

# **Comfort and Wearability of Orthodontic Mouthguards in comparison to Custom-made Mouthguards: A Randomised Clinical Trial**

**CASE REPORT BOOKLET v3.0 DATED 3/11/2016**

**PRIVATE & CONFIDENTIAL**

**STUDY patient identifier:**

.....

## ELIGIBILITY CRITERIA

Patient is only eligible If **Yes** is ticked for all inclusion criteria  
and **No** is ticked for all exclusion criteria

Study ID: ..... Patients Initials: .....

### Eligibility - Inclusion Criteria

Source Data Refer to Eligibility Criteria

Form filed in patient notes/case notes

Undergoing fixed appliance treatment for a minimum period of 9 months Y

Plays a sport where use of a mouthguard is recommended Y

Plays at least 120 minutes of sport in 6-8 week period Y

Able to complete a VAS questionnaire Y

Not diagnosed with a sensory processing disorder (SPD) Y

### Eligibility - Exclusion Criteria

Source Data Refer to Eligibility Criteria Form filed in patient notes/case notes

Does not play a sport that recommends the use of a Mouthguard N

Undergoing orthodontic treatment which is not fixed appliances N

Has Less than 9 Months of fixed appliance treatment left N

Has Been diagnosed with a sensory processing disorder N

Patient unable to complete a VAS questionnaire N

### Eligibility - Confirmation

Source Data Refer to Eligibility Criteria Form filed in patient notes/case notes

Date Eligibility Confirmed //

Confirmed By \_\_\_\_\_

CRF completed By (name): \_\_\_\_\_

Signature: \_\_\_\_\_

Date Completed //

# Comfort and wearability of Orthodontic Mouthguards: a R Case Report Form

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Study patient identifier: ..... Patients Initials: .....

## Randomisation

*Source Data Refer to case notes*

Date of Randomisation

  /   /  

Group 1: Custom-made Mouthguard

Group 2: Orthodontic Mouthguard; Boil and Bite

Group 3: Orthodontic Mouthguard; Instant fit

Randomisation performed by: \_\_\_\_\_

CRF completed By (name): \_\_\_\_\_

Signature: \_\_\_\_\_

Date Completed

  /   /  

COMFORT AND WEARABILITY OF ORTHODONTIC MOUTHGUARDS; AN RCT

## Baseline data

*Source Data Refer to case report form*

### Gender

Male  Female

Age

Concomitant Medication(s);

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CRF completed \_\_\_\_\_

Signature: \_\_\_\_\_

Date Completed

//

Study ID: ..... Patients Initials: .....

## First planned Mouthguard Allocation

The Patient will be allocated their first Mouthguard and asked to wear for a period of 6-8 weeks.

Date of visit      □□/□□/□□

They will then be allocated their **first** Mouthguard and a Diary to complete

CRF completed \_\_\_\_\_

Signature: \_\_\_\_\_

Date Completed                      □□/□□/□□

Study ID: ..... Patients Initials: .....

## Second planned visit

*Source Data Refer the VAS questionnaire . Data will be based on the subject completing the questionnaire at their 6-8 review appointment which will include a series of questions and response via a VAS of 100mm line. The patient will be asked to mark a point along the line, which corresponds to how they feel best answers the question regarding the comfort and wearability of the mouthguard of their 1<sup>st</sup> mouthguard*

Date of visit      //

Time VAS questionnaire completed . hrs

They will then be allocated their **second** Mouthguard and a new Diary to complete

CRF completed \_\_\_\_\_

Signature: \_\_\_\_\_

Date Completed                      //

Study ID: ..... Patients Initials: .....

# Questionnaire

Study patient identifier:

Mouthguard type:

1) How comfortable was your mouthguard?

\_\_\_\_\_

Uncomfortable Comfortable

2) How Bulky did you feel the mouthguard was?

\_\_\_\_\_

Bulky Not Bulky

3) How stable in your mouth was the mouthguard

\_\_\_\_\_

Unstable Stable

4) How hard or soft did you feel the mouthguard was?

\_\_\_\_\_

Soft Hard

Study ID: ..... Patients Initials: .....

5) How difficult was it to breathe with the mouthguard whilst doing sports

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Extreme difficulties  
breathing

No difficulties  
breathing

6) How easy or difficult was it to speak with the mouthguard in?

---

Extreme Difficulties Speaking

No difficulties Speaking

7) How dry did you mouth feel whilst wearing the mouthguard

---

Very Dry

No Dryness

8) Did the mouthguard ever make you feel sick

---

Felt sick all the time

Never felt sick

9) Did you find that you chewed the mouthguard

---

Chewed all the time

Never chewed



Study ID: ..... Patients Initials: .....

## Third planned visit

*Source Data Refer the VAS questionnaire . Data will be based on the subject completing the questionnaire at their 6-8 review appointment which will include a series of questions and response via a VAS of 100mm line. The patient will be asked to mark a point along the line, which corresponds to how they feel best answers the question regarding the comfort and wearability of the mouthguard of their 2<sup>nd</sup> mouthguard*

Date of visit      //

Time VAS questionnaire completed . hrs

The participant will then be allocated their **third** mouthguard and a new diary

CRF completed \_\_\_\_\_

Signature: \_\_\_\_\_

Date Completed                      //

Study ID: ..... Patients Initials: .....

# Questionnaire

Study patient identifier:

Mouthguard type:

1) How comfortable was your mouthguard?

\_\_\_\_\_

Uncomfortable Comfortable

2) How Bulky did you feel the mouthguard was?

\_\_\_\_\_

Bulky Not Bulky

3) How stable in your mouth was the mouthguard

\_\_\_\_\_

Unstable Stable

4) How hard or soft did you feel the mouthguard was?

\_\_\_\_\_

Soft Hard

Study ID: ..... Patients Initials: .....

5) How difficult was it to breathe with the mouthguard whilst doing sports

---

Extreme difficulties  
breathing

No difficulties  
breathing

6) How easy or difficult was it to speak with the mouthguard in?

---

Extreme Difficulties Speaking

No difficulties Speaking

7) How dry did you mouth feel whilst wearing the mouthguard

---

Very Dry

No Dryness

8) Did the mouthguard ever make you feel sick

---

Felt sick all the time

Never felt sick

9) Did you find that you chewed the mouthguard

---

Chewed all the time

Never chewed

Study ID: ..... Patients Initials: .....

## Fourth planned visit

*Source Data Refer the VAS questionnaire . Data will be based on the subject completing the questionnaire at their 6-8 review appointment which will include a series of questions and response via a VAS of 100mm line. The patient will be asked to mark a point along the line, which corresponds to how they feel best answers the question regarding the comfort and wearability of the mouthguard of their 3<sup>nd</sup> mouthguard*

Date of visit      //

Time VAS questionnaire completed . hrs

The patient will be asked a final question regarding their preference of which mouthguard is most comfortable and wearable.

This now the end of the trial

CRF completed \_\_\_\_\_

Signature: \_\_\_\_\_

Date Completed                      /

Study ID: ..... Patients Initials: .....

# Questionnaire

Study patient identifier:

Mouthguard type:

1) How comfortable was your mouthguard?

\_\_\_\_\_

Uncomfortable Comfortable

2) How Bulky did you feel the mouthguard was?

\_\_\_\_\_

Bulky Not Bulky

3) How stable in your mouth was the mouthguard

\_\_\_\_\_

Unstable Stable

4) How hard or soft did you feel the mouthguard was?

\_\_\_\_\_

Soft Hard

Study ID: ..... Patients Initials: .....

5) How difficult was it to breathe with the mouthguard whilst doing sports

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Extreme difficulties  
breathing

No difficulties  
breathing

6) How easy or difficult was it to speak with the mouthguard in?

---

Extreme Difficulties Speaking

No difficulties Speaking

7) How dry did you mouth feel whilst wearing the mouthguard

---

Very Dry

No Dryness

8) Did the mouthguard ever make you feel sick

---

Felt sick all the time

Never felt sick

9) Did you find that you chewed the mouthguard

---

Chewed all the time

Never chewed

Study ID: ..... Patients Initials: .....

**FINAL QUESTION**

10) Which Mouthguard do you prefer (Please tick)?

Custom-made mouthguard

Orthodontic Instant Fit Mouthguard

Orthodontic Boil and Bite Mouthgard