

# Complete dentures vs implant prosthesis: a clinical study about which intervention results in better sensory functioning

<b>Submission date</b> 23/08/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/08/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/03/2023	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Edentulism (the condition of having no teeth) is a common condition encountered in dental offices today. For a long time, dentists have designed different prosthetics to solve this problem. Complete conventional dentures have been a common solution to restore chewing function in patients with no teeth. Dental implants have become a great alternative to this kind of prosthesis. When there are no teeth, patients find it hard to eat and chew in a proper way because the teeth provide a lot of sensory information that is important to perform these functions correctly. This can be measured with tactile investigations to find out if a dental rehabilitation is precise or not while chewing or eating. The aim of this study is to find out if there is improved performance in patients treated with dental implants compared with conventional complete dentures.

### Who can participate?

Healthy adults aged 18-99 years with dental implants or complete dentures that are well adapted and adjusted

### What does the study involve?

This study will be performed in three groups of patients with three different prosthetics. Group A consists of people who wear complete dentures in both arches (i.e. both jaws), group B consists of people with an implant prosthesis in both arches, and group C consists of people with an implant prosthesis in one arch and natural teeth in the other. This distribution of groups will show which receptors are activated during chewing in every prosthetic situation. The test consists of introducing thin metal foils between the patient's teeth to see if they are able to notice them while chewing. Foils of three different thicknesses are used and after the test every patient will present a minimum threshold that will match the thinnest foil. Age, gender and prosthesis wearing time are also collected to see if they have any influence.

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

The main benefit is to demonstrate that dental implants are a better solution to restore missed teeth rather than complete dentures. In this way, it will be possible to improve dental

prostheses and patients will have better oral function. There are no risks in this study as it consists of biting metal foils that are harmless to the patient. This procedure is very similar to the dental adjustment performed in dental offices routinely.

Where is the study run from?  
University of Salamanca (Spain)

When is the study starting and how long is it expected to run for?  
September 2021 to May 2022

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Diego González Gil, diegoggil@usal.es

## Contact information

**Type(s)**  
Principal investigator

**Contact name**  
Dr Diego González Gil

**Contact details**  
Facultad de Medicina C/ Alfonso X el Sabio s/n  
Salamanca  
Spain  
37007  
+34 (0)679765668  
diegoggil@usal.es

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
Nil known

## Study information

**Scientific Title**  
Active tactile sensibility in complete dentures vs implant prosthesis: a psychophysical study

**Acronym**  
Act Tact Sens in CD Vs. IP

**Study objectives**

Patients wearing an implant prosthesis have better active tactile sensibility than complete denture wearers.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approval 08/02/2022, comité bioético de la universidad de Salamanca (bioethics committee of the University of Salamanca, Patio de escuelas, 1. Edificio i+d+i. Salamanca 37008, Spain; +34 (0) 923 294430; vic.investigacion@usal.es), ref: 739

### **Study design**

Multicentre psychophysical study

### **Primary study design**

Observational

### **Study type(s)**

Treatment

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

Edentulism

### **Interventions**

Psychophysical study for measuring active tactile sensibility in dental implants and complete dentures. Three groups with different prosthetic rehabilitations will be measured for 5 months:

Group A: patients wearing complete dentures in both dental arches

Group B: patients rehabilitated with implant prosthesis in both arches

Group C: patients wearing implant prostheses whose antagonists are natural teeth

Aluminium thin foils will be introduced to the patient's mouth and they will have to say if they can perceive them while eating. The minimum thickness perceived will be the tactile sensibility threshold of each group.

### **Intervention Type**

Device

### **Phase**

Not Applicable

### **Primary outcome(s)**

The minimum threshold of tactile sensibility (the thinnest foil perceived) measured in microns using an active tactile sensibility psychophysical investigation at a single timepoint

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

Age, gender and prosthetic wearing time measured using a questionnaire at a single timepoint

### **Completion date**

01/05/2022

# Eligibility

## Key inclusion criteria

Adults with good oral health and wearing a well-adapted prosthesis

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Mixed

## Sex

All

## Total final enrolment

67

## Key exclusion criteria

1. Temporomandibular disorders
2. Not well-adapted prosthesis
3. Patients who are unable to understand this procedure

## Date of first enrolment

16/02/2022

## Date of final enrolment

21/02/2022

# Locations

## Countries of recruitment

Spain

## Study participating centre

**University of Salamanca**

Dental Clinic

Faculty of Medicine

C/ Alfonso X el sabio s/n 37007

Salamanca

Spain

37007

**Study participating centre**  
**Clinica Dental Diego González Gil**  
Avda. Virgen de las nieves nº2 bajo  
Santa Marta de Tormes  
Spain  
37900

## Sponsor information

**Organisation**  
University of Salamanca

**ROR**  
<https://ror.org/02f40zc51>

## Funder(s)

**Funder type**  
Other

**Funder Name**  
Investigator initiated and funded

## Results and Publications

### Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date

### IPD sharing plan summary

Data sharing statement to be made available at a later date

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		18/11/2022	01/03/2023	Yes	No