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Effects on sleep bruxism activity of clear aligners detected with nocturnal instrumental recordings

Submission date	Recruitment status	[_] Prospectively registered
03/02/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/03/2017	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
09/03/2017	Oral Health	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Sleep bruxism is the medical term for grinding the teeth and clenching the jaw during sleep. It is associated with a number of clinical problems, including pain, tooth wear and failure of dental restorations. Some of these patients require orthodontic treatment. The use of clear aligners ("invisible braces") has increased in orthodontic practice. They are comparable to occlusal splints, plastic appliances that fit onto the teeth which are routinely used in patients suffering from sleep bruxism to prevent tooth wear. The aim of this study is to find out whether clear aligners can be used to treat sleep bruxism.

Who can partecipate?
Adolescents (aged from 16 years) and adults (>18 years) requiring orthodontic treatment and suffering from sleep bruxism

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group are treated using orthodontic clear aligners. Participants in the second group are treated using a palatal splint with no tooth coverage. For participants in both groups,, sleep bruxism activity is recorded at home in the night at the start of the study and then after 1, 3, 6 and 12 months.

What are the possible benefits and risks of participating?
Participants may be protected against the effects of sleep bruxism (i.e. toothwear, dental fractures, dental sensitivity). There are no risks expected for those taking part in the study.

Where is the study run from?
University of Torino (Italy)

When is the study starting and how long is espected to run for?
May 2014 to February 2017

Who is funding the study?
University of Torino (Italy)

Who is the main contact?
Dr Andrea Deregibus

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
alignerbruxism2016

Study information

Scientific Title
Effects on sleep bruxism activity of orthodontic clear aligners detected with nocturnal instrumental ECG/EMG recording: a randomized clinical trial

Study objectives
The aim of this study is to find out if sleep bruxism activity is influenced by the use of clear aligners.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Committee A.O.U Città della Salute e Della Scienza di Torino, 15/09/2016, ref: 0089211

Primary study design
Interventional

Study design
Single-centre randomized interventional trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied
Sleep bruxism

Interventions
A group of 40 patients will be screened for sleep bruxism with a validated portable device (Bruxoff®, OT Bioelettronica, Torino, Italia) before being randomly allocated (random number list software generated) into two different treatment groups.
Group 1: aligner group (AG) with 20 subjects who will be treated with orthodontic clear aligners (Invisalign®, Santa Clara, CA)
Group 2: placebo group (PG) with 20 subjects who will be treated with palatal splint with no tooth coverage

Both groups will be treated at the Department of Orthodontics of the Dental School of the University of Torino.
Both groups will be recorded with multiple nocturnal instrumental ECG/EMG recordings in order to screen and control possible variation in sleep bruxism activity. The ECG/EMG recording will be conducted with a three channels validate portable device for sleep bruxism diagnosis (Bruxoff ®, OT Bioelettronica, Torino, Italy). Two channels will be used to acquire surface electromyography (sEMG) bilaterally from the masseter, and the third channel will be used to acquire the electrocardiographic activity (ECG). The three signals will be sampled at 800 Hz, with 8 bit resolution. The data will be stored on a MicroSD card as a binary file. The sEMG channels will be filtered between 10 and 400 Hz with gain 4300. The electrocardiographic (ECG) channel will be filtered between 15 and 160 Hz with gain 700. Surface EMGs from the masseter muscle of both sides will be detected with disposable bipolar concentric electrodes (Code®, Spes Medica, Battipaglia, Italy), with a radius of 16 mm and with detection site made of AgCl. The heart frequency will be detected with a disposable bipolar electrode located on the left side of the thorax just below the pectoral muscles. At the beginning of the recording, the subjects will be asked to perform three maximum voluntary clenching (MVC) lasting 3 s each and separated by 10 s of rest. The greatest of the MVC measures will be used for normalizing the EMG values as a percent of MVC. Scoring on the Bruxoff recordings will be automatically performed by dedicated software (Bruxmeter ®, OT Biolettonica, Torino, Italy). The software is able to classify a SB episode if the sEMG burst is greater than 10% MVC and if it immediately follows (1-5 seconds interval) a heart rate increase of 20% with respect to the baseline. Moreover, instrumental evaluation allows to identify specific sEMG signals: tonic, phasic and mixed. The subjects will use the device and mount the electrodes at their homes without technical assistance, after prior training. They will be provided with written instructions and a night-time telephone number to call in the event of difficulties.

For participants in both groups, at baseline and then after 1, 3, 6 and 12 months, nocturnal instrumental recordings of ECG/EMG activity will be recorded in home setting to detect variations in sleep bruxism activity.

Intervention Type
Device

Primary outcome(s)
Sleep bruxism index, determined from Bruxmeter software at baseline, 1 month, 3 months, 6 months, and 1 year

Key secondary outcome(s)
EMG signals (tonic, phasic or mixed), measured with dedicated software at screening, 1, 3 and 6 months, and 1 year

Completion date
20/02/2017

Eligibility

Key inclusion criteria
1. Patients able to give their informed consent
2. Patients suffering from sleep bruxism
3. Good oral hygiene and periodontal status
4. Patients requiring orthodontic treatment
5. Adolescents (aged from 16 years) and adults (>18 years)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients suffering from neurological diseases
2. Patients suffering from signs/symptoms of tempormandibular disorders
3. Patients already wearing occlusal splints
4. Patients with orthodontic treatment in progress
5. Post traumatic patients
6. Patients suffering from other sleep disorders (i.e., sleep apnea, restless leg syndrome)

Date of first enrolment
20/04/2014

Date of final enrolment
20/12/2015

Locations

Countries of recruitment
Italy

Study participating centre
Dental School, Department of Orthodontics
University of Torino
Via Nizza 230
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Sponsor information

Organisation
University of Torino

ROR
https://ror.org/048tbm396

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Torino

Alternative Name(s)
University of Turin in Italy, University of Turin, Italy, Università di Torino, , University of Turin, UNITO

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Prof. Andrea Deregibus

IPD sharing plan summary

Available on request