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Immediate loading of single implants in the anterior maxilla

Submission date	Recruitment status	[_] Prospectively registered
20/04/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/06/2017	Oral Health	

Plain English summary of protocol

Background and study aims
Dental implants are artificial roots (usually titanium screws) which are screwed into the jaw bone to support false teeth or crowns. A crown is an artificial restoration that fits over the remaining part of a tooth to make it strong and give it the shape of a natural tooth. The aim of this study is to assess whether immediate loading (placing a crown immediately after dental implant installation) is a safe and predictable treatment. The immediate loading technique can improve the aesthetic result (appearance) after surgery, is a faster and easier treatment, and avoids the need for removable dentures.

Who can participate?
Adults aged 18 or older who require a dental implant

What does the study involve?
All participants undergo installation of dental implants on the upper frontal area of the mouth under local anaesthetic for soft tissue and bone preparation followed by the implant placement. Implants are placed using the immediate loading technique (placing a crown immediately after dental implant installation). All participants are followed up 4, 8 and 12 months after implant placement to measure implant stability and survival and any complications (e.g., pain and swelling).

What are the possible benefits and risks of participating?
The main benefit of this treatment is immediate restoration of tooth function and appearance with a crown immediately after implant placement, without a period wearing a removable prosthesis that can be uncomfortable and a hassle for the patient. The risks are no different from the typical risks related to implant surgery, are clearly explained to the patients.

Where is the study run from?
The White Clinic Dental Center (Portugal)

When is the study starting and how long is it expected to run for?
January 2013 to December 2015

Who is funding the study?
The White Clinic Dental Center (Portugal)

Who is the main contact?
Dr Filipa Braga
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
White Clinic Study #0001

Study information

Scientific Title
Immediate Loading of Single Implants in the Anterior Maxilla: a prospective clinical study on 34 patients

Acronym
ILSIAM

Study objectives
The aim of this study is to examine the clinical performance of single implants with a knife-edge thread design and a nanostructured calcium-incorporated surface, when placed in the anterior maxilla, subjected to immediate loading.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The present study was carried out in full compliance with the criteria established by the Declaration of Helsinki on clinical trials involving human subjects (2008). Since the immediate loading of single implants represents today a well-established surgical and prosthetic procedure in dentistry, performed by thousands of clinicians in their private practices all over the world, no ethics committee approval is required for the present work (approved by White Clinic Ethics Board).

Study design
Interventional single-centre non-randomised study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Implant dentistry

Interventions
All participants undergo installation of tapered implants with a knife–edge thread design and a nanostructured, calcium–incorporated surface. After CBCT analysis and implant planning, a surgical procedure is performed under local anaesthesia for soft tissue and bone preparation follow by the implant placement. Implants are standardly placed respecting the soft tissue and bone quantity and quality. ISQ (Implant Stability Quotient) is measured and the loading protocol defined immediately after implant placement.

Follow up for all participants takes place 4, 8 and 12 months after implant placement. This involves a clinical and radiographic assessment of the implants, ISQ measuments, peri–implant tissues and prostheses by a periodontologist and a prosthodontist, who were not directly involved in the placement of the implants.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Implant stability is measured using resonance frequency analysis (RFA) at 4, 8 and 12 months after implant placement
2. Implant survival is measured using the status of the implant at 4, 8 and 12 months after implant placement
3. Implant success is measured using the amount of biological complications (post-operative pain and swelling, peri-implant mucositis, peri-implantitis, peri-implant bone loss without infection) or prosthetic complications (mechanical complications like abutment screw loosening and abutment fracture, chipping and fracture) at 4, 8 and 12 months after implant placement

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Patients with one to four single-tooth gaps, or patients in need of replacement of one to four severely compromised, non–restorable teeth in the anterior areas of the maxilla (incisors, canines, first and second premolars)
2. Good state of systemic health
3. Good oral hygiene
4. Age > 18 years
5. Dentition in the opposite arch
6. Willingness to participate in the follow–up study, attending all annualperiodic examinations /controls

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
General exclusion criteria:
1. Uncontrolled or not properly treated diabetes with high blood sugar levels;
2. The presence of immunosuppression
3. History of head and neck cancer with radio– and chemotherapy
4. The presence of blood diseases
5. The presence of psychological or psychiatric diseases
6. Patients in treatment with anticoagulants
7. Patients in treatment with oral/intravenous aminobisphosphonates

The local exclusion criteria:
1. The absence of enough bone to place an implant of at least 10.0 mm in length and 3.5 mm in diameter
2. The need of major regenerative bone techniques (such as onlay/inlay bone grafting) before implant insertion (minor procedures including guided bone regeneration with granulate and membranes or buccal grafting and inter-proximal procedures were not exclusion criteria)
3. The presence of oral diseases (vesiculobullous diseases, ulcerative diseases, white or red lesions, diseases of the salivary glands, the connective tissue or lymphoid lesions, cystic lesions, benign or malignant tumors of the oral cavity
4. The lack of occlusal contacts in the antagonist arch. History of periodontal disease, the habit

of cigarette smoking and the presence of parafunctions were not exclusion criteria for this study; however, patients were advised that these conditions could represent a risk factor for implant therapy.

Date of first enrolment
01/03/2013

Date of final enrolment
31/12/2014

Locations

Countries of recruitment
Portugal

Study participating centre
White Clinic Dental Center
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Sponsor information

Organisation
White Clinic Dental Center

ROR
https://ror.org/008545842

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
White Clinic Dental Center

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Filipa Braga DDS (info@whiteclinic.pt).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2017		Yes	No