

Using dental ceramics in treating patients with worn teeth. A randomized clinical trial.

Submission date 04/03/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/03/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/03/2021	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Tooth wear (TW) is an umbrella term that includes various subforms that result of different physical and chemical impacts that act on tooth surfaces. Patients with worn teeth seek professional help for tooth pain and sensitivity, chewing problems and appearance problems. Although several treatment types are at hand, there has been no long term follow-up study on fixed restorations (permanently attached in patients with excessively worn teeth. The reasons for this are many and could include difficulties in recruiting enough patients, or the challenging nature of the treatment as it may be associated with a high risk of failure.

Metal ceramic restorations are considered the standard treatment for patients treated with fixed restorations including patients with excessively worn teeth. Adverse appearance concerns regarding grayish discoloration and possible exposition of the metal framework margin are known drawbacks. As an alternative, several different all-ceramic materials have been developed that are attractive for dental use because of their appearance and compatibility with living tissue. Developments in ceramic materials have allowed more widespread application of all-ceramic restorations over the past 20 years. The clinical advantage of the modern ceramic monolithic restorations (restorations that consist of only one layer without external porcelain layer) is defined by a significantly reduced material thickness in comparison with veneered restorations (restorations that consist of two layers including external porcelain layer).

The primary aim of this study is to evaluate and compare the 3-5 years clinical performance and success rate of two all ceramic crowns when reconstructing extensively worn teeth. The secondary aim is to examine the opinion of each patient by using two scales/questionnaires.

Who can participate?

Adults aged 17 – 65 years with tooth wear

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive IPS e.max press crowns, and those in the second group receive monolithic BruxZir crowns. These are permanently attached restorations to treat tooth wear. Participants are followed up with clinical photographs and questionnaires at appointments 2-4 weeks and 1, 3 and 5 years after the treatment is completed.

What are the possible benefits and risks of participating?

Participants may benefit from the investigation, treatment and follow up, and are able to provide feedback regarding this. The risk of complications is very small/negligible, the same as with any other prosthodontic treatment.

Where is the study run from?

National Dental Eastman Institute (Folktandvården Eastmaninstitutet) (Sweden)

When is the study starting and how long is it expected to run for?

March 2012 to December 2018

Who is funding the study?

1. Folkstanvården Stockholm län AB (Sweden)
2. Swedish dental research (SOF) and Karoliska institutet (Sweden)

Who is the main contact?

Mrs Wedad Hammoudi (Public)

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Contact information

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Karolinska institutet/Swedish dental research (SOF) project nr 14101913 and Folktandvarden Stockholm project nr.7057

Study information**Scientific Title**

Randomized controlled clinical trial comparing monolithic translucent zirconia and emax press singel crowns used for prosthetic treatment of extensively worn dentition

Study objectives

All ceramic monolithic IPS e.max press and monolithic BruxZir crowns have the same strength and success rate but BruxZir crowns are less aesthetic when used to reconstruct extensively worn dentition.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board Stockholm Sweden, 15/08/2012, ref: 2012/263-31/2

Study design

Single center double blind randomised clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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

Health condition(s) or problem(s) studied

Tooth wear

Interventions

Participants are randomized into two groups according to a randomization list generated by a website (www.randomization.com).

The first group receives IPS e.max press (glass infiltrated lithium disilicate) crowns and the second group receives monolithic BruxZir Crowns (translucent zirconium oxide).

As a standard procedure, diagnostic mock-up and laboratory fabricated temporary bridges precede the prosthetic therapy. Increasing the vertical dimension is only performed when needed.

All restorations are adhesively luted and are examined at 2-4 weeks (baseline), 1 year, 3 years, 5 years after completion of the treatment.

Intervention Type

Other

Primary outcome measure

1. Clinical performance and success rate of the crown is assessed using clinical photographs taken 2-4 weeks (baseline) and follow up visits 1, 3 and 5 years after completion of the treatment.
2. Technical outcome of the reconstructions is examined using the United States Public Health Service (USPHS) criteria at 2-4 weeks (baseline) and follow up visits 1, 3 and 5 years after completion of the treatment.

Secondary outcome measures

The subjective opinion of each patient is measured using the international OHIP and OAS scales at 2-4 weeks (baseline) and 1, 3 and 5 years after completion of the treatment.

Overall study start date

12/03/2012

Completion date

19/12/2019

Eligibility**Key inclusion criteria**

1. Aged 17-65 years.
2. At least 10 teeth in the upper and lower arches

3. Good periodontal status
4. At least TW > grade 2 on any tooth surface on at least four teeth in the same arch according to Smith and Knight's tooth wear index (TWI)

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Max 116 and min 60 patients

Total final enrolment

132

Key exclusion criteria

1. Patients with fixed and removable partial dentures
2. Patients with severe TMJ disorders
3. Patients with gross malocclusion
4. Patients with mineralisation disorders
5. Patients with neurologic, psychiatric, or sleep disorders

Date of first enrolment

12/03/2013

Date of final enrolment

15/12/2018

Locations**Countries of recruitment**

Sweden

Study participating centre

National Dental Eastman Institute (Folktandvården Eastmaninstitutet)

Dalagatan 11

Stockholm

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Sponsor information

Organisation

National Dental Eastman Institute (Folktandvården Eastmaninstitutet)

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

www.ftv.sll.se

ROR

<https://ror.org/02qwvxs86>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Folktandvården Stockholm län AB

Funder Name

Swedish dental research (SOF) and Karolinska institutet

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

Intention to publish date

31/03/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored as a file in a non-publicly available repository; Folktandvården Stockholm data base. Permission for this file is obtained from data inspection board at Folktandvården Stockholm. There are only three

persons who have access to this file; the researcher performing the clinical study (Wedad Hammoudi), the research assistant and the head of the department for prosthetic dentistry at Eastman Institutet as he is the main supervisor (Jan-Ivan Smedberg). Each patient has a specific number in that file. The lists or results to be shared with the statistician who is going to analyse the data do not contain patients' names and identification numbers, they consist only of numbers (i.e. coded lists). Those coded lists and results will be stored as a file at Karolinska Institutet (ELN) according to their new rules concerning all researchers at that institute. Informed consent is obtained from all individual participants included in the study. Participants are informed in the consent that all results as well as all complications will be registered in coded form and responses and results will be processed so that unauthorized persons cannot share them. The results will be stored for about 15 years.

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		07/12/2020	26/03/2021	Yes	No