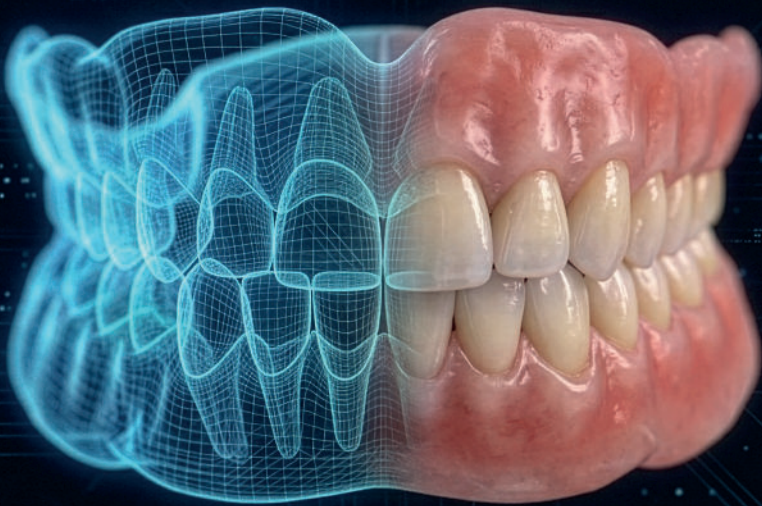


Digital technology in implant-supported overdentures

Patient engagement and costs



Thomas Van de Winkel

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Patient engagement and costs

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from Radboud University Nijmegen
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according to the decision of the Doctorate Board
to be defended in public on

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at 12:30 pm

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Aan Joachim

Ich bin schon lang' nicht mehr auf der Suche nach dem Sinn
Denn er wird sich immer verändern
Und ich weiß ziemlich genau was ich bin
Aber nicht wo das hin will
Das find' ich gar nicht so schlimm...

Gisbert zu Knyphausen – Der Blick in deinen Augen

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CHAPTER 1

General introduction

Edentulism

Edentulism is recognized by the World Health Organization (WHO) as a physical disability, given that the use of complete dentures (CDs) frequently results in functional impairments, including dietary restrictions and speech difficulties.¹ Moreover, the resorption of alveolar bone leads to inadequate support for the facial soft tissues, causing edentulous individuals to exhibit an aged facial appearance.²

Despite the decreasing prevalence of edentulism, demographic trends indicate an anticipated increase in the absolute number of fully edentulous patients due to the ageing population.³ In cases of inadequate CD retention, the current gold standard involves the placement of two interforaminal implants in the mandible to improve prosthetic stability.⁴ Therefore, even when maxillary CD retention is compromised, the current protocol in the Netherlands is to first fabricate a mandibular implant-supported overdenture (IOD) before considering implant treatment of the upper jaw.⁵

Patient Reported Outcome Measures (PROMs)

To evaluate whether the additional costs of an implant-supported overdenture (IOD) justify the potential benefits for the patient, it is crucial to understand how the added value of an IOD is defined. The patient's perspective has gained increasing emphasis alongside traditional 'hard' outcomes such as implant survival and other objective biological parameters.⁶ Most healthcare interventions aim to enhance patients' quality of life or reduce disability and symptoms. These dimensions can only be accurately assessed by the patients themselves.^{7,8}

Moreover, the ITI consensus has emphasized that clinical outcomes should be complemented by Patient Reported Outcome Measures (PROMs) when defining treatment success.⁹ Nonetheless, there remains a scarcity of data on PROMs specifically related to dental implant treatment, and many studies rely on self-constructed questionnaires rather than standardized oral health-specific instruments. This highlights the importance of adopting standardized outcome measures to facilitate interstudy comparability.¹⁰

Several validated questionnaires have been developed to assess either disease-specific or general PROMs in a reproducible and objective manner.⁷ The most commonly used standardized instruments for evaluating general health-related quality of life (GHRQoL) are the Short Form Health Survey (SF-36) and the EuroQol 5D-5L (EQ-5D-5L).^{11,12} In dentistry, the Oral Health Impact Profile (OHIP) is the most frequently employed tool to assess oral health-related quality of life (OHRQoL).^{6,13}

EQ-5D-5L

The EQ-5D-5L measures GHRQoL across five domains - mobility, self-care, daily/usual activities, pain/discomfort, and anxiety/depression - using a single question per domain. Patients rate their health status within each domain using one of five categories: 'no problems', 'slight problems', moderate problems', 'severe problems', or 'extreme problems/unable'. Additionally, patients are asked to evaluate their overall health on a visual analogue scale (VAS).^{14,15}

SF-36

The SF-36 questionnaire comprises 36 questions assessing general health across eight domains: physical functioning, role limitations due to physical health, role limitations due to emotional problems, bodily pain, general health perceptions, vitality (energy/fatigue), social functioning, and mental health.¹² The response options vary depending on the question, ranging from 3-point to 6-point Likert scales (a rating scale with predefined options), with gradations such as 'excellent' to 'poor' or 'not at all' to 'extremely'. The SF-36 is widely recognized as a reliable instrument for assessing GHRQoL.¹⁶

OHIP

The original OHIP-49 questionnaire contains 49 items across seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap.¹⁷ Variants such as the OHIP-20 and OHIP-EDENT have been developed to address the specific needs of edentulous patients.^{13,18} Compared to the SF-36, the OHIP questionnaire is considered more suitable for capturing the impact of oral disorders on patients' quality of life.⁶

Preference-Based Measures

To enable the use of quality of life instruments in health economic evaluations, the collected scores must be converted into preference-based values. This means that the values of the health status obtained via the questionnaire are weighed within the context of a specific society.^{16,19} The outcomes of these weighed values - reported as index scores - are called utilities and typically expressed on a scale from 0 to 1. They represent the score a society gives to a particular condition which can then be expressed as a price. Given that the perceived burden of health conditions can differ culturally, these utilities yield different outcomes across countries.^{11,15}

Cost

Financial considerations in dental implantology

The ageing population across the EU and the UK is expected to drive a substantial increase in healthcare expenditures, rising from €966 billion in 2014 to €1258 billion in 2050, representing an annual growth of approximately 0.8%.²⁰ Even in scenarios with significant risk reduction for conditions such as stroke, diabetes, and cardiovascular diseases, the demographic shift towards an older population is expected to exert a greater impact on healthcare costs.²⁰ Within the field of dentistry, the anticipated escalation of economic burden underlines the need for policy reform to sustain affordable and accessible care, as annual dental expenditures in most European countries are predicted to double between 2015 and 2040.²¹

Despite the surgical nature of implant placement, the general public's acceptance of dental implants has increased as implant therapy has become more prevalent over time. However, the perceived high cost of dental implants and IODs continues to pose a significant barrier to their broader adoption.²²

Economic evaluations in prosthetics and prosthodontics

Economic evaluations serve as essential tools for policymakers to assess whether the benefits of a specific intervention justify its associated costs. However, significant variation and differences in the quality of economic evaluations can complicate the interpretation of findings.^{23,24} Additionally, international comparisons of absolute costs are often challenging due to differences in country-specific healthcare systems and cost structures.²⁵ Nevertheless, relative cost ratios between treatment modalities can be informative. For instance, numerous studies comparing the cost of mandibular CDs to that of IODs consistently report that an IOD with two implants (IOD-2) is approximately two to three times more expensive than a CD.^{26,27}

To date, cost analyses of maxillary IODs are limited, with to us at the onset of this project only one known study. Comparing IOD-4 with IOD-6 it was concluded that patients are more satisfied with an IOD-6 than the cheaper IOD-4, but that more evidence is needed for judgements about the value for money.²⁸ While many authors adhere to the CHEERS (Consolidated Health Economic Evaluation Reporting Standards) criteria, noticeable methodological differences persist between studies, highlighting the need for greater consistency in economic evaluations.

Approach

The most precise approach for cost calculation in health economics is bottom-up microcosting, meaning that all costs per individual care unit are valued per patient.^{29,30} To enhance comparability of economic evaluations in the Netherlands, the National Health Care Institute (Zorginstituut Nederland) has issued a guideline instructing that economic evaluations adopt a societal perspective.^{31,32} This comprehensive perspective requires the inclusion of all costs, irrespective of who bears them, encompassing not only healthcare expenditures but also costs incurred by patients, their families, and other sectors, such as productivity losses.³²

The most frequently used economic evaluation methods in healthcare include Cost-Effectiveness Analysis (CEA), Cost-Utility Analysis (CUA), Cost-Benefit Analysis (CBA), and Cost-Consequence Analysis (CCA).³³⁻³⁵

- *Cost-Effectiveness Analysis (CEA)*: This approach evaluates the clinical effectiveness and cost - value for money - of an intervention, with outcomes expressed in terms of a clinical measure, such as reduction in blood pressure or decrease in tooth loss. In case a product or intervention costs more, but also has a larger effect, the extra costs per extra effect gained are reported as incremental costs.
- *Cost-Utility Analysis (CUA)*: Unlike CEA, CUA uses preference-based measures, typically using quality-adjusted life years (QALYs) to assess gains in general health-related quality of life. Results are reported as incremental cost-effectiveness ratios (ICERs), representing the cost per gained QALY.
- *Cost-Benefit Analysis (CBA)*: This method captures both health-related and non-health-related benefits (e.g., productivity gains), with costs and benefits expressed in monetary terms. The outcome is reported as a net value comparing total costs to achieved benefits.
- *Cost-Consequence Analysis (CCA)*: The CCA is the broadest approach, encompassing health and non-health outcomes for patients and other stakeholders. Costs and outcomes are reported separately, allowing decision-makers to weigh the relative importance of each measure.

Factors affecting IOD production cost

Digital Techniques

The integration of digital files, such as cone beam computed tomography (CBCT) scans, intraoral scans (IOS), and facial images, enables the digital design and fabrication of implant-supported overdentures (3D-IODs). By

eliminating the need for conventional impressions, IOS significantly enhances patient comfort.³⁶

CAD-CAM

Computer-aided design and computer-aided manufacturing (CAD-CAM) have become essential in prosthodontics and are increasingly applied to CD fabrication.³⁷ Compared to conventionally fabricated CD's, CAD-CAM dentures offer several benefits: reduced number of clinical appointments, decreased chairside treatment time, and enhanced accessibility through digital archiving.³⁸ Milled dentures exhibit better material properties, including higher toughness, increased yield strength, and decreased microbial adhesion.³⁸ CAD-CAM technology is also used for designing and manufacturing the underlying infrastructure, such as bar attachments, offering here as well distinct advantages over conventional manufacturing methods.^{38,39} Moreover, the total cost of CAD-CAM dentures is lower. As CAD-CAM uses prefabricated PMMA discs, there is no need to mix monomers in the dental laboratory, thereby eliminating exposure to toxic emissions.³⁸

Attachments for IODs

The attachment system connecting the denture base to the implants plays a significant role in the overall cost. Over time, various attachment systems have been developed, including bar attachments, magnets, ball or stud attachments, and Locators™.⁴⁰ While many attachment systems, such as ball or stud attachments and Locators™, are commercially available “off-the-shelf”, others, like bar attachments, are custom designed and manufactured. The choice between splinted attachments (e.g., bar attachments) and unsplinted attachments (e.g., ball or Locator™ attachments) remains a topic of ongoing research and debate.⁴¹

Attachments for the Mandibular IOD

At the time this study was conceptualized, bar attachments were considered superior to unsplinted attachments due to a more even stress distribution, reduced bone loss, and improved implant survival rates.⁴²⁻⁴⁴ Some authors report marginal bone loss to be slightly lower in bar attachments,⁴⁵ while others find no significant differences between bar and ball attachments.⁴⁶ A recent meta-analysis demonstrated comparable outcomes in bone loss and implant survival for splinted and unsplinted attachments.⁴⁷

Moreover, bar attachments provide excellent retention, even when implants are not parallel, and are associated with fewer complications than

ball attachments.^{41,47} Nevertheless, meta-analyses emphasize that the choice of attachment system should also consider clinical factors such as implant size and position, interarch space, oral hygiene, and the maxillomandibular relationship.^{41,45,47}

Attachments for the Maxillary IOD

Similar to the mandible, bar attachments are often preferred for maxillary IODs due to better stress distribution.^{44,48} However, no significant differences have been reported in implant or overdenture survival rates between splinted and unsplinted attachments.⁴⁹ Therefore, as with mandibular IODs, it is recommended to base the choice of attachment for maxillary IODs on specific clinical considerations, such as the maxillomandibular relationship.⁴⁸

Aim of this thesis

Over the years digitalization has become a quintessential basis of dental techniques. Regarding prosthetics, however, practitioners remained reluctant to implement a digital workflow in daily practice. This research aims to investigate the feasibility of fabricating an implant-supported overdenture (IOD) using an entirely digital workflow (3D-IOD). Particular emphasis is placed on Patient-Reported Outcome Measures (PROMs), reflecting the patient's satisfaction, perceived oral health, and quality of life. In parallel, it is aimed to assess from a societal perspective the costs associated with the production of conventional IODs as well as 3D-IODs.

Outline of this thesis

PART I - Digital workflow & review of PROMs and costs

The first part aimed at developing a fully digital workflow to produce implant-supported overdentures (3D-IODs) and to review the costs associated with the production of conventional IODs (C-IODs).

This fully digital technique is illustrated in **Chapter 2**. The costs for the production of C-IODs is described in **Chapter 3**. In addition, methods for cost analyses, health economic evaluation, as well as the added value of IODs compared to conventional dentures (CDs) were analyzed. Finally, Patient-

Reported Outcome Measures (PROMs) for evaluating the quality of life related to IODs were discussed in **Chapter 3**.

PART II - Randomized crossover study

Using a randomized crossover design, the second part aimed to assess whether 3D-IODs outperform C-IODs in terms of General (GHRQoL), or Oral Health-Related Quality of Life (OHRQoL). The enrolled patients wore both the 3D-IOD and C-IOD for one year each, in a randomized sequence.

In **Chapter 4** the comparison of both IOD types is presented using PROMs. In **Chapter 5** the financial differences between the production of a C-IOD and a 3D-IOD, including production costs as well as indirect costs, were assessed. Moreover, a cost consequence analysis for the 3D-IOD was presented. Furthermore, a Budget Impact Analysis anticipating the implementation of 3D-IODs was produced.

General discussion, future perspectives and summary

Chapter 6 provides a general discussion and **Chapter 7** the future perspectives. A summary is given in **Chapter 8**, followed by a Dutch summary in **Chapter 9**.

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PART I

MANUFACTURING OF A 3D-IOD

CHAPTER 2

Fully digital workflow for producing implant-supported overdentures milled from PMMA on titanium bars using PEEK as the female part/sliding mechanism with three clinical visits: A case report.

Van de Winkel T, Delfos F, van der Heijden O, Verhamme L, Meijer G. Fully digital workflow for producing implant-supported overdentures milled from PMMA on titanium bars using PEEK as the female part/sliding mechanism in three clinical visits: A case report. *Int J Oral Implantol (Berl)*. 2022 Sep 9;15(3):277-286. PMID: 36082661.

Abstract

Purpose

To prove that a fully digital workflow, even for registration of the maxillomandibular relationship, can be employed to produce implant-supported overdentures and demonstrate that CAD/CAM techniques can be used to mill permanent implant-supported overdentures from polymethylmethacrylate discs, using polyetheretherketone as the sliding mechanism.

Materials and methods

An edentulous 64-year-old woman received six implants in the maxilla after a bone augmentation procedure and two implants in the mandible. Five months after implant placement, intraoral scans were taken of her original complete dentures, of each prosthesis individually, and of both in centric relation (CR), and another was taken of both edentulous arches, including the scan bodies. Along with facial photographs, sufficient digital data were gathered to design and mill titanium bars, polyetheretherketone female parts, and a trial implant-supported overdenture. The tooth positions and colour were discussed with the patient using Smile Design software (3Shape, Copenhagen, Denmark). In the second session, the bars and trial implant-supported overdenture were inserted and checked, and in the third session, the final implant-supported overdentures were installed.

Results

The milled titanium bar exhibited a passive fit, as did the implant-supported overdentures. After 1 year, no prosthetic complications were noted; the measured pockets were all less than 4 mm in depth. On a visual analogue scale from 0 to 10, with 0 being the worst and 10 being the best, the patient awarded a score of 9 for her satisfaction with the implant-supported overdenture.

Conclusion

A fully digital workflow enables the production of robust wear-resistant IODs milled from PMMA, using PEEK female parts as the sliding mechanism, in just three clinical sessions.

Introduction

Although chewing function may be restored with complete dentures (CDs), this is only possible to a limited degree.¹ Unfortunately, due to the ongoing alveolar crest resorption, CD retention decreases over time. Insertion of dental implants to facilitate implant-supported overdentures (IODs) or fixed restorations is the logical next step towards improving chewing efficiency of edentulous patients. With respect to implant survival, both full-arch screw-retained restorations and IODs are similarly successful in completely edentulous jaws; however, the costs for the latter are significantly lower.² Furthermore, in the event of prosthetic complications, repairs can be more easily executed for removable IODs than for screw-retained fixed restorations. New IODs can also be rapidly manufactured to replace lost or broken prostheses because the digital design is always available.³

The rapid development of digital procedures has facilitated the integration of digital files into the same software package. As a result, traditional clinical and laboratory steps can be replaced using CAD/CAM technology, making prosthodontic treatment faster and less expensive.⁴ Furthermore, patient comfort is increased because conventional impressions can be substituted with intraoral scanning.⁵

Using digital techniques can also save laboratory time. Stone master casts can be replaced easily with printed polymethyl methacrylate (PMMA) models, based solely on the digital information provided by intraoral scans (IOSs). In addition, the conventional mounting of stone models in an articulator can be replaced by registration in a Virtual Articulator (3Shape, Copenhagen, Denmark). Furthermore, the teeth can be positioned digitally using a Smile Design model (3Shape). Ultimately fabrication of the IOD can be achieved using CAD/CAM milling, thus avoiding the traditional heat pressing of two-component PMMA.⁶

Previous research has shown that, for conventional CDs, patients tend to be more satisfied with those that are CAD/CAM-fabricated than those that are produced in a traditional manner,^{7,8} although intermediate conventional steps are still required to record the maxillomandibular relationship.^{9,10}

Many articles have been published about the digital workflow of denture manufacture; however, registering the maxillomandibular relationship was always executed conventionally using templates in these studies.⁴⁻¹³ The use of polyether ether ketone (PEEK) as a sliding mechanism was only mentioned in two publications, in which it was used solely in temporary IODs in preparation for screwed implant-supported constructions.^{11,12}

The present article outlines the case of a patient for whom permanent IODs were designed and fabricated using a fully digital workflow. Registration of the maxillomandibular relationship was also executed digitally, with information being extracted from the original CDs. The IOD base was milled from prefabricated PMMA discs, as were the teeth. The bars were CAD/CAM milled from titanium, and the sliding female parts from PEEK.

Materials and Methods/Case report

The present study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Arnhem/Nijmegen, 2017-3671, 12 December 2017. A 64-year-old woman who had been edentulous since the age of 25 presented with her sixth set of CDs, which were 5 years old and had been recently rebased. She complained about her lack of eating efficiency, loosening of her CDs when speaking, and feelings of embarrassment about her appearance, all of which reduced her Oral Health Related Quality of Life (OHRQoL) greatly. CBCT imaging showed a dramatic loss of the alveolar bone in the maxilla.

Inserting dental implants to support IODs or fixed restorations would be the logical next step to remedy these complaints. Dutch national insurance companies reimburse the cost of a maximum of six implants in the edentulous maxilla and two in the edentulous mandible, provided that only IODs are manufactured on these implants. In the present patient's case, a shortage of maxillary alveolar bone meant that a bone augmentation procedure had to be performed first to enable implant placement. This treatment plan was discussed in detail with the patient, who subsequently agreed to undergo the surgery.

In the first surgical session a sinus floor elevation procedure was performed under general nasotracheal anaesthesia using cancellous bone chips harvested from the iliac crest.^{14,15} To create sufficient alveolar crest width, cortico-cancellous bone strips were fixated in an imbricated manner.

After 5 months, another CBCT scan was made. In total, six NobelParallel Conical Connection implants (Nobel Biocare, Zürich, Switzerland) were planned virtually using the Procera Clinical Design software (Nobel Biocare), then, a surgical template was printed. In the second surgical session, implant installation was performed under general nasotracheal anaesthesia according to the NobelGuide (Nobel Biocare) procedure.¹⁶ A further five months later, both the maxillary and mandibular final IODs were designed

and manufactured in three consecutive clinical sessions, with two laboratory sessions in between.

To record the patient-reported outcome measures (PROMs), general satisfaction with the IOD was rated using a visual analogue scale (VAS) score from 0 to 10 at the start of treatment and after 1 year of wear. The patient was also asked to complete the Oral Health Impact Profile-20 (OHIP-20) questionnaire,¹⁷ composed of 20 questions covering seven domains: functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability and handicap. The response to each question is rated on a Likert scale ranging from 1 for “never” to 5 for “very often,” meaning total OHIP-20 score ranges from 20 to 100, with a lower score indicating a higher OHRQoL.

Clinical session 1

First, the original set of CDs was checked to determine whether centric occlusion (CO) was still present. As this was the case, the individual CDs were scanned (TRIOS 3; 3Shape). In addition, after both CDs were fixated in CO with a minimal amount of bite registration material (Futar D Fast, Kettenbach, Eschenburg, Germany), the buccal surfaces of the maxillary and mandibular teeth were scanned, thus recording the CO and the maxillomandibular relationship.

A lip and cheek retractor (Ultradent Products, _South Jordan, UT, USA) was placed, the implant system-dependent scan bodies (TRIOS 3) were mounted onto the implants, and an IOS of the maxilla and mandible was taken (Fig 1a). With regard to the soft tissues, the aim was to capture at least the attached gingiva of the alveolar process and the palate.

In addition, facial photos were taken (Fig 1b). Based on these and the original CDs, the future arrangement of the teeth was discussed with the patient. It was important to establish whether the median line was still correct and whether the vertical dimension of the occlusion (VDO) was still accurate or needed to be increased. It was also necessary to consider any specific wishes expressed by the patient regarding the colour or position of the teeth. To assess aesthetic appearance, the 3Shape Smile Design program was used to inventory the patient’s wishes (Figs 1c to e). First, digital points were applied manually on both pupils, the left and right paranasal area, and both corners of the mouth. Next, the contour of the mouth was indicated by applying digital points. The program then superimposed a matrix of tooth shapes over the mouth, thus facilitating the design of the final contour of the teeth (Fig 1d). The designed tooth alignment was fused with the image of the

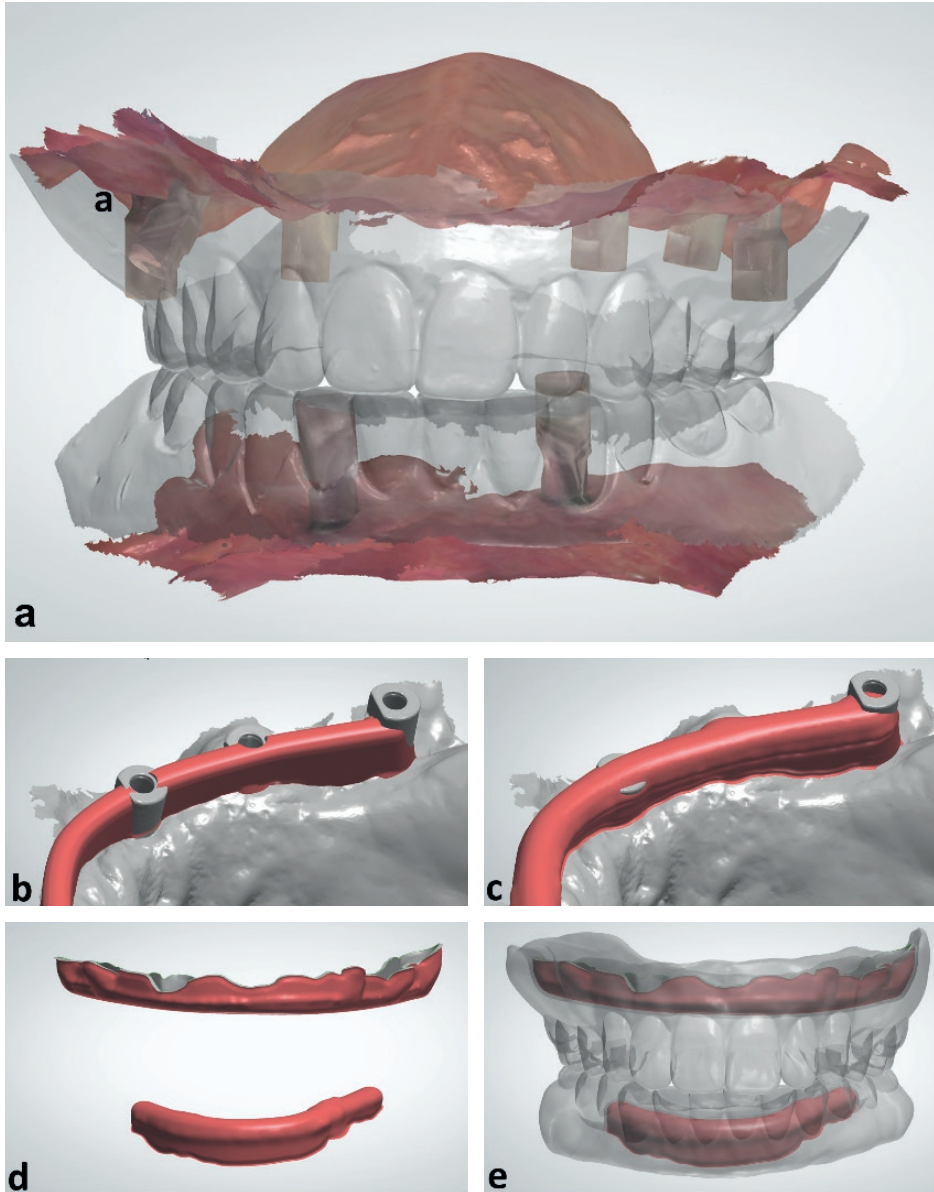


Figs 1a-e. Images captured in clinical session 1.(a) All scan bodies mounted on the maxillary implants; (b) facial photographs taken while wearing the original CDs; (c) orientation lines were drawn at the midline and in the paranasal region; (d) new teeth were designed over the original maxillary CD; (e) the same tooth design was transferred under the lip.

original denture teeth, with the lip overlapping the teeth (Fig 1e). The length and width of each tooth, as well as its colour (shade, brightness), could still be adjusted individually.

Laboratory session 1

The inside of the original CDs was digitally matched with the soft tissues as they appeared on the scans, including the scan bodies, to create a digital model (Fig 2a). By matching the CDs with a scan of the buccal surfaces of the maxillary and mandibular teeth in CO, the proper maxillomandibular relationship was determined and uploaded to the Smile Design. These data were then exported to the TRIOS Design Studio program (3Shape), which contains the Virtual Articulator tool. In cases with a low VDO, this could be lifted digitally by lengthening the articulator pin. From this point onwards, the teeth were visualized in 3D: the shape, size, and position of each individual tooth could be adjusted, with a view to achieving a lingualized occlusion. Using the Real View tool, such changes were immediately reflected in the two-dimensional facial photograph.

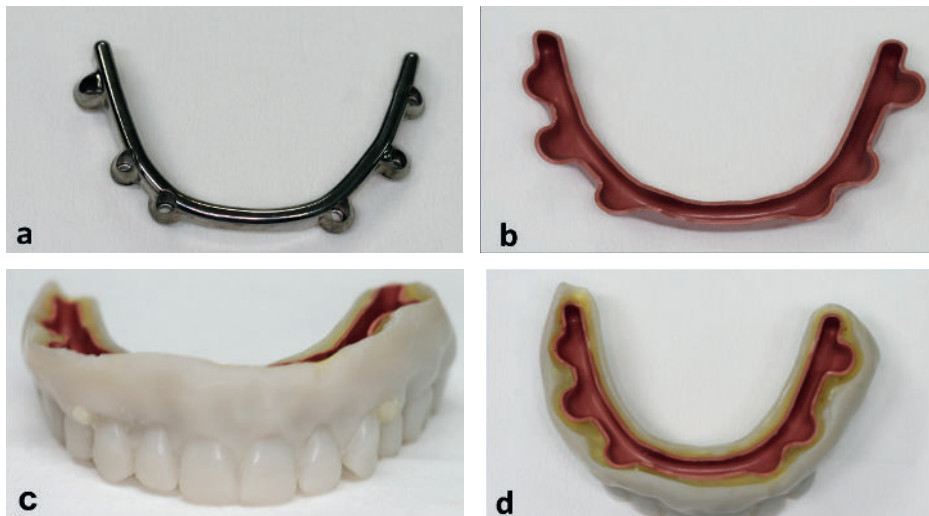


Figs 2a-e. Digital designs of the titanium bar and the PEEK sliding mechanism in laboratory session 1. (a) The original CDs in CO were matched with the IOS of both the edentulous maxilla and mandible, with the scan bodies included; (b) design of the bar, (c) design of the PEEK female part over the bar, (d) the PEEK female parts in isolation, (e) the original CDs and planned position of the PEEK parts.

Once the arrangement of the teeth was approved, the amount of remaining space was known, and the titanium bars in the maxilla and mandible could be positioned to the implant shoulder (Fig 2b) using the attached gingiva and the virtual teeth for orientation. Care was taken to follow the contour of the alveolar mucosa with a bar width of only 2 mm. The bar was designed to be as high as possible, allowing optimal friction between it and the PEEK female part. Subsequently, based on the digital bar design, the female parts were designed digitally in the same session (Figs 2c to e).

The bars were milled from Core Titanium (Core3dcentres, Las Vegas, NV, USA) using five-axis precision milling machines (CORiTEC 350i, imes-core, Eiterfeld, Germany) (Fig 3a) and the computer-assisted manufacture program hyperDENT (FOLLOW-ME! Technology, Munich, Germany). The bars were machined from a solid titanium monoblock, making them stronger and more accurate than traditional castings. The female parts were milled from PEEK discs (PEEK Med; Dental Direkt, Spenge, Germany) (Fig 3b).

Based on the patient's aesthetic wishes and the digital information obtained from the original CDs, a trial IOD was printed using NextDent Try-In (NextDent, Soesterberg, The Netherlands) to check the VDO, CO, tooth alignment, tooth size and lip support. In preparation for the second clinical

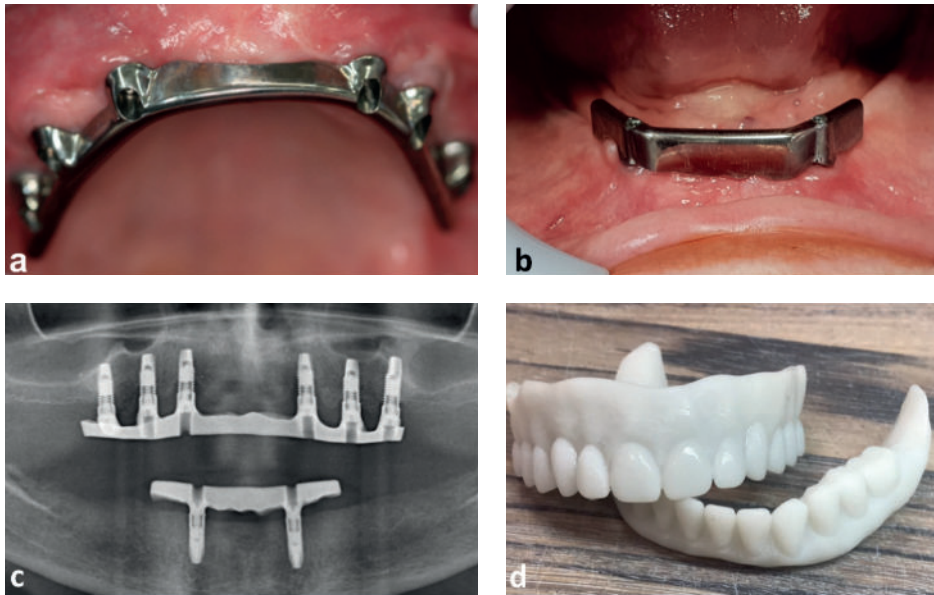


Figs 3a-d. The titanium bar and PEEK sliding mechanism produced in laboratory session 1. (a) Maxillary titanium bar; (b) milled PEEK female part; (c) frontal view and (d) view from underneath of the PEEK female part fixed into the maxillary trial IOD using yellow wax.

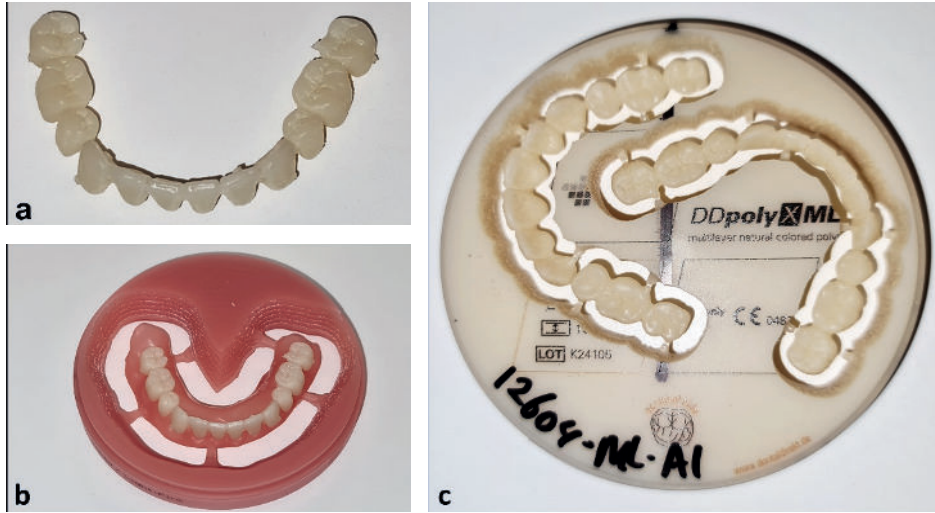
session, the PEEK female part was secured temporarily with yellow wax in the maxillary and mandibular trial IODs (Fig 3c and d).

Clinical session 2

The titanium bars were temporarily placed onto the implants (Figs 4a to c) and the trial IOD was inserted (Fig 4d). The VDO and CO were checked and approved. Using the Design Studio program in combination with the Real View tool, the aesthetics were discussed with the patient, and a slight correction was made to the midline in the final digital design.



