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Clinical Study: Determining the Quality of Life (QOL) for patients using various types of partial dentures

Submission date
12/07/2017

Recruitment status
No longer recruiting

Registration date
01/08/2017

Overall study status
Completed

Last Edited
15/06/2022

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
As a result of increased life expectancy and oral health promotion, there has been a gradual shift in the amount of people who are totally edentate (lacking teeth). Advancements in the field of dentistry have provided more options for patients who have experienced tooth loss. While treatment such as the use of implants exists, removable partial dentures (RPDs) are widely used in clinical practice for their advantages in many cases. RPDs are available in a variety of types. Among them is the conventional removable partial denture (CRPDs) with metal clasps. While they are a popular option, there are drawbacks such as impairment of esthetics (looks), discomfort, and metal allergy when using them. To overcome these disadvantages, the next type, the non-metal clasp denture (NMCDs) was developed. NMCDs are made using a thermoplastic (a substance that become plastic when heated and harden on cooling) denture base resin and do not have a metal clasp. As they are increasingly being used, the application of it is mostly based on the clinician's preference and there is limited amount of research conducted on this type of denture. In addition to these two types of dentures, there is also the shortened dental arch (SDA) which does not require restoration (repair) of the full dental arch. This concept, while having been proposed over the years, is somewhat controversial in that it attempts to prioritize functionality over complete restoration. With all of these options, it is important to properly evaluate the patient-related outcomes in situations where implants are not to be used (which is often still the case in general), for the benefit of the patient. The aim of this clinical trial is to investigate the oral health-related quality of life (OHRQoL) among participant patients who have received CRPDs, NMCDs, and SDAs.

Who can participate?
Adults aged 24 to 85 have mandibular free edge loss patient.

What does the study involve?
Participants are allocated to one of six different groups. Each group received the three types of treatment (CRPDs, NMCDs, and SDA) in one of six preset sequences. Dentures are delivered to the patients and control appointments were scheduled few days afterwards. Each type of treatment is used for two weeks. At the end of each usage, participants arerequested to answer

questions to assess oral function, facial appearance, any pain, and impact. After finishing the three treatments, two options for prosthesis are presented for the patient to choose. A follow-up appointment take place three to six months for adjustments.

What are the possible benefits and risks of participating?
As far as benefits, patients have a more active role in choosing the type of prosthesis they feel is the best for them. There are no major risks because all forms of treatment are noninvasive and do not require surgery

Where is the study run from?
Nakai Dental Office (Japan)

When is the study starting and how long is it expected to run for?
January 2015 to July 2017

Who is funding the study?
Investigator initiated and funded (Japan)

Who is the main contact?
Dr Tadafumi Kurogi

Contact information

Type(s)
Scientific

Contact name
Dr Tadafumi Kurogi

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NA

Study information

Scientific Title
Oral health-related quality of life of non-metal clasp dentures and shortened dental arch with unilateral mandibular distal-extension edentulism: a within-subject controlled clinical trial

Study objectives
The aim of this study is to investigate the Oral Health-related Quality of Life (OHRQoL) in participant patients who use various types of treatment for partial edentulism.

Study hypothesis:
There are three prosthetic options, conventional removable partial dentures (CRPDs), non-metal clasp dentures (NMCDs) and shortened dental arch (SDA), for the unilateral mandibular distal-extension edentulism will not lead to different oral health-related quality of life (OHRQOL).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Nagasaki University Hospital Japan, 03/03/2015, ref: 15022313

Study design
Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

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
Oral Health-related Quality of Life (OHRQoL)

Interventions
In order to ensure that the process is exactly the same so as not to include confounder, participants are allocated to one of six groups,
treated as sequences ABC, ACB, BAC, BCA, CAB and CBA. Each participant receive a written description of the experimental procedures and informed consent is obtained prior to enrollment into the study. Participants are divided and assigned to six different groups. Each group receive the three types of treatment (CRPDs, NMCDs, and SDA) in one of six preset

sequences. Dentures are delivered to the patients and control appointments are scheduled few days afterwards.

