

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/04/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/09/2022	Condition category 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

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

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Additional identifiers

Clinical Trials Information System (CTIS)

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 Käkkirurgiska 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-publicly 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