Influence of thin and thick biotype on aesthetic outcome and possible manipulation of the biotype to enhance aesthetic result; a one-year randomized controlled clinical trial

Published: 11-10-2013
Last updated: 19-03-2025

Investigation of the influence of gingival biotype on the aesthetics and manipulation of the gingival biotype in order to convert a thin biotype into a thick biotype by application of a connective tissue graft or a synthetic graft material in...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON38618

Source
ToetsingOnline

Brief title
Influence and manipulation of the gingival biotype on aesthetic outcome

Condition

- Other condition

Synonym
missing tooth, Non preservable tooth

Health condition

Tandheelkundige implantologie

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Geistlich Pharma AG, Wolhusen, Zwitserland ,Nobel Biocare AB, Gothenburg, Sweden ,Nobel Biocare stelt het implantaat en de bijbehorende onderdelen ter beschikking. Geistlich Pharma AG stelt het Geistlich Mucograft ter beschikking.

Intervention

Keyword: Aesthetic outcome, Gingival biotype, Single-tooth implants, Tissue manipulation

Outcome measures

Primary outcome

The main study parameter is the change in mid-facial soft tissue level from

placement to 18 months thereafter.

Secondary outcome

- Aesthetics of the soft and hard tissue

- Implant survival

- Clinical peri-implant variables

- Change in volume labial gingival

- Change in bone resorption

- Patient satisfaction

Study description

Background summary

The application of dental implants for single-tooth replacements in the maxillofacial aesthetic zone has evolved into a viable prosthodontic alternative to conventional fixed bridgework, resin-bonded restorations or

removable partial dentures. Because of the high levels of survival, the focus of attention is moving from *survival* to *quality of survival* and the aesthetics are becoming the measure of success. The peri-implant soft tissue plays an important role. This involves the establishment of a soft tissue contour that is harmonious with the gingiva of the adjacent teeth. Unfortunately, a major concern in achieving harmonious aesthetics and an aesthetic final result is the peri-implant soft tissue recession of the mid-buccal mucosa after placing an implant.
According to several authors the aesthetic success of implant placement in terms of soft tissue recession is dependent on the gingival biotype. A thin gingival biotype is said to be more prone to recession of the mid-facial peri-implant mucosa. A thick biotype is said to result in a more predictable and satisfactory aesthetic result in harmony with neighbouring teeth. Connective tissue grafting in combination with single implant placement and immediate provisionalization is reported to be able to convert a thin gingival biotype into a thick gingival biotype and in this way influencing predictability of the aesthetic outcome.
However, this type of treatment has been evaluated scarcely in combination with single tooth replacement and evidence from a randomized controlled clinical trial is missing.

Study objective

Investigation of the influence of gingival biotype on the aesthetics and manipulation of the gingival biotype in order to convert a thin biotype into a thick biotype by application of a connective tissue graft or a synthetic graft material in combination with a single implant placement.

Study design

A single blinded, randomized clinical trial.

Intervention

For this study a single implant is placed in the extraction wound or in healed extraction sites and immediately restored with a screw-retained temporary crown. Depending on the studygroup the mid-buccal mucosa is manipulated by a autologous or synthetic tissue graft.

Study burden and risks

All patients have three additional research appointments. During these appointments digital intra-oral pictures and impressions are taken. Furthermore an intra oral examination of the peri-implant mucosa is done and the patients are asked to fill out a questionnaire.

Contacts

Public
Universitair Medisch Centrum Groningen

Poortweg 2
Groningen 9713 AV
NL
Scientific
Universitair Medisch Centrum Groningen

Poortweg 2
Groningen 9713 AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- The patient is 18 years or older;
- The missing tooth, lost tooth or about to loose tooth is an incisor (central or lateral), a canine or a first premolar in the maxilla; the adjacent teeth are natural teeth;
- Sufficient healthy and vital bone to insert a dental implant with a minimum length of 10 mm and at least 3.5 mm in diameter;
- The implant site must be free from infection;
- Adequate oral hygiene (modified plaque index and modified sulcus bleeding index <= 1);
- Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration;
- The temporary restoration can be designed free from occlusal contact;
- The patient is capable of understanding and giving informed consent.

Exclusion criteria

- Medical and general contraindications for the surgical procedures;
- Presence of an active and uncontrolled periodontal disease;
- Presence of pathologic microflora;
- Bruxism;
- Site of implant placement is an extraction wound younger than three months;
- Smoking (patients who stop smoking six weeks before the operation can be included);
- A history of local radiotherapy to the head and neck region.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-11-2013
Enrollment:	140
Type:	Actual

Medical products/devices used

Generic name:	Geistlich Mucograft - 3D collagen matrix
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	11-10-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved	
Date:	19-06-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	24-03-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO	
Date:	28-06-2018
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

ID: 25914
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL43085.042.13
Other	TC 3815
OMON	NL-OMON25914