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Digital versus traditional full dentures – does the new technology feel better? A patient-centred pilot study

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27/05/2025

Recruitment status
No longer recruiting

Registration date
29/05/2025

Overall study status
Completed

Last Edited
29/05/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Losing all upper teeth (full maxillary edentulism) affects daily life. Conventional dentures are handcrafted while digital dentures are designed on a computer and 3D printed or milled. This study aims to discover which feels better to patients.

Who can participate?
Adults aged 40 years and over with no upper teeth and good general health

What does the study involve?
Participants receive two new upper dentures: one conventional and one digital. They wear each for 6 months in a random order and rate comfort, fit, appearance and function on simple questionnaires.

What are the possible benefits and risks of participating?
Both dentures are accepted standard care; participants may benefit from two high-quality dentures and any improvements in fit. The risks are minor (temporary sore spots).

Where is the study run from?
Dentexpert Private Practice and the Faculty of Dentistry, George E. Palade University of Medicine, Pharmacy, Science & Technology of Târgu Mureș (UMFST) (Romania)

When is the study starting and how long will it run?
January 2024 to December 2024

Who is funding the study?
Dentexpert Private Practice SRL (Romania)

Who is the main contact?
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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
1/2025

Study information

Scientific Title
Patient satisfaction and perception with digital complete dentures compared to conventional complete dentures: a randomized crossover pilot study

Acronym
PSPDCDCCCD

Study objectives
By using a crossover design, each patient served as their own control, which we anticipated would provide a sensitive comparison between the two fabrication methods. The null hypothesis was that there would be no difference in patient satisfaction between digital and conventional complete dentures.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/01/2024, Dental Practice Dentexpert (Bd 1848 nr 20E/2, Targu Mures, 540429, Romania; +40 (0)722649493; ethics@dentexpert.ro), ref: IRB/2023/7

Study design
Prospective randomized two-sequence cross over trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Dental clinic

Study type(s)
Quality of life

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
Oral healthcare for edentulous patients

Interventions
A prospective, randomized crossover clinical trial was conducted in 2023–2024 involving 40 completely maxillary edentulous patients meeting specific inclusion criteria. The two prosthetic restorations assessed were the maxillary conventional complete denture (C-CD) and digital maxillary complete denture (D-CD). Participants were randomly allocated into two sequence groups: Group 1 (n = 20) received C-CD first, and Group 2 (n = 20) received D-CD first, each for 6 months (T1), followed by crossover to the alternate denture for another 6 months (T2). Patient satisfaction was measured using a 10-item questionnaire at 6 and 12 months.

Randomization and Crossover Procedure:
Participants were randomly allocated into two equal groups to determine the order of denture type received. A computer-generated random sequence was used for allocation, and group assignments were concealed in sealed opaque envelopes opened after each patient's enrollment. Group 1 (n = 20) received a conventionally fabricated complete denture (C-CD, (Ivobase+Phonare II, Ivoclar)) first, followed by a digitally fabricated complete denture (D-CD, CAD/CAM-designed, Denture 3D+, NextDent+Harz Labs Dental Sand), while Group 2 (n = 20) received the D-CD first, then the C-CD. Each patient used the first denture for a period of 6 months (T1), after which they crossed over to the alternate denture type, which was then used for another 6 months (T2). There was no washout period between treatments, as removing a functional denture for an extended time was not feasible; however, a 1-2 week adaptation period was allowed with the new prosthesis before data collection at each crossover point. Importantly, each patient received new maxillary dentures fabricated by both methods. This means that during each phase, the patient wore a conventional or digital denture. All patients received thorough instructions on denture use and maintenance at delivery.

Conventional Denture Fabrication:
Conventional complete dentures were fabricated following standard clinical and laboratory protocols. First, preliminary impressions of the edentulous ridges were made using alginate in stock trays. From these, preliminary casts were obtained and custom trays were fabricated. The borders of the custom tray were adjusted, and border molding was performed using modeling compound to achieve proper extension. Final impressions were taken with medium-body polyvinyl siloxane (PVS) material to capture detailed anatomy. Master casts were poured in dental stone from the final impressions. On each master cast, a baseplate and wax rim were constructed; these record bases were used to record the maxillomandibular relationship (jaw relations) and to determine vertical dimension and centric relation. The tooth selection (shape and shade) was done per patient's esthetic preferences and prosthodontist's guidance. The teeth (acrylic denture teeth) were arranged in wax on the master casts and a wax try-in was conducted for each patient. After verification of fit, occlusion, and esthetics at the try-in stage, the dentures were processed in heat-cured polymethyl methacrylate resin using the compression molding technique. The finished conventional dentures were then deflasked, trimmed, and polished. Any necessary laboratory remount and occlusal adjustments were performed to refine occlusion. All laboratory procedures were carried out by the same experienced dental technician to ensure consistency in denture fabrication quality.