Figs 4a-d. Placement of the titanium bars and insertion of the trial IOD in clinical session 2. Insertion of the (a) maxillary and (b) mandibular titanium bars; (c) panoramic radiograph; (d) trial IOD.



Figs 5a-c. CAD/CAM milling of the final IOD in laboratory session 2. (a) A row of teeth as milled; (b) view from above of the maxillary and mandibular teeth milled from the multilayered natural-coloured polymer block; (c) the teeth were positioned in the milled denture base.

Laboratory session 2

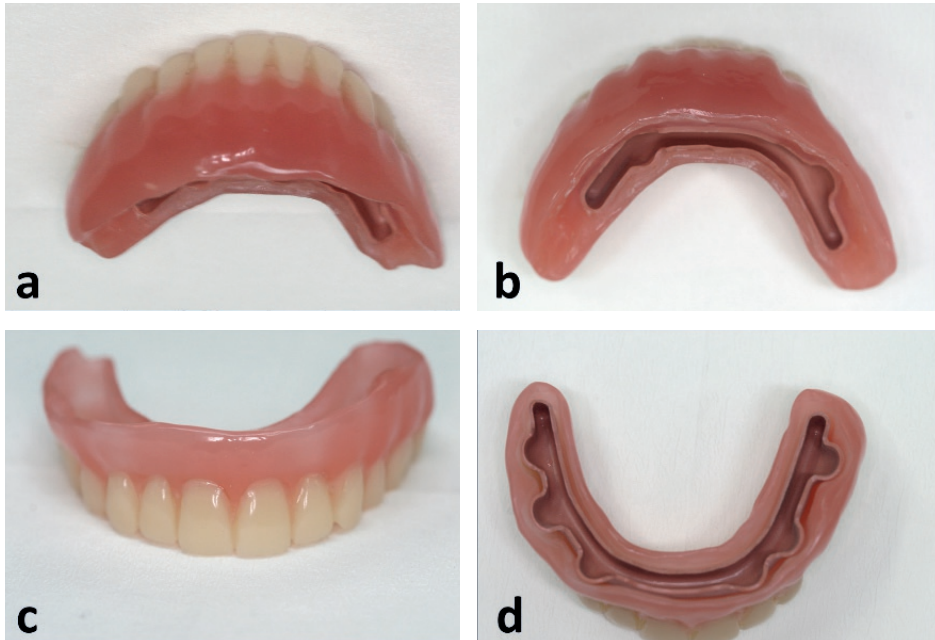
After all the adjustments were processed, the final IODs were fabricated. The teeth were all milled together in a row (Fig 5a) from a DDpolyXML disc (Dental Direkt), which consists of a multilayer acrylic resin polymer based on PMMA (Fig 5c). The IOD base itself was milled from a Vita Vionic Base (VITA Zahnfabrik, Bad Säckingen, Germany), which is composed of a high-quality industrially polymerized acrylic resin polymer that features shade stability and a flexural strength of 91 megapascals, according to the manufacturer's specification (figure 5c). In contrast to the maxillary IOD, the PEEK part was already glued into the mandibular IOD.

Clinical session 3

In the final clinical session, both titanium bars were placed onto the implants, then the mandibular IOD was inserted first (Figs 6a and b).

Subsequently, the PEEK female part was slid onto the maxillary bar. To allow for correction, the IOD was first fitted over the PEEK part. After confirmation that the IOD had achieved the appropriate dental display in the proper VDO and CO (Fig 6c), patient's mandible was manually guided into CO, and its position was consolidated using bite compound. Subsequently,

through small perforations in the PMMA base, a self-curing Ufi Gel (VOCO, Cuxhaven, Germany) was injected to fix the PEEK female part into the maxillary IOD (Fig 6d). The remaining space between the PEEK female part and prosthesis was then filled with Ufi Gel and smoothed. Finally, the maxillary IOD was also inserted (Fig 6e).



Figs 6a-d. Insertion of the final IODs in clinical session 3. (a) Frontal view of the mandibular IOD, including the PEEK female part; (b) view from underneath the mandibular IOD, including the PEEK female part; (c) final maxillary IOD base without the PEEK female part; (d) view from underneath the maxillary IOD with the PEEK female part glued in position.



Fig 6e frontal clinical view: final IODs in position.

Results

Clinical outcome after one year

No prosthetic complications were noted after 1 year. Oral hygiene was sufficient, and the measured pockets were less than 4 mm deep for all implants. The stability of the IODs exceeded expectations; during speaking and eating, they did not lose their retention. Even after 1 year of wear, the patient still had to exert considerable force to remove her IODs. She stated that she would recommend this type of IOD also to others and was especially enthusiastic about the small size and therefore nicknamed her maxillary IOD her “bikini prosthesis”.

Patient-related outcome measure (PROM)

The patient awarded a VAS score of 3 and an OHIP-20 score of 63 for her level of satisfaction with her original CDs. After 1 year, the VAS score increased to 9. The OHIP-20 score improved to 22, thus almost achieving the maximum score of 20.

Discussion

The present case report demonstrates the use of a fully digital workflow, including registration of the maxillomandibular relationship, to produce permanent IODs milled from prefabricated PMMA discs using PEEK as the sliding mechanism. This workflow offers various benefits; it reduces costs and the number of treatment sessions required and enables the patient to participate actively in the design stage using the Smile Design program.

Registration of the maxillomandibular relationship has always been challenging in the CAD/CAM fabrication of dentures. This present report was the first to have used the original CDs to achieve this goal; however, it is crucial that the original CDs have the correct CO when using this approach. In the Netherlands, patients who want their insurance company to reimburse them for their IODs must already be wearing CDs that provide a proper fit and CO. The cost of IODs can only be reimbursed if the treating dentist has officially certified prior to implant treatment that, despite having a set of well-designed and well-fitting CDs, the patient still suffers from poor CD retention that heavily impairs oral functions, such as eating and drinking. If this condition is not met, new CDs must first be manufactured and worn for 1 year before the patient is eligible for reimbursement of both their implants and IOD production.

If an inadequate fit is identified in the first clinical session, the denture base can be relined with soft material (Soft-Liner; GC, Tokyo, Japan) before scanning. When a premature contact is present, a correct CO can be achieved by selectively grinding and then fixating the CO with bite compound. Only when CDs show a proper fit and CO can a digital model be created that allows for the design of the bars, female parts, and trial IODs.

Due to its favorable strength, rigidity, and lightweight nature, PEEK is often used for prosthodontic solutions, such as crowns, and removable and fixed partial dentures, and for maxillofacial prostheses.¹⁸ PEEK is extremely resistant and has a low modulus of elasticity (3.6 GPa), which is over 30 times lower than titanium (120.0 GPa). It is therefore an ideal material for load-bearing indications, as it reduces the load on the titanium bar. It is monomer-free, adheres to PMMA, and shows outstanding sliding qualities, for example in telescopes.¹⁸

Spies et al¹¹ examined the employment of PEEK as a sliding mechanism in IODs, but only for temporary use. They fabricated a trial IOD from PMMA, which slid over two separate implant-supported bars positioned in the lateral areas of the maxilla, and after three months of wear, this PMMA prototype was scanned and used for the final IOD design, which was subsequently milled from zirconia, into which PEEK female parts were polymerized.¹¹ Mangano et al,¹² meanwhile, used PEEK make the bar and fixed four ball attachments to it, with their final IOD being made from traditional two-component PMMA. In a clinical session, after inserting the female parts onto the ball attachments, these were polymerized into the IOD.¹²

Using a trial IOD offers the advantage of allowing the retention, fit, lip support, occlusal plane, dental display, midline, and speech to be checked. Corrections can be made chairside, for example, by adjusting the CO by grinding, drawing the correct midline, applying yellow wax when more lip filling is needed, and, if indicated, by performing a new maxillomandibular registration in CO using bite compound, after which the scanned buccal surfaces can be transferred into the digital model.

Temporary PMMA prototypes were also used in to fabricate fixed restorations.^{4,13} First, the original CDs were transformed into an initial screw-retained interim prosthesis, which was then digitalised, then based on this, a second screw-retained interim prosthesis was printed from PMMA.^{4,13} After 3 months of wear, sufficient prosthetic information had been gathered to produce the final construction: a screw-retained full-arch implant-supported zirconia prosthesis.^{4,13} As a variation of this, Scarano et al¹⁹ produced fixed zirconia prostheses cemented on a titanium bar.

Today, highly cross-linked industrially polymerized PMMA discs exhibit sufficiently high homogeneity, strength and colour stability to produce the denture bases and teeth of permanent IODs and can thus compete with zirconia constructions. Unlike zirconia, PMMA can be repaired easily using conventional PMMA resins. Although a low failure rate was reported for zirconia constructions in the short term, they run a substantial risk of minor complications related to the chipping of veneered porcelain.²⁰ Long-term research is needed to determine whether IODs milled from PMMA discs will continue to function well over time.

Compared with traditional two-component PMMA, CAD/CAM milling of PMMA discs offers multiple advantages. There is no need to flush out toxic residual monomer and no press-heating is required, thus removing the issue of shrinkage and the resulting problems with the fit. One disadvantage of the proposed digital workflow is that it omits the traditional aesthetic try-in

phase, during which the patient wears a trial denture wax-up onto which small adjustments can be made directly. Instead, the patient judged the colour and arrangement of her teeth by her facial image, which can be easily edited on site using a Smile Design program. Future research should focus on establishing whether there is a difference between aesthetic result achieved using Smile Design and that obtained with the traditional aesthetic try-in phase.

Conclusions

By making prudent use of the information gathered from the original CDs, IODs can be designed using a fully digital workflow. In particular, scanning the original CDs in CO is essential to generate data that can be transferred to the final IOD design. By milling both the teeth and the denture base from PMMA discs, permanent robust IODs can be produced in just three clinical sessions. The associated PEEK female parts/sliding mechanisms are resistant to wear and provide sufficient retention, resulting in a high OHRQoL and patient satisfaction.

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PART I

CURRENT EVALUATIONS OF PROMS AND COST ANALYSES

Summary Box

What is known

Implant-supported overdentures (IODs) increase clinical effectiveness: bite forces and chewing efficacy increase.

Implant-supported overdentures (IODs) also increase patients' oral health related quality of life (OHRQoL) as compared to conventional dentures (CDs).

What this study adds

The existing evidence on the added value of IODs and the methodologies used were reviewed.

Cost-effectiveness analyses (CEAs) and cost-utility analyses (CUAs) are the proper instruments to calculate the incremental costs (IOD versus CD) in relation to the incremental health improvement.

CHAPTER 3

What is the evidence on the added value of implant-supported overdentures?

Van de Winkel T, Heijens L, Listl S, Meijer G. What is the evidence on the added value of implant-supported overdentures? A review. *Clin Implant Dent Relat Res.* 2021 Aug;23(4):644-656. doi: 10.1111/cid.13027. Epub 2021 Jul 15. PMID: 34268866; PMCID: PMC8457103.

Abstract

Background

Implant-supported overdentures (IODs) have been reported to increase patients' oral health-related quality of life (OHRQoL) in comparison with conventional dentures (CDs); however, the conclusiveness of evidence on the clinical effectiveness and value for money of IODs versus CDs remains unclear.

Purpose

To review how the added value of IODs is demonstrated in literature.

Materials and Methods

MEDLINE, EMBASE, and the Cochrane Database were searched for randomized control trials, controlled clinical trials, and prospective cohort studies containing evaluations of the economic and health benefits and costs of IODs. Information about clinical effectiveness, such as magnitude of bite forces or chewing efficacy, OHRQoL, costs, and cost-effectiveness of IODs, was extracted.

Results

A total of 17 articles were included, reporting 15 economic evaluations: 11 cost utility analyses (CUAs), 2 of which were combined with a cost-effectiveness analysis (CEA), and 2 cost-benefit analyses (CBAs). Seven CUAs used the Oral Health Impact Profile (OHIP) questionnaire while four used satisfaction questionnaires to assess the OHRQoL. One study applied quality-adjusted prosthesis years (QAPYs) for this purpose. The CBAs expressed both the beneficial outcome and the costs of the IOD in monetary terms. The included studies employed a large variety of economic evaluation methods, which limited cross-study comparability.

Conclusions

On the basis of existing economic evaluations, IODs have frequently been suggested to be a cost-efficient treatment alternative to CDs; however, the comparability between the various economic evaluation studies was limited due to the different outcome measures used. In addition, it remains unclear whether the additional health benefits of IODs outweigh the higher costs. This is largely dependent on the decision maker's valuation of oral health outcomes. Future research is encouraged to further elucidate patient willingness to pay for IODs and the societal return on investing in IODs more generally.

1. Introduction

Edentulism (being toothless) can lead to significant functional impairment, as well as unfavorable esthetic and psychological changes in patients. Reported drawbacks include restrictions in diet and a limited ability to eat certain foods,¹ speech impairment, and the loss of support for facial musculature, which has an ageing effect on appearance.² Edentulism is even classified as a physical handicap by the World Health Organization.³

Installing dental implants has the potential to mitigate these drawbacks. Many articles corroborate that implant-supported overdentures (IODs) provide significantly higher satisfaction levels, quality of life, and better mastication than mandibular conventional dentures (CDs).⁴⁻¹⁰ As a result of these positive findings, since 2002 it has been recommended that, in case of lack of retention, a mandibular IOD retained by two interforaminal implants (IOD-2) should be considered the first treatment choice.¹¹ Because of the palate as substantial bearing surface, the CD remains the first step in prosthetic rehabilitation for the edentulous maxilla. Nevertheless, the success of IODs in terms of stability, function, speech, and patient satisfaction has also been shown for the upper jaw.¹¹⁻¹³ An extra advantage of the presence of functioning implants is that clinically significant progressive bone loss is prevented.¹⁴ Disadvantages, however, are the invasive treatment, need for maintenance, high costs and risks for peri-implantitis.

Despite their benefits, IODs also incur higher treatment costs than CDs, leading to the question of whether IODs provide reasonable value for money. An economic evaluation means “ensuring that the value of what is gained from an activity outweighs the value of what has to be sacrificed”.¹⁵ Such economic calculations can inform patients, healthcare providers, insurers, and policy makers about IOD value for money.¹⁶⁻¹⁸ In order to determine whether the benefits produced by a particular program exceed the opportunity costs of providing that program, a reliable method of measuring and comparing outcomes is required.⁽¹⁹⁾ After all, the diversity in included cost-categories, the various types of economic evaluation used and the different interpretations of it, may complicate the drawing of firm conclusions.

Beneficial aspects for patients can be expressed in terms of clinical effectiveness, such as the number of prosthetic complications, the magnitude of bite forces in newtons, or measuring the masticatory efficacy. In contrast, patient-reported outcome measures (PROMs) describe patient’s perceived health benefits in qualitative terms; for example, patient satisfaction is often scored with the aid of questionnaires asking about general satisfaction and/or

masticatory ability with different food types. Another way to identify PROMs is to measure the oral health-related quality of life (OHRQoL). In dentistry for this purpose the Oral Health Impact Profile (OHIP)-list is often used.²⁰

Various types of economic evaluation have been presented.^{21, 22} Both cost-effectiveness analyses (CEAs) and cost-utility analyses (CUAs) calculate the incremental costs of a specific treatment in relation to incremental health improvement. CEAs describe clinical effectiveness, such as the number of prosthetic complications or magnitude of bite forces in newtons. CUAs are typically expressed in natural (qualitative) units such as OHRQoL, life years gained, or quality-adjusted life years (QALYs). Both CEAs and CUAs rely on the incremental cost-effectiveness ratio (ICER), which compares the difference in costs against the health improvement associated with two or more treatment alternatives.^{17, 21} CEAs and CUAs are especially suitable for interventions that are more effective than their alternatives but also cost more. In cost–benefit analyses (CBAs), both health outcomes and costs are expressed in monetary terms, thus enabling a direct comparison. For example, it has long been recommended to assess patient preferences in terms of “willingness to pay” (WTP) for different treatments, such as implant placement.²³

Conceptually similar to WTP is the concept of WTA (“willingness to accept”), in which patients are asked which amount of money they would accept to go back to their baseline situation, for example from their IOD to their CD. For nonpatients, this is the maximum amount that they are willing to receive to forgo implant therapy. WTP/WTA are thought to be important in health technology assessments by providing insight into the impact that the risks and benefits of treatments have on society.²⁴

2. Materials and Methods

Thomas Van de Winkel and Laura Heijens conducted a search of the literature written in English and published between January 1995 and August 2020 that compared health outcomes to the involved costs with respect to an IOD. Special attention was focused on the relationship between costs and the extent of the increased OHRQoL.

The MEDLINE, EMBASE, and the Cochrane Database were screened using the following terms: (economic evaluation) and (dental implant) and overdenture. As the search results were minimal, it was decided to choose for the more general terms: cost and (dental implant) and overdenture.

Table 1. The PICO (population, intervention, control, and outcomes) format as strategy for the research question

PICO principle	
Population	Edentulous patients
Intervention	Treatment with IOD
Comparison	CD (new or pre-existing)
Outcomes	(1) Health benefits, such as satisfaction, chewing capacity, OHRQoL (2) Costs, (3) Value for money.

Inclusion criteria: for this review, only studies that focused on economic evaluations while providing information about both benefits in OHRQoL and costs of IODs were included, meaning CEAs, CUAs, and CBAs.

Exclusion criteria: case reports, articles which were written in a language other than English, or those involving patients who still had natural teeth were excluded.

Systematic reviews and meta-analyses obtained from the database search were subsequently perused for other papers on this topic (snowballing). The selected articles were independently evaluated by two reviewers (Laura Heijens and Thomas Van de Winkel). In case of disagreements about inclusion, a consensus discussion was conducted. If no consensus could be reached, Gert Meijer took the final decision. A Cohen's kappa analysis was calculated to determine the inter-evaluation reliability of the articles included between the two evaluators.²⁵

2.1 Quality assessment

For each selected article, the 24-item checklist of the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) was used to evaluate whether each item was met. As the aim of the CHEERS list is to optimize the reporting of health economic evaluations, only the quality of reporting is judged, not the quality of conduct.^{21, 22} The selected randomized controlled trials (RCTs) and clinical controlled trials (CCTs) were evaluated by two independent reviewers (Laura Heijens and Thomas Van de Winkel). In case of disagreement, first a discussion took place to come to a mutual agreement. If no agreement was reached, a final decision was made by Gert Meijer.

To further appraise the risk of bias and the methodological approach of the selected RCTs and CCTs, the respective studies were evaluated by two independent reviewers (Laura Heijens and Thomas Van de Winkel) using Cochrane Risk of Bias Tool.²⁶ Again, in case of dispute, discussions were held to reach agreement, which, if unsuccessful, was followed by a final decision

of Gert Meijer. The articles were screened for randomization, blinding of randomization, selective reporting, blinding of staff and participants, blinding of the results, and the presence of incomplete data. Studies were judged to have a “high risk of bias” if one of the items showed a high bias score. If one of the items had an “uncertain risk of bias”, but no “high risk of bias” on the other items, the study was considered as an “uncertain risk of bias”. In cases where all items scored a low risk of bias, the study was categorized as “low risk of bias”. Cohort studies were qualitatively assessed using Form III for assessing a cohort study by the Dutch Cochrane Center (2003). In addition, the articles were screened for the following confounding factors: whether the research was funded by the manufacturer (potential benefit), inclusion or exclusion criteria related to patient factors (disease, mental state), individual factors such as age and number of dental implants, and date of publication with reference to costs.

2.2 Data extraction

For the selected articles, it was first noted if a CEA, CUA, or CBA was included. Furthermore, the following items were recorded: authors, year of publication, inclusion and exclusion criteria regarding the health of the participants, number and age of the participants, follow-up period, number and location of the implants, outcome measures, and the raw data and conclusions about the increase in OHRQoL. Specifically, information was gathered about the type of costs, such as for IOD fabrication and costs incurred by loss of working time due to travel and attending treatment sessions.

For analytical purposes, it was also noted in which year and in which currency the costs were presented. All raw data were converted to the same currency (US dollars; USD) using the exact exchange rate of the year in which the investigation was performed to allow an optimal comparison.²⁷ If the year in which the costs were incurred was not clear, the relevant author of the article was consulted.

3. Results

A total of 355 studies were identified based on the search terms. After the first screening, which consisted of reading titles and abstracts, 59 and 45 articles were selected, respectively. After intensively evaluating the relevant 45 articles, it appeared that some publications lacked important data or described the same patient population. Ultimately, 17 studies remained

that were suitable for analysis (Figure 1). With respect to the inclusion of the selected articles, between the two reviewers a substantial agreement (Cohen’s kappa: 0.72) was measured.⁽²⁵⁾

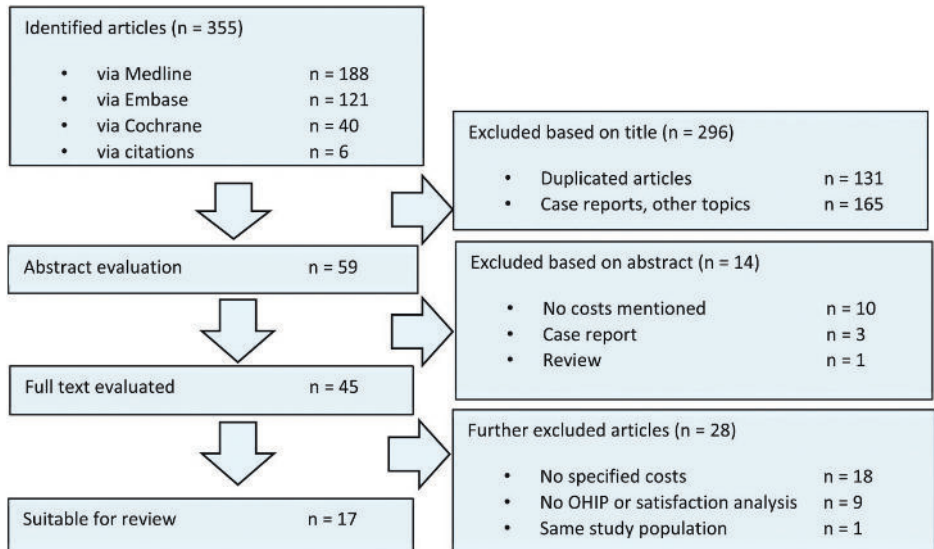


Figure 1. The search strategy used to identify the 17 articles to be reviewed

3.1 Characteristics of included studies

In Tables 2 and 3, the characteristics of all 17 included studies are presented, comprising five RCTs,²⁸⁻³² five CCTs,³³⁻³⁷ two cohort studies,^{38, 39} and five economic evaluations.⁴⁰⁻⁴⁴ For a single study population in the Netherlands, Timmerman and colleagues reported the mandibular IOD satisfaction score³² and Stoker and colleagues the mandibular IOD costs.³¹ Taking these articles together, this randomized study can be labelled a CUA. The same accounts for the two studies presented by Wetzels and colleagues; functional benefits were described in 2016, and costs in 2017. As such, they provided a CEA/CUA analysis of the installation of a mandibular IOD-2 in patients who have been treated for oral cancer.^{35, 36}

In total, nine CUAs^{28, 29, 31, 33, 34, 37-40} were presented, plus two combinations of CEA/CUA^{31, 32, 35, 36} and four CBAs.⁴¹⁻⁴⁴ The scores of the 24-item CHEERS checklist varied between 10 (42%) and 20 (83%).²²

Of the RCTs and CCTs, seven studies presented a “high risk of bias”,^{28, 30, 33-37} as did the two cohort studies.^{38, 39} An “uncertain risk of bias” was noted for three studies.^{29, 31, 32} In summary, the quality of all included RCTs, CCTs, and cohort studies was debatable or low.

3.2 CEA/CUA: Study design

In total four studies presented a follow-up period varying between 6 month and 1 year and involved real spend costs.^{28-30, 34} Calculated costs were also reported over a 5-year period³⁹ and over 8 years.^{31, 32} The only long term study involving real costs followed patients for a 14-year period.³³ Although Heydecke and colleagues presented costs over an even longer period (17.9 years), real costs were not included, but calculated based on the Delphi group opinion technique, using an annual price increase of 3-5%.^{29, 45}

The same accounts for the study of Zitzmann and colleagues: they collected financial data over a three years period and estimated costs for a 10-year period also using an annual price increase of 3-5%.³⁷ List and colleagues calculated costs that were based on the German private dental insurance fee.⁴⁰ Within this system, providers’ fees can be adjusted by different factors corresponding to the treatment complexity (factor 1: low complexity; factor 2.3: average complexity; factor 3.5: high complexity). One study reported maintenance costs as a percentage of the initial costs.³⁸

Most studies compared the IOD to the original CD.^{28, 30-32, 35-40} In two studies patients were divided into groups in which patients received a new CD or a IOD-2.^{29, 37} In two other studies, first a new CD was manufactured. Subsequently, a few months later implants were installed and the IOD-2 delivered.^{33, 34}

Most studies focused on IOD’s on conventional implants, two studies concentrated on IODs on MDI’s.^{28, 30} All but one study addressed IODs in the lower jaw. Solely Listl and colleagues calculated costs for an IOD-4 versus IOD-6 in the upper jaw.

Table 2. Characteristics of the included studies

Author	Study type	Type of analysis / Score of CHEERS list	Patients (n)	Follow-up period (months)	Short description of study	Outcome Reported
Alfadda and Attard³³⁾	CCT	CUA 18 (24) 75%	75	168	Cost analysis for IOD; immediate versus conventional loading	Total costs, OHIP-20, ICER.
Attard and colleagues³⁴⁾	CCT	CUA 14 (24) 58%	77	12	Clinical costs, PROMS for immediate loading protocol for IOD	Total costs, OHIP-20, ICER.
Della Vecchia and colleagues²⁸⁾	RCT	CUA 17 (24) 71%	120	6	Cost-effectiveness analysis of IOD. MDI versus conventional implants	Total costs, OHIP-EDENT, ICER.
Heydecke and colleagues²⁹⁾	RCT	CUA 19 (24) 79%	60	60		Total costs, OHIP-20, cost-effectiveness.
Jawad and colleagues³⁰⁾	RCT	CEA/CUA 14 (24) 58%	46	6	Cost-effectiveness analysis of IOD-2 or IOD-4 MDIs versus conventional implants	Total costs, OHIP-20, cost-effectiveness. Chewing capacity
Listl and colleagues⁴⁰⁾	EE	CUA 20 (24) 83%	833	120	Cost-effectiveness analysis of 6 and 4 implants in the edentulous maxilla	Manufacturing-, maintenance cost, CEAC
Matthys and colleagues³⁸⁾	Cohort study	CUA 10 (24) 42%	56	60	Maintenance cost ratios of Locators	Cost ratio OHIP-14
Matthys and colleagues³⁹⁾	Cohort study	CUA 17 (24) 71%	116	60	Initial and maintenance costs for Locator versus Dalla Bona ball implants	Cost-effectiveness plane, OHIP-14
Stoker and colleagues³¹⁾ and Timmerman and colleagues³²⁾	RCT	CUA 15 (24) 63%	110	96	Cost analysis for three types of IOD in lower jaw.	Total costs
	RCT		110	12	Satisfaction for three types of IOD in lower jaw	Satisfaction questionnaire
Wetzels and colleagues³⁵⁾ and Wetzels and colleagues³⁶⁾	CCT	CEA/CUA 16 (24) 67%	193	60	Outcome of two implants installed during ablative surgery (DAS protocol) or postponed (P protocol)	Costs, chewing capacity, satisfaction questionnaire
	CCT					
Zitzmann and colleagues³⁷⁾	CCT	CUA 18 (24) 75%	60	36	Cost effectiveness analysis of two different IODs and CD	Total costs and ICER (QAPYs)

Abbreviations: CCT, controlled clinical trial; CEA, cost-effectiveness analysis; CEAC, cost-effectiveness acceptability curve; CUA, cost-utility analysis; EE, economic evaluation; ICER, incremental cost-effectiveness ratio; OHIP: Oral Health Impact Profile, PROM, patient-related outcome measure; RCT, randomized clinical trial; QAPY, quality-adjusted prosthesis years.

Table 3. Characteristics of the economic evaluation (EE) studies describing WTP

Author	Type of analysis / Score of the 24-items CHEERS list	Patients (n)	Follow-up period (months)	Short description of study	Outcome reported
Esfandiari and colleagues⁴¹	CBA 12 (24) 50%	36	24	WTP/WTA IOD-2	<ul style="list-style-type: none"> Satisfaction score (VAS 0–100) 61% (n): WTP: \$3399 USD^a 89% (n): WTP: \$3399 USD^b in case of monthly payments 92% (n): WTA: priceless
Sendi and colleagues⁴²	CBA 15 (24) 63%	16	60	WTP/WTA IOD-2	<ul style="list-style-type: none"> Satisfaction (VAS 1–10) WTP: 4971 USD^b WTA: 26157 USD^b
Srivastava and colleagues⁴³	CBA 12 (24) 50%	38	N/A	(partially) dentate were interviewed WTP/WTA IOD -2	<ul style="list-style-type: none"> WTP: \$5481 USD^c WTP: \$171 USD^c as one-time payment, with 20% chance of becoming edentulous WTA: priceless
Srivastava and colleagues⁴⁴	CBA 12(24) 50%	317	N/A	WTP/WTA (partially) dentate were interviewed about IOD-2	<ul style="list-style-type: none"> WTP: \$5348 USD^d WTP: \$27 USD^d, as monthly payment with a 20% chance of becoming edentulous WTA: priceless

Abbreviations: CBA, cost-benefit analyses; CHEERS, Consolidated Health Economic Evaluation Reporting Standards; WTA, willing to accept; WTP, willing to pay

^a Esfandiari and colleagues⁴¹ used 2008 Canadian dollars (CAD) in their article (1 CAD = 0.9441 USD)

^b Sendi and colleagues⁴² used 2013 Swiss francs (CHF) in their article (1 CHF = 1.0793 USD)

^c Srivastava and colleagues⁴³ used 2011 Canadian dollars (CAD) in their article (1 CAD = 1.0114 USD)

^d Srivastava and colleagues⁴⁴ used 2012 Canadian dollars (CAD) in their article (1 CAD = 1.0002 USD)

With respect to the aims: two studies compared an IOD-2 to a CD,^{29, 37} two studies compared conventional versus immediate loading,^{33, 34} and one group compared two surgical protocols in oncology patients.^{35, 36} And the others compared two treatment modalities, for example, MDIs versus conventional implants,^{28, 30} ball attachment versus locators,³⁹ and ball attachments versus bar attachment.^{31, 32}

3.3 CEA/CUA: Total costs

In Table 4, the "total costs" of various CD and IOD types for the edentulous lower jaw are shown.

Initial costs were low in Canada; \$627 for a CD versus \$1796 for an IOD-2.²⁹ In Switzerland initial prices were higher: \$1540 for a CD and \$4230 for an IOD-2.³⁷ It became clear that an IOD-2 is 2-3 times more expensive than a CD in terms of initial costs.

