionally sufficient, aesthetically adequate, and economically affordable" (81). There are many ways to re-establish function and aesthetics. The crux of the matter is how to define the terms "sufficient", "adequate" and "affordable". It is likely that these words carry different meanings for different individuals, patients and dentists alike. The goal of the cited consensus paper was to present solutions complying with all aspects of individual patient requirements (81). Some aspects, e.g., affordability and patient-reported outcomes, have been insufficiently evaluated. The overall aim of the present thesis was therefore to contribute to our knowledge about these aspects, specifically regarding treatment of the edentulous maxilla.

The main findings of this thesis were that:

- Clinical outcomes of maxillary implant-supported overdenture treatment can be successful and comparable to implant-supported fixed partial dentures, after a one-year follow-up.
- Total costs for implant-supported fixed partial dentures were significantly higher than for implant-supported overdentures; however, there were no differences in cost for maintenance and repair during the one-year follow-up. The lack of difference in costs for maintenance and repair over the first year suggests that implant-supported overdentures will remain the least costly treatment option for the edentulous maxilla, at least in a medium-term perspective.
- There were statistically significant improvements in aesthetics and function according to patient reports, suggesting that edentulous patients experience

equal positive treatment outcomes with implant-supported restorations in a short-term perspective, regardless of whether the superstructure is fixed or removable.

Survival of implants and restorations

Most of the findings in Studies I and II are in agreement with other studies stating that key factors related to successful treatment with overdentures include the number, location and distribution of implants and choice of attachment (82). There was, however, a difference regarding the effect of the number of implants, where the retrospective study found no influence of the number of implants on outcome but the systematic review noted higher failure rates for ISODs supported by fewer implants. This difference might be due to the type of study, where the retrospective study represents results from only one local study whereas the review is based on several studies and is likely to be more representative (83,84).

No implants or restorations were lost in the clinical trial. The 19-year cumulative survival rate (CSR) for dental implants in our systematic review was 70.4%, and the first year was found to be the most critical period for failures. Messias et al. report a 97.4% implant survival rate for overdentures supported by four or more implants for follow-up ranging from one to 10 years. An explanation for the lower survival rates in our systematic review could be the longer follow-up. In the retrospective study, all failed ISODs resulted from loss of implants, particularly the turned maxillary implants. This is in agreement with other studies, irrespective of whether the implants support fixed or removable restorations (83,85). Consensus regarding the use of moderately rough surface implants has been established for a long time, its positive influence on implant survival is well-known, and these types of implants were used in the clinical trial. In a recent comprehensive study on implant failure, Malm et al. concluded that there was a significantly higher incidence of early failures with turned implants in the maxilla than moderately rough implants (86). Smoking, systemic disease and allergies were other factors associated with early failure. Few of our patients smoked, all were of good general health, and none had allergies. These factors may have contributed to the positive early outcome of the present study. In the studies from Malm et al., older age was associated with lower risk for early implant failures (86–88). The median age for the patients in our clinical trial was 63-70 years, which could be considered “old”, and this is another factor that could have contributed to the absence of early implant loss.

The cumulative survival rate (CSR) for implant-supported maxillary overdentures in our systematic review was 79.8% after 19 years (84). High overall prosthesis survival rates of 96.9% to 100% can be obtained for implant-

supported overdentures according to a recent consensus report (82). These numbers are comparable with implant-supported fixed partial dentures (89). Lower survival rates have however been reported for overdentures with a lower number of supporting implants (90). There are no specific guidelines for the number of implants necessary to support a maxillary overdenture, but the consensus report states that no maxillary overdentures should be supported by fewer than four implants (82). Our clinical study shows a positive outcome so far despite only using two implants for support. One explanation for the beneficial outcome could be the fact that this study is a study where ISOD treatment was a planned treatment where the prosthetic and surgical team carefully selected patients, rather than a rescue treatment. An unplanned overdenture is often an emergency/rescue situation, where an insufficient number of implants are left or installed in suboptimal situations after previous implants have failed (91–93). For instance, Jemt et al. disclose that overdenture is often a treatment option in compromised patients, where fixed prostheses fails (94). The literature describes a better survival rate for planned cases than for unplanned cases (92,95,96). For example, Bergendal et al. showed that there is high implant survival rate when the overdenture is well-planned (42).

