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Control of parafunction with bite plane therapy

Submission date	Recruitment status	[ ] Prospectively registered
19/10/2017	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/11/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
01/04/2019	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Grinding and clenching the teeth have been associated with joint pain, muscle pain, headaches and tooth wear. The symptoms are very common and often are present with awakening in the morning. A common treatment for jaw pain and headaches has been the construction of bite planes. However, bite plane therapy often fails to control the symptoms of headache and pain. The aim of this study is to use the concept of stretching the muscles that close the jaw in order to have the muscles relax and therefore, decrease the force of grinding and clenching at night time.

Who can participate?
Females aged 20-57 years old who grind or clench their teeth.

What does the study involve?
Participants are examined clinically, complete clinical histories, have impressions taken for fabrication of their bite planes, and have lateral cephalograms (x-rays of the side of the face) and panoramic radiographs (dental x-rays) taken. Participants undergo sleep studies before treatment and after treatment while wearing their new altered bite plane. Participants are assessed for their grinding and clenching level.

What are the possible benefits and risks of participating?
Participants may benefit from a reduction or illumination of their symptoms of pain and headache. There are no risks to any of the patients who have been recruited into the study as all have had biplanes in the past and have not responded to treatment.

Where is the study run from?
1. University Hospital London Health Sciences Centre (Canada)
2. Private office of Dr. Douglas Awde (Canada)

When is the study starting and how long is it expected to run for?
August 1999 to February 2001

Who is funding the study?
Investigator initiated and funded (Canada)

Who is the main contact?
Dr Douglas Awde
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Study information

Scientific Title
Pilot study of the effect of altered vertical dimension bite plane therapy on myofascial pain dysfunction and temporomandibular joint dysfunction

Study objectives
The aim of this study is to determine whether the use of variable thickness bite planes would control parafunction in patients who had previously not responded to splint therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The University of Western Ontario Review Board of Health Sciences Research Involving Human Subject, 15/12/1999, ref: Review number: 7340

Study design
Single centre interventional study, evaluating the symptoms of TMD/MPD and the sleep patterns of 19 female patients with altered vertical dimension bite planes who had previously failed bite plane therapy.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
TMD, MPD, Sleep Stages

Interventions
Patients are examined clinically, complete clinical histories, have impressions taken for fabrication of mandibular Gelb bite planes, and have lateral cephalograms and panoramic radiographs taken. Participants undergo sleep studies prior to the start of treatment and after the treatment is completed wearing their new altered bite plane. Patients complete the TMJ Scale, the McGill pain questionnaire, the Epworth Sleepiness Scale, and the Helkimo Clinical Dysfunction Assessment. Bite planes are increased in thickness in a 4 week schedule if signs of parafunction are present on the splint and if symptoms are present.

Intervention Type
Device

Primary outcome(s)
1. TMD symptoms are measured using the TMJ scale at baseline and study end
2. Bruxism is measured using the polysomnograph at baseline and study end
3. Daytime sleepiness is measured using Epworth Sleepiness Scale at baseline and study end
4. Pain symptoms with treatment is measured using the McGill pain questionnaire at baseline and study end
5. Patient symptoms are measured using the Helkimo Index at baseline and study end

Key secondary outcome(s))
There are no secondary outcome measures.

Completion date
01/02/2001

Eligibility

Key inclusion criteria
1. Permanent dentitions with no more than 1 tooth missing per quadrant (excluding wisdom teeth)
2. No implants or partial dentures
3. Not undergoing current treatment for TMD/MPD
3. Females aged 20-57

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Male
2. Children and seniors
3. Multiple missing teeth in each quadrant
4. Dental implants
5. Partial dentures
6. Active treatment for TAD/MPD

Date of first enrolment
01/01/2000

Date of final enrolment
01/06/2000

Locations

Countries of recruitment
Canada

Study participating centre
University Hospital London Health Sciences Centre
339 Windmere Road
London, Ontario
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Study participating centre
Private office of Dr. Douglas Awde
525 Oxford Street East
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Sponsor information

Organisation
Ontario Thoracic Society Block Term Grant

ROR
https://ror.org/02pwbvs75

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

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 Dr. Douglas Awde. E-mail: awdedouglas@gmail.com, please CC. doug@adpcorp.ca

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet		01/11/2017	01/04/2019	No	Yes