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Anatomic zirconia dental implants compared with non-zirconia implants

Submission date	Recruitment status	[_] Prospectively registered
31/03/2021	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/04/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/08/2022	Oral Health	

Plain English summary of protocol

Background and study aims

The use of dental implants to replace lost teeth is an acceptable and common treatment with success rates of 90-100%. Titanium has been widely used in the manufacture of dental implants and the fact that cosmetic expectations in dentistry increased and research in the field of using whole ceramic materials to compensate for the natural tooth was widely used. Zirconia was used for the manufacture of anatomical ceramic implants due to its excellent biological acceptance, good biomechanical properties, and being anatomical, as it takes the shape of the natural tooth root in addition to the color match.

The aim of this study is to evaluate the clinical performance of anatomical zirconia implant and to compare it with non-anatomical zirconia implant, in addition, to evaluate the effect of different types of crowns (composite resin and porcelain fused to metal) on the success of anatomically modified zirconia implants.

Who can participate?

Adults over 18 years, who require a tooth replacement

What does the study involve?

Half of the participants will receive anatomical zirconia implant and the other half will recieve non-anatomical zirconia implant. Patients will be followed up for 12 months.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Damascus University (Syria)

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

November 2018 to September 2021

Who is funding the study?

Damascus University (Syria)

Who is the main contact?
Dr Alaa Aldebes, dr.alaa-aldebes@outlook.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
Nil known

Study information

Scientific Title
Evaluation of clinical performance for different types of modified anatomic zirconia implants restoration

Study objectives
1. Composite resin crowns may be better than porcelain fused to metal crowns over zirconia implants in terms of bone absorption around them
2. Anatomical zirconia implant might be better than non-anatomical zirconia implant

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 29/04/2019, Council for Scientific Research and Upper Graduate Studies (Damascus University, Faculty of Dentistry, Mazzeh Highway, Damascus, Syria ; +963113341864; manager@hcsr.gov.sy), ref:2552

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Replacement of hopeless teeth with zirconia implant

Interventions
Group1: 20 anatomical zirconia implants divided into 10 implants will receive 10 composite resin crowns and 10 implants will receive 10 porcelain fused to metal crowns.
Group 2: 20 non-anatomical zircon implants divided into 10 implants will receive 10 composite resin crowns and 10 implants will receive 10 porcelain fused to metal crowns.
Randomisation is by sealed envelope.

The patient will be examined, the clinical and medical story will be taken, the oral healthcare will be evaluated, the work plan is explained to him and the written consent is taken to enter the research sample and after the clinical examination of the patient is conducted, Anterior, lateral, occlusal, photographs and cone beam computerized radiograph (CBCT) will taken, which are used for the radiographic evaluation of the tooth to be extracted, to make measurements of the level alveolar bone, and to measure the bone density around the root.

The extracted tooth is taken to the dental laboratory and a scan is performed using a scanner and by computer aided design -computer aided manufacturing device (CAD-CAM) , we can add an abutment in the coronal section of the root, thus obtaining the final implant shape then we will got the anatomical zirconia implant the same as the extracted tooth. Similarly the non anatomical zirconia implant is manufactured to replace lost teeth in the old extraction area using the final drill that will be used by scanning it to manufacture the implant as the same of it. The retention of the implants is measured immediately after the implantation and after one and three months, using the perio test device, additionally the Bone absorption measured using periapical radiographs immediately after implantation , 3,12 months later. Three months after implantation the implants divided randomizelly to receive final composite resin crowns or porcelain fused to metal crowns, discoloration of the crown will measured using crown discoloration index, and crown fracture will measured using crown fracture index 6,12 months later.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Retention of the implants is measured using perio test device immediately after implantation and at 1 and 3 months

Key secondary outcome(s))
1. Bone absorption measured using periapical radiographs immediately after implantation and 3 and 12 months
2. Discoloration of the crown measured using crown discolouration index at 6 and 12 months
3. Crown fracture measured using crown fracture index at 6 and 12 months

Completion date
15/09/2021

Eligibility

Key inclusion criteria
1. Good oral health
2. The absence of general systemic diseases that prevent the extraction procedure or impede healing and the occurrence of osseointegration such as uncontrolled diabetes and other metabolic diseases that are not controlled
3. Not to be subjected to any radiotherapy or chemical treatment during the past five years
4. There is a clear indication for extraction:
4.1. A hopeless tooth that cannot be restored
4.2. Vertical or horizontal fracture
5. The normal position of the tooth that will be extracted within the dental arch
6. The presence of the teeth adjacent to the tooth that will be extracted
7. The absence of acute inflammation in the extraction area
8. Upper or lower premolar
9. The length of the root that will be extracted at least 10 mm
10. Type D2 and D3 of the bone around the tooth that will be extracted
11. The absence of periodontal diseases
12. The absence of bad oral habits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
40

Key exclusion criteria
1. The patient's age is less than 18 years or older than 60 years
2. Patients with uncontrolled diabetes
3. Poor oral healthcare
4. The presence of diseases in the periodontal tissues
5. Pregnant females

6. Smoking
7. The root that will be extracted is absorbed, leaving half or less of its length
8. A periapical lesion around the tip of the tooth, with a size greater than 2 mm

Date of first enrolment
28/11/2018

Date of final enrolment
15/09/2020

Locations

Countries of recruitment
Syria

Study participating centre
Damascus University
Mazzeh highway
Damascus
Syria
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Results and Publications

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/08/2022	09/08/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes