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

Submission date
23/08/2022

Recruitment status
No longer recruiting

Registration date
31/08/2022

Overall study status
Completed

Last Edited
01/03/2023

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Psychophysical study

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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

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

Overall study start date
01/09/2021

Completion date
01/05/2022

Eligibility

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

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
70

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
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Study participating centre
Clinica Dental Diego González Gil
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Sponsor information

Organisation
University of Salamanca

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Sponsor type
University/education

Website
http://www.usal.es/webusal/en

ROR
https://ror.org/02f40zc51

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
01/03/2023

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?
Results article		18/11/2022	01/03/2023	Yes	No