ISRCTN68590603 https://doi.org/10.1186/ISRCTN68590603

Randomised multicentre study of prosthetic treatment options for shortened dental arch: pilot trial

Submission date	Recruitment status	[_] Prospectively registered
07/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/04/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2010	Oral Health	

Plain English summary of protocol
Not provided at time of registration

Contact information

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

Acronym
SDAS - pilot

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 multicentre 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.

Please note that the pilot phase of this trial has been completed. Details of the full trial may be found at http://www.controlled-trials.com/ISRCTN97265367

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. Duration of follow-up: 5 years

Secondary outcome measures
The following were assessed at baseline (4-8 weeks after insertion), 6 month, then annually from Year 1 to 5:

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), gingival index(index according to Sillnes and Loe: 0-3), bleeding on probing (BOP)(+/-), tooth mobility (index 0-3) , mucosa lesions (California Dental Association [CDA] Criteria)
2. Clinical dysfunction index (Helkimoindex): Muscle pain via palpation (m. masseter pars profunda et superficialis, m. temporalis pars posterior et anterior,m. suboccipitalis, m. sterno-cleidomastoideus, m. pterygoideus medialis et lateralis, t. temporalis)
2.1. Range of movement (mm): maximal opening, maximal lateral movements, maximal protrusion
2.2. TMJ function: Description of pain on movement/path of movement, palpation/auscultation
3. Technical (according to the CDA criteria): Treatment performance, preparation form, marginal fit, occlusion static/dynamic im µm, proximal contacts (shape/ strength)
4. Technical performance (according to the CDA criteria): Evaluation of used materials, prosthesis and bridge design, saddle extension, attachment performance, possibility of dental hygiene
5. Aesthetics (according to the CDA criteria): rated by the dentist, surface, color, translucency, contour
6. Ridge reduction: (x-ray examination according to Steen)

Subjective:
7. Oral health related quality of life (OHIP-Questionnaire): Measure of self reported dysfunction, discomfort and disability attributed to oral conditions
8. Dworkin Index Axis II (questionnaire): Assessment of psychological distress and psychosocial dysfunction including questions regarding:
8.1. Graded chronic pain severity
8.2. Depression
8.3. Vegetative symptoms and somatization subscales of the SCL-90-R developed by Derogatis and others
8.4. 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
26/11/2007

Eligibility

Key inclusion criteria
1. Patients over 35 years of age, male and female
2. Those 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
3. Rejection of implant treatment by the patient
4. Patients with general health according to American Society of Anesthesiologists (ASA) classification group one ore two
5. 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
6. Caries free adjacent teeth
7. 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
72

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
26/11/2007

Locations

Countries of recruitment
Germany

Study participating centre
Fetscherstr. 74
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Government

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Funder(s)

Funder type
Government

Funder Name
German Research Foundation (Deutsche Forschungsgemeinschaft) (Grant ref: WA 831/2-1 to 2-6) (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2005		Yes	No