

Immediate loading of single implants in the anterior maxilla

Submission date 20/04/2017	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/04/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/06/2017	Condition category Oral Health	<input type="checkbox"/> Individual participant data

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

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Non randomised study

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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

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 followed 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 measurements, 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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/01/2013

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 annual periodic examinations /controls

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

25-35

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

Sponsor details

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Sponsor type

Other

ROR

<https://ror.org/008545842>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

White Clinic Dental Center

Results and Publications**Publication and dissemination plan**

Planned publication in a peer reviewed high impact journal.

Intention to publish date

30/04/2017

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