Single final vs. multiple temporary implant abutments: A prospective randomized controlled clinical trial of peri-implant hard/soft tissue and bacteriological changes

Published: 27-01-2015
Last updated: 21-04-2024

Primary Objective: To compare peri-implant hard and soft tissue changes as measured on standardized intraoral radiographs and direct digital intraoral scans between the group of single final and and the group of multiple repeated abutment dis/re-...

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

Summary

ID

NL-OMON40820

Source
ToetsingOnline

Brief title
Single or multiple abutments

Condition

- Other condition

Synonym
peri-implant tissue changes, tissue volume changes

Health condition

Healed extraction site

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Computer assisted, Dental Abutments, Dental Implants, Surgery

Outcome measures

Primary outcome

To compare hard and soft tissue changes

Secondary outcome

-peri-implant microbiological evaluation.

-evuation of guided surgery accuracy

Study description

Background summary

To overcome the obstacles posed by repeated dis/re connections, a concept for immediate final abutment placement at implant surgery was developed (Canullo 2010), referred to as initially as *one abutment- one time*. Few recent reports have demonstrated the applicability of the one abutment- one time concept in the clinical situation (Degidi et al. 2011; Grandi et al. 2012; Degidi et al. 2013; Canullo 2010), with follow ups up to 3 years, measured in standardized periapical radiographs. However, the influence of several parameters in this *one abutment one time* concept on the gingival contour volume maintenance and peri-implant alveolar bone resorption rate are yet to be investigated .

To connect the final abutment at implant placement, the implant should be inserted in the ideal 3-dimensional and prosthetically driven position. For this purpose, guided surgery might be a useful tool. The goal of computer-aided implant surgery is to minimize the error in implant positioning compared to manual or conventional surgical guide implant placement (Yamada et al. 2011), accomplishing optimal implant localization and reducing the risk of damage to

adjacent structures (Brief et al. 2005). Additionally, it facilitates flapless surgery and immediate abutment tightening.

Study objective

Primary Objective:
To compare peri-implant hard and soft tissue changes as measured on standardized intraoral radiographs and direct digital intraoral scans between the group of single final and and the group of multiple repeated abutment dis/re- connections.

Secondary Objective:
- To measure and compare the microbiological flora around the abutments between the two groups through culturing of the periodontal samples.
- To evaluate the precision of the Nobel Clinicians ® guided implant surgery by superimposing the volumetric 3D models between the planned and the placed implant position.
- To compare the following clinical parameters between the two groups: Peri-implant pocket depth, bleeding on probing and plaque percentage.

Study design

The study design is a prospective randomized controlled clinical trial (RCT). Patients in need of one single implant in the (pre)molar region of the upper jaw, who fulfill the inclusion/exclusion criteria (see section 3.1.1 and 3.1.2) will be enrolled in the study.
Randomization will allocate patients into two groups: The test group will have final abutments placed and torqued at implant placement (from now on referred to as test group: TG), and the control group will follow a conventional protocol with healing abutments placed at implant placement and dis/re-connected multiple times (from now on referred to as control group: CG).
Soft and hard tissue behaviour changes will be analyzed and followed up at 3, 6 and 12 months following implant placement.

Intervention

N/A

Study burden and risks

This study is a non-interventional study and therefore the risks are negligible. Both approaches as outlined in this protocol are routinely applied in the clinic and this study aims to compare both approaches in a scientific manner.
Because of the non-interventional nature of this study, also no additional

benefits are expected for the subjects.

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

1. Patients of at least 25 years of age and who are able to sign an informed consent.
2. In need of a single implant.
3. Healed site (healed site defined by restored gingiva, free of inflammation and scar tissue (Zuhr, Hurzeler 2012. Book), with a keratinized band of 3mm from crest to muco-gingival junction, and sufficient osseous architecture to receive an implant (Koutouzis 2013) with a minimal diameter of 3.5 mm).
4. (Pre)molar region.
5. At least one neighbouring tooth is present.
6. Absence of visible active periapical or periodontal inflammation.

7. Adequate oral hygiene: PI< 20%, BoP< 20%.
8. Sufficient occlussal units mesial or distal and antagonizing, including the diastema to be restored: 4 occlusal units.

Exclusion criteria

1. Medical condition that contraindicates surgery: ASA -score >= III
2. History of radiotherapy in the head and neck region.
3. History of Biphosphonate medication.
4. Medium smokers >= 10 cigarettes per day.
5. Patients unwilling or incapable of signing the informed consent.
6. Active caries

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2015
Enrollment:	40
Type:	Actual

Medical products/devices used

Generic name:	Dental Implant System and Guided surgery system
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	27-01-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL50019.029.14