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Evaluation of tissue conditioner-assisted complete denture restoration

Submission date
12/03/2024

Recruitment status
No longer recruiting

Registration date
18/03/2024

Overall study status
Completed

Last Edited
02/09/2024

Condition category
Digestive System

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

Plain English summary of protocol

Background and study aims
As the population ages, oral diseases are increasing, and the proportion of edentulous patients with no natural teeth remaining has risen annually. Although implant technology has greatly improved edentulous restoration outcomes, including improved denture comfort and masticatory efficiency, complete dentures remain the preferred restoration method for most edentulous patients for economic reasons, trauma considerations and general health impacts. There are few in-depth explorations on how to use tissue conditioners to fabricate transitional or therapeutic dentures clinically. Thus, this study explores the method of obtaining dynamic functional impressions with tissue conditioners and preliminarily evaluates the clinical efficacy of complete denture restoration based on this method.

Who can participate?
Physically healthy people with edentulous upper and lower jaws

What does the study involve?
Participants will be randomly divided into three groups: a conventional impression group (CI group), a closed-mouth impression group (CM group) and a tissue conditioner group (TC group). The treatment lasted for 3 months.

CI Group: This group uses a traditional method of taking impressions with open-mouth techniques. It involves multiple steps including alginate impressions, custom tray fabrication, silicone impressions, and clinical try-ins to ensure proper fit and occlusion of the dentures.

CM Group: This group involves taking impressions with the mouth closed. Similar to the conventional group, it involves custom tray fabrication, impression taking, and clinical try-ins to ensure proper fit and occlusion of the dentures.

TC Group: This group involves applying tissue conditioners to dentures after initial delivery. The tissue conditioner is applied to the denture base and molded in the patient's mouth to improve fit and comfort. Regular adjustments and evaluations are made to ensure proper adaptation and functionality.

All participants are required to wear the dentures for a specified period, and evaluations are conducted to assess factors such as fit, comfort, and occlusion. The study aims to determine which method produces the best outcomes for denture fit and patient satisfaction for edentulous individuals.

What are the possible benefits and risks of participating?
Participants may get better results from new technologies. On the closed-mouth impression technique basis, using tissue conditioners for dynamic functional impressions can further enhance denture retention and stability, fully resolving clinical problems such as poor retention and recurrent mucosal pain and diffusing tenderness with complete dentures, thereby achieving stable and comfortable restoration effects (including ensuring good chewing function) and improving patient satisfaction.

There is a risk that the repair effect of the denture was not good, with repeated tenderness and rupture, which could not be alleviated by repeated adjustments and needed to be remade.

Where is the study run from?
Wuxi Stomatology Hospital (China)

When is the study starting and how long is it expected to run for?
December 2021 and September 2023

Who is funding the study?
Wuxi Dental Hospital (China)

Who is the main contact?
Dr Li-Qin Gong, liqingong_g61@163.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Evaluation of tissue conditioner-assisted complete denture restoration: a randomised controlled clinical trial

Study objectives
To evaluate the clinical effect of three impression methods, conventional, closed-mouth and tissue conditioner, on complete denture fabrication.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/12/2021, Wuxi Stomatology Hospital (No. 6 of Jiang Kang Road, Liang Xi District, WuXi , 214000, China; +86 82808866; wxkqyybgs@126.com), ref: 2021121705

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
University/medical school/dental school

Study type(s)
Efficacy

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

Health condition(s) or problem(s) studied
Edentulous with severely resorbed alveolar ridges (Atwood classification III or IV)

Interventions
The patients will be randomly divided using stratified randomisation into three groups: a conventional impression group (CI group), a closed-mouth impression group (CM group), and a tissue conditioner group (TC group).

Conventional Impression Group (CI group):
A two-step impression method will be used to take open-mouth impressions.
1. Suitable aluminum trays will be selected by the clinician and used to make an alginate impression. A stone model will be obtained from the alginate impression, and an individual acrylic resin tray will be made using light-cured resin.
2. Silicone impression (Virtual Heavy and Light Body; Ivoclar Vivadent AG., Schaan, Liechtenstein) will be used by the clinician to make an open-mouth final cast.
3. Temporary denture bases will be made on the final cast by the clinician, using the mandibular rest position method to determine vertical dimensions and the direct occlusal method to determine horizontal dimensions.
4. After the technician completes the wax modeling of the teeth, the clinicians will check the occlusal relationships, lip fullness, and occlusion through clinical try-ins.
5. Upon verification and acceptance of aesthetics, function, and vertical dimensions, the laboratory will proceed to process the complete denture. Upon the patients' return to the hospital, the dentures will be inserted and checked for overextension of the borders, verified for vertical dimensions, and adjusted for occlusion.

