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Rough vs Hybrid-surface implants for maxillary All-on-4 overdentures

Submission date 28/07/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 04/08/2016	**Overall study status** Completed	
Last Edited 06/11/2023	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims

Overdentures, also known as dental implants, are metal posts which are screwed directly into the jaw bone in order to support replacement teeth. These implants provide a strong foundation for permanent or removable bridges (false teeth) to attach onto. For many years, patients had to wait 3-6 months for bridges to be fitted (delayed loading), to allow time for the bone and gums to attach to the implant. There has always been a hesitation about immediate loading of removable bridges in the upper jaw. There is evidence in the dental literature showing successful immediate loading of removable bridges in the lower jaw (mandible), but there is very little evidence regarding the upper jaw (maxilla). This study aims to demonstrate a novel upper jaw dental implant procedure involving immediate loading (same day) onto 4 implants of a full upper jaw removable new set of teeth. The goal is to demonstrate the success of this technique in terms of tissue and bone preservation, how easy it is to look after the new teeth, patient satisfaction measured using a quality of life questionnaire before and after treatment and time spent in the dentist's chair as an aspect of cost. The study findings should help to improve future patient dental care in terms of patient satisfaction, maintenance of new teeth and cost to the patient. The aim of this study is to find out if there is any difference between these two types of implant.

Who can participate?

Patients aged 21 and over who need dentures for their upper jaw.

What does the study involve?

Patients who visit the specialist dental clinic Vermilion and comply to the eligibility criteria are invited to take part in this study. A participation information sheet and consent form is supplied. At the start of the study, participants have the dental status of the lower jaw assessed and recorded, as well as completing a quality of life questionnaire. Participants then undergo surgery, to have the two types of implants fitted. The side of the mouth to receive each type of implant is decided randomly. All patients are treated by the same oral surgeon and prosthodontists (dentist who replaces teeth with implants). After surgery, the patients are given homecare and soft diet instructions. After two weeks, participants attend a checkup to assess how well the mouth is healing, and periapical radiographs (a type of dental x-ray) are taken. After three to six months, the final set of removable teeth are made and fitted. Participants are

followed up after 3 and 6 months, 1, 2, 3 and 5 years, at which time the teeth are examined and further questionnaires about quality of life are completed.

What are the possible benefits and risks of participating?
Participants may benefit from a shorter healing time from their surgery and increased implant success. In addition, participants could potentially have a higher quality of life. The long term cost to the patient may potentially be less in terms of prosthetic maintenance and it may be generally easier to manage removable bridges than fixed bridges. There are no additional risks or burdens than in standard care by participating in the research.

Where is the study run from?
Vermilion (UK)

When is the study starting and how long is it expected to run for?
July 2016 to November 2023

Who is funding the study?
1. Southern Implants (Pty) Ltd (UK)
2. Vermilion (UK)

Who is the main contact?
Dr David Offord

Contact information

Type(s)
Public

Contact name
Dr David Offord

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Additional identifiers

EudraCT/CTIS number

IRAS number
208123

ClinicalTrials.gov number

Secondary identifying numbers
VermilionClinTrial/2, IRAS 208123

Study information

Scientific Title
Rough v's Hybrid- surface Implants for maxillary All-On-4 over-dentures: Clinical, patient and cost outcomes

Study objectives
Null hypothesis:
There is no difference between fully-roughened and hybrid-roughened implants supporting 4-implant full-arch maxillary removable bridges on self-aligning stud-type retention abutments, in terms of clinical outcomes, prosthetic maintenance and Oral Health Related Quality of Life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/06/2017, South East Scotland REC 2 (SESREC2) (Waverley Gate, 2-4 Waterloo Place, Edinburgh, EH1 3EG, UK; +44 (0)1382383871; tay.eosres@nhs.scot), REC ref: 17/SS/0063

Study design
Randomised split-mouth single-centre controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Treatment with full-arch maxillary removable bridges

Interventions
Pre-surgical phase
Patients will be screened through clinical examination, inclusion and exclusion criteria. Recording of opposing dentition. OHRQoL by way of OHIP-14 questionnaire and collection of informed consent.

