

# Comparing two different dental bridge designs made of translucent zirconia

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<b>Registration date</b> 05/05/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/05/2020	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**Contact name**

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**Additional identifiers****Protocol serial number**

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

**Primary study design**

Interventional

**Study design**

Interventional randomized control trial

**Study type(s)**

Treatment

**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(s)**

Measured using visual inspection at one month, 6 months, one year, two years:

1. Prosthesis 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 prosthesis /prosthesis is movable
3. Discoloration: no discoloration/surface discoloration/discoloration towards the pulb

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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

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## **Sponsor information**

**Organisation**

Damascus University

**ROR**

<https://ror.org/03m098d13>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

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