After 1 year Heydecke and colleagues¹² calculated \$1385 of total costs for a CD, which increased to \$3801 after 17.9 years.²⁹ For the IOD-2 costs were \$2458 after one year, which went up to \$5960 in 17.9 years. Initially an IOD-2 was almost 3 times more expensive than a CD, however, after 17.9 years this ratio decreased to less than 2 times.²⁹ Apparently, an IOD-2 becomes relatively cheaper in time, however, continues to be more expensive than a CD.²⁹ This outcome was corroborated by Zitzmann and colleagues, who calculated that total costs after three years were \$2242 and \$ 5413, for a CD and IOD-2, respectively, resulting in a ratio of 2.4.³⁷

Although the phrase "total costs" was often used, the definitions of this term varied. Initial costs were calculated mostly on an individual basis including, if present, the national dental tariff structure for the purchase of the implants, costs of surgical treatment such as the salary of the clinical workers and supporting personnel, the use of the operating room, and medicines. Costs of the prosthodontic treatment were also included in this category, in addition to laboratory fees. "Maintenance costs" comprised the ongoing costs of the prosthodontic treatment and laboratory fees, such as remakes, relines, hardware replacement, and professional services provided by the prosthodontist and/or the surgeon. Sometimes, the costs of annual recall visits ("recall costs") were included in the "maintenance costs". Only few studies included "patient time costs", corresponding to the loss of income from missing work due to treatment or travelling.^{33, 34, 37}

3.4 CEA/CUA: Patient-reported outcome measures

PROMs can be expressed using satisfaction questionnaires. For example, the McGill denture satisfaction questionnaire⁴⁶ was applied by Della Vecchia and colleagues.²⁸ Using a VAS scale (0–100 mm), the following variables were assessed: general satisfaction, ability to speak, and esthetics. In addition, the ability to chew five different foods was recorded: standard-sized pieces (3 x 1 x 1 cm) of raw apple, bread, raw carrot, cheese, and dry sausage. An alternative is the Denture Satisfaction Scale (DSS),⁴⁷ as executed by Attard and colleagues³⁴, which comprises 12 questions and is scored using a 5-point

Table 4. Type of construction in relation to total costs

Type of construction	Time period	Total costs: initial + maintenance + complication + recall + travel time
CD in mandible	1 year	\$1385 ^a ; Heydecke and colleagues ²⁹
	17.9 years	\$3801 ^a ; Heydecke and colleagues ²⁹
	3 years	\$2242 ^b ; Zitzmann and colleagues ³⁷
IOD on two mandibular implants	14 years	\$4349 ^c ; Alfadda and Attard ³³ (conventional loading)
	14 years	\$4022 ^c ; Alfadda and Attard ³³ (immediate loading)
	1 year	\$1983 ^d ; Attard and colleagues ³⁴ (immediate loading)
	1 year	\$1779 ^d ; Attard and colleagues ³⁴ (conventional loading)
	0.5 year	\$566 ^e ; Della Vecchia and colleagues ²⁸
	1 year	\$2458 ^a ; Heydecke and colleagues ²⁹
	17.9 years	\$5960 ^a ; Heydecke and colleagues ²⁹
	0.5 year	\$1048 ^f ; Jawad and colleagues ³⁰
	5 years	\$4716 ^g ; Matthys ³⁹ (ball attachment)
	5 years	\$4302 ^g ; Matthys ³⁹ (locator attachment)
	8 years	\$3683 ^h ; Stoker and colleagues ³¹ (Dalla Bona ball)
8 years	\$3849 ^h ; Stoker and colleagues ³¹ (bar construction)	
5 years	\$3288 ⁱ ; Wetzels and colleagues ³⁵ (DAS protocol)	
	\$6108 ⁱ ; Wetzels and colleagues ³⁵ (P protocol)	
3 years	\$5413 ^b ; Zitzmann and colleagues ³⁷	
IOD on four mandibular implants	8 years	\$4912 ^h ; Stoker and colleagues ³¹ (bar construction)
	3 years	\$10,881 ^b ; Zitzmann and colleagues ³⁷
IOD on mandibular MDIs	0.5 year	\$318 ^e ; Della Vecchia and colleagues ²⁸ (two MDIs)
		\$511 ^e ; Della Vecchia and colleagues (2018) ²⁸ (four MDIs)
	0.5 year	\$620 ^f ; Jawad and colleagues (2017) ³⁰ (two MDIs)
IOD-4 in maxilla	10 years	\$7494; Listl and colleagues (2014) ⁴⁰ (IOD-4)
IOD-6 in maxilla		\$8697 ^j ; Listl and colleagues (2014) ⁴⁰ (IOD-6)

Abbreviations: CD, conventional denture; IOD, implant-supported overdenture; MDI, mini dental implants. Note: Conversion table:²⁷ <https://www.ofx.com/en-au/forex-news/historical-exchange-rates/yearly-average-rates/>

^aHeydecke and colleagues used 1999–2000 Canadian dollars (CAD) in their article (1 CAD = 0.6733 USD)

^bZitzmann and colleagues used 2000 Swiss francs (CHF) in their article (1 CHF = 0.61 USD)

^cAlfadda and Attard used 2016 Canadian dollars (CAD) in their article (1 CAD = 0.7551 USD)

^dAttard and colleagues used 2002 Canadian dollars (CAD) in their article (1 CAD = 0.6367 USD)

^eDella Vecchia and colleagues used 2014 Brazilian reals (BRL) in their article (1 BRL = 0.5720 USD)

^fJawad and colleagues used 2017 British pound sterling (GBP) in their article (1 GBP = 1.288 USD)

^gMatthys and colleagues used 2020 Euros (EUR) in their article (1 EUR = 1.1290 USD)

^hStoker and colleagues used 2000 Euros (EUR) in their article (1 EUR = 1.0850 USD)

ⁱWetzels and colleagues used 2008 Euros (EUR) in their article (1 EUR = 1.4713 USD)

^jListl and colleagues used 2014 Euros (EUR) in their article (1 EUR = 1.3292 USD)

Likert scale with the following categories: (1) *totally satisfied*, (2) *very satisfied*, (3) *reasonably satisfied*, (4) *not very satisfied*, and (5) *not at all satisfied*. Other authors compiled their own questionnaire with different numbers of questions and scales.^{32, 35-37, 40-42}

To measure OHRQoL in dentistry, one of the Oral Health Impact Profile (OHIP)-lists can be used, which focusses solely on toothless patients, such as OHIP-14, OHIP-EDENT, and OHIP-20, which comprise 14, 19, and 20 questions, respectively.⁴⁸ Similar to the original OHIP-49, the OHIP-20 and OHIP-14 cover the same seven domains: functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap.²⁰ The responses are based on a Likert scale ranging from 0 for “*never*” to 4 for “*very often*”, meaning the maximum score for OHIP-20 is 80; the lower the score, the higher the OHRQoL that is achieved.

The effect of treatment using the OHIP system as PROM is depicted in Table 5. The OHIP-20 questionnaire was applied in four studies^{29, 30, 33, 34} the OHIP-14 in two studies,^{38, 39} and the OHIP-EDENT in one study.²⁸ Sometimes different Likert scales were used; for example, with total scores in the range of 0–80^{29, 33} or of 20–100.³⁴ Others introduced their own OHIP-20 version,³⁰ a six-point Likert scale varying between 1 and 6, covering nine items: (1) *ease of cleaning*, (2) *general satisfaction*, (3) *ability to speak*, (4) *comfort*, (5) *esthetics*, (6) *stability*, (7) *ability to chew*, (8) *function*, and (9) *oral condition*.³⁰

The OHIP-14 comprises 14 questions, each with a score between 0 (very positive) and 4 (very negative), resulting in a maximum score of 56. This was only used by Matthys and colleagues^{38, 39}

Della Vecchia and colleagues had a preference for the OHIP-EDENT, which consists of 19 questions with answers on a Likert scale of 0-2, leading to a maximum score of 38.²⁸ Only four domains were covered: masticatory discomfort, psychological discomfort, social disability, and oral pain/discomfort.⁴⁹

As alternative measure for PROMs, Zitzmann and colleagues used QAPYs, which corresponds to functioning for one year in the best possible prosthetic state.³⁷

Table 5. Change in OHIP points as a result of a CD, IOD-2, IOD-4, IOD on two MDIs, IOD on four MDIs.

Article	Mandibular IODs versus CDs: OHRQoL scored in three types of OHIP questionnaires; OHIP-14, OHIP-20, and OHIP-EDENT	Effect in QAPYs		
Alfadda and Attard ⁵³	CD 'old' (baseline)	71 OHIP-20 (Likert 0–4)		
	CD new	51 OHIP-20 (Likert 0–4)		
	IOD-2 'immediate' loading	28 OHIP-20 (Likert 0–4; after 1 year) 25 OHIP-20 (Likert 0–4; after 5 years) 34 OHIP-20 (Likert 0–4; after 14 years)		
Attard and colleagues ³⁴	CD 'old' (baseline)	71 OHIP-20 (Likert 1–5)		
	CD new	50 OHIP-20 (Likert 1–5)		
	IOD-2	24 OHIP-20 (Likert 1–5; after 1 year)		
Della Vecchia and colleagues ²⁸	CD 'old' (baseline)	14–18 OHIP-EDENT (Likert 0–2)		
	IOD-2	6 OHIP-EDENT (Likert 0–2; after 0.5 years)		
	IOD-2 on MDIs	3 OHIP-EDENT (Likert 0–2; after 0.5 years)		
	IOD-2 on MDIs	2 OHIP-EDENT (Likert 0–2; after 0.5 years)		
Heydecke and colleagues ²⁹	CD 'old' (baseline)	56 OHIP-20 (Likert 0–4)		
	CD new	47 OHIP-20 (Likert 0–4; after 1 & 17.9 years)		
	IOD-2	31 OHIP-20 (Likert 0–4; after 1 & 17.9 years)		
Jawad and colleagues ³⁰	IOD-2	41 OHIP-20 (Likert 1–6; after 0.5 years)		
	IOD-2 on MDIs	56 OHIP-20 (Likert 1–6; after 0.5 years)		
Matthys and colleagues ³⁸	CD 'old'	20 OHIP-14 (Likert 0–4; during intake)		
	IOD-2	3 OHIP-14 (Likert 0–4; after 1 & 5 years)		
Matthys and colleagues ³⁹	IOD-2 (Locators)	9 OHIP-14 point reduction; after 5 years		
	IOD-2 (ball attachment)	3 OHIP-14 points reduction; after 5 years		
Zitzmann and colleagues ³⁷	IOD-4	dental health state	CD 'old' (baseline): 0.37	IOD-4: 1.57
	IOD-2	preference	CD 'old' (baseline): 0.35	IOD-2: 1.46
	CD new	VAS 0–1	CD 'old' (baseline): 0.52	CD new: 0.68

Abbreviations: CD, conventional denture; IOD, implant-supported overdenture; MDI, mini dental implants; OHIP, Oral Health Impact Profile, QAPYs, quality-adjusted prosthesis years.

3.5 CEA/CUA: Incremental cost-effectiveness ratios

The cost-effectiveness of an IOD on 4–6 maxillary implants was calculated in only one study.⁴⁰ All others addressed an IOD in the lower jaw.²⁸⁻³⁹

In a CEA or CUA always an ICER is presented. For a mandibular IOD-2 versus a new CD, the ICER was \$81 per OHIP-20 point after one year³⁴ and \$152 per OHIP-20 point after 17.9 years.²⁹ Costs went up as the years passed: \$129, \$159, and \$362 per OHIP-20 point after one, five, and 14 years, respectively.³³

Using the OHIP-EDENT questionnaire, two studies proved that a mandibular IOD-2 on two MDIs resulted in a lower ICER score than an IOD on conventional implants: \$28 versus \$47²⁸ or \$17 versus \$39.³⁰ Even an IOD-4 on MDIs was cheaper than an IOD-2 on conventional implants (ICER \$38 versus \$47).²⁸

Zitzmann and colleagues also calculated an ICER, but formulated the measured effect in QAPYs.³⁷ The costs per QAPY were \$5551 for an IOD-2 versus \$12078 for an IOD-4 after three years. These amounts reduced in a 10-year period to \$2318 and \$4331 for an IOD-2 versus an IOD-4, respectively (Table 6).

3.6 CBA: Willingness to pay

All four included CBA studies (Table 3) focused on the costs of a mandibular IOD-2. Three studies originated from Canada,^{41, 43, 44} while one was conducted in Switzerland.⁴²

Esfandiari and colleagues⁴¹ interviewed patients who participated 2 years earlier in a RCT⁸ in which they all received a new CD in their upper jaw, combined with a new CD or an IOD-2 in their mandible. The authors claimed that about 50% of the participants would pay 3 times more for a mandibular IOD-2 (\$3399) than for a CD (\$1133). If payment in monthly instalments was allowed, even 96% of the respondents stated that they would pay \$3399 for an IOD-2 (Table 3). An average of 5 years after the mandibular IOD-2 installation, Sendi and colleagues conducted a telephone interview with the request to answer eight questions. Retrospectively, satisfaction rate was queried for the time of IOD-2 delivery, after six and 24 months, and at the moment of the interview.⁴² The average WTP price for an IOD-2 was \$4971.

Both studies conducted by Srivastava and colleagues addressed patients who were still dentate. In the first study questionnaires were used, in the second study WTP data were collected through telephone interviews or internet-based questionnaires. Both studies delivered the same WTP price (about \$5500) in one payment on condition of a 90% success rate.^{43, 44} Patients

Table 6. Incremental cost-effectiveness ratio (ICER) of a CD, IOD-2, IOD-4, IOD on two MDIs, IOD on four MDIs in the lower jaw in USD

Type of prosthesis in the lower jaw		Cost-effectiveness presented as ICER
IOD-2 implants	versus new CD	\$86 ^b per OHIP-20 point after 1 year; Attard and colleagues ³⁴ \$152 ^a per OHIP-20 point after 17.9 years; Heydecke and colleagues ²⁹ \$129 ^c per OHIP-20 point after 1 year; Alfadda and Attard ³³ \$159 ^c per OHIP-20 point after 5 years; Alfadda and Attard ³³ \$362 ^c per OHIP-20 point after 14 years; Alfadda and Attard ³³
IOD-2	versus CD 'old' (baseline)	\$47 ^d per OHIP-EDENT point after 0.5 years; Della Vecchia and colleagues ²⁸
IOD-2 on MDIs		\$28 ^d per OHIP-EDENT point after 0.5 years; Della Vecchia and colleagues ²⁸
IOD-4 on MDIs		\$38 ^d per OHIP-EDENT point after 0.5 years; Della Vecchia and colleagues ²⁸
IOD-2 IOD-2 MDIs	versus CD 'old' (baseline)	\$39 ^e per OHIP-EDENT point after 0.5 years; Jawad and colleagues ³⁰ \$17 ^e per OHIP-EDENT point after 0.5 years; Jawad and colleagues ³⁰
IOD-2 implants	versus new CD	\$5551 ^f per QAPY after 3 years; Zitzmann and colleagues ³⁷ \$2318 ^f per QAPY after 10 years; Zitzmann and colleagues ³⁷
IOD-4 implants	versus new CD	\$12,078 ^f per QAPY after 3 years; Zitzmann and colleagues ³⁷ \$4331 ^f per QAPY after 10 years; Zitzmann and colleagues ³⁷

Abbreviations: CD, conventional denture; IOD, implant-supported overdenture; MDI, mini dental implants; OHIP, Oral Health Impact Profile, QAPYs, quality-adjusted prosthesis years.

^aHeydecke and colleagues used 1999–2000 Canadian dollars (CAD) in their article (1 CAD = 0.6733 USD)

^bAttard and colleagues used 2002 Canadian dollars (CAD) in their article (1 CAD = 0.6367 USD)

^cAlfadda and Attard used 2016 Canadian dollars (CAD) in their article (1 CAD = 0.7551 USD)

^dDella Vecchia and colleagues used 2014 Brazilian reais (BRL) in their article (1 BRL = 0.5720 USD)

^eJawad and colleagues used 2017 British pound sterling (GBP) in their article (1 GBP = 1.288 USD)

^fZitzmann and colleagues used 2000 Swiss francs (CHF) in their article (1CHF = 0.61 USD)

are willing to prepay \$171 as one-time assurance premium for private dental insurance, meaning that they will be fully covered for a mandibular IOD-2 if needed in the future based on a 20% chance of becoming toothless.⁴³ In case of a 20% chance to become edentulous, the WTP was \$27 as monthly

payments for private insurance. The WTP was higher when household income or dental needs were higher.⁴⁴

In short, both dentate participants,^{43,44} as well as edentulous patients who have already been treated with implants^{41,42} were asked about WTP. Patient WTP for an IOD-2 on interforaminal implants varied from \$3399⁴¹ to \$4971⁴².

The WTA numbers are particularly interesting; when asked for how much money they would turn in their IOD-2 and go back to their original CDs, five patients valued the IOD-2 state from \$26.157⁴² to priceless⁴¹⁻⁴⁴ (Table 3).

4. Discussion

The findings of the present review indicated considerable variation in the type, reporting, and quality of economic evaluation studies on IODs in comparison with their baseline situation, which was always the existing or "old CD". Different questionnaires, diverse definitions of costs versus health outcome calculation methods, and varying timeframes were applied. With respect to IODs, variations in availability and affordability, pricing policies, level of reimbursement, and the discount rate made a comparison of the selected studies difficult.

Checklists such as CHEERS are commonly used in reviews to standardize the assessment of quality or completeness with respect to the economic evaluations. There is some discussion about how to interpret such checklists; with respect to CHEERS, the minimum reported cutoff for an evaluation to be considered "high quality" was 63%, while the maximum cutoff was 94%.²²

In our analysis, most CEA/CUA studies scored 63% or more, and thereby are judged at least as 'acceptable',^{32,33,35-37,39-41,43,44,46}

Three studies scored between 42-58%; their contribution was "average" or "low".^{30,34,38}

Except for one study (Sendi and colleagues⁴⁶) scores for CBAs were 50% illustrating that their contribution was "average".^{41,43,44}

4.1 CEA/CUA: Total costs

In Table 4, the "total costs" of various CD and IOD types for the edentulous lower jaw are shown.

Initial costs were low in Canada; \$627 for a CD versus \$1796 for an IOD-2.²⁹ In Switzerland initial prices were higher: \$1540 for a CD and \$4230 for an IOD-2.³⁷ It became clear that an IOD-2 is 2-3 times more expensive than a CD in terms of initial costs.

After one-year Heydecke and colleagues¹² calculated \$1385 of total costs for a CD, which increased to \$3801 after 17.9 years.²⁹ For the IOD-2 costs were \$2458 after one year, which went up to \$5960 in 17.9 years. Initially an IOD-2 was almost 3 times more expensive than a CD, however, after 17.9 years this ratio decreased to less than 2 times.²⁹ Apparently, an IOD-2 becomes relatively cheaper in time, however, continues to be more expensive than a CD.²⁹ This outcome was corroborated by Zitzmann and colleagues, who calculated that total costs after 3 years were \$2242 and \$5413, for a CD and IOD-2, respectively, resulting in a ratio of 2.4.³⁷

4.2 Initial costs/total costs

Costs of interventions are not limited to the initial treatment, but also include costs for follow-up care, maintenance, complications, and patient time lost due to the performance of the treatment working and travelling. In addition, total costs need to be assessed over time. As such, costs should be discounted by an annual set rate.¹⁸ Taking all these factors in account, an IOD-2 is initially 2-3 times more expensive than a CD in terms of initial costs. After 17.9 years this ratio decreased to less than two times.^{29,37}

Costs may differ significantly between patients and between healthcare systems; therefore, economic evaluations should be interpreted in the context of such cost structures. To allow comparison between studies, costs must at least be specified thoroughly within the environment in which they have been conducted.

4.3 Patient-reported outcome measures

In health-related economic evaluations of treatments, QALYs are used to express the gain both in the quality and length of life. For non-fatal conditions however, alternatives can be applied, such as satisfaction scores, OHIP indices or QAPYs.^{50, 51} However, these differing evaluation methods cannot be compared to QALYs.⁵²

With respect to satisfaction questionnaires, current score lists vary in scoring methodologies: some perform a VAS score, usually on a scale of 0–10 or 0–100, while others use a Likert scale to display their results. The use of the same questionnaire and the same scoring method enables the direct comparison of different studies. It is also crucial to realize that VAS scores are not ratio scale measurements. This implies that, for example, a difference between satisfaction scores of 20 and 40 is not comparable to a difference between scores of 70 and 90.⁵³

A popular method is the use of OHIP question lists; however, these lists are not mutually comparable, and the scale also differs. To interpret, for example, an exact OHIP-20 score, it is essential to know if a scale of 0–80 or 20–100 was used; however, differences calculated in OHIP-20 points remain scale-independent.

As the OHIP-14 ranges from 0 to 56, and the OHIP-EDENT from 0 to 38, the results described for the various outcomes are incomparable. To still allow comparison, the concept of a “minimum important difference” (MID) was introduced, which indicates the number of OHIP points that reflect a significant improvement. Locker and colleagues determined the MID for OHIP-14, which was five scale points, or approximately 10% of the scale range of 56 points.⁵⁴ For the OHIP-20, a MID-range was defined between 7 and 10, with a guide value of 9.⁵⁵

When comparing the “old” CD (71 OHIP-20 points) versus a mandibular IOD-2 after one year (28 OHIP-20 points), an improvement of 43 points was detected, which is more than four times the MID of nine points.³³ The same trend was seen in the study by Attard and colleagues; an improvement of 47 points was detected for an IOD-2 versus the “old” CD.³⁴ In comparison with a new CD, 16-point²⁹ or 26-point³⁴ differences in OHIP-20 points were detected for the mandibular IOD-2, which is about 2-3 times the MID value of 9 points.

Della Vecchia and colleagues reported in OHIP-EDENT points.²⁸ Although the MID was not established for the OHIP-DENT, it could be set to four points using the 10% rule. In comparison with the “old” CD, an improvement of 16 points for the IOD-2 on implants, of 11 points for the IOD-2 on MDIs, and of 13 points for the IOD-4 on MDIs was reported, all of which were about 3-4 times the MID; thus, similar to the level of change detected when using one of the other OHIP lists.²⁸ In OHIP-14 points, Matthys and colleagues presented an improvement of 16 points, which was more than 3 times the MID value of 5 points.³⁸

In short, reported increases in OHRQoL are similar, regardless of if the OHIP-14, OHIP-20, or OHIP-EDENT methodology was used. Also, in QAPYs, a mandibular IOD-2 yielded a satisfaction score four times higher than the “old” CD (0.35 vs. 1.46).³⁷

4.4 Economic evaluations (ICERs)

With respect to CUAs delivering ICERs, four studies delivered an ICER comparing IODs with a new CD.^{29, 33, 34, 37} Another four studies compared IODs with an existing CD.^{28, 30, 38, 39}

Heydecke and colleagues compared “between” two groups receiving either a new CD or a mandibular IOD-2.²⁹ The ICER for the IOD-2 versus the new CD after 17.9 years was \$152.²⁹ Attard and colleagues measured “within” groups; first new dentures were made, then immediate-loaded implants were installed and attached to the CDs to deliver an IOD-2.³⁴ After the first year they produced a lower ICER (\$86), as no maintenance and recall costs were involved.

As the years go by, absolute costs increase over time due to continuous maintenance costs: \$129 per OHIP-20 point after 1 year, \$159 per OHIP-20 point after 5 years, and \$362 per OHIP-20 point after 14 years.³³ To illustrate the extra value of an ICER, compared with a new CD, a maximum of \$362 per OHIP-20 point for the mandibular IOD-2 was paid over a 14-year period.³³ In light of the reported improvement of 17 OHIP points over the full 14 years, this represents a total amount of \$6154 after 14 years (or \$440 per year).

Over the long term, Heydecke and colleagues reported lower costs.²⁹ After 17.9 years they presented an ICER of \$152 per OHIP-20 point versus the new CD. With respect to the assessed decrease of 16 OHIP points, this translates to \$136 per year for 17.9 years.²⁹

The higher ICER (\$362) and higher annual costs (\$440) can be explained by the fact that Alfadda and Attard included the actual maintenance costs, while Heydecke and colleagues made an assumption about the long-term costs using the Delphi group opinion technique.^{29, 33}

In the short observation period of 0.5 years, it was concluded that a mandibular IOD-2 on MDIs (\$28 per OHIP-EDENT point) was more cost-effective than an IOD-2 on conventional implants (\$47 per OHIP-EDENT point).²⁸ This conclusion was corroborated by Jawad and colleagues, who presented a value of \$17 per OHIP-EDENT point for an IOD-2 on MDIs versus \$39 per OHIP-EDENT point for an IOD-2 on conventional implants.³⁰ In both studies, solely edentulous individuals who wore clinically acceptable maxillary and mandibular CDs were included, and only the price of the implants and the attachment system, not the prosthetic costs, were included.

Using the method of calculating QAPYs, “total costs” were calculated for each QAPY. For a mandibular IOD-2, \$5551 per QAPY after three years was calculated and \$2318 per QAPY after 10 years.³⁷ The latter is in line with the \$2432 calculated by Heydecke and colleagues.²⁹ Also applying the QAPY methodology, costs are observed to decrease significantly over time.

WTP values for a mandibular IOD-2 varied between \$3399 and \$5481^{41, 44} while WTA values varied from \$26157⁴² to priceless,^{41, 43, 44} thereby underlining the beneficial effect of an IOD. As WTP surveys patient preferences for an IOD in monetary terms, not only is the appreciation of the IOD itself reflected, but in a way it also clarifies how a patient may endure discomfort, inconvenience, and a loss of time.⁵⁶ Considerable bias can be introduced by misleading, ambiguous, or inappropriate questions however.⁵⁷

5. Conclusions

Total costs for a mandibular IOD-2 were associated with 2-3 times higher total costs compared to a CD. Regardless of whether QAPYs or one of the OHIP lists was used, this resulted in a significant improvement in OHRQoL of about 2 times the MID in comparison with a new CD.

Although ICERs give an improved insight into the relationship between incremental costs and increases in OHRQoL, the comparability of the different economic evaluation studies is still complicated by the use of different outcome measures.

Using the same strategy to register outcomes and the same method of presenting costs would be helpful. However, uncertainty remains as to whether the additional health benefits of an IOD outweigh the higher costs, and this largely depends on the decision maker's valuation of oral health outcomes. As hypothesized, the information available in so far literature seems too diverse to draw firm conclusions. Future research is encouraged to enhance the comparability of oral health outcomes with overall health and wellbeing.

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PART II

RANDOMIZED CROSSOVER STUDY

Summary Box

What is known

Implant-supported removable complete overdentures (IOD) are a commonly accepted treatment option in case of edentulism. The design and manufacturing of a conventional IOD (C-IOD) is time-consuming for both the patient and healthcare provider and can be shortened using a digital workflow. The OHIP-20 is a renowned questionnaire for measuring oral health-related quality of life in edentulous patients.

What this study adds

After wearing both the C-IOD and the digitally designed and manufactured IOD (3D-IOD) for 1 year each in a randomly assigned order, patient-reported outcome measures were significantly better for the 3D-IOD.

CHAPTER 4

Fully digital versus conventional workflow: Are removable complete overdentures equally good?

Van de Winkel T, Delfos F, van der Heijden O, Bronkhorst E, Verhamme L, Meijer G. Fully digital versus conventional workflow: Are removable complete overdentures equally good? A randomized crossover trial. *Clin Implant Dent Relat Res.* 2025 Feb;27(1):e13398. doi: 10.1111/cid.13398. Epub 2024 Sep 30. PMID: 39350584; PMCID: PMC11739062.

Abstract

Introduction

Implant-supported removable complete overdentures (IODs) are a common treatment in case of edentulism and malfunctioning of the conventional denture. Manufacturing IODs in a conventional way (C-IODs) is time consuming, but in a digital workflow this can be done in three sessions. Digitally produced IODs (3D-IODs) are also more advantageous than C-IODs because lost or broken 3D-IODs can be swiftly reproduced as the digital design is always available

Purpose

To prove in a non-inferiority study, with a margin of 0.3 point per Oral Health Impact Profile-20 (OHIP-20) question, that IODs made according to a fully digital workflow (3D-IODs), function as good as C-IODs with respect to patient-reported outcome measures (PROMs).

Materials and Methods

This randomized crossover study included 36 fully edentulous patients who showed extreme resorption of the maxillary alveolar process, making denture retention difficult. After a maxillary bone augmentation and the installation of 4–6 implants, each patient wore both types of IOD for 1 year each, with the order reversed in two subsets of patients. The 3D-IODs and C-IODs were fabricated in advance for both jaws (at least two mandibular implants were already present).

The OHIP-20 survey was performed at baseline, after 1 year (before the IOD switch), and after 2 years to determine patient satisfaction scores using a visual analog scale (VAS). The general health status was assessed using the Short Form (SF-36) questionnaire.

Results

Regarding the PROMS, patients preferred the 3D-IOD the improvement on the overall OHIP scale (0-4), expressed as a mean, was 0.26 point greater than for the C-IOD ($p < 0.001$). This applied also to the VAS scale (1-100) with an increase of 7.37 points; ($p < 0.001$). Regarding the SF-36 scale, only for the item “emotional well-being”, the 3D-IOD scored significantly better ($p = 0.033$).

Conclusion

Compared with conventionally fabricated C-IODs, fully digitally produced 3D-IODs resulted in significantly higher OHIP-20 and satisfaction scores.

1. Introduction

Since 2001, edentulism has been classified as a physical disability by the World Health Organization¹ as it leads to chewing difficulties and compromised aesthetics. In the United States alone, it is estimated that approximately one-third of adults aged ≥ 65 years are edentulous.² Although a decline in edentulism rate has been reported in the United States and other Western countries, this drop is more than compensated by the growth of the adult population over 55 years of age.³ Edentulism thus remains an important clinical topic.

The first step in the treatment of edentulism is the placement of a complete denture (CD). Unfortunately, CDs only partially restore aesthetics and chewing capacity.⁴ An additional drawback is the CD-induced compressive force during chewing, leading to an ongoing process of jawbone resorption, complicating the retention and stability of the CD. Consequently, denture rubbing causes pain, which makes daily life more difficult, both in a physical and psychological sense.⁵

To overcome CD-related complaints, an implant-supported overdentures (IOD) retained by two interforaminal implants is considered the first choice of treatment for the edentulous lower jaw.⁶ Studies on mandibular IODs typically report a successful outcome, as they result in a high patient satisfaction (PS), upgrade the oral health-related quality of life (OHRQoL), and improve the chewing capacity.⁶⁻¹² When used in the upper jaw, implant treatment also enhances stability, function, speech, and PS.¹³⁻¹⁷ In addition, implants prevent progressive alveolar bone loss.¹⁸ Disadvantages include the invasive nature, the need for maintenance, high costs, and the risks of peri-implantitis.

After osseointegration of the implants, an IOD or implant-fixed prosthesis (IFP) can be installed. Of these two options, IFPs initially seem to be the best solution; however, an IOD may be the better choice in cases of reduced posterior bone quality, anatomical limitations, and systemic medical conditions.¹⁹⁻²¹ Furthermore, IODs are documented to be less invasive and more economical than IFPs.²²⁻²⁴ In the event of prosthetic complications, repairs can be executed more easily for removable IODs than IFPs. If the IOD is manufactured using a digital workflow, prostheses can be reproduced more quickly when lost or broken, because the digital design always remains available.²⁵

The high costs of IFPs have led Dutch national insurance companies to reimburse a maximum of six implants in the edentulous maxilla and two in the

edentulous mandible on the condition that (1) an extremely resorbed alveolar process is present, and (2) only IODs, so no fixed prostheses, are delivered.²⁶

IODs can be manufactured in a conventional way (C-IODs) or with the use of a fully digital workflow (3D-IOD).²⁷ Data were gathered concerning patient-reported outcome measures (PROMs) for both C-IODs and 3D-IODs. These data were collected at baseline, and after 12 and 24 months of treatment. With respect to the PROMs, it was hypothesized that patients would rate both C-IOD and 3D-IOD as equivalent.

2. Materials and Methods

The present study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Arnhem/Nijmegen, NL 2017-3671, December 12, 2017 (Dossier number: 2017-3671 NL-number: NL63073.091.17). The article was drafted according to the “Checklist for Non-inferiority and Equivalence Trials” which conform the CONSORT guidelines.²⁸ The raw data are archived in the “Data Archiving and Networked Services” (DANS) of the Royal Netherlands Academy of Arts and Sciences (KNAW) under the Persistent identifier 10.17026/dans-25s-6cdk and hence are accessible for the public.

For the PROMs, the OHRQoL was measured using the organ-specific Oral Health Impact Profile-20 (OHIP-20) questionnaire. PS was scored using a visual analog scale (VAS). To inventory the IOD impact on general well-being and functioning, the Short Form 36 Questionnaire (SF-36) instrument was completed, as suggested by Heydecke et al.¹³

This non-inferiority study entailed a randomized crossover prospective clinical trial. With respect to OHIP-20 and PS-VAS scores, it was hypothesized that patients would rate both the C-IOD and 3D-IOD as similarly beneficial.

2.1 Trial design

Patients were asked to wear the C-IOD or 3D-IOD for 1 year before alternating to the other type for a second year. At baseline, and after each year of wearing one of the IOD types, the patients responded to the following PROMs: the OHIP-20 questionnaire,²⁹ the PS-VAS, and the SF36 health questionnaire.³⁰

From the primary outcomes, the biggest differences were expected for the OHIP-20; therefore, a power calculation was focused precisely on this. The sample size calculation was performed using the available literature data, with the aim of obtaining about the same number of OHIP-points for the

3D-IOD and C-IOD after 1 year of use. This crossover randomized prospective study was analyzed as a non-inferiority study, with a power of an 80% chance of detecting 3D-IODs scoring six points less (inferiority margin) than the C-IODs. It was not feasible to calculate the required sample size based on a multilevel model; therefore, the sample size was determined using a t-test approach, which can be expected to have a similar power. The standard deviation (sd) of the OHIP-49 for comparable populations is approximately 31,³¹ which was translated into a sd of 13 for the OHIP-20. As within-person comparisons were performed, the correlation between two measurements in one person was estimated to be 0.5, meaning a gain of a factor $1/\sqrt{2}$ in the sd as compared with a parallel group design. Using an alpha of 0.05, a power of 80%, an inferiority margin of 6, and a sd of $13/\sqrt{2} = 9.2$, this implied that our randomized prospective study must include 30 subjects, wearing both a C-IOD and a 3D-IOD. In addition, as two treatment centers were to be included on this crossover trial, a fixed effect for center had to be included in the analysis, slightly reducing the power. Combining this with the loss to withdrawal of patients, estimated to be six at most, a total of 36 patients needed to be included.

Participants were randomly assigned to either the A group, which started with a 3D-IOD and subsequently wore the C-IOD, or to the B group, which started wearing the C-IOD and ended with the 3D-IOD. For an optimal comparison, it was decided that equal groups should be formed; 18 patients were assigned to the A group and 18 to the B group.

Assignment to group A or B was executed with a 1:1 allocation as per a computer-generated randomization schedule and using permuted blocks of random sizes. The block sizes were not disclosed. This procedure enabled the evaluation of preliminary data, which facilitated the optimization of both the treatments and procedures during the study. The participants were randomized using an online randomization tool.

An independent secretary prepared a stack of sealed study envelopes noting the group (A or B), which was opened in sequence only by the clinician treating the patients. After the patient had given permission to participate in the study, the secretary announced to the treating dentist which type of IOD should be placed. The order of patient registration determined which envelope had to be opened. As such, both patient and investigator were blinded.

2.2 Centers

Two centers were involved: a dental clinic affiliated with the Radboud University Medical Center (Radboudumc) in Nijmegen, the Netherlands, and a center for special dental care at the Amphia Hospital in Breda, the Netherlands. In each center, a lockable filing cabinet was present, in which the individual case report forms (CRF) containing the clinical scores and all questionnaires were stored.

2.3 Study population

All patients included were edentulous in both the upper and lower jaw and suffered from eating deficiency, loosening of their CDs during speaking, and feelings of embarrassment about their appearance. Cone Beam Computer Tomography (CBCT) imaging confirmed the assumption of an extreme loss of alveolar bone in the maxilla. To make implant installation feasible, all participants needed an extensive maxillary bone augmentation procedure. Permission was obtained from the health insurance company for all patients prior to treatment, which covered all costs except for a relatively small personal contribution. If no implants were present in the lower jaw, mandibular implants were also placed there during the installation of the maxillary implants.

Patients with uncontrolled systemic diseases, an immune-compromised status, those who had been previously treated with oral or intravenous bisphosphonates, or who had undergone prior radiotherapy in the maxillofacial area were excluded from the study, as well as smokers. Patients were urged to remove their IODs at night, thus preventing the overloading of the implants.

Ethnic backgrounds are not reported in the literature surrounding IOD satisfaction. With respect to age and gender, no differences in satisfaction were observed for the IODs;^{32,33} therefore, no distinction was made for these items when reporting patient results.

Because the 3D-IOD was made during the same sessions as the C-IOD, the patients were not informed whether they would start with the 3D-IOD (group A) or with the C-IOD (group B) type first. Furthermore, researchers and research assistants were blinded when assessing the data outcome and statistical analyses. To anonymize the data, the patients were coded using the first letter of the research location, B(reda) or N(ijmegen), followed by the serial number of inclusions. All research data were imported into Castor™ (New York, USA).

