

# The effect of Ultrasound therapy on quality and quantity of bone around dental implants

<b>Submission date</b> 01/02/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 07/02/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 23/11/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Dental implants are used to support false teeth. It involves a procedure that places a screw into the jawbone. However, bone loss around dental implants is inevitable process and the maximum amount of bone loss occurs first year after dental implant placement. This affects the function and aesthetic (looks) therefore, replacement or bone re-growth is very important to improve and increase the success rate of dental implant. Ultrasound therapy could be used to regenerate and facilitate bone growth. The aim of this study is to examine the implant of ultrasound therapy on bone loss after a dental implant procedure.

### Who can participate?

Adults aged 20-40 years old who need a simple standard tooth implant.

### What does the study involve?

Participants are randomly allocated to one of two groups. All participants undergo the first part of the dental implant procedure. Those in the first group receive the ultrasound therapy twice a week for 20 minutes two weeks after their dental implant and this is continued for two weeks. Those in the second group receive the standard level of care after the procedure. At two months, impressions of the teeth and the installation of the crown (a cap for a tooth) is placed. The same therapy is repeated two weeks after the tooth is placed for another 10 weeks for those in the first group. Participants are followed up to examine their bone loss three and six months after the procedures.

### What are the possible benefits and risks of participating?

Participants may benefit from an increased success rate of their dental implant procedure and decreased bone loss. There are no risks or harm in any means to the patients as the used ultrasound generates minimum heat and it might cause only a very mild or minimum discomfort which negligible by the patients. Regarding the dental implant, it has been used for quite some time now with a very good success rate and it has no complications as the normal consequences of dental implant placement as tolerable pain and mild swelling if it occurs.

### Where is the study run from?

University Dental Hospital Sharjah (UAE)

When is the study starting and how long is it expected to run for?  
September 2014 to July 2015

Who is funding the study?  
College of Medicine and Health Sciences, United Arab Emirates University (UAE)

Who is the main contact?  
Dr Elaf Abdulhameed (Scientific)  
elaf.alzubaidi@gmail.com

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**

-

## Study information

**Scientific Title**  
The effect of ultrasound therapy on osseointegration and marginal bone loss around implant-supported prosthesis

**Study objectives**  
Null hypothesis:  
There is no association between the quality of osseointegration and the marginal bone loss when using therapeutic ultrasound during alveolar bone healing period in dental implantology.

**Ethics approval required**  
Old ethics approval format

## **Ethics approval(s)**

1. University Research and Humans Ethics Committee at University of Sharjah, 05/01/2015, ref: ERC / 05/01/15/01
2. USM Human Ethics, ref: JEPeM Code USM/JEPeM/14120529

## **Study design**

Interventional randomised controlled clinical trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Dental implant treatment (Osseointegration)

## **Interventions**

The aims and objectives of this study are to evaluate the effect of ultrasound therapy on osseointegration using clinical assessments, measurements of RFA values and radiological assessments using linear measurement of marginal bone loss around the dental implant supported prostheses using CBCT. The selected age groups were between 20 and 40 years old. All patients were recruited following specific criteria of inclusion and exclusion.

Patients of this study randomly allocated to one of two groups either the Ultrasound group or the Control group. Each participant receive one dental implant to replace single missing maxillary first or second premolar teeth.

In the first trial group (ultrasound), the ultrasound therapy is applied twice a week for 20 minutes that commences two weeks after stage I implant surgery and continued for 10 weeks. At two months, uncover and placement of gingival former for 10 days is carried on for all patients in both groups (ultrasound and control) then the impression taking was done for all patients and installation of screw-retained porcelain to fused crown are performed two weeks later after the impression was taken.

The same ultrasound therapy protocol is repeated two weeks after the crown installation for another 10 weeks.

In the control group, participants are not subjected to application of ultrasound therapy. Clinical data collections composed of measurements of Resonance Frequency Analysis (RFA) values using osstell ISQ device and linear measurements of different variables using CBCT images taken immediately after the placement of the implant and during follow-up clinical examinations at three months and six months postoperatively.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

1. Marginal bone lose at 3 different views (Coronal,Sagittal and Axial) is measured using the CBCT scan at at baseline (day of implant placement), 3 months and 6 months
2. The highest increase bone found in buccal bone plate at coronal view

**Key secondary outcome(s)**

1. Gingival overgrowth is measured using clinical assessment at baseline, day 3 and 6 months
2. Peri-coronal bone around dental implant is measured using CBCT scan at baseline, day 3 and 6 months
3. Resonance Frequency Analysis (RFA) is measured using Osstell device at baseline, day 3 and 6 months

**Completion date**

01/07/2015

**Eligibility****Key inclusion criteria**

1. Patients' age between 20-40 years
2. No systemic diseases or medical contraindications to oral surgical procedure
3. Well motivated patients with good oral hygiene
4. Presence of maxillary single missing first or second premolar teeth with adequate available bone height and width
5. Presence of intact adjacent teeth
6. The patients needed simple standard implant surgery without the need for soft or hard tissue grafts

**Participant type(s)**

Healthy volunteer

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

22

**Key exclusion criteria**

1. Patients younger than 20 years and older than 40 years
2. Patients with systemic diseases or syndromes that might affect bone metabolism or patients with para-functional habits
3. Patients with active periodontal diseases and bad oral hygiene
4. Smokers
5. Inadequate available bone height and width or hard and soft tissue grafts needed
6. Pregnancy
7. Implant surgery needed to replace previous failed implant

**Date of first enrolment**

02/10/2014

**Date of final enrolment**

01/11/2014

## Locations

**Countries of recruitment**

United Arab Emirates

**Study participating centre**

**University Dental Hospital Sharjah**

Sharjah

Sharjah

United Arab Emirates

P.O.Box 27272

## Sponsor information

**Organisation**

University Dental Hospital Sharjah

**ROR**

<https://ror.org/00engpz63>

## Funder(s)

**Funder type**

University/education

**Funder Name**

College of Medicine and Health Sciences, United Arab Emirates University

**Alternative Name(s)**

CMHS, UAEU

**Funding Body Type**

Government organisation

**Funding Body Subtype**

Local government

**Location**

United Arab Emirates

# 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. Elaf Akram Abdulhameed (Tel: 00971507108284) at [elaf.alzubaidi@gmail.com](mailto:elaf.alzubaidi@gmail.com).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	15/04/2018	23/11/2020	Yes	No
<a href="#">Participant information sheet</a>		01/02/2018	21/02/2018	No	Yes