ISRCTN17902623 https://doi.org/10.1186/ISRCTN17902623

# The mini-implants with angulated and non-angulated abutment

**Submission date**
09/10/2015

**Recruitment status**
No longer recruiting

**Registration date**
16/10/2015

**Overall study status**
Completed

**Last Edited**
28/06/2016

**Condition category**
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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. Alveloar bone height is measured 6 mnoths 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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Public

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
N/A

# 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.

## Study design
Randomized two-arm parallel design

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

## 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 measure

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

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

### Overall study start date
01/10/2012

### 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

### Age group
Other

### Sex
Male

### Target number of participants
30 patients responded to an advertisement campaign, but only 20 patients met the selection criteria

### 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
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# Sponsor information

**Organisation**
Albaha University

**Sponsor details**
Al-Baha
Al Baha province
Saudi Arabia
00966

**Sponsor type**
University/education

**ROR**
https://ror.org/0403jak37

# Funder(s)

**Funder type**
University/education

**Funder Name**
Albaha University (Saudi Arabia)

# Results and Publications

**Publication and dissemination plan**

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

## IPD sharing plan summary

Available on request