

Comparison of denture tooth position using two neutral zone techniques

Submission date 06/06/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/07/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/02/2018	Condition category Oral Health	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised cross over trial

Study setting(s)

GP practice

Study type(s)

Treatment

Participant information sheet

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

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 measure

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 impression technique designed to record the optimal balanced position in the mouth for denture teeth to sit.)

Secondary outcome measures

No secondary outcome measures

Overall study start date

20/06/2012

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

24

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

England

United Kingdom

Study participating centre

Leeds Dental Institute

Leeds

United Kingdom

LS2 9LU

Sponsor information

Organisation

University of Leeds (UK)

Sponsor details

3 Cavendish Road
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England
United Kingdom
LS2 9JT

Sponsor type

University/education

ROR

<https://ror.org/024mrxd33>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Leeds Dental Institute (UK)

Results and Publications**Publication and dissemination plan**

Not provided at time of registration

Intention to publish date**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