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Specific occlusal scheme for patients with TM disorders

Submission date	Recruitment status	[_] Prospectively registered
02/11/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/11/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/01/2020	Oral Health	

Plain English summary of protocol

Background and study aims
Temporomandibular disorders (TMD) affect the jaw and the muscles around the face and head. It can cause pain, jaw locking, and headaches. Patients who are endentulous (missing teeth) require dentures to help them chew but this can lead to pain in the temporomandibular joint areas. The dentures should be able to allow wearers to be able to move their jaw while avoiding painful areas. The aim of this study is to provide specific dentures, removable partial acrylic dentures, for those who are partially endentulous to relive TMD related pain.

Who can participate?
Adults aged 46 and older who are partially endentulous.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive their standard level of care. Those in the second group receive the partial acrylic dentures. Participants wear their dentures and are followed up to assess their pain, movement ability and success of the dentures at three, six, nine, 12, 24, 36 and 48 months.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
The Faculty of Stomatology, University of Beograd (Serbia)

When is the study starting and how long is it expected to run for?
June 2016 to January 2019

Who is funding the study?
The Faculty of Stomatology of Beograd (Serbia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
36-18

Study information

Scientific Title
Specific occlusal scheme for partially edentulous patients with TM Disorders

Study objectives
Hypothesis:
The specific occlusal scheme established in NPRAD for the partially edentulous patients of this study will provide positive therapeutic effects. The specific occlusal scheme established in NPRAD for the partially edentulous patients of this study will complicate the prosthetic therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethic Committee of the Faculty of Stomatology, University of Beograd, 21/06/2016, ref: Confirmation number: 36/18

Study design
Single centre single blind randomised controlled trial

Primary study design
Interventional

Study type(s)

Diagnostic

Health condition(s) or problem(s) studied
Patients with problems in oro-facial function and temporo-mandibular disorders will be examined with respect to therapy with acrylic partial dentures for their lower jaws, applying specific occlusal scheme in artificial teeth of dentures

Interventions
Treatment actions are related to occlusal corrections on masticatory-occlusal surfaces of artificial teeth in partial acrylic dentures, as well as composite restorations of incisal edges of anterior remaining teeth of the lower jaws.

The randomisation process is done based on the assessment of a capability of a patient to accept and to adapt to new formed occlusal scheme.

This study has two arms. Those in the first arm (the control arm) receive the fabrication of acrylic conventional complete upper denture and partial acrylic lower dentures with conventional occlusal scheme of occlusal contacts. This methodology assumes firstly the preliminar impressing of the edentulous maxilla and partially edentulous mandible using alginate (Alginogal, Galenika, Serbia). Then, preliminary maxillary and mandibular casts are formed. Additionally, maxillary and mandibular custom trays will be fabricated (Palavit L, ICN Galenika) on preliminary study casts. After that the final functional maxillary impression will be done using zinc oxide–eugenol impression paste (Coe-Flo, Coe Laboratories, Chicago, IL. USA; Zn-oxide eugenol paste Vomogal, Galenika, Serbia). The final mandibular impression will be taken using elastomer-silicone impression material (Oranwash, Zherrmack, Germany) and zinc oxide–eugenol impression paste (Vikopres, ZnO-eugenol, ICN Galenika, Serbia) in one time. Master casts will be fabricated using hard stone (Gipsogal dental stone, type 3, Galenika, Serbia).

Baseplates (Bazogal, Galenika, Serbia) will be adapted on the surfaces of the master casts, and the occlusal rims will be outlined. The upper occlusal rim will be preformed, and then the facebow registration will be completed. The facebow and fork will be attached to the articulator (Dentatus ARLS, Dentatus, Sweden) and the maxillary master cast will be mounted on the articulator, using plaster. Lately, the occlusal rims will be positioned into the mouth, and the final centric record will be made. The mandibular cast will be positioned into the articulator according to the centric record, and the plaster of the mandibular cast will be allowed to set . Wax records for protrusive and lateral position registrations will be created using dental wax (Vomogal C, medium hardness modeling wax 4 plates, ICN Galenika, Serbia). The positions of the patient’s mandibles will be recorded in protrusion and in right and left lateral excursions. The protrusive, as well as lateral condylar paths will be adjusted according to the wax records in an articulator. Artificial acrylic teeth (anterior teeth: Optodent; posterior teeth: Optognath; Bayer, Bayer-Galenika, ICN Galenika, Serbia), will be selected according to the individual criteria. Try-in positioning of the anterior teeth will be done, and rechecking of the condylar relationships and rechecking of centric record will be provided. In addition, the posterior artificial teeth will be positioned onto wax surfaces.

