ISRCTN97265367 https://doi.org/10.1186/ISRCTN97265367

Randomised multicentre study of prosthetic treatment options for shortened dental arch

Submission date
26/02/2008

Recruitment status
No longer recruiting

Registration date
04/04/2008

Overall study status
Completed

Last Edited
29/01/2016

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Losing teeth is an inevitable part of the aging process for some people. The gaps left by missing teeth can cause problems with eating or speech, as well as affecting appearance, which can be distressing for the sufferer. Losing all of the molars (back teeth used for grinding food) in the upper or lower jaw can be treated in different ways. The main options being replacement with removable dentures (false teeth), dental implants (metal posts which are screwed directly into the jaw bone in order to support replacement teeth) or shortened dental arch (SDA) treatment. SDA is a cost-effective treatment in which only the missing teeth towards the front of the mouth are replaced using fixed bridges (a way of attaching the artificial tooth (or teeth) to a permanent (natural) tooth. There is currently a lack of evidence as to which of these techniques is more beneficial in the long-run. The aim of this study is to compare the effects of SDA and removable partial dentures on future tooth loss and oral health in the long-run.

Who can participate?
Adults over 35 years old who have asked for prosthetic dental treatment who are missing all molars in one jaw and with at least both canines and one premolar left on each side

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group are given removable partial dentures to replace their missing molars. Those in the second group receive SDA treatment to replace only the essential premolars (teeth between the canines and molars). All participants are examined after 8 weeks, 6 months, 1 year and then every year after the treatment for 5 years. After this, participants have dental exams at 8, 10 and 15 years after treatment. During these examinations dental and oral health are recorded as well as any further tooth loss.

What are the possible benefits and risks of participating?
There is no direct benefit for participants taking part in the study, although participants will receive financial support and compensation for the dental treatments and examinations. There are no risks of taking part other than the general risks associated with having dental surgery.

Where is the study run from?
The study is run from the Departments of Prosthetic Dentistry at the Universities of Berlin, Bonn, Dresden, Freiburg, Giessen, Greifswald, Jena, Kiel, Leipzig, Mainz, Munich, Wuerzburg, Witten and Homburg.

When is the study starting and how long is it expected to run for?
October 2000 to December 2022

Who is funding the study?
German Research Foundation (Germany)

Who is the main contact?
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Study website
http://zahnreihe.klinikum.uni-muenster.de/

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Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DFG WA 831/2-1 to 2-6

Study information

Scientific Title
Randomised multicentre study of prosthetic treatment options for shortened dental arch

Acronym
SDAS

Study objectives
Over the last 20 years a mechanistic attitude correlated with a lack of longitudinal controlled randomised trials regarding the question of prosthetic treatment after tooth loss. The need assessment considered the replacement of all missing teeth by fixed or removable partial dentures or dental implants as a necessity especially in cases of shortened dental arches. Modern prosthetic concepts distinguish between different dimensions of need (normative need, perceived need) being well aware of the fact that perceived need has been under-represented in the past. An innovative sight puts a higher emphasis to the subjective components of need assessment and outcome measurement. Generally three adverse effects of non-replacement of molars were postulated: temporomandibular joint (TMJ) disorders, tooth migration /overeruption, insufficient chewing ability. However, no evidence based on randomised trials has been provided concerning the incidence of the adverse side effects mentioned above, nor is there high-level evidence regarding a benefit of removable dentures for molar replacement. On the contrary removable partial dentures are compromised by a high incidence of adverse side effects such as plaque accumulation and peridontal breakdown.

Among therapeutic alternatives, an approach with a limited restoration goal focused on incisors, canines and premolars (shortened dental arch [SDA] concept) has been described and implemented although discussed controversially. Within this concept, fixed partial dentures are used for tooth replacement of which a superior performance compared with removable partial dentures has been reported. The multi-centre study was initiated in 2000 because evidence was lacking concerning the benefit of different therapeutic options regarding the preservation of oral health, oral health related quality of life, patients satisfaction, absence of discomfort, satisfactory chewing ability and aesthetic satisfaction. Public health aspects of the study lie in the fields of health economics, avoidance of over-treatment, and therapy guidelines on a population based level.

Two prosthetic therapy arms will be compared:
1. The replacement of posterior teeth at last up to the first molar by removable partial dentures
2. Prosthetic treatment according to the shortened dental arch concept. To avoid removable partial dentures, posterior teeth are replaced up to the second premolar by fixed restorations, if necessary. Molars are not replaced.

