Costs of Implant-supported Over-Dentures (IOD) can be halved using a digital workflow

Published: 12-12-2017
Last updated: 26-10-2024

Our goal is to manufacture a 3D-IOD which is designed digitally, and subsequently 3D-printed. Such 3D-IOD, can be made cheaper, faster and more patient friendly. To prove such a statement, patients should at least be even satisfied about their 3D-...

Ethical review	Approved WMO
Status	Completed
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON44248

Source
ToetsingOnline

Brief title
Costs of IODs can be halved

Condition

- Other condition

Synonym
edentulous patient; retention of their denture is improved by dental implants

Health condition

tandelose patienten

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMw,CorDent BV, Maartensdijk,Vertex BV, Soesterberg

Intervention

Keyword: dental implants, digital workflow, edentulous, quality of life"

Outcome measures

Primary outcome

Oral health related quality of life

Patients will receive a 20-item Oral Health Impact Profile (OHIP-20) questionnaire to determine the Oral Health Related Quality of Life (OHRQoL) at baseline of the study. Twelve months after installation of the first IOD-type, patients receive a second questionnaire to determine changes in the Oral Health Related Quality of Life (OHRQoL). After the switch of IOD-type again after 12 months (24 months after the start of the study) patients will be asked to fill in the third OHIP20-questionnaire.

At the same time points the general IOD-satisfaction using a 10 cm VAS score will be executed.

Secondary outcome

During 24 months following installation, clinical parameters will be registered during supportive care appointments at 12 and 24 months. The peri- implant health is determined by means of bleeding & plaque index

Each technical complication related to the overdenture or implants e.g. abutment screw loosening, fracture of abutments or teeth are calculated as treatments occurring per patient per year (T/P/Y).

Digital radiographs are taken from each individual implant using an individualized guiding system in order to obtain standardized radiographs. Data will be collected after installation of the overdenture and at 12 and 24 months of follow-up.

Costs analysis within healthcare: all healthcare costs associated with the making of 3D-IODs and C-IODs. These include patient visits, scanning costs, costs of making the IOD, therapeutic costs, use of other relevant healthcare services, and relevant medication.

Costs analysis with respect to costs made by patients/family. These include travel costs for which a standardized distance to the hospital by car/ public transport will be used, out-of-pocket expenses and time costs associated with the whole procedure.

Costs in other sectors than healthcare: costs of productivity loss while working (paid and unpaid).

Study description

Background summary

INTRODUCTION/RATIONALE
Edentulism (being toothless) can lead to significant functional impairment, as well as unfavorable aesthetic and psychological changes in patients. Reported drawbacks include restrictions in diet and limited ability to eat certain foods, speech impairment, loss of support for facial musculature which leads to an ageing effect. Edentulism is even classified as a physical handicap by the WHO.

The conventional method for treating edentulism is to provide Complete Dentures (CD). However, CDs do restore chewing function only to a limited degree. Due to unfavorable forces, an irreversible and progressive decrease of basal bone volume is induced, leading to loss of retention and stability. Subsequently, due to soreness, further impaired functioning will occur, also in psychological sense.

As the amount of bone loss is four times higher in the lower jaw than in the upper jaw, retention problems will first occur in the lower jaw. Therefore, most edentulous patients are provided with dental implants already within the first years of edentulism. With respect to their upper-CD, patients function satisfactorily during the first 10 years. However in time, due to progressive resorption, also retention problems of the upper-CD will occur.
Fortunately, to overcome the above mentioned drawbacks of CD*s, the success of Implant-retained Over-Dentures (IOD*s) in terms of stability, function, speech, and patient satisfaction has been shown in many studies; both for the lower jaw as the upper jaw. An extra advantage of the presence of functioning implants is that also the clinically significant progressive bone loss is prevented.

Of the Dutch population 11.6% above 16 years (1.6 million) is fully edentulous; so 1.6 million persons wear a CD in both the upper and lower jaw. Another 4,9% (700.000) is edentulous in one jaw. According the report of Zorginstituut Nederland, every year about 40.000 patients are treated with Conventionally produced IODs (C-IODs) with a total yearly cost for fabrication of ¤105 million.

Study objective

Our goal is to manufacture a 3D-IOD which is designed digitally, and subsequently 3D-printed. Such 3D-IOD, can be made cheaper, faster and more patient friendly. To prove such a statement, patients should at least be even satisfied about their 3D-IOD as their C-IOD (non-inferiority). In the same time, cost and time spent on treatment sessions should be significantly lower. In literature no publications can be found which compare C-IODs with 3D-IODs, simply because of the fact that a digitally designed and 3D-printed IOD is a novel technique.

Besides costs, the most striking benefits are the reduction of the number of treatment sessions and the active participation of the patient in designing his 3D-IOD. Also, technical advantages are introduced. Traditionally, C-IODs are press-cured using 2-component PMMA, which has a major drawback; toxic residual monomer needs to be flushed out meticulously. Furthermore, shrinkage will occur after press-heating, thus frustrating its fit. Such complications are bypassed using 3D-printing techniques

Study design

This effectiveness study entails a randomized controlled trial; 36 patients will be provided both with Conventionally Implant supported Over Dentures (C-IOD's) as with 3D-printed Implant supported Over Dentures (3D-IOD's) in both the lower jaw as well in the upper jaw.

Follow-up period is 24 months; 18 patients will start the first year with a C-IOD, followed by wearing a 3D-IOD the next year (group A). The other 18 patients wear their IOD*s in reverse order (Group B). The C-IOD and 3D-IOD data will be compared on a number of outcome variables: before treatment, after 12 months and after 24 months of follow- up.

Before start of the treatment, and after 12 months, patients in both group A and B will receive a questionnaire (OHIP-20) to determine changes in the Oral Health Related Quality of Life (OHRQoL) after the first IOD-installation. After one year, patients of group A and group B switches from one IOD-modality to the other. At 24 months again the OHIP-20 questionnaire needs to be filled in.

According to the protocol, which is generally used in implant treatment, immediately after IOD-installation and during the supportive care appointments after 6, 12, 18 and 24 months, the clinical variables PPD (Pocket Probing Depth), CAL (Clinical Attachment Level) will be recorded. Additionally, at the start of the study, after one year and after two years, standardized radiographs will be made.

Based on above mentioned data, implant survival, marginal bone level, changes in soft tissue (PPD, CAL) position will be assessed. In addition patient*s overall satisfaction will be scored.

Study burden and risks

The only burden is the extra time spent on

1) the registration of the digital data during the making-of the conventional IOD (2 hours)
2) the session in which one IOD-type will be changed for the other (1 hour)
3) time to fill in the OHIP-20 questionnaire and the overall satisfaction VAS

score (three times 0,5 hour).

The clinical parameters are measured during regular controls and would be executed anyway, as these are a part of the regular control.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 14
Nijmegen 6525GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 14
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Edentulous patients with retention problems of their conventional denure, in whom already 2-6 implants in the edentulous upper jaw and 2-4 implants in their edentulous lower jaw have been installed (or will be installed). Obviously, the patient is willing to participate in this cross-over study

Exclusion criteria

Physically unsuitable to visit the treatment and control sessions

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	01-02-2018
Enrollment:	36
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-04-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63073.091.17