

The mini-implants with angulated and non-angulated abutment

Submission date 09/10/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 16/10/2015	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 28/06/2016	Condition category Oral Health	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Overdentures, also known as dental implants, are metal posts which are screwed directly into the jaw bone in order to support replacement teeth. Abutments are connectors that are placed on the top of a dental implant to connect the implant to the replacement tooth. Mini-implants have been successfully used to support complete dentures in edentulous patients (patients with no natural teeth) that have wasting (or resorption) of the bone holding the teeth (alveolar bone). The aim of this study is to see whether mini-implants with an angulated abutment (that is, an abutment placed at a different angle to the denture) is better than a non-angulated abutment (that is, an abutment placed at the same angle than the denture).

Who can participate?

Patients who, having responded to an advertising campaign, have no natural teeth and have ill-fitting dentures due to resorption of the alveolar bone.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 receive a non-angulated abutment. Those in group 2 receive angulated abutment. Alveolar bone height is measured 6 months after treatment and again at 12, 18 and 24 months.

What are the possible benefits and risks of participating?

The use of mini-implants with non-angulated abutment may provide benefits for patients such as a stable, immediately functional aesthetic for overdentures for patients with wasting of the alveolar bone. There are no reported risks to taking part.

Where is the study run from?

Al-Azhar University, Faculty of Dentistry (Egypt)

When is the study starting and how long is it expected to run for?

October 2012 to December 2014

Who is funding the study?

Albaha University (Saudi Arabia)

Who is the main contact?

1. Professor Khalid Arafa (scientific)
2. Dr Hashim Ahmed (public)

Contact information

Type(s)

Scientific

Contact name

Prof Khalid Arafa

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Type(s)

Public

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Additional identifiers

Study information

Scientific Title

Effects of angulated and non angulated mini-implants abutment supporting mandibular overdenture on peri-implant bone height

Study objectives

The mini-implants with angulated abutment is better than non-angulated abutment

Ethics approval required

Old ethics approval format

Ethics approval(s)

Dental Health Department at the Faculty of Applied Medical Sciences, Albaha University.

Primary study design

Interventional

Study design

Randomized two-arm parallel design

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mini-implants used to support complete dentures in edentulous patients with little bone width or length.

Interventions

One of the initial steps in non-angulated mini-implant insertion include the use of a surgical stent to the determined position of the abutment with four holes. Participants in this study were randomly allocated to one or two groups.

1. Group 1: received lower overdentures with non-angulated abutment. A non-angulated abutment means there is overstructure without any changes in angle of the abutment.
2. Group 2: received lower overdentures with angulated abutment, which means the angulated abutments were essential to redirect the screw holes in a communal pathway of attachment to help in the fabrication and fitting of the prosthesis. Furthermore, the abutments were utilized to redirect these holes in the lingual path. Lastly, in specific cases, it may not be possible to redirect and fabricate the screw with an angle of pre-fabricate 45° angulated abutments (selecting direction is easy with the octa 45° rotation angles).

Bones were evaluated for height after 6, 12, 18, and 24 months with panoramic x-ray. The mini-implants used were manufactured by Dentium, Slim Line, No: SDM1304.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Alveolar bone height, measured after 6 months with panoramic x-ray.

Key secondary outcome(s)

Alveolar bone height, measured after 12, 18, and 24 months with panoramic x-ray.

Completion date

12/12/2014

Eligibility**Key inclusion criteria**

Patients with a lower flat ridge due to completely edentulous maxillary and mandibular ridges with resorbed ill-fitted lower dentures

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

Male

Key exclusion criteria

Patients without a lower flat ridge due to completely edentulous maxillary and and mandibular ridges

Date of first enrolment

01/10/2012

Date of final enrolment

01/06/2014

Locations**Countries of recruitment**

Egypt

Saudi Arabia

Study participating centre

Al-Azhar University

Assiut Branch

Faculty of Dentistry

Cairo

Egypt

00966

Sponsor information**Organisation**

Albaha University

ROR

<https://ror.org/0403jak37>

Funder(s)**Funder type**

University/education

Funder Name

Albaha University (Saudi Arabia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request