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Aesthetic evaluation of different materials for implant-supported teeth

Submission date	Recruitment status	[_] Prospectively registered
09/10/2020	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
14/10/2020	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/01/2024	Oral Health	

Plain English summary of protocol

Background and study aims
The introduction of dental implants as an option to replace missing teeth is considered one of the most revolutionary developments in modern dentistry. One of the key aspects for these implants to be successful is to have an aesthetic tooth on top that blends harmoniously with the neighbouring teeth. The material used for this prosthetic tooth is of the utmost importance to achieve the desired aesthetic result. However, the wide variety of existing materials and the lack of solid evidence to guide the clinician's choice is reported as one of the main challenges to overcome. Based on this, the aim of this study is to compare three types of materials to fabricate prosthetic teeth over implants.

Who can participate?
Patients aged over 19 years requiring single tooth extraction in the upper anterior and premolar region of the mouth

What does the study involve?
Participants are randomly allocated to receive a metal-porcelain implant tooth, an E-max implant tooth or a zirconium implant tooth to replace the missing one. The success of these restorations is evaluated at 12 months.

What are the possible risks and benefits of participating?
The main benefit of this study is providing the participants with a dental implant to replace a missing tooth instead of another treatment that would not suit their needs or may have a negative impact on neighbouring teeth, such as a fixed dental prosthesis. The potential risks associated with this treatment are mainly associated with the minor surgical procedure needed to place a dental implant and the unlikely scenario in which a dental implant failed. The main risks are listed below:
Swelling of the lips, chin, cheeks, and other tissues of the face, mouth, and neck with possible bruising and discoloration. Damage to and possible loss of other teeth, fillings, or other dental work, which will require root canal treatment, tooth extraction, or new fillings or restorations. Infection which will require antibiotic treatment, possibly further surgery, and may lead to loss of the implant. Discomfort which may require the use of pain medication for several days or longer, and which will also require at-home recuperation for the same period of time or longer.

Bleeding which may be prolonged or heavy, and may require additional surgery or other treatment. Sinus or nasal problems, including but not limited to nasal stuffiness, bleeding, infection, or creation of an opening between the nose or sinus and mouth, which may require surgery. Poor healing of the gum tissue which may result in exposure of the implant and its loss. Loss or resorption of the bone which may result in failure of the implant. Injury of the nerves near the treatment site which causes pain, numbness, or tingling of the lips or areas of the face. This effect is usually temporary but may be permanent. Stretching or damage to the corners of the mouth with cracking, bleeding, and bruising.

Where is the study run from?
Universidad de Murcia (Spain)

When is the study starting and how long is it expected to run for?
July 2016 to May 2020

Who is funding the study?
1. Universidad de Murcia (Spain)
2. Avivent (Spain)
3. Osteogenoss (Spain)

Who are the main contacts?
1. Dr Guillermo Pardo Zamora
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2. Dr Ruben Garcia
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
1746/2017

Study information

Scientific Title
Aesthetic evaluation of different materials for implant-supported, single-tooth restorations: a randomized controlled clinical trial

Study objectives
1. There are differences in the Pink Aesthetic Score (PES) at 12 months between the crowns made of different materials
2. There are differences in radiographic bone levels, periodontal measurements, White Aesthetic Score (WES) and patient-reported outcomes between the crowns made of different materials

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/02/2018, Ethical committee of Murcia University (Comité Ético de Investigación Clínica (CEIC); Calle Santo Cristo, 1, Murcia, Spain, 30001; +34 (0)868883614; comision.etica.investigacion@um.es), ref: 1746/2017

Study design
Single-center randomized controlled parallel-arm blinded study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Single-tooth implant replacement

Interventions
Forty-five immediate dental implants are provided for 45 adult patients who require the extraction of a single tooth in the maxillary aesthetic region. A temporary prosthesis is provided at 8 weeks after placement followed final prosthesis at 24 weeks post-implantation. Once the impression for the final restoration is taken, patients are randomly allocated into three groups:
15 patients in the control group received a metal-porcelain restoration
15 patient in test group 1 receive an E-max restoration
15 patients in test group 2 receive a zirconium restoration

Aesthetic indexes (PES/WES), radiographic bone loss, periodontal parameters and visual analogue scale are evaluated at the time of final restoration placement (T0) and at 12-months post-loading (T12).