A further factor that may have positively influenced the outcome is the fact that treatment was performed by specialists in a university environment (97).

The retrospective study found that ODs opposed by natural dentition or fixed prostheses presented with more complications (83). This is in agreement with the consensus report (82). In our clinical trial, however, we did not note any influence of opposing dentition. Nineteen out of twenty-four patients had natural dentition or implant-supported fixed partial dentures in the opposing jaws. Yet again, the clinical trial may have been limited by the few number of patients and short follow-up.

In summary, our findings suggest that implant and prosthesis survival may not be compromised with the use of fewer implants, although the results are based on a limited number of patients and short follow-up. However, the results are interesting as the recommendations in the consensus report are not based on RCTs demonstrating that a particular number of implants offered better outcomes (98). Furthermore, most failures for both implants and prostheses seem to occur within the first year after installation, which makes our results worthy of discussion (99).

In the prospective clinical trial, we used the Locator attachment. This is a low-profile resilient attachment, with a universal hinge that allows free-floating movement between the nylon retention liner and its metal housing and offers different vertical heights, durability, and can compensate implant angulation (100,101). Previous studies, including our systematic review, have noted an

influence of attachment systems on implant and overdenture outcomes. The Locator attachment was one of the systems with the least number of implant failures in the review. It has been shown to perform excellently in terms of survival rate, tissue response and patient satisfaction. However, it requires higher maintenance and repair (102). Perhaps the choice of attachment and design of the overdenture to permit greater flexibility allow slight movement of the denture on the soft tissues, minimising the forces dispersed upon the dental implant. The ODs could thus have benefited from additional mucosal support (103). However, the design including mucosal support and two implants has also been criticised as it could give rise to complex stress patterns in the restoration and on the implants (84).

Palatal coverage is sometimes problematic for edentulous patients as taste and comfort may be affected. However, reduction of the palatal coverage in complete maxillary dentures may lead to weakening of the retentive potential (104). Early pioneering work by Smedberg et al. used a hybrid prosthesis fixed to a bar on splinted implants with no palatal coverage (105). These restorations functioned well. Yet, the presence of palatal coverage and/or metallic structure/reinforcement did not seem to have an influence on the failure rates in our review (84). This is in agreement with Messias et al., where survival rate was high regardless of splinted or unsplinted implants. Mo et al., in their study, show that patients rehabilitated with a maxillary palate-less overdenture appear to require more maintenance visits when the prosthesis is retained by two freestanding implants in comparison to four implants (106). Our clinical study did not show any difference regarding outcome in terms of maintenance or patient satisfaction between ISODs with palatal coverage or fixed restorations without palatal coverage. Zembic et al. compared implant-supported overdentures with and without palatal coverage and found no significant differences (107). Further similar research, comparing different ISOD designs, is needed.

Cost of treatment

The present thesis ended in conflicting results regarding the cost of treatment. The systematic review and the retrospective study suggest OD treatment to be more costly than fixed restorations since ODs involve greater needs for maintenance and repair. However, the cost analyses in the prospective clinical trial found no differences in costs for maintenance and repair between the fixed and removable restorations. The results from the clinical trial are preliminary and comparison with results from other groups is difficult as there is a lack of similar studies on different treatment for the edentulous maxilla that includes cost analyses (79).

The fact that initial costs varied significantly between groups was unsurprising as implant treatment requires substantially higher initial costs. The costs for maintenance and repair may however outweigh these initial differences if the need for such adjustment is great. Many studies, including our retrospective study, state that overdentures require constant maintenance and repair, but most complications were with the attachment system, which can often be easily managed with little effort regarding time and cost (82). For fixed restorations, most complications were related to chipping, which can be much more time-consuming and costly to repair (82). The technical complications related to the attachment system indicate a need to further develop and improve such systems. This may help to reduce costs.

Our one-year results are early predictions. However, Attard and Zarb (108) report that most of the costs for prosthetic repairs usually occur during the first year. The most costly of all complications is perhaps the loss of implant support. According to our results, the first year was the most critical period for such failures.

Our study was a comparative cost analysis and not a true cost effectiveness study. As described by Drummond (2015), health economic evaluation is a methodology that can maximise health benefits and minimise opportunity costs by comparing the health benefits and costs of alternative resource allocation decisions. However, a complete economic evaluation, such as cost-effectiveness analysis, assess both the costs and effectiveness of alternative interventions, whilst a comparative cost analysis, as in this study, focuses solely on the cost difference between interventions.

Indirect costs such as loss of income, transportation, etc. were not included in our analysis. This was a deliberate decision based on the fact that the majority of patients were retired with similar income from pensions and residing close to the clinic, i.e., it was concluded that indirect costs would not differ between groups and would therefore not be a relevant variable. This could however be relevant for other studies based on other populations with different types of income.

Patient-reported outcomes

Our main findings regarding PROMS, i.e. the lack of differences between fixed and removable treatment options, are interesting. They challenge preconceived notions about what the optimal treatment is for edentulous patients (36). In Sweden, there may be a preconceived notion that fixed reconstructions are always

preferable. There are no references to confirm this, but our hypothesis can be illustrated by statistics from the Swedish Social Insurance Agency, which show that more fixed constructions are made (Table 2 and 3) than removable ones. Furthermore, patients examined prior to participation in the project admitted that they had never received any information about a removable overdenture alternative at previous consultations (109). This is problematic in our opinion, as the choice of treatment should be based on respect for patient expectations and wishes as much as anatomical limitations and financial issues.

The concept of Oral Health-Related Quality of Life (OHRQoL) has numerous definitions, and assessment methods vary. Locker has suggested that a questionnaire assessing OHRQoL should contain items dealing with aspects of daily life that are of importance to the target population (110). The use of patient-reported outcome measures (PROMs) in clinical practice helps to ensure that the patient's perspective is present in all aspects of care, to ensure therapeutic management remains patient-centred. Patient-reported outcomes include several domains such as function, aesthetics, social impact of oral status, and overall satisfaction (111). For this reason, we used three different instruments for evaluating patient-reported outcomes: OHIP to measure patients' perception of the social impact of oral disorders on their well-being, JFLS to assess functional status of the masticatory system, and OAS to assess how patients perceived their dental and facial aesthetics. The instruments used in the present thesis are validated and reliable (112,113). The use of more than one instrument and the fact that all instruments showed the same outcome, i.e. improvement from before to after treatment and absence of significant differences between the groups, is suggested to be a strength of the clinical studies.

Studies evaluating patient satisfaction have found greater satisfaction with ISFAFDP and ISOD groups than CD wearers in all domains of chewing function, social function and overall satisfaction (35,114). Implant prostheses in the maxilla will probably have the most impact when a patient is struggling with conventional maxillary dentures. But what about differences between various implant-supported treatments? The literature is not clear on which option might be the better treatment or why (115). Information on patient-reported outcomes is largely lacking for maxillary overdentures. However, it is well-known from studies on mandibular overdentures that a removable option may be a satisfactory treatment (29) and even the preferred treatment (41). In some instances, an ISOD has a clinical advantage over ISFAFDPs such as the need for soft tissue support and in case of anatomical limitations that restrict the number of implants to be used. From the patient's point of view, lip support, phonetics and ease of cleaning are factors that may favour an ISOD over an ISFAFDP (41). When stability,

retention, comfort and less tissue coverage are priorities, fixed implant prostheses are favoured.