Digital Denture Fabrication:
Digital Impressions and Jaw Relations:
For patients in the digital denture group, a complete intraoral scanning workflow was employed. Edentulous maxillary and mandibular arches were captured using a high-resolution intraoral scanner (Medit i700, Medit Corp.) to obtain precise digital impressions of the tissue surfaces. To record maxillomandibular relations (vertical dimension of occlusion and centric relation), conventional wax occlusion rims were used on 3D-printed custom record bases. In each case, the wax rim assembly (with the established occlusal vertical dimension and centric bite) was either scanned in the patient's mouth or extra-orally to digitize the jaw relation record. In some cases, an intraoral gothic-arch tracing device was additionally used to fine-tune centric relation; the tracer markings or plates were likewise scanned and aligned with the arch scans. This ensured that the patient's bite registration was accurately transferred into the virtual environment. All digital impressions and bite records were made by the same clinician to maintain consistency across cases.

Virtual Denture Design (CAD):
The digital arch models and jaw relation records were imported into a specialized dental CAD software for complete dentures (exocad DentalCAD, exocad GmbH, Germany). Using this software, a virtual denture setup was designed for each patient. The anatomical landmarks (e.g. midline, smile line, occlusal plane) guided the placement of artificial teeth from the software's tooth library. The maxillary dentures were designed in proper occlusion according to the recorded centric relation and vertical dimension. A virtual articulator function was used to simulate mandibular movements, allowing adjustment of tooth positions to achieve balanced occlusion in excursions. The denture bases were contoured in the software to optimal form and extension, and relief areas were incorporated as needed. The final approved denture design consisted of two sets of STL files – one for the denture base (with sockets for teeth) and one for the denture teeth – exported for 3D printing.

3D Printing and Post-Processing:
The complete dentures were fabricated by additive manufacturing using a stereolithography-based 3D printer. In this study, a digital light processing (DLP, Asiga) printer was used to achieve high accuracy and resolution (layer thickness ~50 µm) for the denture components. Each denture base was printed in a pink biocompatible denture resin (NextDent Denture 3D+, Vertex-Dental B.

V., Soesterberg, NL), while the teeth were printed separately in a tooth-colored microfilled hybrid resin (Harz Labs Dental Sand, shade A3, Harz Labs, Riga, Latvia). The NextDent Denture 3D+ material is a Class IIa medically certified resin with mechanical properties comparable to conventional heat-cured PMMA denture base material (flexural strength ~84 MPa; flexural modulus ~2380 MPa). The Harz Labs Dental Sand resin is a methacrylate-based composite designed for dental applications, characterized by high hardness (~90 Shore D) and strength, making it suitable for durable denture teeth. Printed parts were cleaned of residual resin by rinsing in isopropyl alcohol baths and then post-cured in a light-curing unit (manufacturer-recommended UV oven) to ensure complete polymerization. Any support structures were carefully removed, and the denture base and teeth components were finished as per standard protocols. For assembly, the printed teeth were bonded into the corresponding sockets of the printed base using a light-cured bonding resin matching the denture base material. The assembled dentures were then polished to a smooth finish, especially along the borders and occlusal surfaces. Prior to delivery, each digital denture underwent occlusal adjustment on an articulator (or intraorally) to eliminate any prematurities and to refine centric contacts and balancing contacts. The entire fabrication process for all digital cases was carried out by the same prosthodontist-technician team, standardizing the clinical and laboratory techniques and thereby ensuring consistency across the digital denture cohort.

Intervention Type
Behavioural

Primary outcome measure
Patient comfort measured using Item 1, 10-item Patient Satisfaction Questionnaire (PSQ), 5-point Likert at 6 months (T1) and 12 months (T2)

Secondary outcome measures
1. Retention measured using Item 6, PSQ at T1 and T2
2. Mastication measured using Item 5, PSQ at T1 and T2
3. Post-insertion adjustment visits measured using clinic records at T1 and T2
4. Overall denture preference measured using single forced-choice question at T2

Overall study start date
15/01/2024

Completion date
31/12/2024

Eligibility

Key inclusion criteria
1. The patients included in this study had varying conditions in the opposing mandibular arch, including complete dentures (45%), removable partial dentures (35%) or fixed prosthetic restorations (20%). The presence of different mandibular arch conditions was considered when analyzing the results, as it may influence satisfaction with the maxillary dentures.
2. All participants signed an informed consent form that included a description of the intervention.

Participant type(s)
Patient

Age group
Adult

Lower age limit
40 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Uncontrolled systemic disease
2. Infectious diseases
3. Partial maxillary edentulism
4. Temporo-mandibular disorders
5. Xerostomia
6. Oro-facial pain
7. Patients who could not read informed consent form
8. Patients with congenital or acquired defects in maxilla and/or mandible
9. Patients considered ineligible for study inclusion by the principal investigator

Date of first enrolment
01/02/2024

Date of final enrolment
30/06/2024

Locations

Countries of recruitment
Romania

Study participating centre
Dentexpert
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Sponsor information

Organisation
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Sponsor type
Other

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Dentistry Journal

Intention to publish date

Individual participant data (IPD) sharing plan
Datasets (anonymised PSQ scores and visit counts) will be deposited in the Open Science Framework (OSF) – public release scheduled for 01/07/2025 under a CC-BY 4.0 licence. Participants provided consent for data sharing; no identifying data are included.

IPD sharing plan summary
Stored in publicly available repository