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Optimizing clinical workflows for 3-D printed dentures

Submission date	Recruitment status	[_] Prospectively registered
27/01/2020	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/04/2020	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/04/2020	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Dentures are made by pouring liquid acrylic resin (a type of plastic) into moulds based on the patient's mouth. When the acrylic resin cools and sets, it contracts, which means there can be distortions resulting in the denture not fitting perfectly into the mouth. 3D printing, where a solid form is built up under the control of a computer, can now be used to create dentures and this process avoids the distortion from the cooling resin. The researchers want to compare the traditional method of denture production with 3D printing in a future clinical study. First they want to find out what is the best workflow for producing 3D-printed dentures. This study will investigate the best way of producing the virtual 'map' of the participant's mouth used to construct a 3D image of the denture prior to printing, whether a 3D-printed baseplate should be used in the intermediate stages of manufacture, and whether the 3D-printed dentures should be painted to improve their appearance. This will involve recruiting participants who need to have dentures made and creating two sets for them - one traditionally made and the other made using 3D printing.

Who can participate?
Adults who need a replacement set of complete dentures and who do not have problems with their mouth such as cancer, extreme dryness or inflammation.

What does the study involve?
Each participant will have two sets of dentures made and fitted - one traditionally made and the other made using 3D printing. They will be asked at various points in the process to score the two sets of dentures and to choose which they prefer or if they have no preference because they are equally bad or equally good.

What are the possible benefits and risks of participating?
The participant will receive an additional set of dentures. This is both a benefit and a potential burden. Having a 'spare set' will be beneficial. Having a denture fitted can on occasion be uncomfortable. This is uncommon but there is a potential burden for the participant to go through the additional insertion of the extra denture. While the researchers anticipate that the 3D-printed extra dentures will be a better fit when compared to conventional dentures, this is not certain. All possible care will be taken to help the patient during the process of having the

addition 3D-printed denture fitted.
Some participants may find the additional time needed for the research to be a burden. Both these issues are mentioned in the Participant Information Sheet and will be discussed prior to consent. If a participant finds either of these issues becomes a problem for them, they will be able to withdraw from the study with no consequences for their treatment.

Where is the study run from?
University of Leeds School of Dentistry (UK)

When is the study starting and how long is it expected to run for?
September 2018 to March 2020

Who is funding the study?
Dunhill Medical Trust (UK)

Who is the main contact?
Dr Andrew Keeling, a.j.keeling@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Keeling

ORCID ID
http://orcid.org/0000-0003-4598-3744

Contact details
School of Dentistry
University of Leeds
6.094 Worsley Building
Clarendon Way
Leeds
United Kingdom
LS2 9LU
+44(0)113 343 1762
a.j.keeling@leeds.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
246234

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 39220, IRAS 246234

Study information

Scientific Title
A preliminary study, evaluating and optimizing the clinical workflows to enable a pilot RCT of 3-D printed dentures

Study objectives
There is a small but well known distortion produced when dentures are manufactured by the traditional method. Dentures are manufactured within registered dental laboratories by a process which heats acrylic resin under pressure while it is encased within plaster cast molds. The contraction that occurs when the acrylic sets distorts the denture.
A new manufacturing process now facilitates denture production by 3-D printing with CE marked resins within the registered dental laboratories. A randomised controlled trial (RCT) would be indicated to investigate the potential benefits between these two ways of producing dentures. However, before we can undertake a pilot RCT, some preliminary work is required to optimise and standardise the clinical workflow. This preliminary project aims to establish the optimum clinical protocol for a pilot RCT of 3-D printed dentures.
Specifically we want to confirm the best way to control 3 variables within the clinical workflow:
1. We wish to establish the best way of producing the virtual 'map' of the participant's mouth used to construct a 3-D image of the denture prior to printing.
2. We wish to know if using a 3-D printed 'baseplate' for the intermediate stages of denture construction is beneficial.
3. We wish to know if post-production painting of the dentures is necessary and/or beneficial to enhance the aesthetic appearance of the 3-D printed dentures.
In order to investigate these three aspects of the clinical workflow we wish to invite 20 patients who are about to have new dentures made to take part in the research project. After they consent, in addition to providing traditionally constructed dentures, we will construct a set of dentures by the 3-D printing process. The dentures we produce will be formally assessed by the participants, by the clinicians and by measuring the precision of the fit.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/09/2018, Yorkshire & The Humber - Leeds East Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ; +44 (0)207 104 8081; nrescommittee.yorkandhumber-leedseast@nhs.net), ref: 18/YH/0288

Study design
Randomised; Interventional; Design type: Treatment, Device, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Dentures produced by 3D printing

