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Biting contacts before and after treatment of worn teeth

Submission date	Recruitment status	[X] Prospectively registered
28/07/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
17/08/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
26/08/2016	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

The management of worn upper and/or lower anterior (front) teeth is a challenge, as the teeth often become much shorter in length. This affects the appearance and function, and there is no space to add to or build up the individual teeth to their original size without opening up the bite at the back of the mouth (posterior teeth).

In 1975, Dahl described a planned approach whereby the anterior worn teeth were built up, regardless of the fact that this produced a gap between the posterior teeth. It was observed that over a few months the back teeth would then grow back into contact with their opposing teeth to re-establish the bite around the whole mouth. This is because teeth, if they are not in contact, tend to continue to move (erupt) until they contact an opposing tooth. There has been no work to analyse the changes that occur between the quality of the original posterior contacts and the new ones produced after the Dahl approach has been used. Some recent studies have reported on whether contacts are re-established completely or partially but with no reference to the ideal occlusion, as described in standard textbooks.

The aim of this study is to investigate the quality of biting contacts after a specific restorative technique has been applied for the treatment of worn teeth, through analyses of dental casts /models of the upper and lower teeth to identify the contacts between them before and after treatment and to compare them to the ideal occlusion.

Who can participate?

Adult patients (male or female, age 18+) treated at the Leeds Dental Institute, who have received direct composite restorations as a fixed Dahl appliance for the treatment of worn anterior upper and/or lower teeth.

What does the study involve?

The subjects recruited will be asked to attend one short research appointment (30 minutes) at the Leeds Dental Institute between November 2012 and February 2013 to have an upper and a lower jaw alginate impression taken, and will be discharged afterwards. Casts will be produced from these impressions and they will be digitally scanned and compared through a computer program to the existing casts taken from the same patient prior to the suggested treatment.

The computer program will show the biting relationship before and after the treatment. This data will be compared to assess if the biting contacts remain the same as previously to the treatment, or if they rearrange in a better/worse functional position.

What are the possible benefits and risks of participating?
There will be no direct benefits to the participants other than the knowledge that their involvement may allow a deeper understanding of their own condition. There are no known risks to the participants in addition to those associated with a routine dental impression of the upper and lower jaws.

Where is the study run from?
The Leeds Dental Institute at the University of Leeds (UK).

When is the study starting and how long is it expected to run for?
Recruitment and data collection will run from November 2012 until February 2013.

Who is funding the study?
University of Leeds (UK).

Who is the main contact?
Gabriel Simon
dn11ghs@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Gabriel Simon

Contact details
University of Leeds
247 Hyde Park Road
Leeds
United Kingdom
LS6 1AG

Additional identifiers

Study information

Scientific Title
Analysis of occlusal contacts in ICP before and after treatment of the worn anterior dentition with direct composite restorations as a fixed Dahl Appliance

Study objectives
Null hypothesis:
The re-establishment of biting contacts remain the same as previously to the treatment.

Alternative hypotheses:
1. The re-establishment of biting contacts rearrange in a better functional position than previously to the treatment
2. The re-establishment of biting contacts rearrange in a worse functional position than previously to the treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dental Research Ethics Committee (DREC), Leeds Dental Institute, 10 September 2012
Yorkshire and the Humber Research Ethics Committee, October 2012

Primary study design
Observational

Study design
Repeated measures design single-centre trial

Study type(s)
Treatment

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

Interventions
The procedure for comparing occlusal relationships before and after the treatment of worn mandibular anterior dentition with direct composite restorations as a fixed Dahl type appliance