Closed-Mouth Impression Group (CM group):
A two-step impression method will be used to take closed-mouth final impressions. Following the above method, preliminary impressions will be taken, and custom trays without handles will be made. Maxillary open-mouth final impressions will be taken clinically, and maxillomandibular relationships will be determined using the above-mentioned method. Mandibular closed-mouth final impressions will be made in centric occlusion. Occlusal relationships will be confirmed again through tooth arrangement and clinical try-ins. After successful try-ins, denture packing will be completed, and the final dentures will be delivered for patients to wear for the first time.

Tissue Conditioner Group (TC group):
Transitional dentures will be made by referring to the closed-mouth impression method used in the CM group. After initial denture delivery, the tissue conditioners (GC Tissue conditioner; GC Corp., Tokyo, Japan) will be lined onto the denture base tissue surface as follows:
1. The clinicians will evenly grind 1.5 mm of resin from the tissue surface.
2. The clinicians will mix the tissue conditioner into a creamy state according to the product instructions, place it in the ground denture area, and after inserting the denture into the mouth, have the patient occlude in centric occlusion to complete a series of molding actions (pursing lips, moving the tongue, swallowing, etc).
3. After the tissue conditioner has set (around 10 min), the clinicians will remove it and trim excess material with a surgical knife, asking the patient to occlude again to check applicability.
4. After wearing the dentures, patients will be recalled regularly (weeks 1, 2, 4, and 8) to trim exposed denture bases and overextended borders, reline with the tissue conditioner, and inspect occlusion.
5. After 4–8 weeks, when the transitional denture has recorded each patient's requirements (including stable reproducible occlusion, accurate tissue surface morphology, border position, and morphology), the clinicians will transfer all patient requirements by duplicating the denture and making the final denture.

All participants will be required to wear the dentures for at least 8 hours daily. The same dentist with over 3 years of complete denture restoration experience will perform all the procedures, and the same dental technician team will complete all the lab work.

Intervention Type
Procedure/Surgery

Primary outcome measure
The clinical effect of the three impression methods, conventional, closed-mouth and tissue conditioner, on complete denture fabrication measured objectively by the same clinician at 1, 2, 4, and 8 weeks and three months after the final denture completion.

Secondary outcome measures
Denture quality of all three groups measured objectively by the same clinician using a comprehensive evaluation of denture quality between groups based on age, sex, or Atwood classification and the Oral Health Impact Profile-Edentulous Questionnaire 3 months after the final denture completion at follow-up visits at 1, 2, 4 and 8 weeks

Overall study start date
01/12/2021

Completion date
30/09/2023

Eligibility

Key inclusion criteria
1. Physically healthy with a positive mental state and sufficient understanding ability and able to cooperate with the treatment plan and complete the final questionnaire survey
2. Edentulous upper and lower jaws, mandibular alveolar ridge resorption of Atwood class III or IV
3. Flabby ridge: relatively poor mucosal conditions (complex morphology, multiple folds) or edentulous with abused oral tissues and deformation or ulcers resulting from poor stimulation from wearing dentures

Participant type(s)
Patient

Age group
Mixed

Lower age limit
59 Years

Upper age limit
88 Years

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria

1. Severe systemic diseases, stroke, mobility difficulties or drastic hormone-level changes
2. Severe oral mucosal diseases or limited mouth opening
3. Poor compliance or unwillingness to cooperate with the treatment plan or follow-up
4. Temporomandibular joint disorder syndrome or unstable mandibular positional relationship, stiff and tense perioral muscles or functional degradation

Date of first enrolment
01/01/2022

Date of final enrolment
30/06/2023

Locations

Countries of recruitment
China

Study participating centre
Wuxi Stomatology Hospital
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
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Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Wuxi Dental Hospital

Results and Publications

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

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/08/2024	02/09/2024	Yes	No