Interventions
A prospective cohort study of 20 patient participants is proposed. In order to gain the maximum input from experienced clinicians, this preliminary study is taking place in 3 centers of excellence within leading UK Dental Schools (Manchester, Birmingham and Leeds). We will recruit 20 participants (at least 6 at each centre) for this preliminary work. The case series will look at alternative clinical workflows and come to a consensus opinion of the best way to produce 3-D printed dentures. Patients who are attending one of the three Dental Schools will be approached and asked if they wish to take part in a research project. If they express an interest in participation they will be informed of the study and given a Participant Information Sheet (PIS) which provides details of the project. At Study Clinical Visit 1 (at least 24 h later) they will be asked if they have any questions about the research, and, after a conversation and discussion, if they wish to take part in the project. If they wish to participate they will be asked to sign the written consent form.
Following consent they will proceed with the routine clinical stages of denture production; moving on directly to primary impressions at Study Clinical Visit 1. The primary impressions will follow the normal clinical routine. The participants will be randomised using computer-generated block randomisation to one of three different strategies for producing the scan used to design the dentures.
At Study Clinical Visit 2, the patient will have the normal definitive impression taken using a standardized procedure. Following the definitive impression, after the participant has left the clinic, the impressions will be optically scanned to produce a 3-D digital 'map' of the surface (this is known as an .stl file). The impression will then be cast in dental stone. (These are the routine procedures for the production of the conventional denture.) Following the casting of the impression the resultant dental cast will be optically scanned to produce another .stl map of the surface. Finally a hybrid .stl file will be produced which 'fills in' discrepancies in the impression scan with patches from the model scan. Each of these three ways of digitally re-producing the shape of the patient's mouth will then be compared in turn to each of the other two scans. This is done by overlaying each pair of scans and producing colour-coded contour maps which display the discrepancies between the two scans. Later in the research, this type of of colour-coded contour mapping will be used to compare the fitting surface of the 3-D printed dentures and to the fitting surface of the conventionally processed dentures.
At Study Clinical Visit 3, the normal routine treatment is to record the position of the lower jaw relative to the position of the upper jaw (this is referred to as the jaw registration). In order to perform the jaw registration the dental laboratory is asked to produce a wax jaw registration block.
For this research project, in addition to the normal jaw registration block, the dental laboratory will be asked to produce a 3-D printed base-plate. (A base-plate is the bottom of the denture which fits against the patients mouth) and then build the additional wax jaw registration block on the 3-D printed base-plate.

During Study Clinical Visit 3, the clinician carrying out the research will assess and report the retention and stability of the two types of jaw registration blocks. They will then choose and report the block they prefer to use for the jaw registration. The participant will have each jaw registration block placed in their mouth for this assessment of retention and stability. It is estimated that the assessment will take 2 min - it is an additional procedure that the participant will undergo for purposes of research. The assessment of retention and stability of the two jaw registration blocks will use 5-point Likert scales (analysed by Wilcoxon Signed Rank test). The null hypothesis for this section of the project is that there is no difference in retention and stability between the two alternative jaw registration blocks; the alternative hypothesis is that there is a difference. The preference of the clinician carrying out the research will be reported as a simple choice but with options for 'no preference - both satisfactory''and 'no preference - both unsatisfactory' (analysed by McNemar's test). The null hypothesis for this section of the project is that there is no preferred choice for the type of jaw registration block; the alternative being there is a preference.
After the clinician carrying out the research has chosen the bite block they prefer, the patient participant will be asked to assess the two jaw registration blocks for comfort and for stability using 5-point Likert scales (analysed by Wilcoxon Signed Rank test). The null hypothesis for this section of the project is that there is no difference in patient assessment of comfort and stability between the two alternative jaw registration blocks; the alternative hypothesis is that there is a difference.
Following the participant's assessment of the jaw registration blocks, the clinician carrying out the research will carry out the routine treatment to record the position of the lower jaw relative to the upper jaw.
For Study Clinical Visit 4, a single wax trial denture will be produced in the normal way. The clinical procedures to check the wax denture will follow the normal routine and no research procedures will be undertaken. It is normal routine for the wax dentures to be adjusted and altered until both participant and clinician are satisfied with the denture. When both are satisfied the visit is complete.
Following the routine appointment, when the participant has gone, the upper surfaces of wax dentures will be scanned. This scan of the wax denture will be merged/combined with either: the scan of the impression, the scan of the dental cast, or the hybrid scan to produce a printable file of a denture. For six or seven participants the printable files will be produced by combining the scan of the wax trial denture with the impression scan, for another six or seven participants we will combine it with the scan of the cast and for the remaining six or seven participants we will use the hybrid scan. The teeth are digitally removed from the combined printable .stl file and the resultant file printed. Following printing, the teeth are re-attached. The resultant 3-D printed denture will be returned to the clinician for fitting. The conventional denture for the participant will be produced in the traditional way and be returned to the clinic alongside the printed denture.
Before the dentures are returned to clinic both the conventional denture and the 3-D printed denture will be scanned on the 'fitting' surface. The scans of the fitting surface of the dentures will be compared to the scans detailed above using visual inspection of the colour-code contour maps for any distortion or other discrepancies. In this way, for each participant, we will be able to assess the trueness and precision of the fit of each denture. The null hypothesis for this section of the project is that there is no difference in the fitting surface of the processed denture when compared to the model or impression from which it was made, the alternative hypothesis is that there is a difference.
At Study Clinical Visit 5 there will be two sets of dentures to fit and assess. Each set of dentures will be fitted and, if necessary, adjusted in the normal way. The participant will then be asked to assess the 3-D printed dentures for comfort, for stability, and for aesthetics using 5-point Likert scales (to be analysed by Wilcoxon Signed Rank test). The conventionally constructed dentures will act as the reference for this assessment and then be formally assessed in the same manner.