2.4 Surgery

In Nijmegen, all 29 patients underwent a bone augmentation procedure. Cortico-cancellous bone blocks were harvested under general anesthesia from the superior anterior medial iliac crest.³⁴ After performing a sinus floor elevation procedure, vertical augmentation was achieved by applying bone chips.^{35,36} To broaden the upper jaw, bone blocks were fixated against the alveolar process with the use of osteosynthesis screws (2.0-mm Champy System, KLS Martin, Tuttlingen, Germany). Effort was made to position the screws in the most horizontal position³⁷ to allow optimal support for the guided template in a later stage.

In Breda, three patients were treated as described above, while the other four patients only underwent a sinus floor elevation procedure.

2.5 Implants

In Nijmegen, a total of 4-6 maxillary Nobel Parallel Conical Connection™ implants (Nobel Biocare, Kloten, Switzerland) were planned for each patient based on CBCT images using the Procera Clinical Design™ software (Nobel Biocare). Parallelism of the implants was pursued, and care was taken to position at least the apex of the implants into the original maxillary bone. Furthermore, peri-implant bone thickness was aimed to be at least 2 mm.³⁸ Hereafter, a surgical template was printed to install the implants according to the NobelGuide™ procedure (Nobel Biocare), which means that the implants underwent flapless placement. To create optimal template stability, the osteosynthesis screws were partially unscrewed before the implant installation to allow the template to rest on them.³⁷ If not already present, two Nobel Parallel Conical Connection™ implants were installed in symphysis region of the lower jaw.

In Breda, all patients received 4-6 Straumann Tissue Level Implants (Standard Plus) with a diameter of 4.1 mm (Institute Straumann, Basel, Switzerland) in their upper jaw. An open procedure was executed, beginning with the preparation of a subperiosteal flap. Implants had already been installed in the lower jaws of these patients.

In all augmented patients, the maxillary bone volume was sufficient at the time of implantation. Healing abutments were positioned onto all implants. Two weeks later, patients were allowed to wear their denture again; sufficient space was created around the abutments, and a fresh relining was conducted. The use of denture adhesive was permitted. The relined upper denture was checked every 6 weeks for any overloading of the abutments.

2.6 Prosthetics

In advance of the study, a final C-IOD and 3D-IOD were fabricated for each patient (Figures 1 and 2). The treatment sessions were combined to hide from the patient which techniques were used for which IOD type. The identity of the installed IOD remained hidden from both the patients and researcher (TW). After opening the research envelope, only the clinician knew which IOD type was to be installed first.

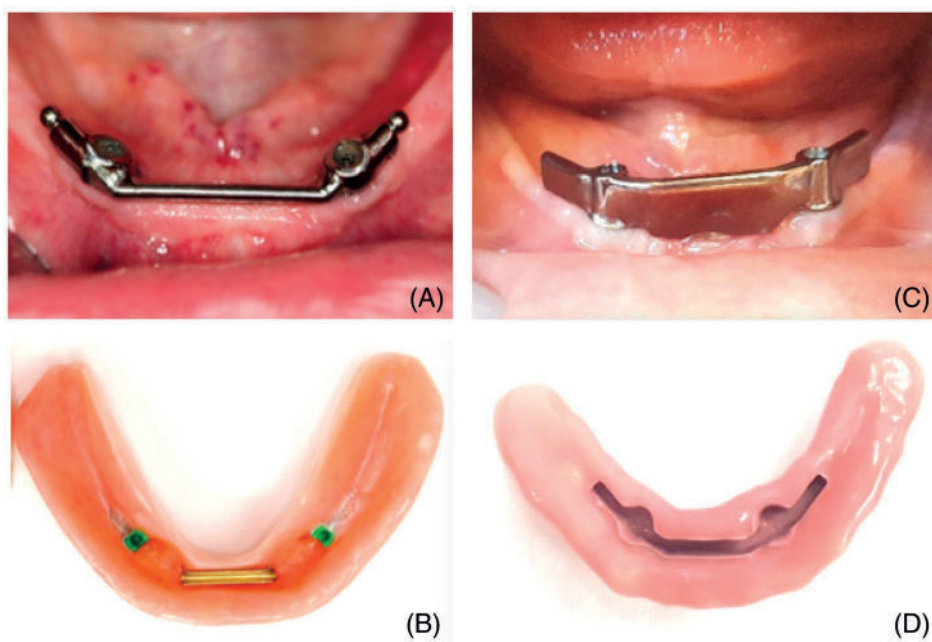


Figure 1. The mandible

(A) Intraoral view of a conventional bar including ball attachments, (B) Inside the C-IOD the green VKS matrices are visible, (C) Bar suitable for the PEEK sliding attachment, (D) Inside the 3D-IOD

2.7 C-IOD

C-IODs were manufactured in 5–6 clinical sessions. First, a preliminary impression of the patient's mouth was taken using stock trays. After pouring the impression in dental stone, custom trays were fabricated. At the second appointment, final impressions were taken, representing both the soft tissue and the exact position of the implants. In the third session, the centric

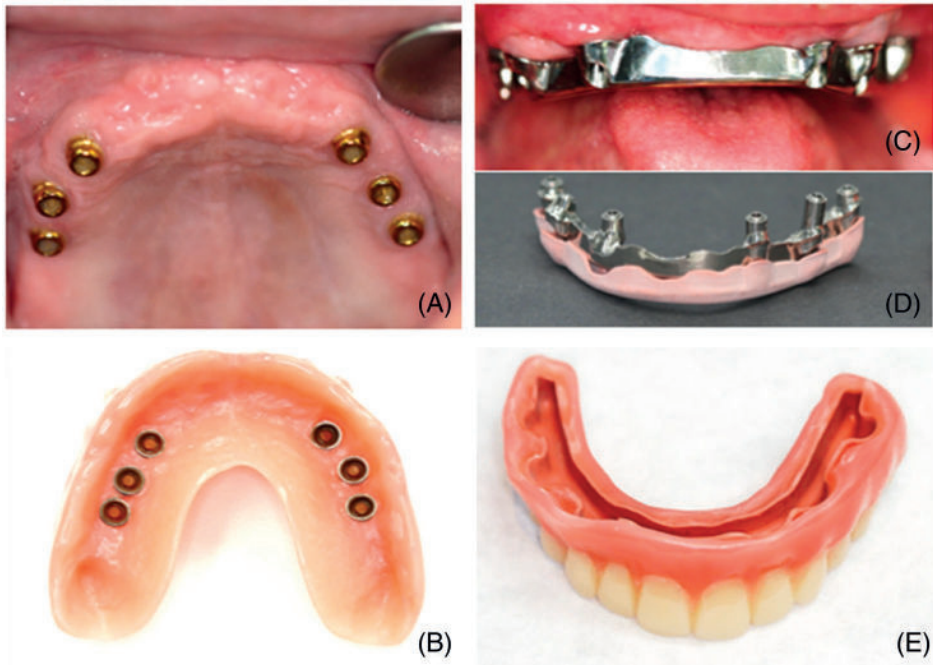


Figure 2. The maxilla

(A) Intraoral view of the maxillary Locators. (B) Inside the upper C-IOD, showing the nylon rings. (C) 3D bar suitable for the PEEK sliding attachment. (D) The thin (2-mm) 3D bar in combination with the PEEK attachment. (E) Inside the C-IOD, into which the PEEK is glued

occlusion, vertical dimension of occlusion, and position of the teeth were registered.

In Nijmegen, a milled titanium bar with distal extensions (Atlantis™, Charlotte, North Carolina, USA) together with a Dolder matrix (Cendres Metaux, Biel, Switzerland) was used as a click-retention system for the lower implants (Table 1). To provide additional retention to the C-IOD, the mandibular titanium bar ended in a ball attachment combined with a VKS™ matrix (Bredent Medical, Senden, Germany; Figure 1A,B). For the upper implants, the treating dentist preferred the Locator™ system (ZEST Anchors, Carlsbad, California, USA) (Figure 2A,B). In Breda, a milled titanium bar (Atlantis™) together with a Dolder matrix (Cendres Metaux) was used for implants in both the upper and lower jaws (Table 1).

A "wax-up" was then made, in which commercially available acrylic teeth were arranged. At the fourth visit, the "C-IOD in wax" was checked for fit,

function, and aesthetics, together with the click-retention system. Changes to the design could still be made at this stage. If this was the case, an additional clinical session was indicated. As a final step, the C-IOD was heat-pressed using two-component polymethylmethacrylate (PMMA) in the dental laboratory and placed.

2.8 3D-IOD

The creation of a 3D-IOD using a fully digital workflow has been extensively described.²⁷ In the first clinical session five steps need to be followed. The 3Shape Smile Design™ (3Shape, Copenhagen, Denmark) program was used to identify the patient's expectations (step 1). After loading the patient's facial image, a preliminary digital setup was projected onto it. The aesthetic items discussed included the shape and color of the projected teeth, as well as their visibility (step 2).

Subsequently, digital data were collected to create a virtual head. The existing dentures were checked to determine whether they were still in centric occlusion (step 3). After scanning (TRIOS 3™; 3Shape) both the upper and lower denture (step 4), an intra-oral scan of the maxilla and mandible was taken with scan bodies (TRIOS 3™) mounted onto the implants (step 5). Matching each individual scanned CD with a scan of both CDs in occlusion allowed the correct maxilla-mandibular relationship to be captured.

In the first laboratory session, after importing all data into the TRIOS Design Studio program (3Shape™), the final 3D-IOD was designed. Digitally, the shape, size, and position of each individual tooth could still be adjusted. In the Real View™ tool, all modifications were immediately exhibited in the facial photograph. Furthermore, the titanium bar was digitally engineered down to the implant level (Figure 1C, D and 2C-E), with a frictional guide plane to provide excellent retention and stabilization of the 3D-IOD.³⁹ In the same session, the matrix, that is, the future sliding mechanism made of polyetheretherketone (PEEK), was digitally designed (Figure 2D,E). The bars were milled from Core Titanium™ blocs (Core3dcentres, Las Vegas, Nevada, USA), and the matrices from PEEK discs (Dental Direkt™, Spenge, Germany). All components were assembled and secured in a printed trial IOD.

In the second clinical session, the fit of the bar, vertical dimension of occlusion, centric occlusion, tooth alignment, tooth size, and lip support were checked in the patient. If necessary, changes were made to the trial IOD, which was then re-scanned.

In the second laboratory session, after all adjustments were digitally imported into the TRIOS Design Studio program (3Shape™), the final IOD was manufactured. Using computer-aided design and manufacture (CAD-CAM), the final teeth were milled from a DDpolyXML disc (Dental Direkt™), which consists of a multilayer acrylic resin polymer. The IOD base itself was milled from a block VITA Vionic Base™ (VITA Zahnfabrik, Bad Säckingen, Germany). Compared with heat polymerized acrylic resin and 3D printed resins, CAD-CAM milled resins exhibit greater flexural properties and hardness.⁴⁰

In the third clinical session, both titanium bars were placed onto the implants and the mandibular and maxillary 3D-IOD were installed.

Table 1. Number of patients and type of click-attachment: per center, for both maxilla and mandible.

Center	Number of patients	Maxilla: C-IOD on Locators™ versus 3D-IOD on 3D-bar	Maxilla: C-IOD on bar versus 3D-IOD on 3D-bar	Mandible: C-IOD on bar versus 3D-IOD on 3D-bar	Mandible: Solely C-IOD on bar (thus no 3D-IOD)
Nijmegen	27	27		18	9
Breda	5		5	4	1
Total	32	27	5	22	10

2.9 PROMs

2.9.1 Oral health impact (OHIP-20)

To assess the OHRQoL, patients were asked to complete the OHIP-20 questionnaire at baseline, after 12 months at the exchange from IOD type A to B (or vice versa), and after 24 months at the end of the study. The OHIP-20 is recommended for use in edentulous patients. Earlier findings showing that the OHIP-20 possesses good psychometric properties of value for clinical trials, particularly for oral prostheses.²⁹

The OHIP-20 comprises 20 questions covering seven domains: functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. The response to each question was rated on a Likert scale ranging from 0 for “never” to 4 for “very often”, meaning the total OHIP-20 score ranges from 0 to 80, with a lower score indicating a higher OHRQoL.

Data from the OHIP-20 were presented as a sum score, that is, the score of all 20 questions added together. However, to facilitate the comparisons of analyses between both the overall OHIP as well as its individual domains, it was decided to present the improvement on the overall OHIP scale (0-4), expressed as a mean.

2.9.2 Patient satisfaction (PS)

At baseline and after 1 year of wearing each IOD type, the PS was rated using a VAS ranging from 1–100.

2.9.3 SF-36 questionnaire (QoL)

The SF-36 questionnaire is a well-documented generic tool that aims to assess the general health status of the population, as well as the impact of clinical and social interventions.³⁰ This survey consists of eight scales yielding data on both physical and mental health (i.e., Physical functioning, Limited due to physical health, Limited due to emotional problems, Energy, Emotional well-being, social functioning, Pain, and General health). The higher the score (0-100), the better the health.

2.10 Statistics

For both the OHIP-20, as well as for PS and SF-36 data, multilevel regression analyses (MRAs) were performed with the OHIP (or PS, or SF-36 scale) as the dependent variable, while both experimental conditions, center, and period (year 1 vs. year 2) were considered independent variables. The variable ‘patient’ was added as a random intercept. An analysis of variance (ANOVA) was used for the statistical test, implying that the dependent variable was not the change in OHIP-20 (or PS, or SF-36 scale), but instead, its value measured at the baseline, centered around its population mean, which was added to the regression model.⁴¹

Results

Patients

In total, 36 patients were included in this study (Figure 3), of whom 29 in Nijmegen (N1–N29) and seven in Breda (B1–B7). The patients were recruited between January 1, 2018, and October 1, 2019, and the study ended on December 1, 2021. Four patients discontinued the study: two had passed away (one from a heart attack, the other due to tumor metastasis); one

patient’s vision deteriorated, which prevented her from traveling; and another participant moved abroad. In total, 32 patients, 16 men and 16 women, completed the study. At baseline, their mean age was 62,8 years (sd: 6), with a range of 51 - 72 years.

3.2 Implants

A total of 181 maxillary implants were placed in 32 patients. During osteointegration, four implants failed, two of which had been placed in one patient. Another implant was lost during the first year, while wearing a C-IOD on Locators™. All five losses involved Nobel Parallel Conical Connection™ implants, representing a failure rate of 2.8% (survival 97.2%) after two years of function.

In the lower jaw, most patients (n = 30) had two implants. Each of the other two patients had four preexisting mandibular implants. None of these installed or preexisting mandibular implants (n = 68) failed over the course of the study.

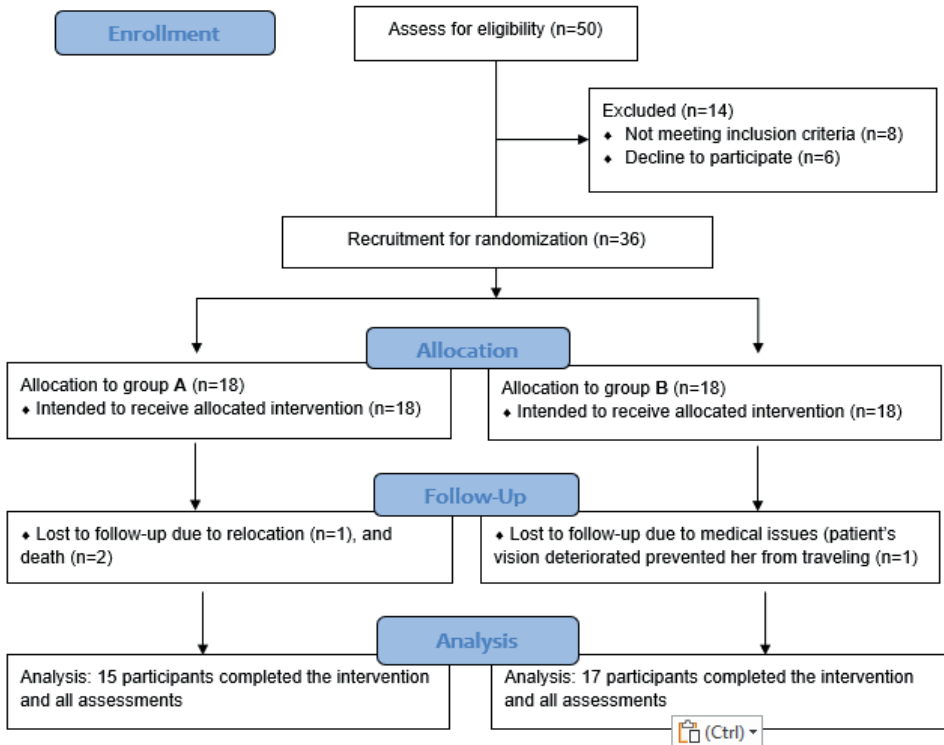


Figure 3. Enrollment for the study

3.3 Prosthetics

All 32 patients received a 3D-IOD in their maxilla, of whom 22 also received one in their mandible (Table 1). In the remaining 10 patients, a lower C-IOD was worn throughout the entire 2-year study period, as relatively unknown implant brands had already been installed. These implant brands were not represented in the TRIOS™ Design Studio program (3Shape), making the creation of a 3D design impossible (Table 1).

For the upper jaw, the C-IOD on Locators™ showed 47 complications, such as pressure ulcers, changing nylon rings or losing housing matrices. The bar-retained 3D-IOD exposed 16 complications, such as pressure ulcers and correction of occlusion. For the lower jaw the C-IOD scored 49 complications and the 3D-IOD a total of 39. With respect to the C-IOD, mainly pressure ulcers and loosening of the ball attachment were observed. Regarding the 3D-IOD mostly loosening of fixation screws of the bar was noticed.

3.4 Non-inferiority analysis

For the first primary outcome, the OHIP-20 score, the non-inferiority margin was 6 points for all OHIP-20 questions, which equates to 0.30 per mean OHIP question. For the 3D-IOD, the per-OHIP question score was 0.257 lower, thus better than that of the C-IOD ($p < 0.001$) (Figure 4A).

Also, for the VAS score, the superiority analysis showed a significantly better result (7.3-point improvement) in the 3D-IOD compared with the C-IOD (Figure 4B).

4 PROMs

4.1 Oral health impact (OHIP-20)

For the preoperative CD, the total OHIP score was 45.8. This improved to 12.0 for the C-IOD and even further to 6.8 for the 3D-IOD.

To facilitate the comparison between the OHIP scores, the improvement on the overall OHIP scale (0-4) was presented, expressed as a mean (Table 2).

With respect to the effect of "IOD type" (Table 2), a mean improvement of 0.257 OHIP-20 points was observed for the 3D-IOD ($p < 0.001$).

For "period", a significant difference in OHIP score was observed (Table 2). In the second period of the study, patients scored 0.184 points lower (better) than in the first period regardless of the type of IOD worn at that time ($p = 0.002$).

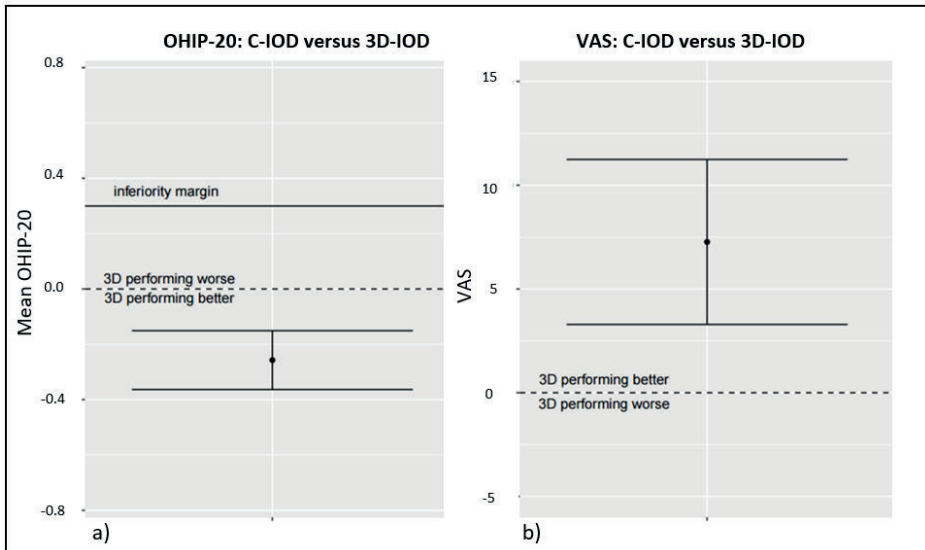


Figure 4. For both the OHIP-20 (A) and patient satisfaction (VAS: 1-100) (B) the superiority analysis is depicted: both the inferiority margin and turning point of performing “better or worse” are shown.

Regarding the assessment of the original CD (see “OHIP score at baseline” in Table 2), each OHIP point of disapproval at baseline also implied a more negative judgment of the final IOD irrespective of the IOD type, although this was not statistically significant (mean effect: 0.171; $p = 0.069$).

Patients treated in Breda (see “center” in Table 2) scored 0.234 OHIP-points better than the patients treated in Nijmegen, although not to a significant level ($p = 0.191$). The statistical insignificance was caused by the high statistical spread (95% confidence interval [CI]: -0.103 to 0.571).

Table 2. Main analysis of OHIP-20 and VAS-score: "C-IOD versus 3D-IOD"; first versus second period of the study; OHIP-20/VAS scores at baseline.

Mean OHIP points		Estimate	p-value	2.5 %	97.5 %
(Intercept)		1.501	<0.001*	1.184	1.818
IOD-type	3D vs. C	-0.257	<0.001*	-0.364	-0.151
Period	2 nd vs. 1 st	-0.184	<0.002*	-0.290	-0.078
OHIP scores at baseline		0.171	0.069	-0.003	0.345
Center	Nijmegen vs. Breda	0.234	0.191	-0.103	0.571
VAS score		Estimate	P-value	2.5 %	97.5 %
(Intercept)		76.734	<0.001*	6.928	84.186
IOD-type	3D vs. C	7.265	<0.001*	3.291	11.238
Period	2 nd vs. 1 st	8.267	<0.001*	4.291	12.238
VAS scores at baseline		-0.022	0.983	-1.971	1.926
Center	Nijmegen vs Breda	-0.9	0.823	-8.517	6.706

Note: OHIP-scores are presented as mean OHIP-20 points (0-4).

* $p \leq 0.05$.

Subsequently, a sensitivity analysis (Figure 5) was performed to assess if the "center" effect was caused by the fact that C-IODs on conventional bars were provided only in Breda and C-IODs on Locators™ only in Nijmegen (Figure 5). However, the effect (0.056 for OHIP-20 and 0.348 for VAS) was small and non-significant.

Also, no significant effect was observed for wearing a mandibular C-IOD or a mandibular 3D-IOD compared with the baseline analysis, showing only a small effect (0.046 for OHIP-20 and 0.392 for VAS).

With respect to the different domains, the 3D-IOD scored significantly better for functional limitation (gain 0.586; $p = 0.000$), physical pain (gain 0.315; $p = 0.001$), physical discomfort (gain 0.216; $p = 0.020$), and physical disability (gain-0.272; $p = 0.001$) than the C-IOD (Table 3).

4.2 VAS (PS)

At the baseline (CD), and after wearing the C-IOD or 3D-IOD for 1 year, the VAS outcomes were 25.6, 79.8, and 87.6 points, respectively. As such, the 3D-IOD scored 7.265 points higher than the C-IOD in PS (Table 2). The MRA (Table 2) showed a significant effect for "IOD type" and "period", but not for "VAS score at baseline" (Table 2).

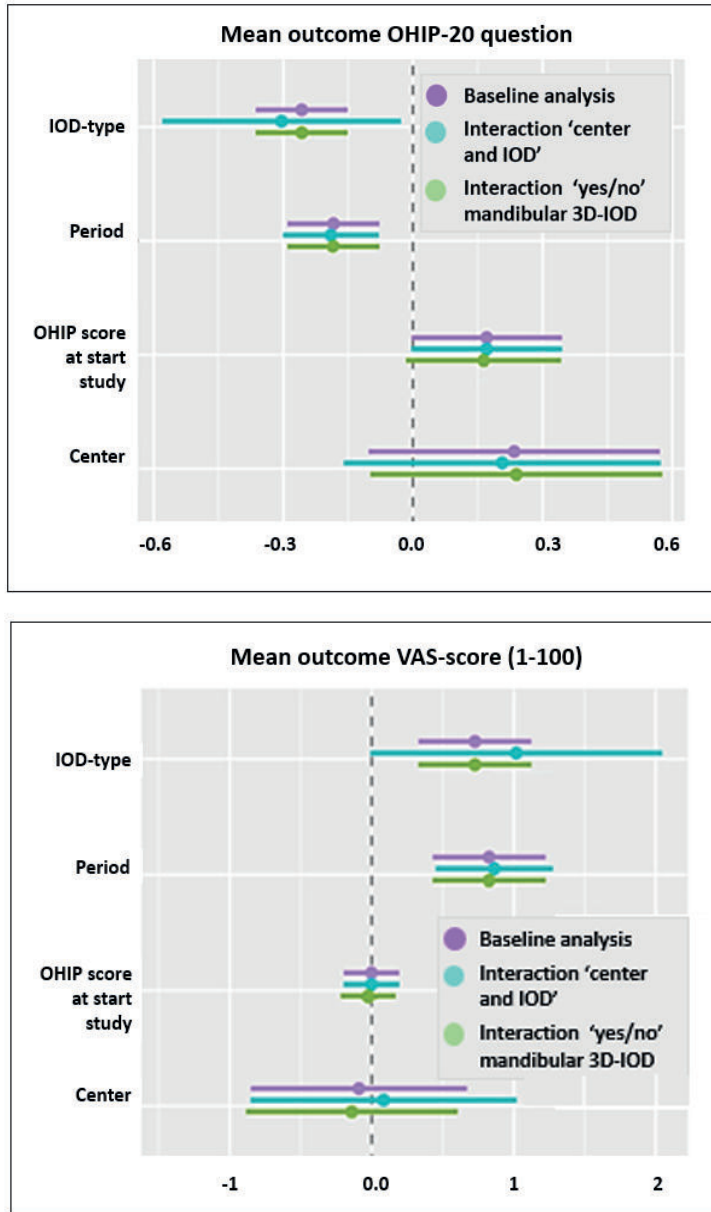


Figure 5. Sensitivity analysis on the OHIP-20 and VAS-score.

Interaction of “center and IOD” and “yes/no” mandibular 3D-IOD (i.e. mandibular 3D-IOD vs mandibular C-IOD); regarding IOD-type (i.e. C-IOD vs. 3D-IOD); Period (i.e. first vs. second year); OHIP score at the start of study (i.e. OHIP-20 score at baseline); Center (i.e. treated in Breda vs. Nijmegen, representing maxillary bar vs. maxillary Locators™).

4.3 SF-36 questionnaire (QoL)

The 3D-IOD was only significantly preferred in the context of "emotional well-being" (4.5% higher; $p = 0.033$) (Table 3).

Table 3. The 3D-IOD versus the C-IOD; differences for the various OHIP-20 domains (scores are presented as mean OHIP-20 points (0-4), as well as for the SF-36 (0-100))

OHIP-20 domains				
	Estimate	p-value	2.5 %	97.5 %
Functional limitation	-0.586	<0.000*	-0.878	-0.295
Physical pain	-0.315	<0.001*	-0.486	-0.144
Psychological discomfort	-0.216	0.020*	-0.388	-0.044
Physical disability	-0.272	<0.001*	-0.421	-0.123
Psychological disability	-0.080	0.117	-0.177	0.017
Social disability	-0.040	0.465	-0.146	0.066
Handicap	-0.143	0.135	-0.326	0.039

	Estimate	p-value	2.5 %	97.5 %
Physical functioning	0.078	0.969	-3.824	3.981
Limited due to physical health	-8.873	0.282	-24.703	6.958
Limited due to emotional problems	10.327	0.152	-3.269	23.922
Energy	3.995	0.110	-0.752	8.719
Emotional well-being	4.504	0.033*	0.568	8.423
Social functioning	4.191	0.193	-1.966	10.348
Pain	0.172	0.968	-8.160	8.503
General health	0.093	0.971	-4.871	5.057

* $p \leq 0.05$.

5 Discussion

5.1 Patients

Before this study, it was expected that the transition from one IOD type to the other could be complicated by peri-implant mucosal swelling; however, this was not the case. Furthermore, patients did not object to the switch from C-IOD to 3D-IOD, or vice versa. To verify whether the study was really blinded for the participants, all were asked at the end of the study if they were confident about the type of IOD they were wearing at that moment; 14

patients guessed correctly and 18 guessed incorrectly. Of the latter group, two patients were convinced they wore a 3D-IOD when in fact a C-IOD on Locators™ was installed. Apparently, patients were more concerned about the esthetics and functionality of their IOD, rather than whether it was handmade or digitally manufactured. At the end of the study, patients were invited to decide which IOD type should be finally placed; 11 patients preferred the C-IOD, 21 preferred the 3D-IOD.

5.2 Implants

Participants in this study were recruited from edentulous patients referred to the hospital departments for oral maxillofacial surgery in Nijmegen and Breda for maxillary bone augmentation.

By providing implants with a roughened surface, their success rate (SR) has greatly increased in enlarged edentulous maxilla, becoming almost as high as in pristine maxillary bone, varying between 91–100%;⁴² this was also corroborated in the present study (SR: 97.2%).

5.3 Prosthetics

5.3.1 Maxillary IOD

The decision to choose for a bar-retained IOD, or an IOD on single abutments depends on the personal favor and experience of the dentist. In Nijmegen, as standard procedure for the upper jaw, the Locator™ system was chosen. In Breda, the preferred approach was the use of a titanium bar.

Generally, when 4-6 implants have been installed in the maxillary arch, a bar attachment is propagated,^{17, 43} because stresses are more equally distributed and cross-arch stabilization is induced.⁴⁴ Also, the SR is higher for the splinted implants (bar attachment) than for individual, thus unsplinted, implants.^{17, 44} Moreover, bar attachments have the advantage of managing non-parallelism using angulated abutments.^{45,46}

Locators™ are freestanding and can be ideally used in cases of reduced height. Due to the male attachment/patrix being made from nylon, micromovements are allowed. Furthermore, for Locators™ improved peri-implant hygiene parameters were scored.⁴⁷

In a randomized controlled trial, patients (n=50) wearing a maxillary IOD retained by either Locators™ or a bar were compared. After five years, with respect to chewing ability and PROMS (OHIP-49), no differences were observed for the two attachment types.⁴⁸ This was corroborated in our study as the sensitivity analysis showed that no differences in OHIP-20 and

PS-score were present due to the difference between a bar attachment and Locator™ attachment.

5.3.2 Mandibular IOD

Both in Breda and Nijmegen a bar attachment was preferred in the lower jaw. For edentulous mandibles, a recent meta-analysis stressed that a bar attachment provides the most superior retention. An individual attachment system may be a favorable choice only in case of limited inter arch space and parallel implant placement.

At the start of this study in 2017, PEEK had already been introduced as a promising material. It can be easily CAD/CAM milled and its use as sliding mechanism on bars was first suggested by Spies et al.⁴⁹ Subsequently, others used PEEK as individual inserts in housings in a maxillary overdenture.⁵⁰ In mandibular IODs, as compared to conventional metal housings, PEEK housings showed higher PS regarding retention, stability, and speech,⁵¹ together with a significantly lower incidence of female housing wear and clip fracture/renewal. In our study, the retention of the PEEK sliding mechanism was satisfactory for maxillary IODs, as demonstrated by the favorable OHIP-20 and PS outcome.

Regarding a mandibular C-IOD using bar/metal clip attachment and a 3D-IOD using a bar/PEEK attachment, the sensitivity analysis pointed out that no significant difference was seen. Between both modalities only a small difference (0.046 OHIP-20 point) was calculated.

5.4 Non-inferiority analysis – MRA analysis

The mean improvement of 0.257 points (see “IOD type” in Figure 4) per OHIP-20 question for the 3D-IOD ($p = 0.001$), was unexpected as our aim was to only show non-inferiority.

There is a tendency that each “OHIP point of disapproval at baseline” also implied a more negative judgment of the final IOD (mean effect: 0.171; $p = 0.069$, Table 2), irrespective of IOD type, indicating that the more that patients are disappointed about their CD, the more they are dissatisfied with their final IOD. A negative judgment of both the CD and the final IOD may point to a negative emotional state, caused by adverse emotions, such as feelings of guilt, envy, anger, anxiety, and depressed mood, which may lead to a lower OHRQoL,⁵² particularly because psychosocial impact is one of the four dimensions of OHRQoL.^{53,54} In advance of the treatment, these items should therefore be discussed with the patient. Because these lower OHRQoL scores were reported for both IODs, this did not affect the non-inferiority analysis.

A relatively high "center" effect of 0.234 points was presented (see "Center" in Table 2), with Nijmegen scoring worse than Breda, however this was not significant ($p = 0.191$), due to the relatively high confidence interval (CI). The latter is explained by the study design, which aimed to examine the effect of "IOD type", not "center".

The subsequent sensitivity analysis (Figure 5) denies that the "center" effect was caused by the fact that C-IODs on conventional bars were provided only in Breda and C-IODs on Locators™ only in Nijmegen (Figure 5). A possible explanation of the "center" effect is the population variety: in Breda patients were more grateful to participate in this study.

As it was judged that the effects of the dentures on PROMs would be limited to the period using that very denture, carry-over effects were not expected; therefore, no washout period was incorporated in the study design.⁵⁵

In the second period of the study (Table 2), patients scored on average 0.184 points lower, thus better, than in the first period, regardless of which type of IOD was worn at that time ($p = 0.002$). *This contrasts with our expectation that, after a negative experience with a CD, the first intervention would tend to be scored more positively than the second intervention.* An explanation could be that patients had to adjust to the phenomenon of an implant-borne construction during the transition from the CD to the first IOD, while patients were already used to it during the transition from the first to the second IOD.

Both groups were the same size, so any period effects would be expected to have been cancelled out.⁵⁵

5.5 PROMs

This study was designed according to the latest International Team for Implantology (ITI) consensus on reporting PROMs in implant dentistry.⁵⁶ Although other questionnaires are recognized, the OHIP-20 is especially effective and well-focused for use with edentulous patients.⁵⁷

An important fact is that all patients were dissatisfied with their upper CD. Previous studies with patients who were pleased with their maxillary CD, reported almost no improvement in general PS, stability, retention, esthetics, mastication, or speech when IODs were installed.^{13,58} The effects of implants on OHRQoL are greater in patients who requested implants themselves.⁵⁹ In our study, patients complained about the loss of retention of their upper CD. All were highly motivated, as shown by their willingness to undergo an augmentation procedure beforehand. All expressed high expectations about

the outcome, which may explain the improvement in OHIP-20 points for both the C-IOD and the 3D-IOD.

To allow for a comparison between various OHIP scales in other publications, the total score was converted to a scale of 0–1, as was propagated in a recent review about mandibular IODs.⁶⁰

For direct normalization: $x_n = \frac{x - \min}{\max - \min}$ was used, for inverted normalization $x_n = \frac{\max - x}{\max - \min}$, where x_n is the normalized value, x is the value in the original tool scale, and \max and \min are the highest and lowest values of the original tool scale, respectively.

Tables 4 and 5 list randomized clinical trials (RCTs) related to maxillary and mandibular IODs, applying the OHIP method to measure the OHRQoL. In Table 4, the opposing dentition is specified, while in Table 5, representing mandibular IODs, an upper CD was present in all patients.

Although crossover studies are more intensive, they are worth the effort because they reduce the sd, reaching statistical significance sooner with fewer patients. Only three crossover studies used the OHIP methodology for edentulous maxillae. The first two studies compared maxillary IODs "with and without" palatal coverage,^{75,76} while the other compared ball retention and Locators™.⁶¹

As shown in Tables 4 and 5, it is important to realize that the calculated OHIP values (0-1) should be interpreted with care and within the context of the performed studies. This is illustrated, for example, by the fact that the OHIP value (0.95) for a mandibular IOD-2 compared with a maxillary CD⁷⁰ showed a similar value (0.89-0.98) as for a mandibular IOD-2 versus a maxillary IOD-4.⁶¹

Most studies only show whether one treatment is more successful than the other, but scored values are difficult to compare between studies. OHRQoL measurements in patients are, therefore, always relative, and often set against a baseline in a RCT. In a crossover study, more pertinent conclusions can be drawn; indeed, in our study, a 3D-IOD functioned better than a C-IOD, yielding a high OHIP-score (Table 4).

Table 4. Studies for maxillary IODs are shown, in which all OHIP-scores were converted from their original scale to values ranging between 0 and 1.

Author	Type of upper prosthesis	Opposing mandibular dentition	Type of OHIP	Effect (0-1)
Aboelez et al., 2022 ⁶¹	IOD-4 on ball	IOD-2	OHIP-14 (1-56)	0.89
	IOD-4 on Locator	IOD-2		0.98
Al-Zubeidi et al., 2012 ⁶²	CD	IOD-2	OHIP-14 (1-56)	0.77
	IOD-3-splinted	IOD-2		0.90
	IOD-3-unsplinted			0.90
Anadioti et al., 2019 ⁶³	IOD-4 on Locator	IOD (41%), natural dentition (48%), FIP (11%)	OHIP-49 (0-196)	0.88
Bouhy et al., 2020 ⁶⁴	CD	natural dentition	OHIP-20 (20-120)	0.71
	IOD-4 on Locator	natural dentition		0.91
Martínez-González et al., 2013 ⁶⁵	IOD-4	IOD-2	OHIP-19 (0-76)	0.78
	IFP-8	IFP-6 (45%) or natural dentition (55%)		0.80
Mo et al., 2022 ⁶⁶	CD	natural dentition (55%), IFP (13%) IOD (32%)	OHIP-20 (0-80)	0.26
	IOD-3 on Locator	natural dentition (55%), IFP (13%), IOD (32%)		0.69
Van Doorne et al., 2021 ⁶⁷	CD	Natural dentition	OHIP-14 (0-56)	0.62
	IOD-6 on MDI	Natural dentition		0.88
Onclin, et al. 2023 ⁶⁸	IOD-2 on Locator	IOD-2	OHIP-49 (0-196)	0.92
	IOD-4- on Locator	IOD-2		0.91
Van de Winkel et al., 2023 (this study)	CD	IOD-2	OHIP-20 (0-80)	0.43
	C-IOD-6	C-IOD-2		0.85
	3D-IOD-6	3D-C-IOD-2		0.92

Abbreviations: IFP-8, implant fixed prosthesis on eight implants; IOD-2, IOD on 2 implants, IOD-4, IOD on 4 implants; IOD-6, IOD on 6 implants; MDI, mini dental implant.

5.5.1 SF-36 questionnaire

Hardly any significant differences were detected between the two IOD types on any of the SF-36 subscales, suggesting that the oral health status is largely independent from general health status. A statistical change was only found between the C-IOD and 3D-IOD in the context of “well-being”, which was greater in the latter.

In earlier reports, none of the SF-36 scale scores were statistically different, for example between subjects wearing CDs and dentate controls,⁷⁷ or patients wearing CDs or IODs.¹³ The SF-36 domains are not very sensitive

to changes in oral health as it includes questions on a wide range of health aspects, such as the ability to climb stairs, to walk a mile, or to be full of energy, which are hardly influenced by changes in oral condition. Although statistically significant more "well-being" was detected in patients wearing a 3D-IOD.

Table 5. Studies for mandibular IODs are shown, in which all OHIP-scores were converted from their original scale to values ranging between 0-1

Author	Lower IOD opposed to maxillary CDs	Type of OHIP	Effect (0-1)
Alfadda & Attard, 2017 ⁶⁹	CD "old" (baseline)		0.11
	CD new	OHIP-20 (0-80)	0.36
	IOD-2 on bar		0.65
Attard et al., 2006 ⁷⁰	CD "old" (baseline)		0.36
	CD new	OHIP-20 (20-100)	0.63
	IOD-2 on bar		0.95
Della Vecchia et al., 2018 ⁷¹	CD "old" (baseline)		0.58
	IOD-2	OHIP-EDENT (0-38)	0.84
	IOD-2 on MDIs		0.92
Heydecke et al., 2005 ⁷²	IOD-4 on MDI		0.95
	CD "old" (baseline)		0.3
	CD new	OHIP-20 (0-80)	0.41
Jawad et al., 2017 ⁷³	IOD-2 on ball		0.64
	IOD-2 on MDI	OHIP-20 (20-120)	0.79
Matthys et al., 2019 ⁷⁴	IOD-2 on ball		0.64
	IOD-2	OHIP-14 (0-56)	0.95

Note: An upper CD was present in all patients.

5.6 Why was the 3D-IOD preferred over the C-IOD?

The most logical explanation is that the retention of the PEEK attachment was more than sufficient. Furthermore, due to the strength of the CAD/CAM milled PMMA, the 3D-IOD could be made slender and therefore can be compared with a removable full arch bridge. Also, the palate remained more uncovered by the 3D-IOD than the C-IOD (see Figures 1 and 2), although both IOD-types can be defined as free of palatal coverage. Surprisingly, the discussion about palatal coverage is still ongoing. In one study, in which patients wore a maxillary IOD supported by two implants with palatal coverage for two

months and then wore the IOD without palatal coverage for another two months, or vice versa, no differences in OHIP points were calculated.⁷⁶ In another crossover study, using maxillary IODs on four implants, no difference in PS was observed with or without palatal coverage;⁷⁵ by contrast, Al-Zubeidi et al. reported that 85% of the patients preferred no palatal coverage.⁶²

A limitation of this study was that, due to unknown implant brands, it was not possible to place a 3D-IOD in the lower jaw of 10 patients. Furthermore, no uniformity was present between the attachment systems of the maxillary C-IODs: in Nijmegen all 27 patients wore a C-IOD supported by Locators™, whereas in Breda the other five participants were provided with a bar-supported C-IOD.

The present study demonstrated that a fully digital workflow, including registration of the maxillomandibular relationship, can produce permanent IODs milled from prefabricated PMMA discs, using PEEK as the sliding mechanism and titanium as a bar. Whether digital techniques also reduce the number of treatment sessions and costs, as has been claimed,⁷⁸ remains to be thoroughly investigated.

6. Conclusion

It may be concluded that digitally designed and CAD-CAM–produced supported overdentures (3D-IODs) performed better than C-IODs with respect to the OHRQoL. Their slender design, together with the well-functioning PEEK attachment system, may explain the high PS score and the low, thus improved, OHIP-20 score for the 3D-IODs when compared with C-IODs.

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PART II

RANDOMIZED CROSSOVER STUDY

Summary Box

What is known

Despite their advantages, implant-supported overdentures (IODs) also entail high treatment costs.

Thanks to the introduction of new techniques, such as computer aided design and computer aided manufacturing (CAD/CAM), production costs of an IOD can be greatly reduced. However, it is not yet clear how much savings can be achieved. Economic evaluations inventorying the benefits of digital techniques help decision makers, such as patients, healthcare providers, insurers, and policy makers in spending health care resources efficiently.

What this study adds

For the first time a complete Cost Consequence Analysis (CCA) and Budget Impact analysis was executed on patients, who wore for one year a conventionally produced IOD (C-IOD) and thereafter a CAD/CAM produced IOD (3D-IOD), or vice versa. Both healthcare and productivity, time and travel costs were included, such as costs related to therapeutic healthcare, IOD-reparation, real patient travel time, time costs due to treatment sessions, and costs of productivity loss while working (paid and unpaid).

CHAPTER 5

Budget Impact Analysis: Digital workflow significantly reduces costs of implant-supported Overdentures (IODs)

Van de Winkel T, Delfos F, van Oirschot B, Maal T, Adang E, Meijer G. Budget Impact Analysis: Digital Workflow Significantly Reduces Costs of Implant Supported Overdentures (IODs). Clin Implant Dent Relat Res. 2025 Feb;27(1):e13413. doi: 10.1111/cid.13413. Epub 2024 Nov 13. PMID: 39538985; PMCID: PMC11798910.

Abstract

Background

For edentulism, an implant-supported removable complete overdenture (IOD) is an attractive solution to restore patients' chewing capacity, aesthetics, and self-esteem, however, treatment is expensive and time consuming.

Purpose/Aim

To estimate the decline in costs for digitally designed and CAD/CAM fabricated IODs (3D-IODs) compared to conventionally fabricated IODs (C-IODs) at comparable general health related quality of life (GHRQoL)

Materials and Method

A randomized crossover study enrolled 36 fully edentulous patients, in whom six maxillary implants were placed together with two mandibular implants, if not already present.

At the start of the study, a set of C-IODs and 3D-IODs was fabricated for each patient. All patients wore each IOD-type for one year: first the 3D-IOD and the second year a C-IOD, or vice versa. At all three time points patients general QoL was assessed using the EQ-5D-5L questionnaire as well as the SF-36 from which the SF-6D was obtained, to research the anticipation of no significant difference.

To enable cost consequence analysis (CCA), both costs made within healthcare and patient costs were assessed. Subsequently, a budget impact analysis (BIA) was performed to demonstrate the potential savings.

Results

No differences in general GHRQoL were seen between C-IOD ($M = 0.840$, $SD = 0.177$) and 3D-IOD ($M = 0.837$, $SD = 0.156$) (paired t -test ($N=31$): $p = 0.880$).

With respect to the total costs for a complete IOD, however, the digital approach showed a reduction in initial total costs of 14.2% (€4700,33 versus € 4030,61: $p<0.001$), in treatment time of 41.1% (309 versus 182 minutes: $p<0.001$), and in number of treatment sessions of 47.1% (5.68 versus 3.0: $p<0.001$). For repairs for an IOD in both the upper and lower jaw, the C-IOD and 3D-IOD scored similar for treatment time as well as additional costs.

Conclusion

Implementing a 3D workflow in the production of IOD's supplies patients with a high-quality 3D-IOD at lower costs.

Trial Registration

NL-OMON44248: <https://onderzoekmetmensen.nl/en/trial/44248>

1. Introduction

1.1 Edentulism

Edentulism induces functional and esthetic burden.¹ In contrast to the overall trend towards a decrease in edentulism, the group in greatest need of complete oral rehabilitation is the rapidly growing aging population.² The World Health Organization (WHO) corroborated that 22% of the world’s population will be older than 60 years by 2050.³ Therefore, need for rehabilitation of edentulous patients is likely to remain relevant for the foreseeable future.⁴

1.2 Cost reduction of a digitally vs. conventionally fabricated implant-supported removable overdenture (IOD)

Using computer aided design and computer aided manufacturing (CAD/CAM), traditional clinical and laboratory steps can be replaced, making prosthodontic treatments faster and cheaper.⁵ The ability to integrate a variety of digital files such as a cone beam computer tomography (CBCT) scan, an intra oral scan (IOS) and a facial image into the same software package enables to digitally design an IOD (3D-IOD) already after one clinical session

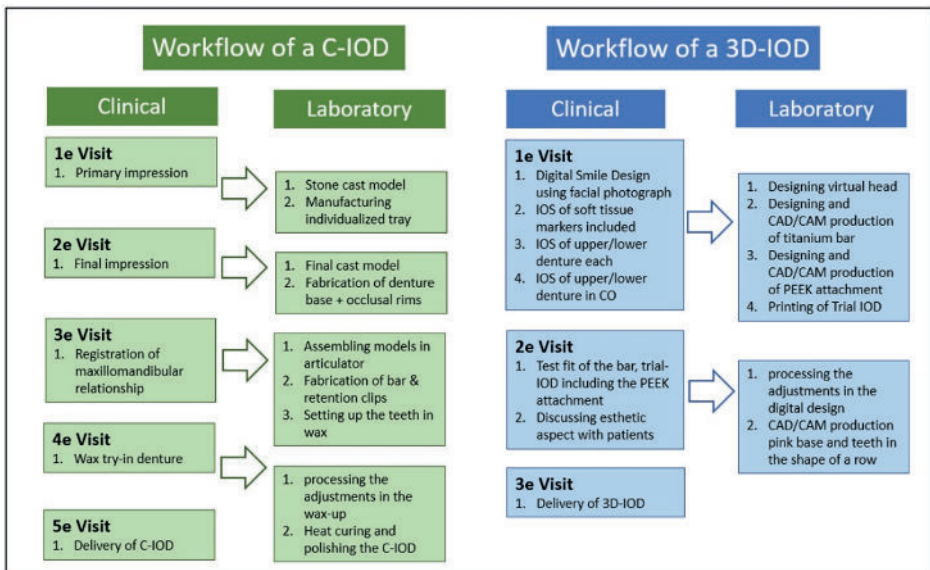


Figure 1. Representation of the fabrication of a C-IOD (5 visits) versus a 3D-IOD (3 visits)

(Figure 1). During the second clinical visit, a trial-IOD can be extensively tested and, if necessary, adjusted. The final 3D-IOD is then delivered in the third session. For the conventional workflow, however, to fabricate an IOD (C-IOD) five sessions are needed (Figure 1).⁶ As an advantage, CAD/CAM skips polluting laboratory steps such as using polymers for mixing PMMA before heat-pressing. Furthermore, intraoral scanning eliminates the need for conventional impression techniques, by which patient comfort is significantly increased.⁷

1.3 Economics in relation to patient reported outcome measures (PROMs)

Health economic analyzes provide information to control costs, not only private costs, but also those related to the public sector in the case of subsidized dental care.⁸

For measuring oral health related quality of life (OHRQoL), the Oral Health Impact Profile (OHIP-20) is the most comprehensive questionnaire and widely used.⁹ However, in order to be a comprehensive tool for economic evaluations, a questionnaire should provide preference-based measures (index scores, or ‘utilities’), meaning that the scores (ranging from 0 to 1) represent the value of a health status based on societal preferences.^{10,11} Unfortunately, the OHIP questionnaires are not preference-based.⁹ Only a few questionnaires, which focus exclusively on assessing general health-related quality of life (GHRQoL), meet this requirement.¹⁰⁻¹²

One of the key preference based measures is the EuroQoL 5D-5L (EQ-5D-5L).¹² Consisting of only five questions however, it is likely to be less sensitive.¹² The SF-36 is a more in-depth health survey with 36 items for assessing GHRQoL.¹³ To enable economic evaluation, a preference-based index can be derived from the SF-36, referred to as the SF-6D.¹²

The aim was to calculate the difference in costs between C-IODs and 3D-IODs and at the same time to demonstrate that both IOD-types lead to a comparable GHRQoL. For interventions that are equally or more effective and cost less, identifying the preferred intervention is rather straightforward, and no incremental cost-effectiveness ratio (ICER) is needed.¹⁴ In those cases a cost consequence analysis (CCA) can be performed.

2. Material & Methods

The present study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Arnhem/Nijmegen, 2017-3671, 12 December 2017 (Dossier number: 2017-3671 NL-number: NL63073.091.17

The article was composed according to the “Consolidated Health Economic Evaluation Reporting Standards 2022”.¹⁵ The raw data are archived in the ‘Data Archiving and Networked Services’ (DANS) of the Royal Netherlands Academy of Arts and Sciences (KNAW) under the Persistent identifier 10.17026/dans-25s-6cdk and hence are accessible for the public.

2.1 Study population

In case of edentulism, Dutch insurance companies reimburse solely IODs, provided that all other prosthetic options have failed, and at the same time extreme resorption of the alveolar ridge can be confirmed radiographically.

Inclusion criteria comprised edentulism in combination with (a) severe retention problems of the upper conventional denture (CD) caused by extreme maxillary bone resorption, requiring bone augmentation prior to implant placement, (b) approved permission from the insurance company to perform bone reconstruction, implant installation and fabrication of the IOD, (c) an IOD already present or planned in the edentulous lower jaw, (d) willingness to participate in the study, and (e) having signed an informed consent. Exclusion criteria were (a) clinical signs of severe oral dysfunction, (b) systemic diseases/conditions that compromise successful implant therapy, (c) smoking (d) non-compliance with the study protocol.

2.2 Centers

Two centers were involved: Radboud university medical center (Radboudumc) in Nijmegen, the Netherlands and the Amphia general hospital in Breda, the Netherlands.

2.3 Implants

In all augmented upper jaws, bone volume was sufficient at the time of implantation. In Nijmegen, in total 4-6 Nobel Parallel Conical Connection™ implants (Nobel Biocare, Kloten, Switzerland) were installed according to the NobelGuide™ procedure (Nobel Biocare, Kloten, Switzerland), which means that the implants were placed without a flap. In the lower jaw, if indicated, two

implants of the same brand were installed using an open procedure, by first preparing a subperiosteal flap.

In Breda, both in the lower and upper jaw, patients received Straumann Tissue Level Implants™ (Standard Plus) with a diameter of 4.1 mm (Institute Straumann AG, Basel, Switzerland). Implant placement was executed in an open procedure.

Immediately after implant installation, onto all implants healing abutments were positioned. Two weeks later the patients were allowed to wear their CD again, which first was modified for this purpose.

2.4 Trial design

In this randomized cross-over study, patients were asked to wear the C-IOD and the 3D-IOD- type alternately for one year each. The Institute for Medical Technology Assessment Productivity Cost Questionnaire (iMTA PCQ) questionnaire, the EuroQoL-5D-5L (EQ-5D-5L) health questionnaire and the 36-Item Short Form Health Survey (SF-36) were accessed prior to the study and after wearing each denture for 1 year. The OHIP-20 was the primary outcome of this research, as described in a previous article, in which a detailed sample size calculation was presented.¹⁶ This resulted in a study population of 36 persons, accounting for a possible dropout of six patients.¹⁶

All patients were randomly assigned; 18 participants to the A-group, who started with the 3D-IOD and switched to the C-IOD after 1 year. Another 18 participants (B-group) began with the C-IOD and ended with the 3D-IOD. Assignment to group A or B was executed with a 1:1 allocation as per a computer-generated randomization schedule stratified (male, female) and using permuted blocks of random sizes. To ensure concealment, the block sizes were not disclosed. Participants were randomized using an online randomization tool.¹⁶

Treatment sessions were combined to hide from the patient which techniques were used for which IOD-type. At the start of the study, both the C-IOD and the 3D-IOD were finalized for each patient. Which IOD-type was placed remained out of sight for both patient and researcher.

2.5 EQ-5D-5L

The EuroQol 5D-5L (EQ-5D-5L) is a standardized GHRQoL instrument that scores on five general health levels: Mobility, self-care, daily activities, pain/discomfort, and anxiety/depression¹² From this, a weighted health index can

be derived for an individual or population. The five questions about health status are scored on a 3-point scale (1-3). This can be converted into a health index ranging from 0 to 1. As the population consists of Dutch patients, the scores were converted to a health index using EuroQol's value set for the Netherlands.^{17,18}

Finally, the patients had to range their general health situation on a scale from 0 to 100 (VAS-score). They were asked to complete the questionnaire before the start of treatment, after 12 months and at the end of the study after 24 months.

2.6 SF-36 and SF-6D

The SF-36 is a health survey for assessing the experienced level of health or GHRQoL. The instrument consists of separate levels for physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue and general health perception.¹³

The SF-36 is one of the most widely used measures for health related quality of life.¹⁰ To perform an economic evaluation based on the SF-36, the SF-6D health state classification needs to be derived from the SF-36.^{10,11}

2.7 Costs

It is important to emphasize that only the costs of the IOD itself were calculated, so the implant treatment, including the implants themselves, were not included as these are the same for both IOD-types. Bottom-up micro-costing, a valuation technique which starts with a detailed identification and measurement of all the inputs consumed in a health care intervention and all of its sequelae,¹⁹ is generally regarded as the most detailed method, as all relevant units of care are identified, and each individual unit of care is valued for individual patients.^{20,21}

Costs for manufacturing and repair of both a C-IOD and a 3D-IOD consisted of the dentist's fee and the dental laboratory costs. Fixed prices applied for both, which are determined annually by the Dutch Healthcare Authority (NZa). Since the dentures were fabricated in 2018 and 2019, the rates for dental care for these years were used. To calculate the laboratory costs, the actual invoices of the dental laboratories were used. In addition, patient travel costs and productivity losses for both paid and unpaid work were assessed in monetary terms.

2.8 Institute for Medical Technology Assessment Productivity Cost Questionnaire (iMTA PCQ)

The iMTA PCQ is the leading Dutch tool to measure and assess productivity losses in the Netherlands.²² It is a short and concise instrument suitable for quantifying presenteeism (“being present at work when sick”) and absenteeism (“taking sick leave”) and relates to both loss of productivity in case of “paid work”, as well as “unpaid work”.^{23,24}

To objectivate the productivity losses of both paid and unpaid work, the Dutch National Health Care Institute’s Guideline for economic evaluations in healthcare was used, which determined the average labor costs per hour for paid work at €34,75 (€36,52 after inflation correction to 2018, the year in which the first IOD’s were manufactured) and the replacement costs for unpaid work at €14,00 (€14,71 after inflation correction).²⁵

The iPCQ was asked to be completed at baseline and after 12 and 24 months (12 months after switching).

2.9 Budget Impact Analysis (BIA).

Purpose of the BIA was to assess the financial impact of implementing 3D-IODs to replace C-IODs in the Dutch health care system in the short-to-medium term from the budget holder’s perspective.²⁶ For this goal, the framework was used as presented in the Dutch guideline for economic evaluations.²⁵ Impact of the new treatment mix on prevalence and incidence was investigated by use of epidemiological data in the Dutch context.

In the BIA, market dynamics were considered, such as estimates of uptake of the treatment mix above. In total three scenarios were presented: Current care, immediate inclusion of 100% 3D-IODs versus gradual implementation in steps of 25% uptake. Furthermore, BIA base-case perspectives, society, health insurance/third party payer and health care were considered. Both annual resource use (in terms of volumes consumed) and cost (volumes multiplied by prices) were presented.

To inventory the amount of care, meaning the number of implant-related treatments that were reimbursed by Dutch health insurers in the years 2013-2021, the associated codes were requested from the National Health Care Institute (ZIN). To perform the BIA, the latest published numbers of 2021 of treatment codes were used. Prices were extracted from the list “Maximum reimbursements for material and technique costs for implantology and suprastructure, January 2021 up to and including 31 December 2021”.²⁷

To inventory the relationship between the use of solitary abutments and a bar construction, an estimation was made based on consultations with oral maxillofacial surgeons, dental technicians, advising dentists for assurance companies and Dutch professors in oral implantology.

2.10 Statistics

For the statistical analyses the 27th version of SPSS was used (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp). Regarding costs as well as treatment time, treatment sessions, travel time, and patient satisfaction, differences between the C-IOD and 3D-IOD were calculated using a paired sample t-test. When subgroups with less than 22 samples were analyzed, the test was bootstrapped by 1000. For the EQ-5D, an analysis of variance (ANOVA) for crossover study was conducted to determine if the GHRQoL was different for the C-IOD versus 3D-IOD group. Only descriptives were performed for the iMTA PCQ since the number of working hours in this population turned out to be too low.

3. Results

3.1 Patients

A total of 29 patients were treated in the Radboudumc, Nijmegen, The Netherlands and seven at the Amphia hospital, Breda, The Netherlands. Of these participants, 32 completed the two-year follow-up, four patients dropped out of the study; two patients died, one was hindered from travelling due to vision difficulties, and the fourth moved abroad. In total 16 men and 16 women completed the study; they started at a mean age of 62,8 years (SD: 6) ranging from 51 to 75 years.

Table 1. Demographics at baseline.

	N	Minimum	Maximum	Mean	Std. Dev.
Male	16	53	75	63,63	6,84
Female	16	51	71	62,00	6,49
Group A	15	59	75	65,40	4,84
Group B	17	51	71	60,53	7,24
Total	32	51	75	62,81	6,61

Note: Group A = started with 3D-IOD, Group B = started with C-IOD.

3.2 Implants

Of the installed 181 maxillary implants, four failed during osteointegration, two of which occurred in one patient. Another implant was lost during the first year. All were Nobel Parallel Conical Connection™ implants which equates to a failure rate of 2,8% after two years of function. In the lower jaw, 68 mandibular implants were present (30 patients with two implants, two patients with four implants), none of which failed.

3.3 Prosthetics

All 32 patients received a 3D-IOD in their upper jaw, 22 also in their lower jaw. For 10 patients, it was not possible to make a mandibular 3D-IOD, because implants of relatively unknown brands were present, which were not recognized by the TRIOS™ Design Studio program (3Shape).

For the mandibular C-IOD, in Nijmegen, a milled titanium bar with distal extensions (Atlantis™, Charlotte, North Carolina, USA) together with a Dolder™ matrix (Cendres Metaux, Biel, Switzerland) was used. For the maxillary C-IOD, preference was given to the prefabricated Locator™ system (ZEST Anchors, Carlsbad, USA).

In Breda, for the mandibular C-IOD solely a milled titanium bar with distal extensions (Atlantis™, Charlotte, USA) was placed as suprastructure. A similar bar was also used as attachment for the maxillary C-IOD.

All patients were able to wear both IOD-types till the end of the study, achieving a 100% survival rate (SR) from a prosthetic point of view. Related to its design and attachment, each IOD-type had its own prosthetic complications as described in Table 2.

3.4 Cost Consequence Analysis (CCA)

3.4.1 Costs made within healthcare – Production of the IOD

With respect to both the upper and lower IOD, the digital approach showed a reduction in total costs of 14.2% (€4700,33 vs. € 4030,61: $p < 0.001$), in treatment time of 41.1% (308,64 vs. 182,05 minutes: $p < 0.001$), and in number of treatment sessions of 47.1% (5.68 versus 3.0: $p < 0.001$) (Tables 3 and 4).

The total costs for a maxillary C-IOD on Locators™ and a maxillary 3D-IOD on a bar ($n=27$) were comparable, namely $\pm \text{€}2400$. This also applied to the laboratorial costs ($\pm \text{€}1760$) for both IOD-types (Table 3).

Table 2. Types of prosthetic complications, as scored for the C-IOD and 3D-IOD, in both the upper and lower jaw.

Complications	Upper C-IOD	Upper 3D-IOD	Lower C-IOD	Lower 3D-IOD
Pressure ulcer	18	6	26	6
Rebasing	3	-	-	-
Optimizing PEEK retention	-	1	-	5
Loose matrix (housing)	11	-	-	-
Changing nylon rings Locator™	9	-	-	-
Changing Locators	2	-	-	-
Loose screws (bar)	-	1	1	11
Fracture of screw	-	-	-	7
Loose ball or VKS attachment	-	-	14	-
Clip activation	-	-	5	-
Tear/Fracture of denture base	1	1	2	2
Fracture of the bar	-	-	1	-
Correction of occlusion	3	6	-	8
Changing position upper teeth	-	1	-	-
Total number of complications	47	16	49	39

As compared to the maxillary bar-retained C-IOD, for the bar-retained 3D-IOD total costs were significantly less (39%; €3659,70 vs. €2239,41; $p < 0.01$), for honorarium 26.8% (€813,10 vs. €595,11; $p = 0.052$) and for laboratorial costs even 42.2% (€2846,60 versus €1644,30; $p = 0.089$) (Table 3).

Regarding the lower jaw, when focussing on the patients (N=22) who wore both the mandibular C-IOD and the mandibular 3D-IOD, total costs were 20% less (€2106,35 vs. €1695,03; $p < 0.001$) and laboratorial costs even 24% (€1579,58 vs. €1200,73; $p < 0.001$; Table 3).

Table 3. C-IOD versus 3D-IOD: Mean costs for both initial production and repair.

	Costs							
	Details of IOD manufacturing						Details of IOD reparation	
	Total costs	Std. Deviation	Lab costs	Std. Deviation	Honorarium	Std. Deviation	Lab costs	Std. Deviation
(N=22)	Upper jaw: Locators C-IOD vs Bar 3D-IOD + Lower jaw: Bar C-IOD vs Bar 3D-IOD							
C-IOD	€ 4.700,33	€ 668,15	€ 3.535,63	€ 584,41	€ 1.164,70	€ 143,38	€ 49,56	€ 168,26
3D-IOD	€ 4.030,61	€ 212,16	€ 2.947,95	€ 131,35	€ 1.082,66	€ 98,06	€ 26,58	€ 53,00
p-value	<0.001*	-	<0.001*	-	0.062	-	0.551	-
Std. Deviation	€ 792,24	-	€ 625,59	-	€ 194,81	-	€ 177,07	-
95% conf. interval	€ 318,46 – € 1020,98	-	€ 310,31 – € 865,05	-	€ -4,33 – € 168,41	-	€ -55,81 – € 101,77	-
(N=27)	Upper jaw: Locators C-IOD vs Bar 3D-IOD							
C-IOD	€ 2.410,96	€ 209,79	€ 1.764,08	€ 253,14	€ 646,87	€ 168,71	€ 1,38	€ 7,16
3D-IOD	€ 2.383,37	€ 72,50	€ 1.759,63	€ 84,78	€ 623,74	€ 84,44	€ 1,66	€ 5,96
p-value	0.532	-	0.924	-	0.244	-	0.881	-
Std. Deviation	€ 226,07	-	€ 239,91	-	€ 100,72	-	€ 9,57	-
95% conf. interval	€ -61,85 – € 117,01	-	€ -90,45 – € 99,36	-	€ -16,71 – € 62,97	-	€ -4.063 – € 3.508	-
(N=5)	Upper jaw: Bar C-IOD vs Bar 3D-IOD							
C-IOD	€ 3.659,70	480,44	€ 2.846,60	490,31	€ 813,10	144,20	€ 19,96	€ 44,63
3D-IOD	€ 2.239,41	237,29	€ 1.644,30	140,76	€ 595,11	127,25	€ 0,00	€ 0,00
p-value	<0.010 ^a	-	0.089 ^b	-	0.052 ^c	-	0.083 ^d	-
Std. Deviation	€ 276,79	-	€ 349,63	-	€ 160,12	-	€ 44,63	-
95% conf. interval	€ 1221,05 – € 1659,64 ^a	-	€ 938,90 – € 1462,50 ^b	-	€ 19,18 – € 416,81 ^c	-	€ 19,69 – € 59,88 ^d	-
(N=22)	Lower jaw: Bar C-IOD vs Bar 3D-IOD							
C-IOD	€ 2.106,35	€ 208,00	€ 1.579,58	€ 192,37	€ 526,78	€ 49,83	€ 43,34	€ 167,76
3D-IOD	€ 1.695,03	€ 126,38	€ 1.200,73	€ 76,11	€ 494,30	€ 71,34	€ 24,55	€ 52,44
p-value	<0.001*	-	<0.001*	-	0.065	-	0.630	-
Std. Deviation	€ 237,84	-	€ 175,84	-	€ 78,15	-	€ 180,38	-
95% conf. interval	€ 305,87 – € 516,78	-	€ 300,89 – € 456,81	-	€ -2,17 – € 67,11	-	€ -61,19 – € 98,76	-

Note: Bootstrap: a= based on 997 samples, b=based on 986 samples, c= based on 999 samples, d= based on 669 samples.

*significant ($p < 0.05$) difference in paired t-test.

3.4.2 Costs made within healthcare – Maintenance and repair

For an IOD in both the upper and lower jaw together, the C-IOD and 3D-IOD scored comparable for time (125.91 vs 102.27 minutes; $p=0.103$) (Table 4), as well as for additional lab costs (€49,56 vs €26,58; $p=0.551$) (Table 3), but the IOD scored slightly better in number of reparation sessions (4.59 vs 3.45; $p=0.037$) (Table 4).

With respect to a bar-retained C-IOD versus a bar-retained 3D-IOD in the lower jaw, no statistical difference was found for the number of reparation sessions ($p=0.646$), reparation time ($p=0.731$), or "extra costs" ($p=0.630$; Tables 3 and 4).

Also, for the maxillary C-IOD on Locators™ versus the bar-retained 3D-IOD (Table 4), no statistical difference was found for the number of reparation sessions ($p=0.327$), or time ($p=0.327$), or 'extra costs' ($p=0.881$). The same applied to the bar-retained C-IOD versus the bar-retained 3D-IOD in the upper jaw (Tables 3 and 4).

3.4.3 Costs on patient level made by patients/family: Real travel costs, out-of-pocket expenses & time costs

Each trip to the clinic cost an average of €13,90 with an average travel time (there and back) of 70 min. Creating a full set of C-IODs took an average of 5.68 sessions, followed by 4.59 repair sessions. For each patient, this meant 10.3 trips at €13,90 per trip (in total €142,75) with a travel time of 719 minutes. Together with a total treatment time of 308.64 minutes, and total repair time of 125.91 minutes, this resulted in a production loss of a total of 1153.45 minutes (19.2 h) per patient.

