

# Patient satisfaction of friction-grip dental implant supported teeth and simple method of removal

<b>Submission date</b> 07/09/2017	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/09/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/09/2017	<b>Condition category</b> Oral Health	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Perhaps the biggest concern in the field of dental implantology is the increasing incidence of peri-implantitis, which is an aggressive form of dental implant related gum disease. The problem is made worse as there is no predictable way to manage the disease when it occurs. There are many factors that can cause the disease but in the case of full arch fixed bridgework (i.e. replacing all the teeth in one jaw), poor prosthesis design is a large risk factor. Large span fixed bridges are very difficult for even the most dextrous patients (as well as dentists and hygienists) to clean effectively so peri-implantitis will always be a risk. However, the market place demands a fixed solution. A well-meaning dentist may praise the virtues of a removable implant-supported set of teeth, but to some patients this is still just a denture and may seem far removed from the whole point of having the implants in the first place. Obviously, a "fixed" implant prostheses can be designed for easier home maintenance but this can be to the detriment of the aesthetics of the teeth. Perhaps understandably, patients demand the best aesthetics when they have paid a premium for their new implant supported teeth. It is possible to get better aesthetics with a full arch fixed bridge but this may necessitate more radical surgery to ensure the fitting surface of the restoration is hidden below the patient's lip line. This only serves to compound the hygiene issue and is a very aggressive surgical approach. The system developed uses existing technology whereby the false teeth are fitted to implants via telescopic style abutments. Although designed to be removable, they are usually very tight and often get "locked-in". A locked-in prosthesis can be removed with a hammer-style device commonly used by dentists but this is not at all comfortable for the patient. The aim of this study is to examine the efficacy of patient utilised removal mechanism for a supported implant bridge which has become "locked in".

### Who can participate?

Any patient of any age fitted with a full arch Conus abutment supported bridge which has exhibited "Lock-in".

### What does the study involve?

10 patients, fitted with a full arch Atlantis Conus abutment supported bridges, and who have

demonstrated "lock-in" are included in this study. Participants are followed up at one, three and six months. They are followed up to see whether their prosthesis is impossible to remove without the method of removal. This is called "Lock-in". Participants are assessed for efficacy of the method, ease of use of the method and if the bridge can re-lock if it is re-inserted by the participant.

What are the possible benefits and risks of participating?

Participants may benefit from using the fixed bridge as they can remove the bridge for cleaning which reduces the risk of peri-implantitis and "fixed" because it is locked-in. There are no direct risks with participation.

Where is the study run from?

The Raglan Suite (UK)

When is the study starting and how long is it expected to run for?

November 2017-June 2018

Who is funding the study?

1. Investigator initiated and funded (UK)
2. Dentsply Sirona (UK)

Who is the main contact?

Dr Timothy Doswell

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Timothy Doswell

**ORCID ID**

<http://orcid.org/0000-0002-5269-3916>

**Contact details**

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## Study information

### Scientific Title

Patient satisfaction of "Locked-in" Atlantis Conus Abutment supported bridges and a simple method of removal

### Study objectives

The aim of this study is to examine the efficacy of patient utilised removal mechanism for a Conus Abutment supported implant bridge which has become "locked in".

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Not provided at time of registration

### Study design

Observational case series

### Primary study design

Observational

### Secondary study design

Case series

### Study setting(s)

GP practice

### Study type(s)

Treatment

### Participant information sheet

Not available

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

Restorative implant dentistry. The use of Conus abutment supported bridges

### Interventions

10 patients, fitted with a full arch Atlantis Conus abutment supported bridges, and who have demonstrated "lock-in" are included in this study.

Participants are followed up at one, three and six months. They are followed up to see whether their prosthesis is impossible to remove without the method of removal. This is called "Lock-in".

The questions in this study include:

1. Efficacy of the method - does the bridge easily dislodge when the method is used?
2. Ease of use of the method
3. Does the bridge then re-lock when the bridge is re-inserted by the patient?

The cases will be either maxillary or mandibular and are evaluated using a scale.

## **Intervention Type**

Device

## **Primary outcome measure**

1. Efficacy of the method (does the bridge easily dislodge when the method is used) is measured using patient questionnaires at one, three and six months
2. Ease of use of the method is measured using a patient questionnaire at one, three and six months
3. How reliably does the prosthesis relic when re-fitted is measured using a patient questionnaire at one, three and six months

## **Secondary outcome measures**

Peri-impant health is measured using a standard BPE probe at one, three and six months.

## **Overall study start date**

01/10/2017

## **Completion date**

01/06/2018

# **Eligibility**

## **Key inclusion criteria**

Any patient of any age fitted with a full arch Conus abutment supported bridge which has exhibited "Lock-in".

## **Participant type(s)**

Patient

## **Age group**

Mixed

## **Sex**

Both

## **Target number of participants**

10

## **Key exclusion criteria**

There is no participant exclusion criteria.

## **Date of first enrolment**

01/11/2017

## **Date of final enrolment**

01/05/2018

# Locations

## Countries of recruitment

England

United Kingdom

## Study participating centre

**The Raglan Suite**

16-18 Raglan Street

Harrogate

United Kingdom

HG1 1LE

# Sponsor information

## Organisation

Tim Doswell

## Sponsor details

The Raglan Suite

16 Raglan Street

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## Sponsor type

Other

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

## Funder Name

DentsplySirona

# Results and Publications

## **Publication and dissemination plan**

Planned publication in a high-impact peer reviewed journal.

## **Intention to publish date**

01/06/2019

## **Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study is not expected to be made available due to the trial data will form part of the patient record initially so there requires patient confidentiality. However, with patient consent, the dataset could be made available.

## **IPD sharing plan summary**

Not expected to be made available