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Immediate versus delayed restoration of immediate single-tooth implants in the anterior maxilla

Submission date 08/05/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 11/07/2008	**Overall study status** Completed	
Last Edited 11/07/2008	**Condition category** Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
The influence of immediate versus delayed restoration of immediate single-tooth implants in the aesthetic region is evaluated. The study documents the treatment outcome of both strategies as well as the hard and soft tissue response. All parameters are carefully recorded to identify the treatment strategy with the best aesthetic results.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Commissie Medische Ethiek (O.G.016) on the 18th October 2007 (ref: B.U.N. B14320072578).

Study design
Single-centre, randomised single-blind controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Dental implants

Interventions
Two separate treatment groups were randomly created:

Immediate restoration group:
The total treatment is be done in one surgical appointment. After extraction of the failing tooth, the implant is immediately inserted into the extraction cavity. Within 3 hours the implant is loaded with a provisional restoration. At the 6 month recall visit the final restoration (crown) is connected.

Delayed restoration group:
This treatment involves two surgical interventions. First the tooth is extracted and an implant is immediately inserted into the extraction cavity. The surgical site is closed and a 3-month healing period started. Following this healing period implants were uncovered at second-stage surgery and a provisional restoration was connected to the implant. Again at the 6-month recall visit the final restoration (crown) is connected.

For both groups the moment of provisional crown connection is selected as baseline. Restorations were followed-up for at least one year following provisional crown connection.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Mucosa levels were recorded by means of an acrylic stent provided with three direction grooves: mesial, midfacial and distal. All measurements were assessed with a periodontal probe.
1. Papilla levels: a papilla level (mesial papilla level - distal papilla level) is defined as the distance between the top of the corresponding groove and the top of the papilla
2. Midfacial mucosa level: the midfacial level is defined as the distance between the top of the groove and the first contact with the peri-implant mucosa

Secondary outcome measures
At each re-assessment, namely 3, 6 and 12 months after baseline (i.e. provisional crown connection), mesial and distal marginal bone changes over time were calculated using standardised peri-apical radiographs.

Overall study start date
01/05/2005

Completion date
01/05/2010

Eligibility

Key inclusion criteria
Patients were selected and consecutively treated in the Dental Clinic of the Free University in Brussels (VUB):
1. 18 years or older, either sex (the mean age was 53 with a range of 24 to 76 years)
2. Good oral hygiene
3. Existence of one failing tooth in the anterior maxilla (15 - 25) with both neighbouring teeth present
4. Healthy soft tissues surrounding the facial aspect of the hopeless tooth in perfect harmony with the adjacent teeth
5. Normal to thick-flat gingival biotype
6. Adequate bone height apical to the alveolus of the failing tooth (greater than or equal to 5 mm) to ensure primary implant stability of at least 35 Ncm

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Two groups of 24 participants

Key exclusion criteria
1. Systemic diseases
2. Smoking (greater than or equal to 10 cigarettes a day)
3. Bruxism, lack of posterior occlusion
4. Non-treated periodontal diseases
5. Presence of active infection (pus, fistula) around the hopeless tooth
6. Loss of the labial crest after extraction of the failing tooth

Date of first enrolment
01/05/2005

Date of final enrolment
01/05/2010

Locations

Countries of recruitment
Belgium

Study participating centre
Laarbeeklaan 1O3
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Sponsor information

Organisation
Free University of Brussels (VUB) (Belgium) - School of Dental Medicine

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Sponsor type
University/education

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ROR
https://ror.org/006e5kg04

Funder(s)

Funder type
University/education

Funder Name
Free University of Brussels (VUB) (Belgium) - School of Dental Medicine

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration