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Differences in biting behavior in patients with teeth connected in small bridges and teeth standing free adjacent to a dental implant

Submission date
08/03/2021

Recruitment status
No longer recruiting

Registration date
01/04/2021

Overall study status
Completed

Last Edited
30/09/2022

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Patients with a missing tooth may have treatment using a dental bridge, where a false tooth sits in place of the missing tooth and is held in place by crowns (a cap that covers a natural tooth) that have been cemented onto the teeth or implants (replacement teeth surgically placed in the jawbone to serve as the roots of missing teeth) on either side of the gap. It has been shown that patients with implant-supported bridges and tooth-supported bridges on both the lower and upper jaw have a decreased ability to control biting forces associated with holding and splitting food between the teeth, compared to patients with full natural teeth. The reduced sensory capacity observed in patients with dental implants is due to the lack of sensory information that would usually be detected and transmitted by receptors via the root of the teeth. However, patients with tooth-supported bridges show similar reduced sensory capacity, despite these receptors being present in the adjacent teeth.

When replacing missing teeth, an alternative to tooth-supported bridges may be implant-supported prostheses that leave the adjacent teeth free to function as sensors, as required for normal biting function. The primary aim of the study is to investigate the sensory-motor capacity in patients with small tooth-supported resin-bonded bridges and with single implants. Further aims are to evaluate the differences in the patient's assessment of function and aesthetics between the two treatments and also to compare this with the aesthetic evaluation of dental professionals.

Who can participate?
Participants older than 18 years old who lack an upper anterior (incisors or canine) tooth which has been currently replaced with a tooth-supported resin-bonded bridge and planned for treatment with single anterior implants.

What does the study involve?
Participants will receive treatment with single anterior implants. The study will involve the assessment of participants on two occasions, once with the resin-bonded bridge in place and once after treatment with the implant crown in place. Assessment involves the performance of a

non-invasive bite test, scanning inside the mouth, having photographs taken, and filling out a questionnaire.

What are the possible benefits and risks of participating?
The benefit of this study is that it may contribute to more knowledge regarding the treatment of tooth loss. There are no risks involved in the study.

Where is the study run from?
Folktandvården Eastmaninstitutet (Sweden)

When is the study starting and how long is it expected to run for?
From March 2016 to August 2022

Who is funding the study?
Karolinska Institutet (Sweden)

Who is the main contact?
Dr Nicole Winitsky, nicole.winitsky@sll.se

Contact information

Type(s)
Scientific

Contact name
Dr Nicole Winitsky

ORCID ID
https://orcid.org/0000-0003-3171-6522

Contact details
Dalagatan 11
Stockholm
Sweden
113 24
+46 709-158258
nicole.winitsky@sll.se

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Sensory-motoric capacity in patients treated with tooth- and implant-supported restorations

Acronym
SMC-TISR

Study objectives
Patients with non-connected teeth adjacent to single implants are able control their biting behavior better and also rate their sensation of biting and esthetics higher than patients with teeth connected with fixed tooth supported bridges.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/11/2018, Regional Ethical Review Board Stockholm (Tomtebodavägen 18A, 171 65 Solna, Sweden; +46 (0)8-524 870 00; kansli@stockholm.epn.se), ref: 2018/1677-31/1

Study design
Single-centre observational cross-sectional case-control study

Primary study design
Observational

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Single anterior tooth loss in the upper jaw

Interventions
Patients planned for single implant treatment of central incisors, at present wearing a resin-bonded bridge, were included in the study. The same sensory-motoric bite-test was run twice. Once prior to implant treatment with the resin-bonded bridge in place and once after implant treatment has been performed. The patients were used as their own controls. Besides biting and force measurements, the patients were scanned with an intraoral scanner, photographed and questionnaires concerning function and aesthetics were filled in by the patient. The aesthetic evaluation will also be performed by professionals.

Intervention Type
Behavioural

Primary outcome(s)
1. Control of biting behavior measured using a custom-built apparatus (Umeå University, Physiology section, IBM, Umeå, Sweden) invented to measure bite forces during hold-and-split tasks before and after the implant treatment
2. Patient Reported Outcome Measure (PROM) of biting measured using a questionnaire before and after the implant treatment

Key secondary outcome(s))

Aesthetics evaluated by patients and professionals using questionnaires and a visual analogue rating scale (VAS) and Pink Esthetic Score (PES)/White Esthetic Score (WES) before and after the implant treatment

Completion date
23/08/2022

Eligibility

Key inclusion criteria
1. Missing a single tooth in position 11 or 21
2. Wearing a resin-bonded bridge planned for single implant treatment
3. Aged ≥18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Nut allergy

Date of first enrolment
08/12/2020

Date of final enrolment
23/08/2022

Locations

Countries of recruitment
Sweden

Study participating centre
Folktandvården Eastmaninstitutet
Dalagatan 11

Stockholm
Sweden
113 24

Study participating centre
Uppsala Käkkrirurgiska center
Vaksalagatan 8
Uppsala
Sweden
753 20

Sponsor information

Organisation
Folktandvården Stockholm AB

Funder(s)

Funder type
University/education

Funder Name
Karolinska Institutet

Alternative Name(s)
Karolinska Institute, KI

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. All of the individual participant data collected during the trial will be made available through the BIOVIA Notebook 2020 SP2- (ELN- The electronic notebook), after deidentification, immediately following publication with no end date. The data will be shared upon request with researchers who provide a methodologically sound proposal. Contact person Dr Nicole Winitsky. Consent from participants has been signed prior to the gathering of data and all information was anonymized.

Additional documents will be made available through the BIOVIA Notebook 2020 SP2- (ELN- The electronic notebook) and possible to view upon request via the details above.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes