Influence of gingivabiotype on aesthetics and possible manipulation of the biotype to enhance aesthetics.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25914

Source
NTR

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

Health condition

Single-tooth implants
Aesthetic outcome
Gingival biotype
Tissue manipulation

Solitair implantaat
Esthetisch resultaat
Gingiva biotype
Weefselmanipulatie

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: UMCG

Intervention

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

1. Aesthetics of the soft and hard tissue;

2. Implant survival;

3. Clinical peri-implant variables;

4. Change in volume labial gingival;

5. Change in bone resorption;

6. 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

It is hypothesized that placement of a single implant with tissue grafting will lead to less mid-facial soft tissue recession.

Study design

1. Aesthetics of the soft and hard tissue; Clinical peri-implant variables; Change in volume labial gingival; Change in bone resorption: 2 weeks before, 1month and 1year after implant placement;

2. Implant survival: 1 year after implant placement;

3. Patient satisfation: 2 weeks before and 1 year after implant placement.

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 tissue graft or nothing is done.

Contacts

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Eligibility criteria

Inclusion criteria

1. The patient is 18 years or older;

2. 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;

3. 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;

4. The implant site must be free from infection;

5. Adequate oral hygiene (modified plaque index and modified sulcus bleeding index ≤ 1);

6. Sufficient mesio-distal, bucco-lingual, and interocclusal space for placement of an anatomic restoration;

7. The temporary restoration can be designed free from occlusal contact;

8. The patient is capable of understanding and giving informed consent.

Exclusion criteria

1. Medical and general contraindications for the surgical procedures;

2. Presence of an active and uncontrolled periodontal disease;

3. Presence of pathologic microflora;

4. Bruxism;

5. Site of implant placement is an extraction wound younger than three months;

6. Smoking (patients who stop smoking six weeks before the operation can be included);

7. 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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	140
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 38618
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3627
NTR-old	NTR3815
CCMO	NL43085.042.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38618

Study results

Summary results
N/A