Surgical phase:
The mouth will be randomized as to which side of the mouth will receive the test implants, using computer generated random numbers corresponding to sequentially sealed opaque envelopes

provided by the study coordinator. This is to avoid confounding results by the oral surgeon's possible preferential ability on either side of the mouth. All patients will be treated by the same oral surgeon and prosthodontists. Surgery will be carried out by raising of flap and placement of implants following manufacturer's recommended surgical procedure. 2 test implants on one side of the mouth and 2 control implants on the other side. Measurement of insertion torque. Immediate placement of Locator abutments. Immediate loading of provisional removable prosthesis where implant insertion torque exceeds 25ncm. Patient homecare and soft diet instructions given out.

2-week follow-up (baseline)
Examination of healing. Peri-apical radiographs are taken. Clinical photographs are taken.

Prosthetic phase
At three – six months, construction of definitive removable prosthesis

Monitoring phase
Follow-ups at 3 months, 6 months, 1 year, 2 years, 3 years, 5 years.

Standardized follow-up assessment to include the following:

Patient centred outcomes:
1. Any issues with implants, any issues with prosthesis
2. OHIP-14 questionnaire

Clinical examination parameters to be assessed:
1. Width of keratinized mucosa buccal/lingual
2. Colour of mucosa buccal/lingual
3. Bleeding on probing (4 sites around abutment)
4. Pocket depths
5. Mobility of abutment or implant Y/N

Radiographic evaluation:
Measurement of distance from implant shoulder to marginal bone on mesial and distal aspects of implant. Digital apical radiographs using guiding system in order to obtain x-ray direction perpendicular to the sensor. Whenever the implant threads are unclear, another radiograph is taken until the bone value can be determined.

Evaluation of technical complications:
These may vary from rocking of prosthesis, worn matrices, lack of retention, too much retention through to worn teeth, prosthesis fracture etc.

Intervention Type
Procedure/Surgery

Primary outcome measure
Implant success is assessed by measuring degree of bone loss using radiographic measurements of distance from implant shoulder to marginal bone on mesial and distal aspects of implant at baseline 3 and 6 months, 1, 2, 3 and 5 years.

Secondary outcome measures
1. Patient satisfaction is measured using the Oral Health Impact Profile (OHIP 14) questionnaire before treatment, 6 months, 1, 3 and 5 years

2. Pocket depth is measured in oral examinations by the clinician at 3 and 6 months, 1, 2, 3 and 5 years
3. Bleeding on probing is measured in oral examinations by the clinician at 3 and 6 months, 1, 2, 3 and 5 years
4. Bone loss is measured by reviewing radiographic data collected at baseline then 3 and 6 months, 1, 2, 3 and 5 years
5. Cost is measured by chair time-recorded for each patient on each clinic visit and prosthetic maintenance (recorded for each patient requiring maintenance) at any time up to the end of the study (5 years)

Overall study start date
20/06/2016

Completion date
04/11/2023

Eligibility

Key inclusion criteria
1. Dentate and fully edentulous patients requiring treatment with full-arch maxillary over-dentures
2. Aged over 21

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
25

Total final enrolment
32

Key exclusion criteria
1. Patients with poor oral health or motivation
2. Patients who smoke and have periodontal disease
3. Previous irradiation treatment to the head and neck
4. Bisphosphonate medication
5. Psychological disorders
6. Immunosuppressed or immunocompromised patients
7. Patients with implants placed with <25Ncm placement torque

Date of first enrolment
01/09/2016

Date of final enrolment
30/08/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Vermilion
24 St Johns Road
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Sponsor information

Organisation
Southern Implants (Pty) Ltd

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Southern Implants (Pty) Ltd

Funder Name
Vermilion

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal mid-way through the trial, after 3 years and a follow up paper at the completion of the trial mid-2021.

Intention to publish date
30/06/2021

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 Nicola Kingsford Vermilion Research and Audit Co-ordinator at Nicola.Kingsford@vermilion.co.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No