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

Submission date
07/09/2017

Recruitment status
No longer recruiting

Registration date
13/09/2017

Overall study status
Completed

Last Edited
13/09/2017

Condition category
Oral Health

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 removethe 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. DentsplySirona (UK)

Who is the main contact?
Dr Timothy Doswell

Contact information

Type(s)
Scientific

Contact name
Dr Timothy Doswell

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IIS ref I-AA-17-007

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 meaured 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
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Sponsor information

Organisation
Tim Doswell

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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