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

Submission date
04/03/2018

Recruitment status
No longer recruiting

Registration date
12/03/2018

Overall study status
Completed

Last Edited
26/03/2021

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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. Folktanvarden Stockholm län AB (Sweden)
2. Swedish dental research (SOF) and Karoliska institutet (Sweden)

Who is the main contact?
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Scientific

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Additional identifiers

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

Study information

Scientific Title
Randomized controlled clinical trial compairing 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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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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113 24

Sponsor information

Organisation
National Dental Eastman Institute (Folktandvården Eastmaninstitutet)

ROR
https://ror.org/02qwvxs86

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Folktanvarden Stockholm län AB

Funder Name
Swedish dental research (SOF) and Karoliska institutet

Results and Publications

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-publically available repository; Folktandvarden Stockholm data base. Permission for this file is obtained from data inspection board at Folktandvarden 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes