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Comparison of denture tooth position using two neutral zone techniques

Submission date
06/06/2012

Recruitment status
No longer recruiting

Registration date
30/07/2012

Overall study status
Completed

Last Edited
27/02/2018

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
The movement of the mouth muscles can displace dentures (false teeth) if they are not positioned correctly. A dental impression (a mould of the mouth) is made to determine where in the mouth the dentures should sit. This space is called the neutral zone, where the forces of the muscles acting on the dentures are equal and opposite. This study will compare two neutral zone impression techniques to find out whether they produce different results.

Who can participate?
Patients aged 18 and over who are having new full dentures made at Leeds Dental Institute.

What does the study involve?
Participants are asked to attend one extra appointment in addition to their normal treatment. Two impression trays are custom made from the existing cast of the patient's mouth. The first impression tray is inserted into the patient's mouth and loaded with the impression material. The patient then performs mouth movements as instructed. Once the impression material has set the impression is removed from the patient's mouth and assessed. This process is repeated with the second impression tray. One impression is taken while the patient is wearing their upper denture and the other impression is the same except the patient does not wear their upper denture. The two impressions are sent to the dental laboratory, where they are compared. Following the extra appointment the patients' treatment continues; they have no further active role in the study and their ongoing treatment is not affected.

What are the possible benefits and risks of participating?
There are no direct benefits of participating, but the results will improve our understanding of a condition that impacts on the quality of life of some denture wearers. There are no known risks in addition to those associated with routine dental treatment for denture work.

Where is the study run from?
Leeds Dental Institute (UK)

When is the study starting and how long is it expected to run for?
June 2012 to June 2013

Who is funding the project?
Leeds Dental Institute (UK)

Who is the main contact?
Alison Birtles

Contact information

Type(s)
Scientific

Contact name
Dr T. Paul Hyde

Contact details
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Randomised Control Trial (RCT) comparing the lower anterior labio-lingual neutral zone position in edentulous subjects with and without their upper denture in-situ

Study objectives
Null Hypothesis
The labio-lingual position of the anterior mandibular neutral zone (NZ) is not affected by the presence of an upper appliance during the impression taking procedure.

Alternative Hypothesis
The labio-lingual position of the anterior mandibular neutral zone is affected by the presence of upper anterior teeth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Yorkshire and The Humber - Leeds Central, 03/05/2012 , REC Ref: 12/YH/0183

Study design

Single-blind single-centre randomised controlled cross-over study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Edentulousness

Interventions
One study arm involves recording the neutral zone impression whilst the patient wears their upper denture. The other study arm is the same but the patient does not wear their upper denture. The order in which each arm of the study is performed, and which tray is used for which arm, is determined by block randomisation and the options will be written down and placed in sealed envelopes.

Both impression trays will be tried in the patient's mouth and assessed for comfort, stability and to ensure that no part of the tray is outside the estimated neutral zone (optimal denture tooth position for stability). The patient will be briefed as to what is expected of them during the procedure; i.e. that after insertion of the impression tray and placement of the impression material they will be instructed to perform the following mouth movements:
1. Brush the tip of their tongue along their lower lip
2. Smile
3. Purse their lips
4. Take a sip of water
5. Say out loud: 'm', 'b', 'p',t,d,'s'

The first impression tray, with or without the maxillary denture in place, (as determined by the random selection of the sealed envelope) will be inserted into the patient's mouth with their existing upper denture in place. After its insertion the loops are loaded with the impression material. The patient then performs the movements stated above.

Once the impression material has set the impression is removed from the patient's mouth and assessed. If the recording is deemed to be acceptable then the next stage can be performed.

The above is repeated; in accordance with the instructions in the envelope (i.e. if no upper denture in place for the first procedure then it will be used for the second impression and vice-versa).

The total duration for both arms (as the data is paired) will be approximately 1 hour

Tests are performed on the impressions in the laboratory. The impressions will be sent to the dental laboratory where they will be placed on the existing dental casts and then mounted on an articulator (which essentially a hinge designed to simulate jaw movements). It will already have the patients dental casts arranged on it as necessary for making the patients new dentures.

A jig will be used to standardise the distance between the articulated neutral zone impression and a camera.

Two 'profile' photographs will be taken, one for each paired record: one of the neutral zone impression recorded with the upper appliance in-situ and one of the neutral zone impression taken without the upper denture in.

The photographs will be used to measure the distance between the front of the articulator and the neutral zone impression. The measurement will be performed using calibrated electronic callipers which are capable of measuring to 0.01mm.

The operator is blinded as to which neutral zone technique was employed when performing the measurements.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To establish whether the 'neutral zone' recording is influenced by the presence of the patient's upper complete prosthesis. (A 'neutral zone' recording is a dental impresion technique designed to record the optimal balanced position in the mouth for denture teeth to sit.)

Key secondary outcome(s))
No secondary outcome measures

Completion date
28/06/2013

Eligibility

Key inclusion criteria
1. At least 18 years old
2. Patient able to attend a 1 hour appointment in addition to their scheduled sequence required for full denture provision
3. Edentulous
4. Competent to freely give positive consent for participation
5. Does not have an allergy to acrylic or Optisil
6. Having complete dentures fabricated for them at the Leeds Dental Institute

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. No known allergy to Optisil
2. Does not have severe xerostomia (Sjogrens syndrome)
3. Does not have an oral tumour
4. Does not require an obturator

Date of first enrolment
20/06/2012

Date of final enrolment
28/06/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leeds Dental Institute
Leeds
United Kingdom
LS2 9LU

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Hospital/treatment centre

Funder Name

Leeds Dental Institute (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes