Evaluation of Zirconia stock and customized implant abutments provided with composite resin crowns: a pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39901

Source
ToetsingOnline

Brief title
Zirconia stock and customized implant abutments

Condition

- Other condition

Synonym
los of oral function, Missing tooth

Health condition

Vervanging van ontbrekende gebitselementen door middel van een implantaatkroon

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,3M,DentsPly,MMM;Astra Tech / Dentsply

Intervention

Keyword: Abutment, CAD CAM, Implant, Zirconia

Outcome measures

Primary outcome

Primary outcome variables are:

1. resistance to static loading bending strength in Newton), comparing experimental stock and CAD-CAM abutments to pristine implant-abutment copies, under the null hypothesis that they are similar (BS);

2. patients* preference, comparing the digital or conventional impression technique as measured on a Visual Analogue Scale, under the null hypothesis that they are similar (PP).

Secondary outcome

Secondary outcome variables relate to clinical performance of the implant and crown. Routine clinical parameters are compared between stock and CAD-CAM abutments after one year, namely:

- Probing Pocket Depth (PPD);

- Bleeding on marginal probing (BOP);

- Recession of the mucosa (REC, difference between the value at placement of the crown and after one year).

Study description

Background summary

Implants are applied in partial edentulous patients to great success and seem the ideal restorative treatment alternative in partially edentulous cases (Pjetursson et al, 2004). Oral implants are placed into the alveolar bone. They support the permucosal implant abutment and crown which are screwed on to the osseointegratded implant. An implant fixed restoration ideally mimics the unrestored natural tooth in all its aspects and blends in with its surroundings. Healthy and geometrically stable soft tissues around the implant crown should be established and maintained for long term service of the implant (Berglundh et al, 1991; Lindquist et al, 1996). The optimal geometry and choice of biomaterial used for implant abutments are relevant to the aesthetic and functional result of treatment.

Study objective

We aim to compare the clinical performance of zirconia stock and CAD-CAM produced implant abutments (experimental group) after one year of function. After one year, the abutments and crowns are removed and subjected to a static bending test in vitro. The specimen with one year of clinical service are compared to pristine exact copies which serve as controls. For the implant crowns to be made, both conventional and digital impressions are made. We study patient*s preference.

Study design

A unicenter randomized clinical trial. Pilot study

Intervention

Implant placement and the provision of an implant-retained crown.

Study burden and risks

Approximately 3 hours of extra time spent, no additional burden.

Contacts

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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 I or II (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

- Previous implant loss
- Irradiation to the maxilla or mandible
- Bruxism

Study design

Design

Study type: Interventional

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2013
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Implant abutment
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	10-04-2013
Application type:	First submission
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	NL42288.042.12