For this study arm the occlusion of artificial teeth will be provided in conventional mode-providing maximum intercuspation in centric occlusion as one single point contacts on the occlusal surfaces of posterior upper and posterior lower teeth positioned on the tips of working-supporting cusps and all marginal ridges, with additional contacts in central fissure and central fossae of molars. After try-in, and finishing of dentures these dentures will be delivered to the patients and positioned into their mouth. The total duration of treatment should be between

one year and four years of wearing of these dentures with subsequent check-ups after 3months, after 6 months, after 9 months, after 12 months etc. during wearing.

Those in the treatment arm receive a different treatment, particularly respecting reorganization of occlusion and occlusal contacts in fabricated dentures. This procedure assumes preliminar impressing of the edentulous maxilla and partially edentulous mandible using alginate (Alginogal, Galenika, Serbia). Then, preliminary maxillary and mandibular casts are be also formed. Additionally, maxillary and mandibular custom trays are fabricated (Palavit L, ICN Galenika) on preliminary study casts. After that the final functional maxillary impression will be done using zinc oxide–eugenol impression paste (Coe-Flo, Coe Laboratories, Chicago, IL. USA; Zn-oxide eugenol paste Vomogal, Galenika, Serbia). The final mandibular impression are taken using elastomer-silicone impression material (Oranwash, Zherrmack, Germany) and zinc oxide–eugenol impression paste (Vikopres, ZnO-eugenol, ICN Galenika, Serbia) in one time. Master casts are fabricated using hard stone (Gipsogal dental stone, type 3, Galenika, Serbia).

Baseplates (Bazogal, Galenika, Serbia) are adapted on the surfaces of the master casts, and the occlusal rims are outlined. The upper occlusal rim are preformed, and then the facebow registration arecompleted. The facebow and fork are attached to the articulator (Dentatus ARLS, Dentatus, Sweden) and the maxillary master cast is mounted on the articulator, using plaster. Occlusal rims are positioned into the mouth, and the final centric record will be made. The mandibular cast is positioned into the articulator according to the centric record, and the plaster of the mandibular cast ise allowed to set . Wax records for protrusive and lateral position registrations are created using dental wax (Vomogal C, medium hardness modeling wax 4 plates, ICN Galenika, Serbia).

The positions of the patient’s mandibles arerecorded in protrusion and in right and left lateral excursions. The protrusive, as well as lateral condylar paths are adjusted according to the wax records in an articulator. Artificial acrylic teeth (anterior teeth: Optodent; posterior teeth: Optognath; Bayer, Bayer-Galenika, ICN Galenika, Serbia), are selected according to the individual criteria. Try-in positioning of the anterior teeth will be done, and rechecking of the condylar relationships and rechecking of centric record will be provided. In addition, the posterior artificial teeth will be positioned onto wax surfaces. For this (experimental) group of the patients occlusal scheme will be provided in the manner that occlusal contacts are established as tripod minor contacts on the side where part of the maxillary edentulous ridge was extensively resorbed towards the distal. Tripod contacts are present (exist) on the opposing occlusal surfaces of the corresponding posterior artificial teeth. Contacts on the opposite side are formed as circumferential surfaces.

Participants are followed up to evaluate their pain and dysfunctional problems as well as any movement of the mandible.

Intervention Type
Device

Primary outcome(s)
1. Dysfunctional problems and pain are measured using the pain questionnaires at the moment of preliminary impressing-starting time of phases of fabrication of dentures, at the moment of delivery of the dentures-baseline, after 3 months, after 6 months, after 9 months, after 12 months, after 24 months, after 36 months or after 48 months
2. Movements of the mandible is measured using millimetric ruler prior to preliminary impressing, and then at the moment of the delivery of the dentures-baseline, after 3 months,

after 6 months, after 9 months, after 12 months, after 24 months, after 36 months or after 48 months
3. Occlusion of artificial teeth of acrylic partial lower dentures and complete upper dentures will be checked by conventional (two-sided) articulating paper are recorded as occlusal contacts on occlusal surfaces of teeth at the moment of delivery of dentures-baseline, after 3 months, after 6 months, after 9 months, after 12 months, after 24 months, after 36 months or after 48 months

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
05/01/2019

Eligibility

Key inclusion criteria
1. Kennedy class II type of edentulous fields in the lower jaw, and edentulous upper jaw
2. Aged 46 and older

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Infectious diseases
2. Previous inabilities to wear partial dentures
3. Poor oral hygienic conditions

Date of first enrolment
01/01/2017

Date of final enrolment
05/01/2017

Locations

Countries of recruitment
Serbia

Study participating centre

The Faculty of Stomatology, University of Beograd, Serbia
Rankeova street , number4
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Sponsor information

Organisation
University of Belgrade

ROR
https://ror.org/02qsmb048

Funder(s)

Funder type
University/education

Funder Name
The Faculty of Stomatology of Belgrade, Serbia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes