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

Submission date	Recruitment status	[_] Prospectively registered
01/02/2018	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/02/2018	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/11/2020	Oral Health	

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
Dr Elaf Abdulhameed

ORCID ID
http://orcid.org/0000-0002-7871-210X

Contact details
College of Dental Medicine
University of Sharjah
Sharjah
United Arab Emirates
P.O.Box 27272
+971 507 108284
elaf.alzubaidi@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
-

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

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, uncovery 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 measure
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

Secondary outcome measures
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 nase;ome, day 3 and 6 months

Overall study start date
01/09/2014

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

Age group
Adult

Sex
Both

Target number of participants
11

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

Sponsor details
Sharjah University Road
Sharjah
United Arab Emirates

P.O.Box 27272
+971 507 108284
elaf.alzubaidi@gmail.com

Sponsor type
Hospital/treatment centre

Website
http://www.sharjah.ac.ae

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

Publication and dissemination plan
Panned publication in a high-impact peer reviewed journal. Additional documentation are available upon request.

Intention to publish date
01/07/2018

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.

IPD sharing plan summary

Available on request

Study outputs

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