1. Preparation of the patient:
Upper and lower dental casts will be obtained:
1.1.1. "BEFORE treatment upper and lower casts": Will be obtained from the patient's records. Pre-operative casts are always routinely taken in planning the treatment and are not an additional aspect of this study.
1.1.2. "AFTER treatment upper and lower casts": On the research session, the patient will receive instructions (i.e. to breathe through the nose while having the alginate impressions taken) and information about the procedure. One upper and one lower alginate impressions will be taken in a standardized manner:
1.2. Appropriate trays will be selected according to each patient's jaws size
1.3. Upper jaw impression will be taken first, alginate will be mixed following the fabricant instructions
1.4. Lower jaw alginate impression will be taken next, alginate will be mixed following the fabricant instructions
1.5. Patients will be thanked for their time and participation
1.6. The impressions will be numbered according to the unique specific number that matches the unique specific number on the consent form
1.7. Impressions will be disinfected and sent to the prosthetics research laboratory based at the Leeds Dental Institute where upper and lower jaw casts will be fabricated.

2. Recording of Data:
2.1. These casts (before and after treatment), for each patient, will be hand articulated into

biting position and mounted in a simple hinge articulator
2.2. An silicon impression material will be used to create a record of the bite relationship
2.3. Dental casts and bite records will be scanned from multiple views using a high precision optical scanner
2.4. Through the use of a special computer program (PolyWorks InnovMetric Software) 3D virtual models will be created for the dental casts and bite records
2.5. Virtual models will be analysed through a computer program (Virtual Dental Patient Minnesota Dental Research Center for Biomaterials and Biomechanics under NIH/NIDCR grant RO1 DE12225)
2.6. The upper and lower virtual casts will be aligned in biting position using the virtual bite record; Virtual biting contacts will be calculated for the articulated virtual casts (virtual cast contacts) using the Virtual Dental Patient computer program (virtual contacts are regions on opposing virtual surfaces that are within 0.350mm of each other).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The difference in the distribution of biting contacts, and near contacts, between the upper and lower pre-operative and post-operative dental casts.

Method to achieve the primary outcome:
1. The dental casts (before and after treatment), for each patient, will be hand articulated into biting position and mounted in a simple hinge articulator;
2. An silicon impression material will be used to create a record of the bite relationship;
3. Dental casts and bite records will be scanned from multiple views using a high precision optical scanner;
4. Through the use of a special computer program (PolyWorks InnovMetric Software) 3D virtual models will be created for the dental casts and bite records;
5. Virtual models will be analysed through a computer program (Virtual Dental Patient Minnesota Dental Research Center for Biomaterials and Biomechanics under NIH/NIDCR grant RO1 DE12225);
6. The upper and lower virtual casts will be aligned in biting position using the virtual bite record; Virtual biting contacts will be calculated for the articulated virtual casts (virtual cast contacts) using the Virtual Dental Patient computer program (virtual contacts are regions on opposing virtual surfaces that are within 0.350mm of each other).

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/01/2013

Eligibility

Key inclusion criteria
1. Adult patients (male or female, age 18+) treated at the Leeds Dental Institute, who have received direct composite restorations as a fixed Dahl appliance for the treatment of worn

anterior upper and/or lower dentition in the last year.
2. Be able to attend a 30 minutes appointment
3. Be competent to freely give positive consent for participation
4. Does not have an allergy to alginate

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients with incomplete development of adult dentition
2. Patients with less than 2 pairs of posterior occluding teeth in each half arch (e.g. two upper premolars occluding on two lower premolars on the left hand side of the jaws and two upper premolars occluding on one lower premolar and one lower molar on the right hand side of the jaws)
3. Patients who have not completed at least 6 months of treatment by this research's "data collection" stage (at the moment stipulated to Nov/2012-Feb/2013).
4. Patients where upper and lower pre-operative study models, taken prior to the execution of the treatment are not available
5. Patients that for any reason can't attend appointments, or can't have upper and lower alginate impressions taken
6. Known sensitivity to alginate

Date of first enrolment
01/11/2012

Date of final enrolment
31/01/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

University of Leeds
Leeds
United Kingdom
LS6 1AG

Sponsor information

Organisation
University of Leeds (UK)

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
University/education

Funder Name
University of Leeds (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration