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Comparing two different dental bridge designs made of translucent zirconia

Submission date	Recruitment status	[ ] Prospectively registered
02/05/2020	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
05/05/2020	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
05/05/2020	Oral Health	[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Translucent zirconia is a new dental material with high potential for dental prosthesis (false teeth); the research is comparing two different dental bridges designs made of translucent zirconia, in the matter of survival rate and clinical performance.
This research is important to develop a protocol for the treatment of missing teeth in specific conditions.

Who can participate?
Adults over 18 years who have lost the second premolar in one side or more.

What does the study involve?
Participants will be randomly allocated to receive either anatomic designed translucent zirconia bridges or traditional designed translucent zirconia bridges.

What are the possible benefits and risks of participating?
There will be no harms for the patients, and the new material has passed through multiple laboratory test before clinical trials.

Where is the study run from?
Damascus University - faculty of dental medicine (Syria)

When is the study starting and how long is it expected to run for?
March 2018 to October 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Shukri Alsamara, Shekrysamara89@gmail.com

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
217/T.M

Study information

Scientific Title
The effect of the prosthesis design (monolithic, traditional) made of translucent zirconia on clinical performance: randomized controlled trial

Study objectives
There is significant difference in clinical performance between anatomic and traditional design.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2017, Ethical Committee of the Faculty of Dental Medicine (Damascus University, Damascus, Syria; +963 113341864; manager@hcsr.gov.sy), ref: 270/T.M

Study design
Interventional randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Patients who have lost one tooth or more and in need for dental prosthesis.

Interventions
Patients have been divided randomly into two group:
Group A: received anatomic designed translucent zirconia bridges.
Group B: received traditional designed translucent zirconia bridges.
Follow up for two years.

Intervention Type
Other

Primary outcome measure
Measured using visual inspection at one month, 6 months, one year, two years:
1. Prothesis fracture: no fracture/color change or small fracture/zirconia fracture/complete fracture in the prosthesis
2. Marginal fit: complete fit/there is evidence of leakage/the probe can access the prothesis /prothesis is movable
3. Discoloration: no discoloration/surface discoloration/discoloration towards the pulb

Secondary outcome measures
Oral health index collected using oral examination and with UNC15 probe (university of North Carolina). Oral data collected from each patient on three different time intervals (after one month, after 6 months, after one year, after two years)
1. Plaque index (PI)
2. Gingival index (GI)
3. Decayed, missing, filled teeth index

Overall study start date
24/01/2017

Completion date
01/10/2020

Eligibility

Key inclusion criteria
1. Lost second premolar in one side or more
2. Good oral hygiene
3. The pontics have good stability
4. Absence of oral dysfunction

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30

Key exclusion criteria
The clinical crown length of the pontics is less than 3 mm

Date of first enrolment
01/03/2018

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
Syria

Study participating centre
Damascus university
Faculty of dental medicine
Almazzah
Damascus
Syria
-

Sponsor information

Organisation
Damascus University

Sponsor details
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Sponsor type
University/education

Website
http://damasuniv.edu.sy/

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/11/2020

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date