In our study, all evaluated treatments, irrespective of design and support, showed similar outcomes from a patient perspective. This confirms that prosthetic treatments can provide improvements in oral health-related quality of life for fully edentulous patients. Smedberg et al. performed a subjective and objective evaluation of their pioneering design for ISODs (116). They used a visual analogue scale and the median score for evaluation of comfort, phonetics and aesthetics was 9 (maximum 10). The results of our clinical trial are promising, as they suggest that a simplified design including palatal coverage may function as well as a fixed restoration even for a group of patients encountering problems with conventional dentures but who have a desire for a low-cost dental implant treatment.

While two endosseous implants are generally considered to provide sufficient support to a mandibular overdenture, the number of implants needed to support a maxillary overdenture is still not set. Roccuzzo et al., in their systematic review, come to the conclusion that the question of how many implants should support a maxillary overdenture is still open (33). Although our study did not note any differences between different patient groups, it might be interesting to compare ODs on 2 and 4 implants respectively in future studies to see if there is a difference in patient experience.

Limitations

The studies in this thesis are not without limitations. Most of the data included in Studies I and II were from retrospective reports, which may be limited by incomplete records about different factors that could exert influence on the survival rates of implants, resulting in gaps in information. For example, there was a lack of information about the systemic conditions and habits (such as smoking and bruxism), factors that could exert some influence on the survival rates of implants as well as the presence of several negative factors in the same patient. Likewise, there was a lack of information on biological factors such as oral hygiene status and periodontal history. Furthermore, there was not always clear or sufficient information about whether the attachments were directly attached to implants or mounted on a bar.

For the prospective clinical trial, patient recruitment was the most challenging factor. If the study had been designed as a multi-centre collaboration, it is likely that a higher number of patients could have been included during the study period. This thesis should therefore be considered a pilot study. A greater number of

long-term longitudinal studies with more patients are needed to help establish better evidence-based treatment planning principles for implant-supported maxillary overdentures, and to assess the causes and effects of complications.

Clinical significance

The results of the present thesis are far from sufficient to form a basis for policies regarding choice of treatment, but they may challenge existing notions about what the optimal treatment is for the edentulous maxilla. As mentioned previously, the dental profession must offer solutions that are "functionally sufficient, aesthetically adequate and economically affordable". These concepts carry different meanings for different individual patients. The results of the present thesis are a first step towards creating more knowledge about the outcomes of maxillary overdentures. The results are interesting, as they suggest that a simple removable and less expensive treatment option may function satisfactorily in terms of survival and complication rates just as well as fixed alternatives from the patient's point of view.

Part of the aim of the thesis was to focus on the elderly patient as edentulousness is more prevalent among. Oral health is not always at the centre of attention when discussing health problems among the elderly, even though edentulism can lead to impaired masticatory function, functional limitations, psychological and social disability, decreased self-esteem and low quality of life. The results of this thesis may be of particular interest for the elderly patient. It is in this group that we find the highest prevalence of edentulous patients. Since fine motor skills decrease with age, a removable type of prosthetic rehabilitation can be easier to clean and maintain for the patient compared to fixed prosthetic reconstructions on implants. As the elderly population increases both in age and in numbers, it is of high importance for society to find ways to take care of them regarding care and maintenance. This is a growing problem, as most edentulous patients are treated with fixed prosthetic reconstructions on implants. When older and/or infirm people can no longer take care of themselves, an overdenture on implants would presumably be easier to clean and maintain oral health. Furthermore, the economic cost of any treatment is perhaps particularly significant for the ageing population, whose income may be decreasing or limited.

Future perspectives

Our aim is to continue recruitment of patients and continue follow-up so that we may provide long-term results. Future studies on maxillary overdentures are needed and should compare overdentures based on different numbers of implants,

different designs such as with or without palatal coverage, and the use of different retentive elements. A multi-centre model would facilitate patient recruitment for such studies.

Future studies on implant-supported restorations should preferably include aspects of patient-reported outcomes and cost analyses in addition to evaluations of implant and restoration survival and complications.

The use of standardised protocols in all clinical trials will also raise the quality of data for retrospective studies and systematic reviews.

A methodology that is seldom used in prosthodontics is qualitative studies. Such studies are time-consuming, but provide a deeper, contextualised understanding that includes depth and detail of an individual´s experience (117).

CONCLUSIONS

Within the limitations of this thesis, it is concluded that:

- The majority of maxillary overdenture failure is due to loss of implants, and the first year is the most critical period for failure. The presence of palatal coverage and/or metallic structure/reinforcement does not seem to have an influence on failure rates (Study I).
- Long-term retrospective data from a group of patients treated at specialist clinic suggest that maxillary overdenture failure was not significantly affected by any of the following factors: sex, age, jaw, bruxism, smoking status, implant surface, number of implants, type of attachment, and opposing arch. It is further suggested that patients with maxillary overdentures need regular maintenance follow-ups (Study II).
- No conclusions regarding the number of implants needed to support a maxillary overdenture can be offered, since Studies I and II show conflicting results, and the clinical trial is limited in terms of number of patients and follow-up (Studies I-IV).
- Results from the clinical pilot trial suggest excellent and similar clinical performance for implant-supported full-arch fixed partial dentures and implant-supported overdentures without differences in maintenance and repair costs in a short-term perspective. The lack of difference in maintenance and repair costs over the first year suggests that implant-supported overdentures will remain the least costly treatment option for the edentulous maxilla, at least in a medium-term perspective (Study III). Furthermore, it is suggested that edentulous patients experience equal positive treatment outcomes with implant-supported restorations whether the superstructure is fixed or removable (Study IV).

The decision to rehabilitate an edentulous patient with an ISFAFDP or ISOD cannot be based only on the existing literature. Each dentist has personal preferences that play a role in the approach chosen, and patient expectations and satisfaction should guide the selection process. There are other important factors to consider, such as the patient's financial means, specific anatomy and other clinical parameters, and most importantly, the patient's needs and wishes.

ACKNOWLEDGEMENTS

My eternal gratitude to Professor Ann Wennerbrg for introducing and giving me the opportunity to become a PhD student and to do this thesis. You have introduced and invited me into a new world. It was an honour to get to know you and work for you.

My endless thanks to my head supervisor Associate Professor Christel Larsson for making this thesis possible by taking over, having patience and availability all the time. To encourage and motivate you and provide ongoing support as a mentor. Without you, the road to the finish line would be endless.

I also want to thank my co-supervisor Associate Professor Bruno Chrcanovic for your forthright and your generous sharing of knowledge and time and our private and professional chats about life and work.

I want to thank my co-supervisor Associate Professor Sofia Petrén for sharing your knowledge and ideas of health economics and that enabled clinical implications of the results of this thesis.

A special thanks to my former supervisors and co-authors, Professor Liselott Lindh and co-author Dr Camilla Ahlgren, for your invaluable input regarding all steps of conducting research with an exceptional fingertip feeling for quality and unwavering accuracy.

Thanks to all personals in department of surgery and specially Associate Professor Jonas Becktor and Dr Marianne Ahmad for the surgery and patient care.

Special thanks to Southern Implants to provide and support the project with necessary implants.

My greatest gratitude and love to my Jafar Moani, who assisted me with the patient treatment and kept all papers, took care of me in the meantime in an impeccable way and encouragement through these years regarding all aspects of research and life.

You have been important to me through the most challenging times and joyful moments.

I want to thank Per-Erik Isberg for the statistical analysis.

I want to thank all the staff at the department of Prosthodontics, Malmö University for invaluable help and support throughout the work with this thesis.

Forever grateful to my parents for saving my life and give me a future by sending me away from the war, despite the agony of living apart for years.

My beloved wife Houda and my dearest daughter Ava, to whom I dedicate this work, for your endless love and support. For making me, what I am today and put up with me during my studies. Ava you asked all the time, when will I complete? I think I am done now.

“May you live every day of your life.”

Jonathan Swift

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