Six or seven of the 3-D printed dentures are constructed form a scan of the impression, six or seven are constructed from a scan of the cast and six or seven from a hybrid scan. The null hypothesis for this section of the project is that there is no difference in retention and stability between the different workflows used in the construction of the 3-D printed dentures; the alternative hypothesis is that there is a difference.
The participants will be asked if they have a overall preference for the 3-D printed dentures or for the convectional dentures with options for 'no preference - both satisfactory' and 'no preference - both unsatisfactory' (to be analysed by McNemar's test). The null hypothesis for this section of the project is that there is no preferred choice; the alternative being there is a preference. If they have a preference they will be asked with an open question why they prefer the denture they have chosen with their answer recorded verbatim for later qualitative analysis and discussion. Following these assessments the participant will be given both sets of dentures and asked to wear each in turn on alternate days over the next week.
At this first denture fit appointment, the clinician carrying out the research will be asked to assess and record the retention and stability of each set of denture again using a 5-point Likert scale (analysed as above). The null hypothesis for this section of the project is that there is no difference in retention and stability between the 3-D printed dentures produced by the different workflows; the alternative hypothesis is that there is a difference. In an open question, they will be asked to record their opinions on the quality of each denture. These notes from the open question will be used as an aide-memoire in later discussions.
The participants will be asked if they would like to have the appearance of either set of dentures altered using specialized CE marked acrylic paints (GC Japan). If they would, one set of dentures at a time will be altered in discussion with the dental technician. The artistic work will be assessed by open-ended questions to the participant and the clinician, recorded verbatim for later discussion.
At the review appointment (Study Clinical Visit 6) the participants will be asked to re-assess and record if they have a preference for either denture (analysed as above). Any adjustments required for the dentures will be made at this visit.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Participant's preference of denture assessed at Study Clinical Visit 5 and analysed using McNemar's test

Secondary outcome measures
1. Clinician's assessment of the retention of the 3-D printed denture bases at jaw registration (Study Clinical Visit 3) and denture fit (Study Clinical Visit 5) using a 5-point Likert scale
2. Clinician's assessment of the stability of the 3-D printed denture bases at jaw registration (Study Clinical Visit 3) and denture fit (Study Clinical Visit 5) using a 5-point Likert scale
3. Clinicians preference for the base plate of the jaw registration blocks with options for 'no preference - both satisfactory' and 'no preference - both unsatisfactory' at jaw registration (Study Clinical Visit 3)
4. Patient assessment of the finished dentures for comfort using a 5-point Likert scale at denture fit (Study Clinical Visit 5)
5. Patient assessment of the finished dentures for stability using a 5-point Likert scale at denture fit (Study Clinical Visit 5)

6. Patient assessment of the finished dentures for aesthetics using a 5-point Likert scale at denture fit (Study Clinical Visit 5)
7. Reason given by the participant for their preferences for the dentures assessed using an open-ended question at denture fit (Study Clinical Visit 5)(to be analysed qualitatively)
8. Participant's opinion of the aesthetics of the dentures assessed using an open-ended question at denture fit (Study Clinical Visit 5) (to be analysed qualitatively)

Overall study start date
10/09/2018

Completion date
04/03/2020

Eligibility

Key inclusion criteria
1. Edentulous
2. Available for follow-up
3. Requires replacement complete dentures
4. Able and willing to complete the informed consent process.
5. Aged 18 years or over at the time of signing the Informed Consent Form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Total final enrolment
22

Key exclusion criteria
1. Oral tumour
2. Denture stomatitis
3. Requires an obturator
4. Extreme xerostomia (e.g. Sjögren's syndrome)
5. Known hypersensitivity to dental materials used in the research
6. Incapable of written informed consent

Date of first enrolment
11/03/2019

Date of final enrolment
08/11/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Dental Institute
The Worsley Building
Clarendon Way
Woodhouse
Leeds
United Kingdom
LS2 9LU

Study participating centre
Birmingham Dental Hospital
5 Mill Pool Way
Birmingham
United Kingdom
B5 7EG

Study participating centre
University Dental Hospital of Manchester
Higher Cambridge St
Manchester
United Kingdom
M15 6FH

Sponsor information

Organisation
University of Leeds

Sponsor details
Faculty Research Office
Room 9.29, Level 9

School of Dentistry
Worsley Building
Clarendon Way
Woodhouse
Leeds
England
United Kingdom
LS2 9LU
+44 (0)113 343 7587
governance-ethics@leeds.ac.uk

Sponsor type
University/education

Website
http://www.leeds.ac.uk/

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Charity

Funder Name
Dunhill Medical Trust

Alternative Name(s)
The Dunhill Medical Trust, DMT

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

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

Intention to publish date
04/03/2021

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?
Participant information sheet	version v0.5	29/08/2018	09/04/2020	No	Yes
Protocol file	version v0.7	04/04/2019	09/04/2020	No	No
HRA research summary			28/06/2023	No	No