ISRCTN24104637 https://doi.org/10.1186/ISRCTN24104637

# 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

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
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

### Secondary study design
Case-control study

### Study setting(s)
Hospital

### Study type(s)
Quality of life

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

### 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 measure
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

### Secondary outcome measures
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

### Overall study start date
18/03/2016

### 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

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
At least 14 patients

### 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

**Sponsor details**
Magnus Ladulåsgatan 65
Stockholm
Sweden
118 27
+46 (0)8-123 166 00
pia.skott@sll.se

**Sponsor type**
Hospital/treatment centre

**Website**
https://www.folktandvardenstockholm.se

# 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

**Publication and dissemination plan**
Planned Publication in a high-impact peer-review journal during 2022.

**Intention to publish date**
12/12/2022

**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