The aim of this trial is to test the hypothesis that the treatment outcome varies depending on the treatment concept (fixed versus removable prostheses) in the therapy of patients with missing molars.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical Faculty of the Technical University of Dresden (Ethikkommission der Medizinischen Fakultät der Technischen Universität Dresden). Date of approval: 19/04/1999 (ref: EK 260399)

Study design
Multi-centre randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Tooth loss/ molar replacement

Interventions
Control group (Therapy A): The molar replacement by removable partial dentures, carried out using fixed crowns and bridges as anchor for removable dentures

Intervention group (Therapy B): Restorations according to the SDA concept, with only fixed restorations or no restoration at all. The maximum extension reached up to the second premolar, and no molars were replaced. All restorations were made according to a standardized procedure (SOP) given by the study protocol.

Standard gold alloys and dental ceramics were used for fixed restorations, base metal alloys for the removable denture frameworks.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Further tooth loss is measured at 5, 8, 10 and 15 years

Secondary outcome measures
The following will be assessed at baseline (4-8 weeks after insertion), 6 month, then annually from Year 1 to 5, and further at 8, 10 and 15 years:
1. Clinical:
1.1. Crown/root caries
1.2. Abrasion (Index 0-4)
1.3. Interdental spacing in the anterior region (Index 0-3)
1.4. Sensibility (+/-)
1.5. Periodontitis/Gingivitis: Plaque-index (index 0-3), probing depth (6 point measurement in mm), attachment loss (6 point measurement in mm), bleeding on probing (BOP)(+/-), tooth mobility (index 0-3), mucosa lesions (California Dental Association [CDA] Criteria)

2. Clinical dysfunction index: Muscle pain via palpation (m. masseter pars profunda et superficialis, m. temporalis pars posterior et anterior, m. pterygoideus medialis et lateralis)
3. Range of movement (mm): maximal opening
4. TMJ function: Description of pain on movement/path of movement, palpation/auscultation
5. Technical (according to the CDA criteria): Treatment performance, preparation form, marginal fit, occlusion static/dynamic in µm, proximal contacts (shape/ strength)
6. Technical performance (according to the CDA criteria): Evaluation of used materials, prosthesis and bridge design, saddle extension, possibility of dental hygiene

Subjective:
9. Oral health related quality of life (OHIP-Questionnaire): Measure of self reported dysfunction, discomfort and disability attributed to oral conditions
10. Dworkin Index Axis II (questionnaire): Assessment of psychological distress and psychosocial dysfunction including questions regarding:
10.1. Graded chronic pain severity
10.2. Depression
10.3. Vegetative symptoms and somatization subscales of the SCL-90-R developed by Derogatis and others
10.4. Jaw disability checklist

The CDA Criteria are used according to the Guidelines for the Assessment of Clinical Quality and Professional Performance of the California Dental Association: http://www.cda.org/library/cda_member/policy/quality/quality.html

Overall study start date
01/10/2000

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Patients over 35 years of age, who requested prosthetic treatment with a minimum dentition of both canines and one premolar per side preserved in at least one jaw (Kennedy class I). A dentition including all anterior teeth up to the second premolar on both sides in one jaw was defined as maximum
2. Rejection of implant treatment by the patient
3. Patients with general health according to American Society of Anesthesiologists (ASA) classification group one ore two
4. All abutment teeth must be free of periodontal disease (pocket depth less or equal 4 mm, tooth mobility <= grade 2, mean plaque index <= grade 2, bleeding on probing at all teeth <=25 %) and caries
5. Caries free adjacent teeth
6. Sufficient treatment of the opposite jaw, extending the dentition depending on the randomized treatment option up to the second premolar or the first molar

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Patients with alcohol or drug addiction
2. Mentally disordered patients
3. Patients with TMJ disorders
4. Dysgnathic patients with Angle class II or III
5. Patients who have received or need orthodontical treatment
6. Patients who have been already sufficiently treated
7. Patients who do not accept a removable deture
8. Patients who demand the replacement of all molars
9. Patients with general health American Society of Anesthesiologists (ASA) classification group four

Date of first enrolment
01/10/2000

Date of final enrolment
31/12/2010

Locations

Countries of recruitment
Germany

Study participating centre
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Sponsor type
Government

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ROR
https://ror.org/018mejw64

Funder(s)

Funder type
Government

Funder Name
German Research Foundation (Deutsche Forschungsgemeinschaft)

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journals.

Intention to publish date
31/12/2010

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/02/2010		Yes	No
Results article	results	01/08/2010		Yes	No
Results article	results	01/07/2012		Yes	No
Results article	results	01/03/2014		Yes	No
Results article	results	01/07/2014		Yes	No
Results article	results	01/07/2014		Yes	No
Results article	results	01/12/2014		Yes	No