ISRCTN83600326 https://doi.org/10.1186/ISRCTN83600326

Use of pig collagen graft to increase the thickness of tissue around dental implants that have inflammation around them in order to strengthen the tissue and resolve the inflammation

Submission date	**Recruitment status**	[X] Prospectively registered
21/11/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
06/12/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
21/01/2020	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Dental implants are artificial roots (usually titanium screws) which are screwed into the jaw bone to support one or more false teeth. Peri-implant mucositis is a condition where the tissue surrounding dental implants becomes inflamed, swollen and bleed. This can be caused by a variety of factors but the majority of cases are caused by a buildup of dental plaque. Good oral hygiene practices are vital for preventing and treating peri-impant mucositis. If left untreated, it can lead to bone loss in the bone supporting the dental implants. The inside of the mouth is lined by a layer called the oral mucosa, which is either keritinised or non-keritinised. Keratinised mucosa is more resilient than non-keritinsed mucosa and provides a less mobile cuff of tissue around dental implants which may facilitate better oral hygiene practices. The aim of this study is to improve the thickness of keratinised mucosa around the dental implants with peri-implant mucositis by using a pig collagen graft.

Who can participate?

Adults aged between 50 and 80 who have dental implants and peri-implant mucositis.

What does the study involve?

Participants receive of dental examinations to measure the width of each patient's keratinised mucosa as well as any inflammation (swelling) and bleeding, to have excess plaque removed (descaling) and be instructed on good oral hygiene pratices. If the inflammation around their dental implants is still there, then one of the two implants in the patient's lower jaw will receive a surgical procedure where a pig graft material following the removal of a cuff of swollen tissue around the implant. Participants have their stiches removed on the fifth visit and undergo descaling again. Participant's mouths are then reviewed after three, six and twelve months to find out if the graft has increased keratinised tissue around the implant that was operated on compared to one which was not.

What are the possible benefits and risks of participating?
Participants benefit from increased keratinised mucosa around their implants, which could lead to better hygiene practices as it is more resilient. There is a very small risk of infection or the graft not working.

Where is the study run from?
Edinburgh Dental Institute (UK)

When is the study starting and how long is it expected to run for?
February 2016 to July 2018

Who is funding the study?
Geistreich Pharma AG (UK)

Who is the main contact?
Mr Charles Maran, cmaran@exseed.ed.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Charles Maran

Contact details
Edinburgh Dental Institute
Department of Restorative Dentistry
2nd Floor, Lauriston Building
Lauriston Street
Edinburgh
United Kingdom
EH3 9HA
+44 131 536 4989
cmaran@exseed.ed.ac.uk

Additional identifiers

Protocol serial number
200247

Study information

Scientific Title
Effect or porcine collagen graft for increasing the width of keratinised tissues on peri-implant mucositis: A clinical and molecular study

Study objectives

For patients with clinically diagnosed peri-implant mucositis and increase levels of inflammatory markers around dental implants with less than 1mm of keratinised mucosa, the use of a porcine collagen graft will increase the thickness of the mucosa, thereby improving the cuff of tissue around an implant to facilitate oral hygiene. This will enable resolution of the peri-implant mucositis and a resultant decrease in the levels of inflammatory mediators.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Split mouth prospective trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Peri-implant mucositis

Interventions
All participants attend 10 study visits. At the first visit, baseline scores for width of keratinised mucosa (which should be less than 2mm for inclusion of the patient in the study), probing depths around the implants, bleeding scores, plaque scores and pro-inflammatory cytokine levels measured from peri-implant sulcular fluid (PISF) are all recorded. At their second visit, patient's receive periodontal debridement with an ultrasonic scaler and are instructed in oral hygiene measures. At their third visit, after a gap of two weeks, the patient's are reviewed with respect to bleeding scores, plaque scores and pro-inflammatory cytokine levels measured from PISF. If the inflammation around the implants has subsided, the patient exits the study at this stage. If the peri-implant mucositis persists (as indicated by the scores recorded at the third visit), the patient's are enrolled for surgery. One of the two implants in the patient's lower jaw will receive a surgical procedure in the fourth visit, where a porcine graft material (Mucograft ® , Geistlich Pharma AG, Wolhusen, Switzerland) will be placed, following the removal of a cuff of inflammatory tissue around the implant. The purpose of the surgery is to help increase the width of the keratinised mucosa around the implant, which will help enable better oral hygiene practice, and hence help resolve inflammation. Three weeks later,at the fifth visit, the patient will have sutures removed from the implant that received the surgical procedure. During the fourth and the fifth visits, the second implant in the lower jaw, which serves as the control, will continue to receive periodontal debridement with an ultrasonic scaler, and oral hygiene instruction. The sixth study visit will be a two week review, the seventh visit a six week review where the plaque and bleeding scores will be recorded.The eighth visit will be the three month review. At this appointment, the width of the keratinised mucosa will be measured, as will the bleeding scores, plaque scores and pro-inflammatory cytokine levels measured from PISF. This would indicate the primary end point of the study. Each patient will have two further visits, at six months and twelve months to follow-up the plaque and bleeding scores which will help assess peri-implant health. Should the results show an improvement in keratinised tissue and

inflammatory markers then the patient will be offered the opportunity to have the other implant treated similarly.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Keratinised tissue width is measured using a periodontal probe at baseline and 3 months.

Key secondary outcome(s)
1. Pro-inflammatory cytokine levels around the implants collected on Periopaper strips analysed with V-PLEX Proinflammatory Panel 1 (human) Kit at baseline and 3 months
2. Probing depths measured with a periodontal probe at baseline and 3 months
3. Plaque and bleeding scores measured by observation following probing at baseline, 3, 6 and 12 months.

Completion date
01/07/2018

Eligibility

Key inclusion criteria
1. Patients with implant retained mandibular over dentures with at least two fixtures
2. Presence of less than 1mm keratinised mucosa at the implant site
3. Clinical presence of peri-implant mucositis
4. Aged between 50 and 80 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
1. ASA III and above
2. Smokers
3. Pregnancy
4. Patients on medications recognised to cause Drug Induced Gingival Overgrowth
5. Patients on anti-inflammatory drugs and steroids

Date of first enrolment
01/01/2017

Date of final enrolment

01/05/2017

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Edinburgh Dental Institute
Lauriston Building
Lauriston Place
Edinburgh
United Kingdom
EH3 9HA

Sponsor information

Organisation
Geistlich Pharma (Switzerland)

ROR
https://ror.org/055f9sm34

Funder(s)

Funder type
Industry

Funder Name
Geistlich Pharma AG

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date