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Clinical efficiency and patient evaluation of digitally manufactured removable complete dentures

Submission date
15/05/2021

Recruitment status
No longer recruiting

Registration date
02/06/2021

Overall study status
Completed

Last Edited
08/07/2021

Condition category
Oral Health

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dentures are removable false teeth that fit over the gum and are used to treat tooth loss and replace missing teeth. Complete dentures (CDs) replace all of the upper and/or lower teeth. Dentures can reduce potential problems in speaking and chewing food caused by tooth loss and can have cosmetic benefits that improve patient confidence.

The introduction of computer-aided design & computer-aided manufacturing (CAD/CAM) technology in the field of prosthodontics (dental procedures that involve repairing or replacing teeth with prosthetics such as dentures) has significantly changed the manufacturing methods of CDs. There have not yet been studies to show ifcomputer-aided planning and production of CDs is superior to the conventional procedure.

The aim of this clinical study is to evaluate if digitizing the process of creating complete dentures is beneficial in terms of the precision, appearance, hygienic performance, and long-term behavior of the dentures. The CERAMILL FULL DENTURE PROSTHETICS material systems for CAD/CAM fabrication of complete removable dentures will be investigated and compared to the conventional process of denture fabrication.

Who can participate?
Adult patients with tooth loss requiring a new set of complete dentures who are willing to participate for the duration of the study (approximately 2 years)

What does the study involve?
A total of ten treatment sessions are scheduled at weekly intervals during participation in this study. The first five appointments will include all necessary treatment steps (from initial impression taking to completion) for the fabrication of both conventional and digital complete dentures for each participant. Participants will be allocated to receive dentures fabricated digitally or dentures fabricated using conventional methods in the first half of the study, with an equal chance of being in either group (like tossing a coin). In the second half of the study, participants will receive the denture type that they did not receive in the first half of the study.

The participant will first be given a pair of dentures (digitally or conventionally fabricated) to wear for two weeks and will then be asked to evaluate their quality of life and satisfaction with the dentures using two questionnaires. At the delivery of each denture type, the dentures will be assessed by two experienced clinicians according to defined grading criteria.

After the first 2 week period, participants will return the new dentures and will wear their old dentures for one week so that the denture support tissue returns to its original shape before the second new pair of prostheses is handed over for another two weeks of wear. The participant will then be asked to complete an evaluation of the second pair of prostheses using the quality of life and satisfaction questionnaires and to state the preference for one prosthesis type. Finally, the patient will be able to keep both denture sets and will benefit from the possibility to have a reserve denture set.

What are the possible benefits and risks of participating?
The introduction of CAD/CAM technology in the field of prosthodontics has significantly changed the manufacturing methods of dentures with the aim of accelerating and facilitating everyday clinical practice. The superiority of computer-aided planning and production of complete dentures compared to the conventional procedure, however, has not yet been scientifically proven. In addition, scientific evidence is also lacking regarding clinical effectiveness of digital complete dentures. The purpose of this clinical study is to compare clinical treatment outcomes and patient satisfaction for digitally and conventionally processed CDs with the aim of finding the most proper therapy option for edentulous patients.

Problems are not expected to occur during the study. There are no injury risks or burden to study participants. The low risk is offset by a high benefit of the study. No adverse events are known to date. The potential risk of allergic reactions is very low.

Where is the study run from?
University Clinic of Dentistry, Vienna (Austria)

When is the study starting and how long is it expected to run for?
From September 2018 to September 2021

Who is funding the study?
The University Clinic of Dentistry Vienna, Department of Prosthodontics (Austria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1.1

Study information

Scientific Title
Comparison of CAD/CAM systems for manufacturing milled removable complete dentures with the conventional technique on clinical efficiency and patient-based outcomes – a prospective crossover study

Acronym
Digital complete dentures

Study objectives
The equivalence of expectancies of patient satisfaction scores, oral health-related quality of life represented as Oral Health Impact Profile score (OHIP-20), and clinical efficacy outcomes (i.e. stability, retention, border extension, palatal base thickness, finish quality (polish), aesthetics, phonetics, occlusion, and vertical dimension) for digital versus conventional CDs

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/06/2018, Ethics Committee of Medical University of Vienna (Borschkegasse, 1090 Wien; +43 1 4040021470; ethik-kom@meduniwien.ac.at), ref: 1062/2018.

Study design
Prospective single-blind randomized crossover trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact email lana.zupanciccepic@meduniwien.ac.at to request a participant information sheet.

Health condition(s) or problem(s) studied
Prosthodontic treatment of edentulous patients

Interventions
Participants will be randomized into 3 groups of different digital denture systems (VITA VIONIC, Ceramill FDS, and Baltic Denture) using a 1:1:1 allocation ratio to ensure a balance in sample size across groups. Within each of these three groups patients will be randomized 1:1 into one of the two sequence groups: receiving first the digital and then, after a washout period of one week, the conventional CD or the other way around. The fabrication type of dentures will be blinded to the patient.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Oral health-related quality of life measured using Oral Health Impact Profile score (OHIP-20) at 2 and 5 weeks

Secondary outcome measures
1. Clinical parameters at the time of delivery of the prosthesis including fit, retention, palatal base thickness, denture quality (polish), aesthetics, phonetics, occlusion, and vertical dimension measured and rated by two independent prosthodontists according to defined grading criteria at 0 and 3 weeks
2. Patient denture preference measured using a standardised questionnaire at 5 weeks

Overall study start date
01/02/2018

Completion date
01/09/2022

Eligibility

Key inclusion criteria

1. Completely edentulous
2. Aged ≥18 years
3. Alveolar ridges Class II, III, or IV according to Cawood and Howell classification
4. Attending the University Clinic of Dentistry Vienna requiring a new set of complete dentures (CD) for the reason of impaired aesthetics and function (for example worn teeth and denture stains) of the existing ones
5. Willing to participate for the duration of the study and provides written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
33

Key exclusion criteria
1. Severely atrophic ridges (Class V and VI)
2. Hypertrophic tissue
3. Maxillofacial defects

Date of first enrolment
01/07/2018

Date of final enrolment
01/07/2022

Locations

Countries of recruitment
Austria

Study participating centre
University Clinic of Dentistry Vienna
Sensengasse 2a
Vienna
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1090

Sponsor information

Organisation
University Clinic of Dentistry Vienna

Sponsor details
Medical University of Vienna
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Sponsor type
University/education

Website
https://www.unizahnklinik-wien.at/en/

Funder(s)

Funder type
University/education

Funder Name
Medizinische Universität Wien

Alternative Name(s)
Medical University of Vienna, MediUni Wien

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Austria

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/09/2022

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?
Protocol file	version v2.0	06/06/2018	08/07/2021	No	No