For a full set of 3D-IODs, three clinical sessions were needed, followed by 3.45 repair sessions, implicating an average of 6.45 trips at €13,90 per trip (in total €89,66) with a duration of 451.5 minutes. As the average total treatment time was 182 minutes, the average repair time 102 minutes, and the travel time of 452 minutes, this meant a production loss of 736 minutes (12.3 h) per patient.

3.4.4 Costs of productivity loss due to IOD manufacturing

3.4.4.1 Productivity loss in case of paid work

The iMTA-PCQ analysis showed that during the research period of 2 years, eight (25%) persons received salary for 31 working hours a week while wearing the 3D-IOD and for 28 working hours a week while wearing the C-IOD (Table 5).

Table 4. C-IOD versus 3D-IOD: Sessions and treatment time for both manufacturing and repair.

	Treatment							
	Details of IOD manufacturing				Details of IOD reparation			
	Sessions (n)	Std. Deviation	Time (min)	Std. Deviation	Sessions (n)	Std. Deviation	Time (min)	Std. Deviation
(N=22)	Upper jaw: Locators C-IOD vs Bar 3D-IOD + Lower jaw: Bar C-IOD vs Bar 3D-IOD							
C-IOD	5.68	0.478	308,64	51.644	4.59	3.53	125.91	108.93
3D-IOD	3.00	0.000	182,05	9.839	3.45	2.46	102.27	84.21
p-value	<0.001*	-	<0.001*	-	0.037	-	0.103	-
Std. Deviation	0.48	-	53.26	-	2.40	-	65.09	-
95% conf. interval	2.470 – 2.893	-	102.98 – 150.21	-	0.74 – 2,20	-	-5.22 – 52.49	-
(N=27)	Upper jaw: Locators C-IOD vs Bar 3D-IOD							
C-IOD	-	-	-	-	1.63	1.52	47.4	47.38
3D-IOD	-	-	-	-	1.66	1.49	47.8	47.03
p-value	-	-	-	-	0.327	-	0.327	-
Std. Deviation	-	-	-	-	0.19	-	1.92	-
95% conf. interval	-	-	-	-	-0.113 – 0.039	-	-1.13 – 0.39	-
(N=5)	Upper jaw: Bar C-IOD vs Bar 3D-IOD							
C-IOD	-	-	-	-	2.0	3.08	31.0	44.22
3D-IOD	-	-	-	-	0.2	0.44	14.0	21.91
p-value	-	-	-	-	0.309 ^a	-	0.463 ^b	-
Std. Deviation	-	-	-	-	3.03	-	54.04	-
95% conf. interval	-	-	-	-	0.40 – 4.60 ^a	-	-22.00 – 57.00 ^b	-
(N=22)	Lower jaw: Bar C-IOD vs Bar 3D-IOD							
C-IOD	-	-	-	-	2.55	2.39	72.0	76.65
3D-IOD	-	-	-	-	2.32	1.89	68.2	60.98
p-value	-	-	-	-	0.646	-	0.731	-
Std.Deviation	-	-	-	-	2.29	-	51.96	-
95% conf. interval	-	-	-	-	-0.787 – 1.24	-	-19.17 – 26.90	-

Note: Bootstrap: a=based on 934 samples, b=based on 993 samples.

*Significant ($p < 0.05$) difference in paired t-test.

According to the Dutch National Health Care Institutes guideline on economic evaluations²⁸ productivity costs are considered at € 36,52 per worked hour. Only eight of the patients (25%) has paid jobs, both in the C-IOD and 3D-IOD group. The mean productivity loss for making the C-IOD, reparations included, was 19.2 h. Multiplied by the productivity costs of € 36,52 per hour, this amounts to a total €701,18 per worker for the C-IOD-group and €447,98 per worker for the 3D-IOD-group (12.3 h at €36.52 per hour). One person was ill for less than 4 weeks while wearing a 3D-IOD and one other person when wearing a C-IOD. Since the illness period was shorter than 4 weeks, according to the Dutch guidelines, it was not indicated to apply the friction cost method.

3.4.4.2 Productivity loss in case of complaints

While wearing a 3D-IOD, three participants each performed 9.7 days of 7 h of paid work despite complaints: A total of 67,9 h. Since they were still able to work at 60%, the 40% productivity loss sums to 27,16 h, which amounts to €991,88 for each of these three patients considering a productivity costs of €36,52 per hour.²⁸

During the period that the C-IOD was worn two participants performed each 15 days of 7 h of paid work despite complaints. Since they were able to work at 90%, the 10% productivity loss amounted to 10,5 h each, or €383,46, for each of the two participants.

Table 5. Outcome iMTA-PCQ differentiated for the period the C-IOD and 3D-IOD were worn.

Outcome iMTA-PCQ questionnaire	3D-IOD	C-IOD
Paid work: number of patients with paid work	8	8
Paid work: percentage of patients with paid work	25%	25%
Paid work: average hours of work per week	31	28
Paid work: average hours of work per day	7.0	7.0
Paid work: patients (n) who did work, although having complaints	3	2
Paid work: average worked days (n) despite having complaints	9.7	15
Paid work: percentage that patients could work despite discomfort	60%	90%
Unpaid work: patients (n) who were limited by complaints	9	7
Unpaid work: days (n) on which less work could be done	16.6	26.7
Unpaid work: hours (n) of unpaid work that were taken over	1.6	2.8

Note: Paid work without complaints (blue); paid work with complaints (green); unpaid work (yellow)

3.4.4.3 Productivity loss in case of unpaid work

Related to unpaid work, nine individuals were able to perform less unpaid work for a period of 16.6 days while wearing a 3D-IOD. When wearing the C-IOD, seven persons were hindered for 26.7 days.

Hours that had to be taken over in terms of housekeeping or informal care were 1.6 h for each of the nine 3D-IOD wearers (in total: €23,54) and 2.8 hours for each of the seven patients wearing a C-IOD (in total: €41,19). To value the costs of unpaid work, the costs of housekeeping (€14,71 per hour) were used, as advised by the National healthcare institute in the Netherlands.²⁸

3.4.4.4 GHRQoL: EQ-5D-5L

The ANOVA analysis of the EQ-5D-5L showed evidence for “intersubject variability” ($p < 0.05$), but not for “treatment” ($p=0,856$) nor “center” ($p=0.099$), “period” ($p=0.818$) or “carryover” effects (Table 6). So, utilities were comparable between C-IOD and 3D-IOD confirming part of our main hypothesis (similar effects on EQ-5D-5L). The paired t-test elucidated no differences in GHRQoL between C-IOD ($M = 0.840$, $SD = 0.177$) and 3D-IOD ($M = 0.837$, $SD = 0.156$) ($N=31$) ($p = 0.880$).

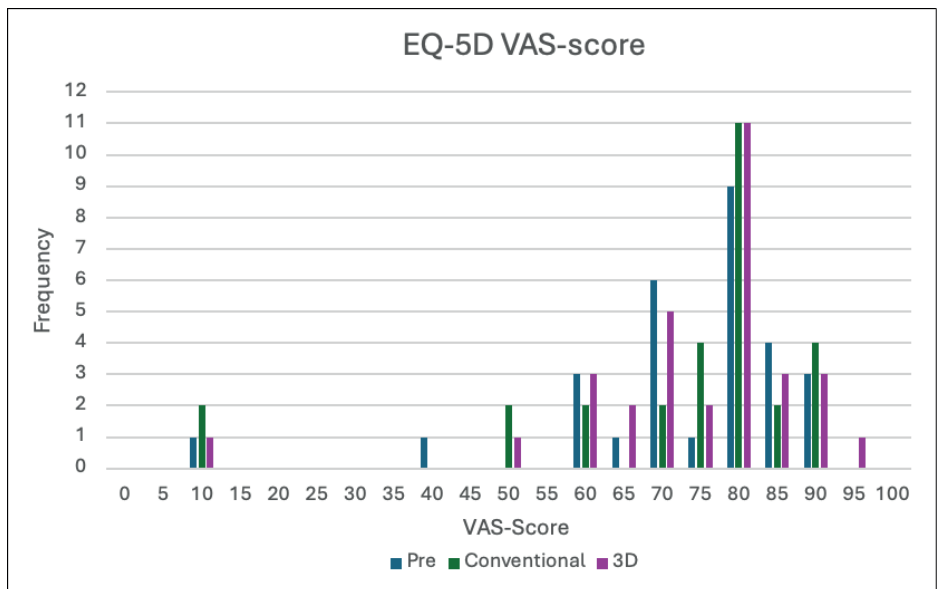
The mean VAS-scores for general health when wearing a conventional denture (at baseline) and after wearing the C-IOD and 3D-IOD measured 73.79, 71.97 and 74.59, respectively (Graph 1). These differences were not significant: Baseline versus C-IOD, $p=0.735$; baseline versus 3D-IOD, $p=0.855$; C-IOD versus 3D-IOD, $p=0.590$.

Both while wearing the C-IOD as well as wearing the 3D-IOD, one patient scored 10 points or lower for general health on the VAS (1-100). The median, however, was 80 points for both overdentures as well as at baseline.

Table 6. ANOVA analysis of the EQ-5D-5L for the effects of center (Nijmegen vs. Breda), sequence (start with C-IOD vs. 3D-IOD, period (first vs. second period), treatment (C-IOD vs. 3D-IOD) and carryover effects.

Source	Number of objects = 63 Root MSE = 0.224			R-squared = 0.055 Adj R-squared = -0.011	
	Partial SS	df	MS	F	Prob > F
Model	0.167	4	0.042	0.84	0.507
Center	0.140	1	0.140	2.81	0.099
Sequence	0.003	1	0.003	0.06	0.800
Period	0.003	1	0.003	0.05	0.818
Treatment	0.002	1	0.002	0.03	0.856
Carryover	0	0	-	-	-
Residual	2.900	58	0.050	-	-
Total	3.07	62	0.049	-	-

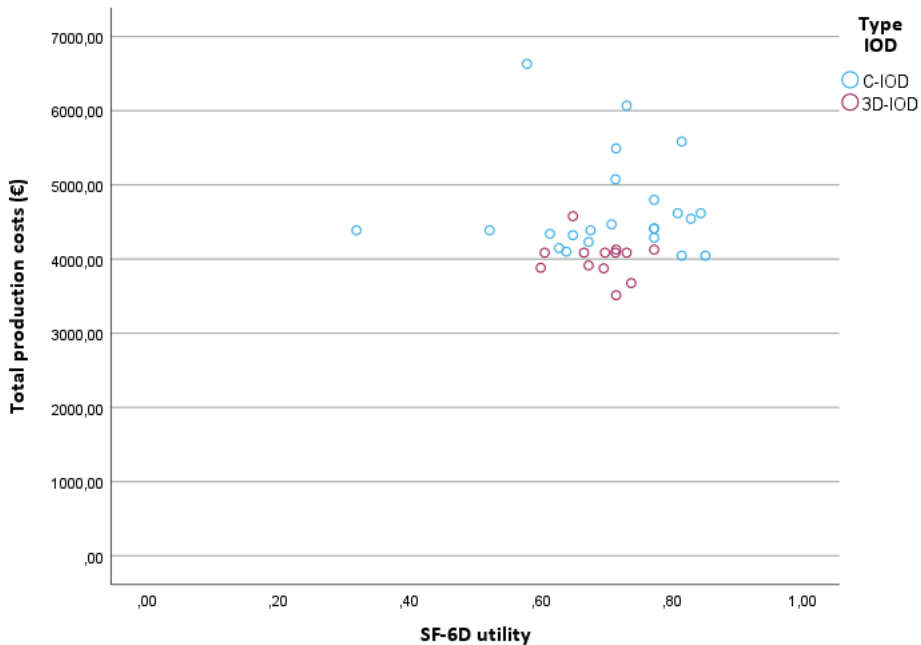
Abbreviations: df = degrees of freedom, F = F-ratio, MS = Mean Square, SS = sum of squares)



Graph 1. Frequency of general Health VAS-score

3.4.4.5 GHRQoL: SF-6D

The SF-6D (Graph 2) yielded equal utilities for the C-IOD and 3D-IOD (0.706 vs. 0.711). However, because the mean total production costs were significantly higher for the C-IOD than for the 3D-IOD (€4700,33 vs. €4030,61 (<0.001)), the 3D-IOD was considered as cost saving and therefore the most efficient modality.



Graph 2: Distribution of costs and SF-6D utility

3.5 Budget Impact Analysis (BIA)

Data provided by the National Health Care Institute indicates how often certain treatment codes were reimbursed (Table 7). There was a specific code for “solitary lower IOD” and “solitary upper IOD”, as also the combination of “upper CD + lower IOD-2”, meaning that in the upper jaw a full CD was placed and at the same time an IOD-2 in the lower jaw. This treatment method is often executed, because when edentulous patients complain about the retention only of their upper CD, the Dutch guideline recommends first making an IOD-2 in the lower jaw.²⁹

So, in total 129.700 (106.100 + 23.600) mandibular IODs-2 were placed in 2021. For the edentulous maxilla, 23.900 IODs were constructed, meaning IODs-4 or IODs-6 in 2021 (Table 7).

In 2021, maximum reimbursement for a C-IOD-2, C-IOD-4, C-IOD-6 was €1458, €2625, and €3375.²⁷ However, when digital manufactured 3D-IODs would have been used, these costs could be reduced to €1185, €1541, and €1798,50, respectively.

Table 7. Numbers and costs of IODs as reimbursed by the Dutch assurance companies between 2013-2021

Codes	Description	2013	2014	2015	2016	2017	2018	2019	2020	2021
Upper CD + lower IOD-2	numbers x 1000	80.1	90.7	100.1	105.2	95.4	107.1	110.0	93.9	106.1
Solitary lower IOD	numbers x 1000	13.6	14.3	15.7	17.0	17.3	21.0	21.6	21.2	23.6
Solitary upper IOD	numbers x 1000	11.1	12.4	14.0	14.9	16.2	20.3	21.3	21.3	23.9

After consultation with experts in the field of implantology, it was estimated that for the upper jaw in $\frac{2}{3}$ of the cases an IOD-4, and in $\frac{1}{3}$ of the cases an IOD-6 was made, and that $\frac{2}{3}$ of the practitioners used bar-retained, and $\frac{1}{3}$ single abutment constructions. In the lower jaw, it was supposed that in 80% of the cases (n=103.760) a bar was used, and in 20% (n=25.940) single attachments.

Digital workflow reduced costs for the upper IODs with €19.907.613 and for the lower IODs with €28.378.360, together €48.285.973 (Table 8).

In total four scenarios were presented. Since a digital workflow takes time to implement in the daily clinic, it was estimated that in the next year 25% of treating dentists will switch to a digital workflow, and so on.

Table 8. Numbers and lab costs of C-IODs which were reimbursed by the assurance companies in the Netherlands for 2021. Costs and savings were specified for the upper IOD-4 and IOD-6, as well as for the mandibular IOD-2. Total costs point to possible savings on a yearly base: 25%, 50%, 75% or 100% (scenarios 1-4)

Maxilla	Estimated number of IOD placements	Lab costs C-IOD	Lab costs 3D-IOD	Total lab costs C-IOD	Total lab costs 3D-IOD	Savings 2021
IOD-4 on bar	10.622 ($\frac{2}{3} * \frac{2}{3} \times 23900$)	€2625	€1541,5	€27.883.005	€16.373.813	€11.509.242
IOD-6 on bar	5.311 ($\frac{2}{3} * \frac{1}{3} \times 23900$)	€3375	€1798,5	€17.924.821	€9.551.834	€8.372.987
Mandible	Estimated number of IOD placements	Lab costs C-IOD	Lab costs 3D-IOD	Total lab costs C-IOD	Total lab costs 3D-IOD	Savings 2021
IOD-2 on bar	103.760 (0,8 x 129700)	€1458	€1184,5	€151.282.080	€122.903.720	€28.378.360
						Accumulated savings 2021
Scenario 1			100% savings		€48.260.589	
Scenario 2			75% savings		€ 36.195.442	
Scenario 3			50% savings		€ 24.130.295	
Scenario 4			25% savings		€ 12.065.147	

4. Discussion

4.1 Cost Consequence Analysis (CCA)

4.1.1 Costs made within healthcare – Initial costs for mandibular IODs

Costs for a for a 3D-IOD were 20% lower than for a mandibular C-IOD (€1695,03 vs. €2106,35; $p < 0.001$).

Various economic evaluations to mandibular IODs-2 underlined their cost effectiveness, meaning that the gain in OHRQoL outweighs the costs.³⁰⁻³⁵ These evaluations comprised also the implant treatment, so no comparison could be made on level of only the prosthetic part of the IOD, and the attachment system. Although absolute costs for the IOD (implants included) differ, it was claimed that the ratios among the various solutions are consistent in literature: Compared to a CD, an IOD-2 is about 2.4 times more expensive, and an IOD-4 around 6 times.^{33,36} When adding the costs for implant treatment in our study, prices for a CD, C-IOD-2 and C-IOD-4 were €1263,54, €3378,74, €5535,72 showing a ratio of 1: 2.7: 4.4.²⁷ When incorporating digital

techniques, 3D-IOD-prices including implants become even more favorable: A ratio of 1: 2.5: 3.5 can be calculated for a CD (€1263.54) versus 3D-IOD-2 (€3121.47) and 3D-IOD-4 (€4452.22).

4.1.2 Costs made within healthcare – initial costs for maxillary IODs

For the maxillary bar-retained C-IOD and the bar-retained 3D-IOD total costs were €3659,70 and €2239,41, including laboratorial costs of €2846,60 and €1644,30 respectively.

Few articles have been published about the costs of maxillary IODs. Listl et al (2014) assessed the cost-effectiveness of a bar-retained maxillary IOD-4 versus a bar-retained maxillary IOD-6: In Germany (2014) material and lab costs, thus without implants, were €4507,82 for the maxillary IOD-4, and €5070,30 for the maxillary IOD-6.³⁷ In contrast, in our study material and lab cost were nearly three times cheaper, namely €1541,50 for the 3D-IOD-4 and 1798,50 for the bar-retained 3D-IOD-6.

With respect to cost effectiveness analyses (CEA) in relation to maxillary IODs, in a recent systematic review, Ghiasi et al. incorporated only two articles, both from Zitzmann et al.^{31,32,38} They concluded that based on these two publications, which evaluated a single patient cohort, no conclusions could be drawn.³⁸

Our results showed that the price for a maxillary C-IOD-6 on Locators™ was lower than for a bar-retained C-IOD-6, which can be explained by the fact that the Locator™ system is an off-the-shelf product, while the bar-retained construction is individually fabricated. However, since a bar-retained 3D-IOD-6 was less expensive, its price became close to a C-IOD-6 on Locators™.

Regarding IOD-attachment systems, Sutariya et al. (2021) concluded that bar-attachment provided the most superior retention, together with a minor prosthetic follow-up.³⁹ Also, Ciftci et al. (2023) advocated the screw-retained bar.⁴⁰ Only in case of limited inter arch space and on condition of parallel implant placement, the move to the Locator™ system can be made.⁴¹

4.1.3 Costs made within healthcare – Maintenance and repair

It should be recognized that the replacement of a CD with an IOD do increase both the objective and subjective chewing capacity.⁴² For an IOD-4, for example, bite forces (334N) went four times up compared to a mandibular CD (76 N).⁴³

With increased bite forces, the weakest link is always at risk; in our study this turned out to be the mandibular IOD-2 for which the most complications

were registered. The bar attachment in the lower C-IOD was particularly susceptible to damage, namely loosening or loss of the ball attachment itself, or the acrylic VKS™ attachment. For the 3D-IOD-2, loose screws (11x) and even screw fractures (7x) were seen. All these negative events occurred only in five patients, all of whom were diagnosed with bruxism. Screw fracture is a serious complication, especially if the screw cannot be removed properly.

Some authors reported that mechanical complications had no impact on the satisfaction and quality of life of patients treated with complete arch implant-supported prostheses, however, these costs should also be implemented in a cost analysis.⁴⁴

Ghiasi et al. (2022) stated that, due to the relative low maintenance and repair costs, large differences in initial cost remain the main component in the total costs, even over time.⁴ This was corroborated in our study: Initial production costs outweighed the maintenance and repair costs substantially. In contrast, major complications in need of extra interventions, such as implant installation due to implant loss, or the fabrication of a new IOD, could indeed affect long-term costs.⁴⁵ In this perspective follow-up longer than one year is relevant.

4.1.4 Costs on patient level made by patients/family, real travel costs, out-of-pocket expenses & time costs

Making a C-IOD in both upper and lower jaw took 19.2 h per patient, both in treatment and travel time, reparations included. A 3D-IOD can be made in two third of that time (12.3 h).

Only eight (25%) participants had a paid job. Productivity loss caused by treatment sessions and travel time were substantially lower for the making of a 3D-IOD: €447,98 versus €701,18 with a C-IOD.

Productivity loss of informal caregivers, for example, the patients' children accompanying or driving their parents to the appointments, was not applicable in this study since every patient was still able to attend the dentist appointment on their own. Especially in an ageing population however, it can be beneficial to bear in mind this aspect of microcosting as well.

4.1.5 In other sectors than healthcare: Costs of productivity loss due to IOD-manufacturing while working (paid and unpaid)

During the research period of two years, also the average time of productivity loss per patient due to illness was relatively low. For the 3D-IOD: €991,88 in case of three persons and €383,47 for the C-IOD in case of 2 persons.

To our knowledge there are two other studies on productivity loss in relation to dental treatment. Since one focused on absenteeism in relation to dental checkups⁴⁶ and the other encountered practical limitations in specifying the oral conditions related to the experienced time loss⁴⁷, their data could not be related to our research.

4.1.5.1 EQ-5D-5L and SF-6D

To measure the health benefits often the EQ-5D-5L questionnaire is used. As shown in our study, this method did not score any changes between groups. In contrast to the sufficient validity in case of persistent orofacial pain,⁴⁸ the EQ-5D-5L apparently appears to be too insensitive to recognize oral health changes, which underlines the importance of oral health disease specific questionnaires.⁴⁹ If these were also preference-based, this could furthermore improve economic evaluations in the field of OHRQoL.

The effect of IOD-type was thought to be limited to the exact period that one of the IOD-types was worn. Therefore, as carryover effects were not anticipated, no washout period was integrated.⁵⁰

4.1.5.2 Patients

The reasons why patients want their CDs changed to IODs on the one hand, and the willingness and ability to undergo surgery and pay the costs on the other hand, determine the final choice between the different types of rehabilitation. In this decision-making process, patient's socio-economic status and geographic location play a pivotal role as do the costs for implant treatment, as it differs substantially between countries and healthcare systems.^{33,51} Still today, essential information about and cost-effectiveness of different treatment options for edentulous situations lacks.⁵²

4.1.5.3 Implants & Prosthetics

Maxillary implant SR was 97,2% after two years of functioning, the mandibular SR 100%, also the prosthetic SR was 100% for both upper and lower IOD, which corroborates the findings in a recent review reporting an SR of 98.3% for six splinted implants supporting an upper IOD combined with a prosthetic SR of 97.9%.⁵³ Also, Milisavljevic et al. reported comparable high SR for both maxillary and mandibular IODs.⁵⁴

The decision to choose for a bar-retained IOD, or an IOD on single abutments rests with the dentist. The reason to choose a bar in the upper jaw is twofold: Bars that splint the implants, induce a higher implant SR than an IOD on single abutments.⁵⁵ Furthermore, non-parallel implants only can be corrected using bars.⁴¹

The argument, that Locators™ are better cleanable, has recently been contradicted. In a 5-year follow-up study of maxillary IODs, the peri-implantitis incidence was 25.8% in the solitary attachment group and only 5.1% in the bar-retained group. Furthermore, it was concluded that for maxillary IODs-4, fewer implants survived in the case of solitary attachment (89.5%, $p=0.027$) than in the case of bar-retained attachment (96.3%). In addition, the IOD-SR was 95.0% for bar-retained and 91.3% for solitary attachment.⁵⁶

4.1.6 Budget Impact Analysis (BIA)

To provide more patients access to the benefits of IODs, costs need to decline, or public funding needs to increase. Key in lowering costs is innovation of both treatment protocols and manufacturing (CAD/CAM) techniques.¹⁴

The application of digital techniques significantly reduced the costs of a C-IOD. It can be highlighted that a high quality (bar-) attachment system can be delivered at the same price as a simple (Locator™-) attachment system when using digital techniques.

To our knowledge, this is the first BIA performed in the field of oral implantology and prosthetics. In dentistry, only one other BIA was found, comparing the effect of fissure sealants with the use of fluoride varnish in children at high caries risk.⁵⁷ Also in the field of oral maxillofacial surgery (OFMS) a recent BIA has been published, comparing orthodontic protraction versus orthognathic surgery to advance the maxilla in patients with cleft lip and palate for the treatment of Class III malocclusion, concluding that orthodontic protraction was the less expensive and less invasive treatment modality.⁵⁸ BIAs are widely accepted within other medical disciplines, such as cardiology in the treatment of heart failure.⁵⁹

Based on our BIA, it was concluded that in the Netherlands about 50 million euro can be saved on an annual basis, thereby enabling insurance parties to provide more patients with an IOD for the same budget. Furthermore, 3D-IODs can be made in less sessions and are, therefore, more affordable for a patient.

5. Conclusion

Implementing a 3D workflow in the production of IOD's supplies patients with a high-quality 3D-IOD at lower costs. The introduction of an oral health related preference-based measure would improve economic evaluations in the field of OHRQoL.

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CHAPTER 6

General discussion

The integration of 3D technology in oral prosthetics is an area of active investigation by engineers, dental clinicians, and dental technicians alike. The data presented in this thesis demonstrate the potential for extending current boundaries and enhancing conventional treatment modalities.

Alongside, prior to the implementation of new techniques, it is essential that available evaluation instruments are thoroughly assessed to ensure the reliability and validity of the measurements obtained.

In particular, before the effectiveness of a fully digitally designed and manufactured implant overdenture (3D-IOD) can be evaluated, it is essential to first examine the instruments used to assess oral health-related quality of life (OHRQoL).

If it can be demonstrated that the improvement in OHRQoL associated with the use of 3D-IODs is at least equivalent to that achieved with conventional implant overdentures (C-IODs), it is important to initiate discussions regarding cost implications. Notably, these discussions should include not only the costs of producing the IODs themselves, but also the indirect costs related to travel, treatment time, and loss of work hours.

Instruments for assessing Oral Health-Related Quality of Life (OHRQoL)

Over time, numerous instruments for assessing oral health-related quality of life (OHRQoL) have been developed.¹ Besides the Oral Health Impact Profile (OHIP) and Visual Analogue Scale (VAS) surveys, the Geriatric Oral Health Assessment Index (GOHAI)^{2,3} is also a widely accepted and standardized instrument for measuring OHRQoL. Similarly, the Oral Impacts on Daily Performances (OIDP) index has been extensively validated.¹

Compared to the GOHAI and the OHIP-14, the OHIP-EDENT has been demonstrated to be the most effective tool for identifying prosthetic complications in patients with complete dentures.^{4,5} It is noteworthy that the OHIP-20 is almost identical to the OHIP-EDENT, comprising 19 identical questions and only a single additional question included (Table 1).

Our decision to utilize the OHIP-20 questionnaire in the context of an implant overdenture (IOD) is consistent with the approach adopted by other authors⁶⁻⁸.

Chapter 3 discusses the OHIP questionnaire versions selected by various authors. Although the OHIP, in contrast to the OIDP, does not measure frequency, the resulting scores appear to be comparable.⁹ Nonetheless, it would have been valuable if our patient cohort had additionally completed a GOHAI- and/or OIDP-based questionnaire. This would have allowed a direct comparison of the utility of these different instruments.

Indeed, such a study was recently conducted^{4,9} and has shown that the OHIP-EDENT (and therefore also the OHIP-20) makes a clearer distinction between oral health-related quality of life in edentulous patients than the other instruments tested.

The optimal number of questions for OHRQoL assessment also remains under discussion. For the OHIP-49, OHIP-20, OHIP-EDENT, and OHIP-14, with 49, 20, 19 and 14 questions respectively, a reduction to as few as five questions has been proposed without compromising the accuracy of the assessment, thereby primarily reducing the burden on patients.^{10,11} However, since the OHIP-5 is not specifically tailored to edentulous patients, we maintain that the OHIP-20 or OHIP-EDENT should be the primary choice for evaluating OHRQoL in patients with dentures and implant overdentures (IODs).

Table 1 provides a detailed comparison of these instruments, highlighting both their differences and areas of overlap. It is important to reiterate that focusing solely on generic items, rather than items specific to denture or IOD experiences, may result in a loss of clinically relevant detail. Furthermore, patients may score lower than they actually perceive, resulting in loss of more subtle differences in patient perceptions of OHRQoL. This limitation can also lead to floor effects, meaning that a test cannot distinguish differences below a certain limit or “floor”.

Table 1. Comparison of OHIP-5, OHIP-14, OHIP-EDENT, OHIP-20, OIDP and GOHAI

Dimension	OHIP-5	OHIP-14	OHIP-EDENT	OHIP-20	OIDP	GOHAI
Functional limitation	<p>Have you had difficulty chewing any foods because of problems with your teeth, mouth, dentures or jaw?</p> <p>Have you felt that there has been less flavor in your food because of problems with your teeth, mouth, dentures or jaws?</p>	<p>Have you ever had difficulty pronouncing words/sentences because of problems with your oral cavity?</p> <p>Have you ever felt unable to taste well because of problems with your oral cavity?</p>	<p>Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?</p> <p>Have you had food catching in your teeth or dentures?</p>	<p>Have you had difficulty chewing any foods because of problems with your teeth, mouth or dentures?</p> <p>Have you had food catching in your teeth or dentures?</p>	<p>Speaking and pronouncing clearly</p> <p>Eating and enjoying food</p> <p>Cleaning teeth</p>	<p>How often did you limit the kinds or amounts of food you eat because of problems with your teeth or dentures?</p> <p>How often have you trouble biting or chewing any kinds of food, such as firm meat or apples?</p> <p>How often were you able to swallow comfortably?</p> <p>How often have your teeth or dentures prevented you from speaking the way you wanted?</p>

Table 1. continued

Dimension	OHIP-5	OHIP-14	OHIP-EDENT	OHIP-20	OIDP	GOHAI
Physical pain	Have you had painful aching in your mouth?	Have you ever had pain in your mouth?	Have you had painful aching in your mouth?	Have you had painful aching in your mouth?	Sleeping and relaxing	How often were you able to eat anything without feeling discomfort?
		Have you ever felt uncomfortable when chewing because of problems in the oral cavity?	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?	Have you found it uncomfortable to eat any foods because of problems with your teeth, mouth or dentures?		How often did you use medication to relieve pain or discomfort from around your mouth?
			Have you had sore spots in your mouth?	Have you had sore spots in your mouth?		How often were your teeth or gums sensitive to hot, cold, or sweets?
			Have you had uncomfortable dentures?	Have you had uncomfortable dentures?		

Table 1. continued

Dimension	OHIP-5	OHIP-14	OHIP-EDENT	OHIP-20	OIDP	GOHAI
<p>Psychological discomfort (orofacial appearance in OHIP-5)</p>	<p>Have you felt uncomfortable about the appearance of your teeth, mouth dentures or jaws?</p>	<p>Have you ever felt worried/ anxious because of problems with your oral cavity? Have you ever felt tense because of problems with your oral cavity?</p>	<p>Have you been worried by dental problems? Have you been self-conscious because of your teeth, mouth or dentures?</p>	<p>Have you been worried by dental problems? Have you been self-conscious because of your teeth, mouth or dentures?</p>		
<p>Physical disability</p>	<p>Have you ever felt dissatisfied with the food you consumed because of problems with your oral cavity? Have you ever had to stop suddenly while chewing food because of problems in the oral cavity?</p>	<p>Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures? Have you been unable to eat with your dentures because of problems with them? Have you had to interrupt meals because of problems with your teeth, mouth or dentures?</p>	<p>Have you had to avoid eating some foods because of problems with your teeth, mouth or dentures? Has the consistency of your food been dissatisfying because of problems with your mouth or denture? Have you been unable to eat with your dentures because of problems with them? Have you had to interrupt meals because of problems with your teeth, mouth or dentures?</p>			

Table 1. continued

Dimension	OHIP-5	OHIP-14	OHIP-EDENT	OHIP-20	OIDP	GOHAI
Psychological disability		Have you ever had difficulty feeling relaxed because of problems in the oral cavity? Have you ever felt embarrassed because of problems with your oral cavity?	Have you been upset because of problems with your teeth, mouth or dentures? Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	Have you been upset because of problems with your teeth, mouth or dentures? Have you been a bit embarrassed because of problems with your teeth, mouth or dentures?	Maintaining usual emotional state without being irritable Enjoying contact with people	How often did you limit contacts with people because of the condition of your teeth or dentures? How often were you pleased or happy with the looks of your teeth and gums, or dentures?
Social disability	Have you had difficulty doing your usual jobs because of problems with your teeth, mouth, dentures or jaws?	Have you ever become irritable because of problems in the oral cavity? Have you ever had difficulty carrying out your daily activities because of problems with your oral cavity?	Have you avoided going out because of problems with your teeth, mouth or dentures? Have you been less tolerant of your partner or family because of problems with your teeth, mouth or dentures? Have you been irritable with other people because of problems with your teeth, mouth or dentures?	Have you avoided going out because of problems with your teeth, mouth or dentures? Have you been less tolerant of your partner or family because of problems with your teeth, mouth or dentures? Have you been irritable with other people because of problems with your teeth, mouth or dentures?	Carrying out major work or social role Smiling, laughing and showing teeth without embarrassment	How often were you worried or concerned about the problems of your teeth, gums or dentures? How often did you feel nervous or self-conscious because of problems with your teeth, gums, or dentures? How often did you feel uncomfortable eating in front of people because of problems with your teeth or dentures?

Table 1. continued

Dimension	OHIP-5	OHIP-14	OHIP-EDENT	OHIP-20	OIDP	GOHAI
Handicap	Have you ever felt that your life is unsatisfactory because of problems with your oral cavity?	Have you ever found it difficult to do anything because of oral problems?	Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures? Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?	Have you been unable to enjoy other people's company as much because of problems with your teeth, mouth or dentures? Have you felt that life in general was less satisfying because of problems with your teeth, mouth or dentures?		

Comparing OHIP outcomes

Even when analyses are limited to the widely used OHIP instrument, comparing outcomes across different OHRQoL studies remains challenging due to variations in outcome definitions and reporting methods. **Chapter 3** already clarifies how baseline scoring (0 versus 1) and maximum scores differ among the various OHIP questionnaires. Additionally, the “minimum important difference” (MID), the number of OHIP-points that reflect a minimum improvement, was discussed. For our study, it was chosen to present OHIP scores using the ‘simple count method’ (SCM), where scores are expressed as a mean on a scale from 0 to 4.^{8,12} In contrast, the ‘additive count method’ (ACM) reports the cumulative score for all items, resulting in maximum scores of 80 for the OHIP-20 (scale 0-4), 120 for the OHIP-20 (scale 1-5), and 196 for the OHIP-49 (scale 0-4).

To promote consistency and enable comparison across different OHIP versions, **Chapter 4** incorporates Zhurakivska’s approach, normalizing OHIP scores to a 0–1 scale.¹³ Despite this normalization, comparing OHRQoL outcomes across studies remains problematic because often different patient populations or differently treated groups are compared, rather than applying multiple treatment modalities within the same group.

Thus, **Chapter 4** concluded that direct comparison of OHIP values between studies is inherently limited. A recent study supports this conclusion: patients dissatisfied with their ‘old’ conventional complete dentures (CD) received either new CDs or implant overdentures (C-IODs). Both groups showed similar OHIP scores, suggesting no difference in OHRQoL between CDs and IODs in general. However, in patients who were dissatisfied with their new CDs, OHIP scores improved dramatically after being provided with an IOD.⁷

Economic evaluation

Economic evaluations and costing studies are critical in assessing the value-for-money of dental health interventions and in informing resource allocation decisions within the healthcare sector.¹⁴⁻¹⁶

However, economic evaluations of dentures lack uniformity due to differences in the devices studied (e.g., partial vs. complete dentures, fixed vs. removable suprastructures, implant-supported vs. non-implant options). Variability in healthcare and insurance systems, as well as the analytical

perspectives used (e.g., patient, healthcare system, or societal), further complicate comparisons. Additionally, national guidelines on health economic evaluations differ: many countries recommend a healthcare perspective rather than a societal perspective.¹⁷⁻¹⁹

Most guidelines do not clearly specify what should be included for each perspective.¹⁷ The health economic evaluation (HEE) guidelines of many countries worldwide are listed by and can be easily accessed via The Guide to Economic Analysis and Research (GEAR) Online Resource.²⁰ Differences between countries nearby are also evident. To illustrate this: In Sweden, a societal perspective is recommended.²¹ In contrast, German guidelines mention multiple perspectives at the insurance level and state that including additional perspectives depends on their relevance to the decision-maker.²² In the UK, the recommended perspective is that of the national health service (NHS) and personal social services (e.g. care homes), with a broader perspective only advised in exceptional cases.²³

In the health economic evaluations presented in **Chapter 5**, the societal perspective was adopted, as recommended by the National Health Care Institute (Zorginstituut Nederland).^{24,25} Compared to approaches in other countries, this guideline seems to indicate most clearly what exactly is meant with a societal perspective.¹⁷ In 2024, the Dutch guideline for economic evaluations in healthcare was updated to offer further clarification on various cost categories including travel expenses, as well as on the costs associated with healthcare interventions and the use of consumer price indices.^{26,27} While this updated costing manual includes more detailed instructions, its scope and comprehensiveness concerning societal perspective costing remain comparable to the 2016 version and would not have led to a different approach.

The societal perspective is the broadest approach, incorporating all costs regardless of the payer. Consequently, adopting this perspective generally results in higher total costs than narrower perspectives. It is essential to recognize that this broader scope may make the intervention appear more costly, which could inappropriately influence the calculated cost-effectiveness ratio.¹⁹ Moreover, spillover effects - unintended impacts beyond the immediate scope of the intervention - should be carefully considered, particularly in the context of patient out-of-pocket expenses.¹⁹ Accordingly, **Chapter 5** highlights especially in an ageing population the importance of including productivity losses of informal caregivers, such as adult children who accompany their elderly parents to dental appointments, to ensure a comprehensive evaluation.

Although all cost categories were incorporated, it was concluded that the initial manufacturing costs of both the conventional implant overdenture (C-IOD) and the 3D implant overdenture (3D-IOD) accounted for the largest portion of the total costs (including expenses related to repairs, travel and productivity loss). Based on these findings, future research could consider adopting narrower perspectives, such as those of the patient or healthcare provider. However, especially in the dental field, with per country differing insurance systems and often only partial reimbursement of treatments, the use of a societal perspective ensures a persistent full view of the costs, even when costs for example are shifted from the healthcare system to the patient.¹⁹

Table 3 in **Chapter 3** addresses the monetary valuation for the gain of healthcare goods and services, willingness to pay (WTP), as well as the monetary compensation for equivalently sized losses, willingness to accept (WTA). Generally, losses in health are valued higher than comparable gains, resulting in WTA prices that exceed the WTP for the same healthcare goods or service. Consequently, the WTA/WTP ratio is typically greater than one.^{28,29} In other words, patients tend to place a lower value on the acquisition of treatments or goods but perceive the loss of it as a great burden. The WTA/WTP ratio is an important measure in reimbursement decision making. A high WTA can make it more challenging to discontinue reimbursement for a particular treatment than to initiate reimbursement for a new, more cost-effective one.^{28,30}

Assessment of WTA and WTP, especially its ratio, remains uncommon in dentistry, particularly in the context of edentulism. Shortly after the submission of our review article (**Chapter 3**), a systematic review on WTA/WTP ratios was published. It reported that the WTA/WTP ratio was higher for implant treatment than for public health measures.²⁹ Since then, only one additional study has been published on WTP in edentulism, describing significantly higher WTP values for IODs compared to CDs, as is in line with the findings discussed in **Chapter 3**.^{31,32} However, these higher WTP values did not exceed the actual production costs of IODs.³¹

Notably, WTA/WTP ratios reported in the literature vary.²⁸ Assessment of both WTA and WTP in the presented randomized crossover trial would have highly contributed to the limited body of evidence regarding these economic measures in dentistry, especially because valuation would have been conducted in a prospective setup and based on actual treatments rather than hypothetical scenarios.³³

Using a digital workflow for manufacturing complete dentures (3D-CDs) and implant-supported overdentures (3D-IODs)

At the start of this study, digital impression-taking was considered an important barrier. One of the most frequently cited limitations of this approach was the challenge of accurately defining denture peripheries, such as the palatal seal, due to the absence of border molding capabilities typically utilized in conventional impressions.³⁴ However, techniques and thus perspectives have evolved over the years. Nowadays, also for CDs, intraoral scanning has become an accepted alternative³⁵, because with IODs the relevance of small peripheral inaccuracies in the prosthesis base is further reduced, because the implant attachments guarantee the desired retention (**Chapter 2**).

If a high-quality digital scan cannot be made for a particular patient, it is advisable to first make conventional impressions and then scan them.³⁵ In **Chapter 2**, a modification of this approach is described, in which the recently rebased denture is scanned to capture an accurate digital model.

The digital capture of the vertical dimension of occlusion and centric relation has not yet been fully described in the literature.³⁵ However, utilizing rebased dentures enables the registration of these maxillomandibular relationships without the need for additional conventional intermediate steps (**Chapter 2**). Although digital tools such as smile design applications are available, Park stated that the use of a wax rim or try-in denture remains advisable to accurately determine the position of the anterior teeth.³⁵ In this regard, the patient's existing denture can also serve as a valuable starting point for establishing the optimal anterior tooth position, as the denture teeth can be readily extended or shortened with wax to achieve the desired esthetic and functional outcome (**Chapter 2**).

Further development based on the Geneva Protocols for digital dentures and a “near-digital” approach Srinivasan et al. (2020)³⁴ has led to the introduction of a digital workflow for CDs based on conventional impressions.³⁶ In this workflow, conventional impressions are digitized, similar to the technique described in Chapter 2, allowing fabrication of CDs in three clinical and two laboratory appointments.

While Grande et al. planned the tooth arrangement digitally, they chose to print only the denture base for the trial prosthesis, subsequently placing standard stock teeth onto the printed base. Nevertheless, the final complete denture in this protocol, like the approach outlined in **Chapter 2**, consists of both the teeth and the denture base fabricated from CAD-CAM milled PMMA.

To facilitate the accurate positioning of individual teeth rather than an entire arch, a 3D printed positioning guide was used to mount each milled tooth onto the base.³⁶

At the start of this project, 3D printed dentures in our pilot set-up exhibited insufficient mechanical strength. Meanwhile, 3D printing technology has evolved and has become a commonly used manufacturing modality for dentures. However, the material's wear resistance remains a concern, rendering 3D printing primarily suitable for provisional dentures.³⁵ Furthermore, post-printing procedures, such as the removal of residual resin and additional curing, introduce extra steps that can potentially compromise the final product quality. In contrast, milled dentures demonstrate more consistent quality outcomes.³⁵

Nevertheless, milling tends to be more time-intensive than printing, and milling equipment generally incurs higher costs compared to 3D printers. Moreover, two-piece milled dentures, in which the base and teeth are milled as separate units from distinct material blocks, demand a more precise technique. This approach, however, has been shown to yield high-quality dentures and is considered the more favorable manufacturing method.³⁵ Nonetheless, as technological advancements in both 3D printing and milling continue to progress, it is anticipated that the quality of dentures produced by these two techniques may reach the same level in the future.³⁵

When an existing CD is available, certain steps in impression taking and capturing maxillomandibular relationships can be combined or omitted altogether (**Chapter 2**). Building on this idea, a recent protocol for bar retained maxillary IODs also used relined existing dentures but continued to rely on conventional impression techniques.³⁷

To date, and to our knowledge, no fully digital workflows for IODs have been reported in the literature. A noteworthy development in this regard is the delivery of an IOD in only two clinical visits by omitting the trial denture stage. This is achieved by a facial scan in combination with well-functioning existing dentures to capture the maxillomandibular relationships.³⁸ (Jeong, Kim, Seong, & Chang, 2023).

At the same time, it can be questioned whether one should aim entirely digital workflows rather than implementing digital techniques where they are beneficial.

CHAPTER 7

Future perspectives

Cost

In analogy to the worldwide trend³⁹ of an absolute increase of edentulous patients due to the ageing population, the same can be expected for the Netherlands. Even though edentulism decreased from 15,7% (2,5 million people) in 2000 to 11,6% (2 million people) in 2009, this trend decline of 0,41% per year is expected to flatten⁴⁰, as is confirmed by the observation that the same decline took place in twice the time between 2021 and 2023⁴¹.

Narrowing down to people of 75 years or older, edentulism decreased from 53,0% in 2009 (583.000 people) to 35% in 2021 (490.000) and 31,9% in 2022 (430.650). Whereas this percentage decreased to 31,2% in 2023, the absolute number increased (468.000).⁴⁰⁻⁴³

Even when accounting for the higher mortality expected around 2040 due to the passing of the baby boom generation, the number of elderly patients of 75 years or older is about to increase until 2050, whereafter it is predicted to stabilize around 3 million people.⁴⁴

In this thesis, it is shown that €48.260.589 per year can be saved when implementing 3D-IODs instead of C-IODs. These savings can be allocated in various ways, of which prevention is one of the fundamental possibilities. In this light, the Dutch National Health Care Institute (Zorginstituut Nederland) published end of 2024 a cost analysis for the dental care for adults, exploring the costs of reimbursement of amongst others dental check-ups. One yearly dental check-up is expected to cost about €144m per year.⁴⁵ The Dutch National Health Care Institute has so far not published any advice to the policymakers. It should be noted that the mentioned cost for dental check-ups, however, should be regarded as an investment rather than an expense, resulting in better future oral health for the population. With full implementation of digital workflows for IODs, one third of the dental check-up cost would be covered. This does not yet consider the savings that can be achieved by introducing a digital workflow for conventional full dentures, a trend that is rapidly emerging. Further cost savings are on the horizon in the future: it is expected that once the quality of 3D printing approaches that of milling, a further 75% in engineering costs can be saved.

On the other hand, by maintaining the current budget levels and keeping the money saved available for IODs, more patients can be treated within the same budget. The 3D-IOD is not only beneficial from a societal perspective, but also for the individual patient. In the upper jaw, bar-retained C-IODs are

less common because they are pricier. However, bar-retained 3D-IODs cost about the same as Locator™-retained C-IODs, offering a more advanced solution without increasing costs. Hence, application of 3D technology enables the provision of a higher-end product to the patient at no additional cost. There should be a political debate on how the savings resulting from the introduction of digital workflows should be distributed.

Study designs

Most studies compare differently treated groups or compare gains of OHRQoL to baseline, complicating comparability between studies. A cross-over study, however, allows for more relevant conclusions as within-patient measurements of different treatment modalities are possible. Hence future research in the field of prosthetics and implantology would yield more valuable outcomes when designed as randomized cross-over study. Additionally, to reduce the burden on the participating patients, one could consider optimizing the assessment instrument used. Regarding the number of questions included in the OHRQoL questionnaires, additional research will be useful to determine the optimal balance between conciseness on the one hand and sufficient questions asked to properly capture the OHRQoL on the other hand.

Till now, except for dental caries, there are no preference-based (meaning that a health status is weighed within the context of a specific society) quality of life measures (PBMs) for OHRQoL.⁴⁶ Considering the enormous improvement in the success rate of implant treatments as well as the superstructures attached to them in the past decades, it can be questioned whether emphasis of further research should be maintained only on technical refinement. Because of the scarcity in health care, a reasonably good treatment or device may be sufficient. It is shown that the 3D-IOD is at least such a provision, if not better. Although both reinvestment options due to the introduction of digital workflows, namely prevention or delivering a higher quality IOD to more patients, are well defensible, the lack of cost-effectiveness studies in dentistry makes it difficult to say how the money saved can best be spent. This issue should be addressed to shift the focus to research on the smartest allocation of goods.

Workflow

In the Netherlands, 210 new dentists graduate each year, while 300 retire.⁴⁷ As a result, 42% of the dentists will retire between 2021 and 2031.⁴⁸ Given the expected population growth, this would mean an increase in the number of patients per dentist, and thus also in the workload. It should be realized that workload reduction can also be achieved through digitalization.

On a governmental level the view on digital techniques seems quite one-sided. The Advisory Committee on Medical Manpower Planning (Capaciteitsorgaan) mentions digitalization primarily as support to decrease administrative burden and in relation to technical advancements of treatment modalities.⁴⁸ However, the simplifying impact of digitalization on the workload of the primary process, the treatments, has not really been addressed yet. For example, the Dutch National Institute for Public Health and the Environment (RIVM) focuses on the financial burden of technical advancements in contrast to the expected quality gains. In their Public Health Foresight Report of 2018, it is estimated that two-thirds of the increase in total expenses will be attributable to developments in medical technology and rising prosperity, and one-third to aging and growth of the population. Digitalization is also labelled as an important issue in their Public Health Foresight Report of 2024, but here as well, ways to decrease healthcare expenditures using digital techniques in treatment are not explored.^{49,50}

Policymakers need to be aware that digital workflows reduces both costs and workload by allowing treatments to be performed in less time and fewer visits.

Furthermore, a patient doesn't necessarily need to visit a dental office to collect data for a 3D-CD or 3D-IOD. Certain steps such as scanning the original CDs, assessing the maxillomandibular relation and taking the facial photograph to allow a Smile Design, can easily be performed at home, or during a visit by a dental professional in for example, a nursing home.

Especially due to the smaller size of intra-oral scanners (as big as a toothbrush), it is no longer a hassle to bring an intra-oral scan device. In addition, improved software and different settings, for e.g. edentulous jaws or copy dentures reduce scanning time to approximately one minute. Moreover, apps like Qlone Dental enable facial scanning suitable for smile design and occlusal plane determination, with only a smartphone. Currently subscription costs are about €200 per year which is in great contrast to the price of purpose-built facial scans, of which some also can track motion, but with prices ranging from €4.000 to €35.000.

As information for the treatment can be obtained remotely using a smartphone, portable intra-oral scanner and a laptop, it is imaginable that dental laboratories and dental practices collaborate in initiatives to visit the patient outside the dental practice.

Implementation

The already mentioned governmental narrow focus is also seen in the policy documents for dental education. The most recent Dutch Dental Education Framework (Raamplan Tandheelkunde) dates from 2020 and anticipates on the Dutch healthcare landscape in 2030.^{51,52} This report, with as motto: “Transcending boundaries in education and training for health and social care in the digital age”, focusses only on data, like patients self-measurement, electronic health records, digital data management, eHealth and telemedicine. Robotics are only very broadly mentioned as a potential future development in the care sectors of the healthcare system. 3D printing is mentioned once as an example in the context of a societal experiment for community induced cure and care solutions.⁵¹

Fortunately, the use of digital techniques and planning software for prosthetics and prosthodontics is already a standard part of the bachelor’s program in dental education in the Netherlands.

It is important to realize that not only the dentist plays a role in designing and manufacturing a CD or IOD. Others are the dental technician, who usually works in a dental lab without patient contact, the ‘clinical prosthetic technician’ who works clinically under supervision of a dentist, and the ‘denturist’ (US) or ‘clinical dental technician’ (UK) who holds a bachelor’s degree, is licensed under the Dutch BIG-register and is authorized to treat patients independently.

For the education of all these three types of technicians, computers and digital technique are essential parts of the education.^{53,54} However, similar to the dentists, digital engagement seems more limited among the more senior colleagues.

Hence, it most probably will only be a matter of time before digital techniques will be embraced by most of the dentists. Still, if policymakers neither are fully aware of the already executed development, nor see the further potential it can be doubted whether manpower planning, reimbursement decisions, funding for education, and reallocation of goods, will be implemented in the most optimal way.

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CHAPTER 8

Summary

Chapter 1 - Introduction

This chapter outlines the burden of edentulism, a condition characterized by the complete loss of natural dentition. Edentulism is associated with significant functional, aesthetic, and psychological impairments. Reported consequences include dietary limitations, impaired mastication, speech difficulties, and the loss of facial muscle support, contributing to an aged appearance. The World Health Organization (WHO) classifies edentulism as a physical disability.

The conventional treatment for edentulous patients is the provision of complete dentures (CDs). However, CDs provide only limited restoration of masticatory function. Due to unfavorable biomechanical forces during mastication, a progressive and irreversible resorption of the alveolar bone occurs, leading to diminished denture retention and stability. This, in turn, contributes to mucosal soreness, impaired prosthetic function, and psychological distress. To address the limitations of CDs, implant-supported overdentures (IODs) have demonstrated superior outcomes in terms of stability, function, speech, and patient satisfaction for both jaws. An additional advantage is the preservation of alveolar bone volume associated with implant loading.

Public acceptance of implantology has increased, driven by its integration into standard dental care. Nevertheless, the high cost of implant placement and IOD fabrication remains a significant barrier. Moreover, the design and manufacturing of IODs is exhaustive for both patients and dental professionals, as it requires many separate visits. Computer-Aided Design and Computer-Aided Manufacturing (CAD/CAM) of IODs may reduce both material and labor costs. Therefore, the following research questions emerge: (1) Does the IOD provide sufficient patient-centered benefits to justify its cost? (2) How can these benefits be objectively measured to support decision making? (3) Is it feasible to produce an IOD in a fully digital workflow? (4) What cost reduction lies in implementing a fully digital workflow?

Chapter 2 - Proof of concept: the fully digital IOD-workflow

This chapter describes the fully digital workflow in a proof-of-concept case involving a 64-year-old edentulous female patient with six maxillary and two mandibular implants. She consented to receive fully digitally fabricated implant-supported overdentures (3D-IODs).

The treatment was completed in three clinical sessions: the first for obtaining the intra-oral scans, the second for verifying and inserting the bars and trial dentures, and the third for delivering the digitally designed IOD (3D-IOD). Following implant osseointegration, sufficient digital data were obtained during the initial clinical session to enable a virtual prosthetic design. Intraoral scans (IOSs) of the patient's existing CDs were taken, individually and in centric occlusion. Additionally, both edentulous arches with scan bodies fixed onto the installed implants were scanned. Facial photographs were captured, and tooth shade and position were evaluated in collaboration with the patient using Smile Design software.

These digital datasets allowed for the design of both the bar structures and attachment systems, along with the virtual tooth arrangement. In the first laboratory session, anterior teeth were positioned using Smile Design software, while posterior occlusion was refined with a virtual articulator simulating mandibular dynamics. Titanium bars and polyether-ether-ketone (PEEK) attachment components were designed and fabricated using CAD/CAM technology. Subsequently, based on the digital design a trial prosthesis was 3D-printed.

During the second clinical session, the trial 3D-IODs and bars were temporarily placed and clinically evaluated, with digital adjustments still possible. Subsequently, in the second laboratory session, both the denture base and teeth were milled separately from polymethyl-methacrylate (PMMA) discs. In the final clinical session, both the definitive upper and lower 3D-IOD were delivered.

After one year, no biological or prosthetic complications were observed. Patient satisfaction was rated nine on a visual analog scale (1-10). This case demonstrated that a fully digital workflow enables the fabrication of durable, wear-resistant IODs in just three clinical sessions.

Chapter 3 - Reviewing the added value of implant-supported overdentures

This chapter reviews the literature evaluating whether IODs improve oral health-related quality of life (OHRQoL) relative to CDs and whether these improvements justify the additional costs. Research focused on the various measurement instruments to determine OHRQoL and how to ultimately determine the economic value. A structured search strategy was developed and applied to MEDLINE, EMBASE, and the Cochrane Database. In total 17 studies met the inclusion criteria for this review.

To standardize the financial data, all reported costs were converted to United States Dollars (USD), adjusted for the year in which each study was conducted, using contemporaneous exchange rates. Initial costs for CDs and IODs supported by two implants (IOD-2) varied by country. For instance, in Canada, average costs were \$627 for CDs and \$1,796 for a mandibular IOD-2, whereas in Switzerland, the respective costs were \$1,540 and \$4,230. On average, IODs-2 dentures were found to cost about 2 to 3 times more than CDs.

The term “total costs” was frequently used in the reviewed studies, but the specific cost components included under this label varied considerably. Most studies included the cost of implant purchase and surgical procedures. Costs related to prosthetic fabrication and dental laboratory services were commonly included, while maintenance costs were less frequently reported. Only a minority of studies considered indirect costs, such as productivity loss and absence from work due to complaints or the time patients invested in attending clinical appointments.

Several validated tools for OHRQoL assessment exist, including the Oral Health Impact Profile (OHIP), the Geriatric Oral Health Assessment Index (GOHAI), the Oral Impacts on Daily Performances (OIDP) index, and the Visual Analogue Scale (VAS) for assessment of satisfaction.

For edentulous patients, commonly utilized instruments included various iterations of the Oral Health Impact Profile (OHIP), such as OHIP-14, OHIP-EDENT, and OHIP-20, comprising 14, 19, and 20 items respectively. These tools consistently assess seven domains: functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability, and handicap. Responses were recorded on a 5-point Likert scale, ranging from 0 (“never”) to 4 (“very often”).

Comparability between the different questionnaires to assess OHRQoL was ensured using the “minimum important difference” (MID), the

questionnaire dependent smallest number of OHIP points that reflects a significant improvement. In this study, OHIP scores were also assessed via the Simple Count Method (SCM), reporting mean scores per item (scale 0-4). Alternatively, the Additive Count Method (ACM) sums item scores, yielding maximum totals of respectively 76 (OHIP-EDENT, scale 0-4), 80 (OHIP-20, scale 0-4) and 196 points (OHIP-49, scale 0-4).

The absence of standardized metrics and the use of diverse outcome measures limits cross-study comparisons. Ultimately, cost justification is subjective and depends on individual patient preferences, value attribution and policy decisions. It was concluded that standardized outcome registration and cost presentation could enhance consistency across evaluations and improve comparability in future studies needed to assess willingness-to-pay and societal benefits of IODs.

Chapter 4 - Fully digital versus conventional workflow: Are removable complete overdentures equally good? A randomized crossover trial

This chapter presents a randomized crossover clinical trial comparing conventional implant-supported overdentures (C-IODs) with CAD-CAM fabricated 3D-IODs, as explained in Chapter 2. Edentulous patients with 2-4 mandibular and 4-6 maxillary implants wore each IOD type for one year in a crossover design. Blinding was maintained by fabricating both IODs before placement of the first IOD-type, preventing patients from knowing which IOD-type they received at baseline.

Patient-reported outcome measures (PROMs) included OHIP-20, overall satisfaction (VAS, 1-100), and the SF-36 health survey. OHIP responses were scored 0 (“never”) to 4 (“very often”), with total scores ranging from 0 (best) to 80 (worst). Data were analyzed using both total and mean item scores according to the Simple Count Method (SCM).

Of 36 participants, 32 (16 males, 16 females; mean age 62,8 years) completed the trial. The non-inferiority threshold was 6 OHIP-20 points, meaning that the 3D-IOD was considered as equally good as the C-IOD if the 3D-IOD did not yield a total score exceeding the C-IOD score by more than 6 points. Calculated to the score per question, this means a worst allowable score of 0.30 per item. On the contrary, the 3D-IOD group showed an improvement of 0.257 points per item ($p < 0.001$), surpassing the non-inferiority

margin and indicating statistical superiority. Total OHIP scores improved from 45.8 preoperatively to 12.0 with C-IODs and to 6.8 with 3D-IODs.

Similarly, VAS scores (scale: 1-100) revealed a statistically significant 7.265-point improvement in patient satisfaction for the 3D-IOD over the C-IOD. SF-36 subscale analyses indicated that OHRQoL, as measured by the OHIP-20, was largely independent of general health status.

In conclusion, the 3D-IODs outperformed the C-IODs in terms of patient-reported OHRQoL and satisfaction. The favorable outcomes may be attributed to the slender design, esthetic customization, and more sufficient retention of the PEEK attachment system.

Chapter 5: Budget Impact Analysis: Digital workflow significantly reduces costs of Implant supported Overdentures (IODs)

Economic evaluations of prosthetic treatments vary widely due to differences in denture types, healthcare systems, and analytical perspectives (patient vs. healthcare system vs. societal). National guidelines differ accordingly. Following Dutch recommendations, this study adopted a societal perspective, accounting for healthcare costs, travel expenses, productivity losses, and consumer price indices.

A cost-consequence analysis (CCA) compared in the crossover trial, C-IOD and 3D-IOD fabrication costs. Implant and surgical costs were excluded due to consistency across groups.

IOD production costs included both the clinician's fees and the dental laboratory charges. These costs were based on standardized rates established annually by the Dutch Healthcare Authority (Nederlandse Zorgautoriteit, NZa). For this analysis, tariffs from 2018 and 2019 were applied, reflecting the years in which the IODs were fabricated. Dental laboratory costs were determined using actual invoiced amounts. In addition to direct healthcare costs, patient-incurred costs, including travel expenses and productivity losses (for both paid and unpaid work), were evaluated. The Institute for Medical Technology Assessment Productivity Cost Questionnaire (iMTA-PCQ) was used to quantify absenteeism (taking sick leave) and presenteeism (being present at work when sick). The questionnaire was administered at baseline, 12 months, and 24 months.

For a complete IOD, the digital approach yielded a 14.2% reduction in total costs (€4700,33 vs. €4030,61), a 41.1% reduction in treatment time (308.64 vs.

182.05 minutes), and a 47.1% reduction in the number of treatment sessions (5.68 vs. 3.0).

For maxillary C-IODs supported by Locators™ versus bar-retained 3D-IODs, total costs were similar (approximately €2.400), as were laboratory costs (approx. €1760). However, in comparison with bar-retained C-IOD designs, the bar-retained maxillary 3D-IODs were significantly cheaper with a total cost reduction of 39% (€3659,70 vs. €2239,41). For the mandibular arch, total cost showed a 20% reduction for 3D-IODs (€2106,35 vs. €1695,03; $p < 0.001$) Repair costs and time were comparable between groups.

Because most patients were retired, only 25% happened to have paid jobs. Productivity loss due to treatment sessions and travel time were substantially lower for the making of a 3D-IOD than C-IOD and amounted a total €701,18 per worker for the C-IOD-group and €447,98 per worker for the 3D-IOD-group. Given the high percentage of pensioners in this population, however, productivity loss only represented a minor component in the total costs.

To perform a Budget Impact Analysis (BIA), data were requested from the Dutch National Healthcare Institute (Zorginstituut Nederland). This shows that a total of 129.700 mandibular IODs-2 were placed in 2021. In 2021, 23.900 maxillary IODs were installed, i.e. either IODs-4 or IODs-6. After consultation with experts in the field of implantology, it was estimated that for the upper jaw, an IOD-4 was placed in $\frac{2}{3}$ of the cases and an IOD-6 in $\frac{1}{3}$ of the cases, for which $\frac{2}{3}$ of the practitioners used a bar attachment and $\frac{1}{3}$ a single abutment construction. For the lower jaw, it was assumed that in 80% of the cases ($n=103.760$) a bar was used and in 20% ($n=25.940$) a single attachment. The BIA shows that in the Netherlands, a digital workflow would reduce the costs for the upper IODs by €19.907.613 and for the lower IODs by €28.378.360, together €48.285.973.

In conclusion, implementation of a fully digital workflow in IOD fabrication enables the production of high-quality, bar-retained 3D-IODs at significantly lower costs than conventional methods, without compromising quality. This transition creates a substantial opportunity for healthcare savings and efficiency improvements, for example by enabling insurance parties to provide more patients with an IOD for the same budget or making 3D-IODs more affordable for a patient. Finally, it was concluded that the introduction of an oral health related preference-based measure would improve economic evaluations in the field of OHRQoL

Chapter 6 - Discussion

Instruments for assessing Oral Health-Related Quality of Life

Alongside the implementation of a new technique comes the importance of thorough assessment of the available evaluation instruments. The OHIP-20 and OHIP-EDENT remain the most reliable choice for the assessment of OHRQoL. Further comparison with shorter and thus more patient friendly questionnaires can be a valuable next step.

Comparing OHIP outcomes

Despite the common use of expressing scores as a mean from 0 to 4 using the Simple Count Method (SCM), as a cumulative score via the Additive Count Method (ACM), or normalizing scores to a 0-1 scale, comparison of OHIP-outcomes remains challenging, because often differently treated groups are compared, instead of various treatments within the same group.

Economic evaluation

In assessing the value-for-money of dental health interventions, various healthcare and insurance systems, and differences in the devices studied (e.g., partial vs. complete, fixed vs. removable) complicate comparisons. Moreover, countries' guidelines for analytical perspectives differ, resulting in variation of the broadness of scope. Using the Guide to Economic Analysis and Research (GEAR) learns that for example The Netherlands and Sweden recommend a societal perspective, Germany focusses more on the insurance level, and that in the UK uses the perspective of the NHS.

Emphasis is placed on acknowledgment of the used perspective, e.g. because the societal perspective is the broadest approach, one should be aware that costs might seem higher than in a narrower perspective. Additionally, the productivity loss of informal caregivers, like adult children accompanying their elderly parents to appointments, is highlighted in the context of an aging society. Finally, the practicality and usefulness of broad perspectives, and possibilities for indicated narrower perspectives were discussed.

Using a digital workflow for manufacturing complete dentures (3D-CDs) and implant-supported overdentures (3D-IODs)

Whereas intraoral scanning was earlier considered a barrier due to difficulties in accurately defining denture peripheries, evolving techniques made it a standard approach nowadays. For capturing the vertical dimension of occlusion and centric relation, a wax rim or try-in denture remains advisable. In this regard, also the use of the patient's old denture is discussed.

Initial experiences with 3D-printed IODs revealed susceptibility to mechanical failure. Despite technological advancements, current 3D printing materials are best suited for provisional prostheses due to limited wear resistance. Milled prostheses, in contrast, offer more consistent quality and are presently the preferred manufacturing method. However, convergence of quality between printed and milled dentures is anticipated in the future.

Ultimately, the question was raised whether fully digital workflows should be pursued unconditionally or that more pragmatically implementing digital techniques where they are beneficial would be commendable.

Chapter 7- Future perspectives

Due to population aging the absolute number of edentulous patients is expected to increase both worldwide and in the Netherlands. This thesis shows that the implementation of 3D-IODs instead of C-IODs can save €48.260.589 per year. One option for allocation of this saved money is supplying patients in need of an IOD with the more advanced solution of a bar retained 3D-IOD rather than a Locator™-retained C-IOD. As an alternative, the 'prevention' destination can be chosen; the calculated savings cover a third of an annual dental check-up.

The study design of a cohort study is advocated because of more relevant comparability. Moreover, the importance of development of a preference-based measure (PBM) for OHRQoL is highlighted. This means that health status is weighed within the context of a specific society, and thus results in enhanced cost-effectiveness. Given the scarcity of funding in healthcare, it is argued that even reasonably good treatment could be sufficient. The focus should be on research into the most effective distribution of resources.

So far, on the level of policy making, digitalization is yet neither considered as a method to decrease healthcare cost, nor are ways in which it can decrease workload sufficiently explored. Additionally, the ability to remotely

gather patient information through digital technologies could lead to new initiatives like visiting patients in nursing homes instead of requiring them to travel to a dental practice.

Even though digital engagement seems limited among senior dentists, the use of digital techniques and prosthetic planning software is a standard aspect in the education of both dentists and dental technicians. Consequently, it is most likely a matter of time before these techniques will be broader implemented. However, policymakers neither recognize the progress already made nor see the full potential of digitalization. Therefore, it raises concerns about whether decisions on manpower planning, reimbursement, funding for education, and reallocation of resources, will be made in the most optimal way.

CHAPTER 9

Nederlandse Samenvatting

Hoofdstuk 1 - Inleiding

Dit hoofdstuk beschrijft de impact van tandeloosheid, een aandoening die wordt gekenmerkt door het volledig verlies van alle natuurlijke tanden en kiezen. Tandeloosheid gaat gepaard met aanzienlijke functionele, esthetische en psychologische beperkingen. Gerapporteerde gevolgen zijn onder andere voedingsrestricties, verminderde kauwfunctie, spraakproblemen en verlies van ondersteuning van de aangezichtsspieren, wat bijdraagt aan een verouderd uiterlijk. De Wereldgezondheidsorganisatie (WHO) classificeert tandeloosheid dan ook als een lichamelijke beperking.

