Zirconia dental implants in the aesthetic zone: a prospective case series study

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

Summary

ID

NL-OMON38915

Source
ToetsingOnline

Brief title
Zirconia dental implants

Condition

- Other condition

Synonym
loss of oral function, Missing tooth

Health condition

Vervanging van ontbrekende gebitselementen door middel van een zirkonium implantaat

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,ZV3

Intervention

Keyword: - Bleeding on Probing, - CAD CAM, - Implant, - Zirconia

Outcome measures

Primary outcome

Primary outcome measure is the health of peri-implant mucosal and hard tissues

as expressed through:

- Bleeding On Probing (BOP)

- Probing Pocket Depth (PPD)

- Recession (REC) compared incisal edge picture with pocket probe measurement

Secondary outcome

Secondary outcome measures include:

- Plaque, calculus and gingival index (PCGI) according to Mombelli

- Marginal Boneloss (BL) as measured on standard intra-oral X-ray pictures

(solo recording, Rinn holder with putty)

- Pink and White aesthetic score (PES/WES) of Belser and Buser, index Groningen

ICAI according to Meijer, Papilla-Index (PI) according to JEMT

- Patient Satisfaction (SAT) according to standard questionnaire

- Microbiological (MB) parameters

- Spectro-photometry (SP) of both the crown and the soft tissue

Study description

Background summary

Titanium (Ti) has been the *gold standard* ground material for the fabrication of oral endosseous implants for over four decades. The clinical-functional results are favourable, with well-documented implant survival rates in partially edentulous patients exceeding 95% after 5 years of functional loading of implants supporting either single crowns or fixed partial dentures (Pjetursson et al. 2007). Nevertheless, titanium also has its drawbacks. High-strength ceramics, in particular zirconia (ZrO_2) may be an attractive alternative. After sintering, Y-TZP has mechanical properties comparable to those of stainless steel. Both bone and soft tissues respond favourable to Y-TZP (Manicone et al. 2007). In vivo studies comparing Ti and Y-TZP implants and abutments have predominantly been concerned with the bone-implant response and to a lesser degree with the soft tissue response (Wenz et al. 2008). Comparable percentages of bone-implant contact between Ti and Y-TZP implants have been observed in animal studies (Wenz et al. 2008; Andreiotelli et al. 2009).

Study objective

We aim to conclude on the application of Zirconia dental implants in the aesthetic zone where we feel that it would have the most advantages as compared to titanium implants. Such an implant system is basically comprised of 2 components: a zirconia implant that osseointegrates with the alveolar bone (a) and a fiberglass post and core that is cemented to the implant and acts as an abutment for a ceramic crown. Clinical, (micro-) biological, and radiographical data are collected and compared to the contralateral natural tooth.

Study design

This pilot study is designed as a prospective case series study. A group of 30 patients in need of a single implant crown replacing a front tooth in the aesthetic zone of the maxilla (teeth 15-25) are selected.

Intervention

All patients will recieve an implant in order to replace a missing tooth.

Study burden and risks

About 3 hours extra time, no extra charge or arrangements.

Contacts

Public
Universitair Medisch Centrum Groningen

A. Deusinglaan 1.
Groningen 9713 AV
NL
Scientific
Universitair Medisch Centrum Groningen

A. Deusinglaan 1.
Groningen 9713 AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Patients should be over 18 years of age, in reasonable to good general health, as expressed by an ASA-score 1 or 2 (de Jong and Abraham-Inpijn, 1994)
- Bone volume should allow the placement of implants with a minimum length of 8 mm and minimum diameter of 3.5 mm

Exclusion criteria

- History of previous implant loss
- Irradiation to the maxilla or mandible
- Medical and general contraindications for the surgical or restorative procedures
- Severe bruxism

- Smokers
- An absent neighboring tooth or neighboring tooth provided with an indirect restoration

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-03-2014
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-07-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	16-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL43024.042.13