

# Control of parafunction with bite plane therapy

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<b>Registration date</b> 02/11/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/04/2019	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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  
doug@adpcorp.ca

## Contact information

### Type(s)

Public

### Contact name

Dr Douglas Awde

### 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

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

**Secondary study design**

Non randomised study

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

See additional files

**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 measure**

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

**Secondary outcome measures**

There are no secondary outcome measures.

**Overall study start date**

01/08/1999

**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

## Age group

Adult

## Sex

Female

## Target number of participants

20 female patients

## 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

Canada

N6A 505

**Study participating centre**  
**Private office of Dr. Douglas Awde**  
525 Oxford Street East  
London, Ontario  
Canada  
N5Y 3H8

## **Sponsor information**

### **Organisation**

Ontario Thoracic Society Block Term Grant

### **Sponsor details**

401-18 Wynford Drive  
Ontario  
Toronto  
Canada  
M3C 0K8  
+1 416 864 9911 ext. 254  
ots@on.lung.ca

### **Sponsor type**

Research organisation

### **Website**

<https://www.lungontario.ca/page.aspx?pid=421>

### **ROR**

<https://ror.org/02pwbvs75>

## **Funder(s)**

### **Funder type**

Other

### **Funder Name**

Investigator initiated and funded

## **Results and Publications**

Publication and dissemination plan

The study will be submitted to the Journal of the American Dental Association, which is a prominent high impact peer reviewed journal.

### **Intention to publish date**

01/01/2018

### **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](mailto:awdedouglas@gmail.com), please CC. [doug@adpcorp.ca](mailto:doug@adpcorp.ca)

### **IPD sharing plan summary**

Available on request

### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>		01/11/2017	01/04/2019	No	Yes