This study employed crossover design, a within-subject controlled clinical trial, for the three treatment options:

1. Conventional removable partial dentures (CRPDs): The conventional removable partial denture (CRPD) is the most common type of removable partial denture. It consists of a set of artificial replacement teeth and metal framework with clasps. The clasps are thin finger-like structures usually made of thin resilient metal alloy that rest upon and wrap around the remaining natural teeth. These clasps keep the prosthesis securely in place, but still allow the user to easily take it out for cleaning and proper brushing of remaining natural teeth. Depending on the denture design which is based on mouth conditions, there may be some show of the clasp (s). This issue with esthetics, along with occasional discomfort and allergic reaction to the metal, are often cited as disadvantages of this type of denture.

2. Non-metal clasp dentures (NMCDs): The non-metal clasp denture (NMCD) was developed to rectify the disadvantages of the conventional removable partial denture with metal clasps. Instead of using metal clasps, this type of denture is fabricated using a thermoplastic denture base resin. The prosthesis is inserted by fitting itself onto the gums of the user and secures itself to the natural teeth and surrounding areas. This type of denture is known to be much more esthetically pleasing and eliminates all issues with metal allergies. While this type treatment has been gaining some popularity over the years, the application of it is based only on the individual clinician's preference.

3. Shortened dental arch (SDA): The Shortened Dental Arch (SDA) comprises of anterior and premolar teeth with missing posterior occlusal units. By focusing treatment on the replacement of teeth towards the front of the mouth, priority is placed on functionality over the restoration of the entire dental arch. This provides efficient dental care with no risk of over-treatment.

Each treatment takes two weeks. The total duration of treatment (including fabrication and adjustment) takes 11 weeks. Each type of treatment are used for two weeks. At the end of each trial, participants are requested to answer an oral health impact profile (OHIP) questionnaire to assess oral function, oro-facial appearance, any oro-facial pain, and psychosocial impact. The Oral Health Impact Profile (OHIP) is a questionnaire that organizes data on the patient rated outcome measures, developed for measuring the oral related quality of life (OHRQOL). Its validity and reliability were previously established and it has been widely used in clinical trials. In this study, the Japanese version of OHIP (OHIP-J49) is used. All treatments and interventions are conducted by one board-certified prosthodontist from the Japan Prosthodontist Society at the same centre.

After finishing the treatments, two options for prosthesis are presented for the patient to choose. A follow-up appointment is scheduled to take place three to six months post-delivery for remounting and adjustments. Treatment is concluded upon agreement between the clinician and patient to terminate.

Intervention Type
Other

Primary outcome measure
Oral-related quality of life is measured using the oral health impact profile (OHIP) at two weeks after each treatment.

Secondary outcome measures
1. The effect of other factors (sex, age, edentulous period and the number of missing teeth) are measured using exploratory analysis at each treatment.
2. Analysis in four sub-domains of oral health impact profile (OHIP) (difference among 3 options test score using the mixed effect model). The questionnaires cover four sub-domains (Oral function, Oro-facial appearance, Oro-facial pain and Psychosocial impact).

Overall study start date
01/01/2015

Completion date
12/07/2017

Eligibility

Key inclusion criteria
1. Mandibular free edge loss patient
2. Person in hope of the production of the denture or adjustment
3. The patient that a document agreement by the free will of a patient was provided after enough understanding after having received enough explanation on participating to this study
4. Aged between 24-85 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. It is the person with the trouble for a question vote answer
2. The person who has a loss on chin face
3. Person considered that the participation in study is difficult having a systemic anamnesis
4. The person that periodontal treatment is not finished
5. In addition, the patient whom a study person in charge judged to be inappropriate as a subject

Date of first enrolment
03/03/2015

Date of final enrolment
12/05/2017

Locations

Countries of recruitment
Japan

Study participating centre
Nakai Dental Office
724-1 Yohojimae-cho
Nakagyu-ku
Kyoto City
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Japan
604-0916

Sponsor information

Organisation
Nakai Dental Office

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://ndo-kyoto.jp/english

Funder(s)

Funder type
Government

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
I intend to analyze data and prepare the manuscript in 2017 and publish my study in JDR CTR in 2018.

Intention to publish date
01/12/2018

Individual participant data (IPD) sharing plan
The data sets generated during and/or analyzed during the current study will be stored privately available repository at the Nakai Dental Office (Japan).

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/06/2022	15/06/2022	Yes	No