De conventionele behandeling voor tandeloze patiënten bestaat uit het vervaardigen van een volledig kunstgebit, ook volledige prothese (VP) genoemd. Een VP biedt echter nauwelijks herstel van de kauwfunctie. Door schuif- en drukkrachten die ontstaan tijdens het kauwen, treedt progressieve en irreversibele resorptie van het alveolaire kaakbot op, hetgeen leidt tot afnemende retentie en stabiliteit van de VP. Dit resulteert op zijn beurt in pijnklachten, verminderde prothetische functie en psychisch ongemak. Om de beperkingen van VP's tegen te gaan bieden door implantaten ondersteunde overkappingsprothesen (IOD's) grote verbeteringen met betrekking tot stabiliteit, functionaliteit, spraak en patiënttevredenheid. Dit geldt voor zowel de tandeloze boven- als onderkaak. Een bijkomend voordeel is het behoud van het kaakbotvolume door belasting, vanwege de geplaatste implantaten.

De maatschappelijke acceptatie van implantologie is toegenomen door integratie in de reguliere tandheelkundige zorg. Desalniettemin vormen de hoge kosten van implantaatplaatsing en IOD-vervaardiging een aanzienlijke drempel. Tegen deze achtergrond rijzen verschillende onderzoeksvragen op: (1) Biedt de IOD voldoende patiëntgerichte voordelen om de kosten te rechtvaardigen? (2) Hoe kunnen deze voordelen objectief worden gemeten ter ondersteuning van de besluitvorming. (3) Is het haalbaar om een IOD te produceren in een volledig digitaal werkproces/workflow. (4) Welke kostenbesparing schuilt er in de implementatie van een volledig digitale workflow?

Hoofdstuk 2 - Haalbaarheidsstudie (proof-of concept) van de volledig digitale IOD-workflow

In dit hoofdstuk wordt een casus beschreven van een 64-jarige tandeloze vrouw, na plaatsing van zes implantaten in de bovenkaak en twee in de onderkaak. Zij gaf toestemming om bij haar een volledig digitaal vervaardigde implantaatgedragen overkappingsprothese (3D-IOD's) te laten vervaardigen.

De behandeling werd uitgevoerd in drie klinische sessies: de eerste voor het maken van de intra-orale scans (digitale afdrukken), de tweede voor het passen van de steg en proefprothese, en de derde voor het plaatsen van de 3D-IOD. Na het vastgroeien in het bot van de boven- en onder-implantaten (osseointegratie) werden tijdens de eerste klinische sessie voldoende digitale gegevens verzameld om een virtueel prothetisch ontwerp te maken. Er werden intraorale scans (IOS) van de bestaande boven- en onder prothese gemaakt, afzonderlijk en in occlusie. Daarnaast werden beide tandeloze kaakbogen gescand, inclusief de op de implantaten vastgeschroefde 'scanbodies'. Tevens werden gezichtsfoto's gemaakt en werden de kleur en positie van de gebitselementen samen met de patiënt geëvalueerd met behulp van Smile Design-software.

Met deze digitale dataset konden zowel de steg als het bevestigingssysteem (het klikmechanisme) worden ontworpen. De fronttanden werden virtueel gepositioneerd met behulp van het Smile Design programma, terwijl de posterieure occlusie werd geoptimaliseerd door gebruik te maken van een virtuele articulator die de kauwbewegingen simuleert. De volgende onderdelen werden met behulp van CAD/CAM-technologie gefreesd: de steggen uit titanium en het klikmechanisme uit polyetheretherketone (PEEK). Vervolgens werd op basis van dit digitale ontwerp een proefprothese 3D-geprint.

Tijdens de tweede klinische sessie werden de steggen en de proefprothese tijdelijk geplaatst en klinisch geëvalueerd, waarna zo nodig digitaal nog aanpassingen konden worden aangebracht. In de laatste klinische sessie werden de definitieve 3D-IOD's geplaatst.

Na één jaar werden geen biologische of prothetische complicaties geconstateerd. De patiënte beoordeelde haar tevredenheid met een negen op een visueel analoge schaal (1-10). Deze casus toont dat het met behulp van een volledig digitale workflow mogelijk is om een duurzame, slijtvaste IOD's te vervaardigen in slechts drie klinische sessies.

Hoofdstuk 3 - Beoordeling van de toegevoegde waarde van implantaatgedragen overkappingsprothesen

In dit hoofdstuk wordt de literatuur besproken die evalueert in hoeverre implantaatgedragen overkappingsprothesen (IOD's) de aan de mondgezondheid gerelateerde kwaliteit van leven (Oral Health-Related Quality of Life: OHRQoL) verbeteren ten opzichte van conventionele volledige prothesen (VPs), en of deze verbeteringen de meerkosten rechtvaardigen. De onderzochte studies richtten zich op diverse meetinstrumenten voor OHRQoL en op methoden om de economische waarde van IOD's vast te stellen.

Een gestructureerde zoekstrategie werd toegepast op de databanken MEDLINE, EMBASE en de Cochrane Database. In totaal voldeden 17 studies aan de inclusiecriteria.-

Om de financiële gegevens te standaardiseren, werden alle gerapporteerde kosten omgerekend naar Amerikaanse dollars (USD), alsmede aan de hand van de toen geldende wisselkoersen gecorrigeerd voor het jaar waarin de betreffende studie werd uitgevoerd. Bijna alle studies onderzochten de meerwaarde van een onderprothese afgesteund op twee implantaten (IOD-2). De initiële kosten voor een VP ten opzichte van een IOD-2 verschilden per land. Zo bedroegen de gemiddelde kosten in Canada \$627 voor een prothese en \$1.796 voor een IOD-2, terwijl deze in Zwitserland respectievelijk \$1.540 en \$4.230 bedroegen. Gemiddeld waren de IOD-2-onderprothesen twee- tot driemaal duurder dan conventionele VP's.

De term "totale kosten" werd frequent gebruikt in de geïnccludeerde studies, maar de specifieke kostencomponenten die onder deze noemer vielen, verschilden aanzienlijk. De meeste studies berekenden de kosten voor de aanschaf van de implantaten en de chirurgische ingrepen. Kosten voor de vervaardiging van de prothese en tandtechnisch laboratoriumwerk werden ook vaak meegenomen, terwijl onderhoudskosten minder vaak werden gerapporteerd. Slechts een minderheid van de studies betrok indirecte kosten, zoals productiviteitsverlies ten gevolge van tandartsbezoeken of ziekteverzuim.

Voor de beoordeling van OHRQoL bestaan verschillende gevalideerde vragenlijsten, zoals de Oral Health Impact Profile (OHIP), de Visual Analogue Scale (VAS), de Geriatric Oral Health Assessment Index (GOHAI) en de Oral Impacts on Daily Performances (OIDP) index.

Bij tandeloze patiënten werden vooral verschillende versies van de OHIP-vragenlijst gebruikt, waaronder de OHIP-14, OHIP-EDENT en OHIP-20,

bestaande uit respectievelijk 14, 19 en 20 items. Deze meetinstrumenten evalueren telkens zeven domeinen: functionele beperkingen, fysieke pijn, psychisch ongemak, lichamelijke beperkingen, psychische beperkingen, sociale beperkingen en handicaps. De antwoorden worden gescoord op een 5-punts Likertschaal van 0 (“nooit”) tot 4 (“erg vaak”).

De vergelijkbaarheid tussen de verschillende OHRQoL-vragenlijsten werd gewaarborgd met behulp van de “minimum important difference” (MID), het vragenlijstafhankelijke kleinste aantal OHIP-punten dat een significante verbetering weergeeft. In deze studies werd de OHIP-score op twee manieren berekend. De *Simple Count Method* (SCM) rapporteert gemiddelde scores per item (schaal 0-4). De *Additive Count Method* (ACM) daarentegen telt alle item-scores op en leidt zo tot een maximale totaalscore van respectievelijk 76 (OHIP-EDENT, schaal 0-4), 80 (OHIP-20, schaal 0-4) of 196 (OHIP-49, schaal 0-4).

Het ontbreken van gestandaardiseerde meetmethoden en het gebruik van diverse uitkomstmaten belemmert de vergelijking tussen studies. De uiteindelijke rechtvaardiging van de meerkosten blijft subjectief en afhankelijk van individuele patiëntvoorkeuren, de daaraan toegekende waarde, en beleidskeuzes. Er werd geconcludeerd dat gestandaardiseerde registratie van uitkomsten en presentatie van kosten de uniformiteit tussen evaluaties kunnen vergroten en de vergelijkbaarheid in toekomstige onderzoeken kunnen verbeteren. Dit is nodig om de betalingsbereidheid voor en de maatschappelijke voordelen van IOD's te beoordelen.

Hoofdstuk 4 - Volledig digitale versus conventionele workflow: zijn uitneembare volledige overkappingsprothesen even goed? Een gerandomiseerde cross-overstudie

Dit hoofdstuk beschrijft een klinische gerandomiseerde cross-over studie waarin conventionele IOD's (C-IOD's) worden vergeleken met digitaal vervaardigde IOD's (3D-IOD's). Tandeloze patiënten, bij wie reeds 2-4 implantaten in de onderkaak en 4-6 implantaten in de bovenkaak waren geplaatst, droegen beide IOD-types elk gedurende één jaar. Blindering werd gegarandeerd door beide IOD-types reeds voorafgaand aan het plaatsen van het eerste IOD-type te vervaardigen, zodat patiënten bij aanvang niet wisten met welke IOD-type zij startten

Patient-Reported Outcome Measures (PROMs) betroffen OHIP-20, de tevredenheid score (VAS 1-100) en de SF-36 gezondheidsvragenlijst. OHIP-scores varieerden van 0 (nooit) tot 4 (zeer vaak), met een totale score van 0 (best) tot 80 (slechtst). Analyses werden uitgevoerd op zowel totaalscore als gemiddelde itemscore.

Van de 36 deelnemers voltooiden 32 het onderzoek (16 mannen, 16 vrouwen; gemiddelde leeftijd 62,8 jaar). De drempelwaarde voor non-inferioriteit werd vastgesteld op 6 OHIP-20 punten (0,30 per item). De 3D-IOD-groep toonde een verbetering van 0,257 punten per item ($p < 0,001$), wat statistische superioriteit aangeeft. De totale OHIP-score verbeterde van 45,8 preoperatief naar 12,0 bij C-IOD's en 6,8 bij 3D-IOD's.

Ook de tevredenheidsscores (VAS-schaal: 1-100) lieten een statistisch significante verbetering van 7,265 punten voor de 3D-IOD zien ten opzichte van de C-IOD. De SF-36 analyses gaven aan dat OHRQoL, gemeten met de OHIP-20, grotendeels onafhankelijk was van de algemene gezondheidstoestand.

Concluderend presteerden de 3D-IOD's beter dan de C-IOD's zowel wat betreft de door de patiënt gerapporteerde OHRQoL alsook de tevredenheid. De gunstige resultaten kunnen worden toegeschreven aan het slanke ontwerp, de esthetische personalisatie, en de betere houvast van het PEEK-kliksysteem.

Hoofdstuk 5 - Budget Impact Analyse: verlaagt een digitale workflow significant de kosten van implantaat gedragen overkappingsprothesen (IOD's)?

Economische evaluaties van prothetische behandelingen lopen financieel sterk uiteen, wat voornamelijk toe te schrijven is aan verschillen in prothesetypes, zorgstelsels en gehanteerde analysekaders (bijvoorbeeld patiëntperspectief, zorgperspectief of maatschappelijk perspectief). Nationale richtlijnen sluiten hierop aan en verschillen navenant. Conform de Nederlandse aanbevelingen is in deze studie gekozen voor een maatschappelijk perspectief, waarbij zowel de directe zorgkosten als reiskosten, de productiviteitsverliezen en consumentenprijsindex in beschouwing zijn genomen.

Een kosten-gevolgen analyse (*Cost-Consequence Analysis*, CCA) werd uitgevoerd ter vergelijking van de vervaardigingskosten van conventioneel vervaardigde IOD's (C-IOD) versus digitaal vervaardigde IOD's (3D-IOD), op

basis van gegevens uit de cross-over studie. Implantaat- en chirurgiekosten werden hierbij buiten beschouwing gelaten, aangezien deze voor beide groepen identiek waren.

De vervaardigingskosten van IOD's omvatten zowel de honoraria van de behandelend tandarts alsook de kosten van het tandtechnisch laboratorium. Deze kosten werden bepaald aan de hand van gestandaardiseerde tarieven, jaarlijks vastgesteld door de Nederlandse Zorgautoriteit (NZa). Voor deze analyse zijn de NZa-tarieven van 2018 en 2019 gehanteerd, overeenkomstig met de jaren waarin de IOD's zijn vervaardigd. De laboratoriumkosten zijn gebaseerd op daadwerkelijke factuurbedragen. Naast de directe zorgkosten zijn ook patiëntgebonden kosten meegenomen, zoals reiskosten en productiviteitsverlies (zowel voor betaald als onbetaald werk). Voor het kwantificeren van ziekteverzuim (absenteïsme) en verminderde productiviteit bij aanwezigheid (presenteïsme) is gebruikgemaakt van de Productivity Cost Questionnaire van het Institute for Medical Technology Assessment (IMTA-PCQ). Deze vragenlijst werd afgenomen bij aanvang van de behandeling, na 12 maanden en na 24 maanden.

Voor een volledige IOD, dus boven- en onderkaak, resulteerde de digitale werkwijze in een kostenreductie van 14,2% (€4.700,33 versus €4.030,61), een tijdsreductie van 41,1% in behandelduur (308,64 versus 182,05 minuten) en een vermindering van 47,1% in het aantal behandelafspraken (5,68 versus 3,0 sessies).

Voor de bovenkaak waren de totale kosten van op Locator™ afgesteunde C-IOD's en op steg afgesteunde 3D-IOD's vergelijkbaar (circa €2.400), evenals de laboratoriumkosten (circa €1.760). Wanneer echter gekeken werd naar op steg afgesteunde C-IOD's in de bovenkaak, bleken de 3D-IOD's aanzienlijk goedkoper, met een kostenreductie van wel 39% (€3.659,70 versus €2.239,41). Voor de onderkaak werd een kostenreductie van 20% vastgesteld bij toepassing van 3D-IOD's (€2.106,35 versus €1.695,03; $p < 0,001$). De kosten voor reparaties en de benodigde tijd waren vergelijkbaar tussen beide groepen.

Omdat de meeste patiënten gepensioneerd waren, had slechts 25% een betaalde baan. Het productiviteitsverlies door behandelsessies en reistijd was aanzienlijk lager voor het maken van een 3D-IOD dan voor een C-IOD en bedroeg in totaal €701,18 per medewerker voor de C-IOD-groep en €447,98 per medewerker voor de 3D-IOD-groep. Gezien het hoge percentage gepensioneerden in deze populatie betrof het productiviteitsverlies echter slechts een klein deel van de totale kosten.

Voor de uitvoering van een Budget Impact Analyse (BIA) zijn gegevens opgevraagd bij het Zorginstituut Nederland. In 2021 werden in de onderkaak totaal 129.700 IOD-2's geplaatst. In de bovenkaak werden datzelfde jaar 23.900 IOD's geplaatst, hetzij een IOD-4 of IOD-6. Na overleg met experts op het gebied van implantologie werd geschat dat in de bovenkaak in $\frac{2}{3}$ van de patiënten een IOD-4 werd toegepast, en in $\frac{1}{3}$ een IOD-6. Verder werd verondersteld dat in de bovenkaak bij $\frac{2}{3}$ van de gevallen een stegconstructie werd gebruikt en in $\frac{1}{3}$ een solitaire abutment-constructie. Voor de onderkaak werd verondersteld dat in 80% van de gevallen ($n = 103.760$) een steg werd toegepast, en in 20% ($n = 25.940$) een solitair abutment.

De BIA toont aan dat in Nederland de implementatie van een digitale workflow een kostenbesparing van €19.907.613 zou opleveren voor bovenkaak-IOD's en €28.378.360 voor onderkaak-IOD's, in totaal een besparing van €48.285.973.

Samenvattend maakt de implementatie van een volledig digitale workflow bij de vervaardiging van IOD's het mogelijk om hoogwaardige, steg-gedragen 3D-IOD's te produceren tegen significant lagere kosten dan bij conventionele productiemethoden, zonder in te boeten op kwaliteit. Deze transitie creëert een substantiële kans voor besparingen en efficiëntieverbeteringen in de gezondheidszorg, bijvoorbeeld door verzekeraars in staat te stellen meer patiënten een IOD te bieden voor hetzelfde budget, of door 3D-IOD's betaalbaarder te maken voor een patiënt. Tot slot werd geconcludeerd dat de introductie van een Preference-Based Measure (PBM) voor mondgezondheid de economische evaluaties op het gebied van OHRQoL zou verbeteren.

Hoofdstuk 6 - Discussie

Instrumenten voor het beoordelen van OHRQoL

Ten behoeve van de implementatie van een nieuwe techniek is een grondige beoordeling van de reeds beschikbare evaluatie-instrumenten van groot belang. Hierbij blijken de OHIP-20 en OHIP-EDENT de meest betrouwbare keuze voor het beoordelen van de OHRQoL. Verdere vergelijking met kortere en dus patiëntvriendelijkere vragenlijsten kan een waardevolle volgende stap zijn.

Het vergelijken van OHIP-resultaten

Ondanks universele rapportagemethodes blijft het vergelijken van OHIP-resultaten een uitdaging. Zo bestaan er meerdere methoden om de scores weer te geven, zoals het uitdrukken in een gemiddelde van 0 tot 4 volgens de Simple Count Method (SCM), als een cumulatieve score volgens de Additive Count Method (ACM), of door middel van het normaliseren van scores naar een schaal van 0-1. De complexiteit bij het vergelijken komt mede doordat vaak verschillend behandelde groepen worden vergeleken in plaats van verschillende behandelingen binnen dezelfde patiëntgroep.

Economische evaluatie

Bij het beoordelen van de prijs-kwaliteitverhouding van tandheelkundige interventies bemoeilijken verschillen tussen zorg- en verzekeringssystemen, alsmede variatie tussen bestudeerde hulpmiddelen (bijv. een partiele versus een volledige, of een vaste versus een uitneembare voorziening) zo'n vergelijking. Bovendien verschillen de richtlijnen van landen voor analytische perspectieven, wat resulteert in variatie in de reikwijdte van het perspectief. Uit de Guide to Economic Analysis and Research (GEAR) blijkt bijvoorbeeld dat Nederland en Zweden een maatschappelijk perspectief aanbevelen, Duitsland zich meer richt op het verzekeringsniveau en het VK het perspectief van de NHS hanteert.

Bewustwording van het gebruikte perspectief werd benadrukt. Zo leidt het maatschappelijk perspectief, dat de breedste benadering voorstaat, tot hogere kosten dan een beperkter perspectief. Daarnaast werd het productiviteitsverlies van mantelzorgers, zoals volwassen kinderen die hun bejaarde ouders vergezellen naar afspraken, benadrukt in de context van een vergrijzende samenleving.

Gebruik van een digitale workflow voor de productie van volledige prothesen (3D-CD's) en implantaatgedragen overkappingsprothesen (3D-IOD's)

Werd vanwege de moeilijkheid om protheseranden nauwkeurig te definiëren, intra-oraal scannen voorheen als 'no go' beschouwd, is het door verbeterde techniek tegenwoordig een standaardaanpak geworden. Voor het vastleggen van de verticale dimensie van occlusie en de centrale relatie blijft een waswal of een pasprothese aan te raden. In een digitale workflow kan hierbij de 'oude gebitsprothese' van de patiënt een belangrijke rol spelen.

De eerste ervaringen met 3D-geprinte IOD's lieten een risico op breuk van de prothese basis zien. Vanwege de beperkte sterkte is ook de huidige

generatie 3D-printmaterialen ongeschikt voor een definitieve prothese. CAD-CAM gefreesde prothesen bieden daarentegen een consistentere en sterkere kwaliteit. Daarom is frezen momenteel de productiemethode van voorkeur. Wel wordt verwacht dat de kwaliteit van geprinte en gefreesde prothesen in de toekomst elkaar zullen benaderen. Bediscussieerd werd of een volledig digitale workflow te allen tijde moet worden nagestreefd, of dat het beter zou zijn om digitale technieken pragmatischer te implementeren, namelijk daar waar ze nuttig zijn.

Hoofdstuk 7 - Toekomstperspectieven

Door de vergrijzing zal het absolute aantal tandeloze patiënten naar verwachting wereldwijd en dus ook in Nederland toenemen. Dit proefschrift toont aan dat de implementatie van 3D-IOD's in plaats van C-IOD's € 48.260.589 per jaar kan besparen. Een optie voor het besteden van dit bespaarde geld is om tandeloze patiënten te voorzien van de geavanceerdere oplossing (3D-IOD met stegconstructie) in plaats van een C-IOD op Locators™. Een andere aantrekkelijke optie is om te investeren in preventie; de gepresenteerde besparing zou al een derde van de jaarlijkse kosten voor tandheelkundige controle kunnen dekken.

Als onderzoeksopzet wordt de cohortstudie aanbevolen vanwege de optimale vergelijkbaarheid van de resultaten. Bovendien wordt geadviseerd om een Preference-Based Measure (PBM) voor OHRQoL te introduceren. Dit betekent dat een gezondheidsstatus wordt gewogen binnen de context van een specifieke samenleving, wat resulteert in een betere bepaling van kosteneffectiviteit. Gezien de schaarste in de gezondheidszorg wordt gesteld dat een redelijkerwijs goede behandeling mogelijk al voldoende is, en dat de nadruk moet liggen op verder onderzoek naar de verdeling van middelen.

Tot nu toe wordt digitalisering op beleidsniveau noch beschouwd als een methode om de zorgkosten te verlagen, noch als methode om evident de werkdruk te verminderen. Dankzij digitale technologieën kunnen patiëntgegevens ook buiten de tandartspraktijk worden verzameld. Dit opent de deur naar nieuwe initiatieven, zoals het bezoeken van patiënten in verpleeghuizen in plaats van hen te laten reizen naar een praktijk.

Hoewel digitale betrokkenheid onder senior tandartsen beperkt lijkt, is het gebruik van digitale technieken en software voor prothetische planning een standaardonderdeel in de opleiding van zowel tandartsen als tandtechnici. Het is dan ook een kwestie van tijd voordat deze technieken breder worden

geïmplementeerd. Beleidsmakers zien echter zowel onvoldoende de reeds geboekte vooruitgang als het volledige potentieel van digitalisering. Daarom wordt betwijfeld of beslissingen over personeelsplanning, vergoedingen, financiering van opleidingen en herverdeling van middelen op de meest optimale manier worden genomen.

APPENDICES

Description of the research data management

Ethics and privacy

Medical and ethical approval

This thesis is based on the results of research involving human participants, which were conducted in accordance with relevant national and international legislation and regulations, guidelines, codes of conduct and Radboudumc policy. The Ethics Committee of Arnhem/Nijmegen (Dossier number: 2017-3671 NL-number: NL63073.091.17; NL-OMON44248 <https://onderzoekmetmensen.nl/en/trial/44248>) has given approval December 12, 2017 to conduct this study.

Privacy measures

According to Dutch legislation, data collection from electronic patient files was performed by personnel with a treatment relationship with the patient and by the researchers upon consent by the study participant.

The privacy of the participants in these studies was warranted by the use of pseudonymization

The pseudonymization key was stored on a secured network drive that was only accessible to members of the project who needed access to it because of their role within the project. The pseudonymization key was stored separately from the research data.

Informed consent

Informed consent was obtained from participants to collect and process their data for this research project. Where possible, the raw qualitative data was anonymized by data aggregation to enable sharing for reuse.

Data collection and storage

Data collection

Data for **Chapters 2, 4 and 5** was retrieved through questionnaire forms and electronic health records and collected in Castor EDC. Data were converged from Castor EDC to SPSS (SPSS Inc., Chicago, Illinois, USA).

Data storage

Data from **Chapters 2, 4 and 5** were stored and analyzed on the department server and in Castor EDC and are only accessible by project members working at the Radboudumc. These secure storage options safeguard the availability, integrity and confidentiality of the data.

Paper data is stored in locked cabinets on the department.

Background information & guidance

Chapters 2, 3, 4 and 5 are published, of which **3, 4 and 5** with **open** access. **Chapter 3** is based on existing data which was obtained from published literature.

The dataset from **Chapters 2, 4 and 5** is published with **open** access in the DANS Data Station (Data Archiving and Networked Services) of the Royal Netherlands Academy of Arts and Sciences (KNAW) (<https://doi.org/10.17026/DANS-25S-6CDK>)

List of publications

Van de Winkel T, Heijens L, Listl S, Meijer G. What is the evidence on the added value of implant-supported overdentures? A review. *Clin Implant Dent Relat Res*. 2021 Aug;23(4):644-656. doi: 10.1111/cid.13027. Epub 2021 Jul 15. PMID: 34268866; PMCID: PMC8457103.

Van de Winkel T, Delfos F, van der Heijden O, Verhamme L, Meijer G. Fully digital workflow for producing implant-supported overdentures milled from PMMA on titanium bars using PEEK as the female part/sliding mechanism in three clinical visits: A case report. *Int J Oral Implantol (Berl)*. 2022 Sep 9;15(3):277-286. PMID: 36082661.

Van de Winkel T, Delfos F, van der Heijden O, Bronkhorst E, Verhamme L, Meijer G. Fully digital versus conventional workflow: Are removable complete overdentures equally good? A randomized crossover trial. *Clin Implant Dent Relat Res*. 2025 Feb;27(1):e13398. doi: 10.1111/cid.13398. Epub 2024 Sep 30. PMID: 39350584; PMCID: PMC11739062.

Van de Winkel T, Delfos F, van Oirschot B, Maal T, Adang E, Meijer G. Budget Impact Analysis: Digital Workflow Significantly Reduces Costs of Implant Supported Overdentures (IODs). *Clin Implant Dent Relat Res*. 2025 Feb;27(1):e13413. doi: 10.1111/cid.13413. Epub 2024 Nov 13. PMID: 39538985; PMCID: PMC11798910.

PhD portfolio of Thomas Van de Winkel

Department: **Oral and Maxillofacial Surgery**

PhD period: **01/04/2020 – 31/12/2025**

PhD Supervisors: **prof. dr. G.J. Meijer, prof. dr. T.J.J. Maal**

PhD Co-supervisors: **dr. L.M. Verhamme, dr. B.A.J.A. van Oirschot**

Training activities

Hours

Courses

- Radboudumc - Introduction day (2019)	6
- Toezichthoudend medewerker stralingsbescherming voor tandheelkunde (CBCT) (2020)	7.50
- RIHS - Introduction course for PhD candidates (2021)	15
- Radboudumc - eBROK course (2022)	42
- Radboudumc - Scientific integrity (2022)	20
- RU - Effective Writing Strategies (2022)	75
- RU - Statistics for PhD's by using SPSS (2023)	60

Seminars

- Webinar NVMKA/SSKMKA Voorjaarscongres (2020)	3
- NVMKA/SSKMKA 67e Najaarscongres (2023)	11
- Lezing: De Grote Sprong Voorwaarts in de implantologie (2024)	4
- Immediaat Implanteren (2024)	6
- Pre Conference Course Facially oriented treatment planning in contemporary implantology (2024)	3
- NVMKA/SSKMKA 68e Najaarscongres (2024)	12
- NVMKA/SSKMKA Voorjaarscongres (2025)	11
- NVMKA/SSKMKA 69e Najaarscongres (2025)	11

Conferences

- 26th Congress of the European Association for Cranio Maxillo Facial Surgery (2022)	24
- AO CMF Lighthouse Course - Trauma, Köln (2023)	14
- Congress of the Scandinavian Association of Oral and Maxillofacial Surgeons, Göteborg (2024)	16
- Face Ahead Congress, Prague (2024)	16
- AO CMF Lighthouse Course - TMJ Surgery, Leiden (2025)	14

Other

- Lidmaatschap UMC-raad (2020 - 2025)	1128
- Lidmaatschap Adviescommissie Opleidingen KNMT (2020 - 2025)	45

Teaching activities

Lecturing

- Oral presentation at the 26th Congress of the European Association for Cranio Maxillo Facial Surgery (2022) 0.50
- Oral presentation: Less is more: betere PROMs bij goedkopere overkappingsprothese gemaakt in minder zittingen, NVMKA 69e Najaarscongres (2025) 0.25

Supervision

- Supervision of dental and medical interns at the department of Oral and Maxillofacial Surgery (2019 -2023)
- Supervision of junior residents at the department of Oral and Maxillofacial Surgery (2021 -2023)

Total

1544.25

Acknowledgements - Dankwoord

“Geluk? Daarover hoor je niet te spreken. Een woord te veel en het is al lachwekkend. Twee woorden en het is verdwenen, weg.”

H.M. van den Brink, Over het water

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Daarnaast is het moeilijk een waarde te verbinden aan enerzijds bijdrage aan dit proefschrift, en anderzijds de bijdrage aan mijn ontwikkeling die hiertoe heeft geleid.

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Lieve Joachim, wat ben ik trots op jou!

Liebe Vici, ich liebe dich!

***"Sverige, Sverige älskade vän [...]
Duka din veranda till fest för en långväga gäst,
i landet lagom är bäst"***

Kent, Sverige, 2002

„Wind en weder dienende kom ik misschien nog wel eens in patria”

Hella S. Haasse, Heren van de thee

Curriculum Vitae

Thomas Van de Winkel was born on the 28th of October 1988 and grew up in Heerlen, the Netherlands. After graduating from the Gymnasium at the Bernardinuscollege in 2007, he moved to Nijmegen to study dentistry.

In 2013, he received his dental degree in the first group to complete the new six-year curriculum. He remained in academia and subsequently studied medicine, while working part-time as a general dentist in both Germany and the Netherlands.



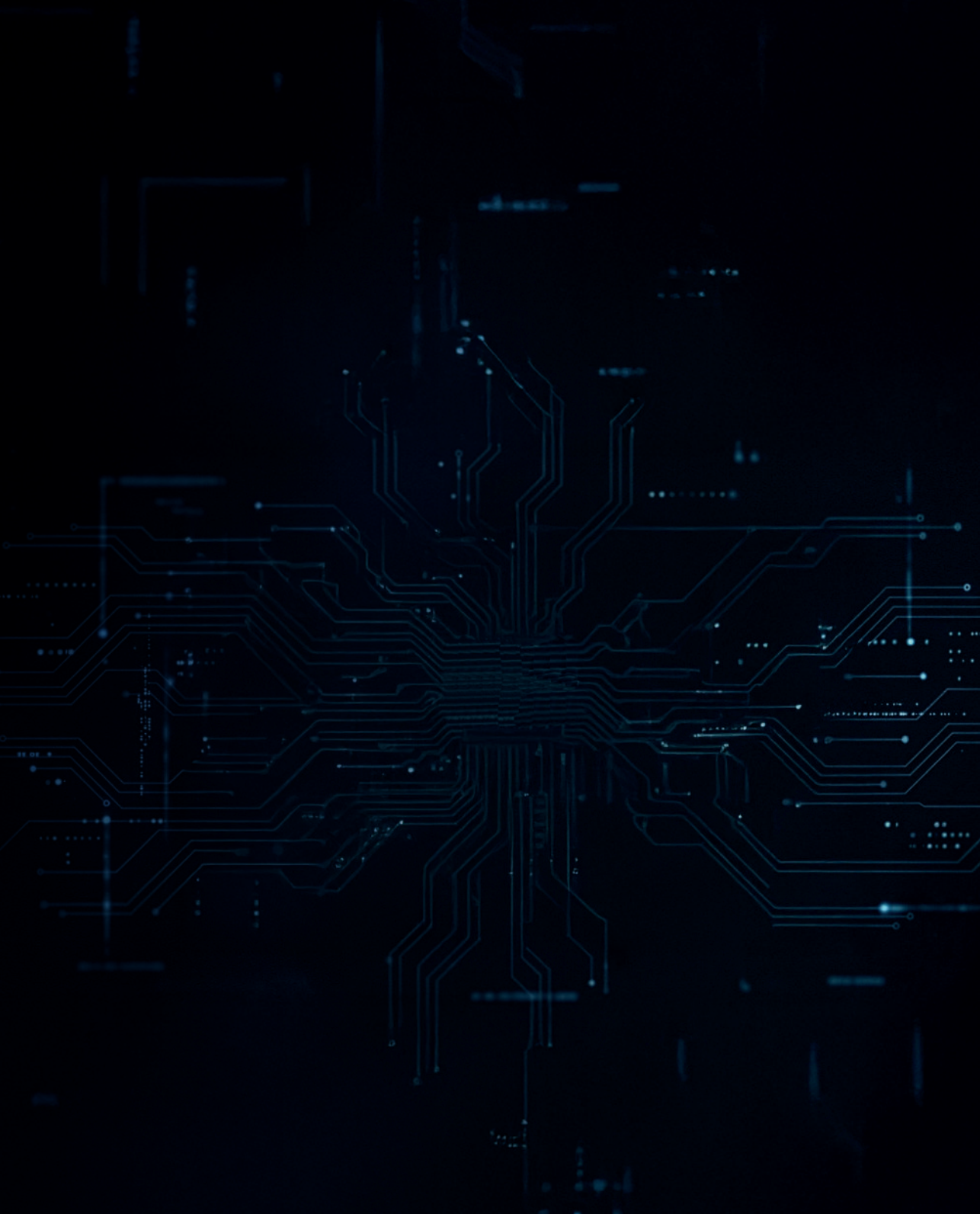
He obtained his medical degree in 2018 and began his Oral and Maxillofacial Surgery residency at the Radboudumc (head of department: prof. dr. S.J. Bergé) in 2019.

Enrolment in this PhD project followed one year later, under primary supervision of prof. dr. G.J. Meijer. In 2023, Thomas successfully finalized his specialist training with an internship at the Norrlands Universitetssjukhus in Umeå, Sweden. Since then, he has worked clinically as a general oral and maxillofacial surgeon alongside his research activities.

As a researcher he presented twice at a EACMFS congress and has peer-reviewed articles for BMC Oral Health and The Journal of Public Health Research. During this PhD project, he developed a special interest in PROMs and valuation of healthcare in addition to implantology and prosthetics. Thomas is married to Victoria and they have a son, Joachim.

*Wahr sind nur
die Erinnerungen, die wir mit uns tragen,
die Träume, die wir spinnen
und die Sehnsüchte, die uns treiben,
damit wollen wir uns bescheiden...*

Dr. Johannes Pfeiffer in 'Die Feuerzangenbowle'



Radboudumc
university medical center



Radboud University