The 45 patients included in the study are randomly assigned to the test (1), test (2) or control group by balanced block randomization using a computer-generated table. Treatment assignment is concealed to the treating surgeon by opaque envelopes that are opened only after taking the impression for final restoration. Patients are blinded regarding treatment allocation.

Intervention Type
Procedure/Surgery

Primary outcome measure
The aesthetic of gums around false teeth measured using the Pink Aesthetic Score index at 12 months from the time the treatment is completed

Secondary outcome measures
1. Radiographic bone loss measured from the mesial and distal aspect of the implant shoulder to the first bone-to-implant contact at 12 months post-loading
2. Periodontal measurements including probing pocket depth, papilla height, gingival margin position, width of keratinised tissue, plaque index and bleeding index, taken on the day of the crown fit (T0) and at 12 months post-loading (T12)
3. The aesthetic of implant-supported false teeth measured using the White Aesthetic score (WES) at 12 months from the time the treatment is completed
4. Patients' reported outcomes measured using a visual analogue scale at 1-year post-loading

Overall study start date
17/05/2017

Completion date
09/09/2020

Eligibility

Key inclusion criteria
1. Adult patients (age above 20 years old) in need of a single tooth extraction in the maxillary incisor, canine, pre-molar area due to trauma, periodontitis, endodontic or unrestorable caries
2. Full mouth plaque (FMPS) below 25% and bleeding scores (FMBS) below 10% at study baseline
3. In case of active periodontal disease, the patient should have successfully completed periodontal treatment before enrolment
4. Good soft tissues contours/profile after dental extraction and at least 2 mm of keratinised

tissue.
5. Adequate mesiodistal space for implant placement (≥6.5 mm)
6. Intact socket after dental extraction with a minimum of 5 mm in apical direction to ensure good primary stability for immediate DI
7. Patient had adequate quantity of native bone to achieve a minimum primary stability. This was defined as a minimum insertion torque of 35 N/cm

Participant type(s)
Patient

Age group
Adult

Lower age limit
20 Years

Sex
Both

Target number of participants
45

Total final enrolment
45

Key exclusion criteria
1. Presence of any chronic diseases or medication/ treatment known to affect oral conditions and bone turnover or contraindicate oral surgical treatment such as uncontrolled diabetes, head and neck radiation for cancer treatment or current treatment with bisphosphonates
2. Physical or mental handicaps that would interfere with the ability to maintain adequate oral hygiene
3. Alcoholism or chronic drug abuse
4. Presence of clinically symptomatic periapical radiolucencies, acute abscesses or chronic sinus tracts at the site of extraction
5. Smoking
6. Absence of one of the neighbouring teeth

Date of first enrolment
07/03/2018

Date of final enrolment
16/01/2019

Locations

Countries of recruitment
Spain

Study participating centre

Universidad de Murcia
Universidad de Murcia Hospital Morales Meseguer
Avda. Marqués de los Vélez s/n
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Sponsor information

Organisation
Hospital General Universitario Morales Meseguer

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.murciasalud.es/seccion.php?idsec=367

ROR
https://ror.org/00cfm3y81

Funder(s)

Funder type
University/education

Funder Name
Universidad de Murcia

Alternative Name(s)
University of Murcia

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Spain

Funder Name
Avivent

Funder Name
Osteogenoss

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Study protocol, PIS, the results of any statistical analysis, statistical analysis plan are provided upon request and under the conditions stated.

Intention to publish date
30/01/2021

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. Guillermo Pardo Zamora (gparza@um.es). This data will become available once the study results are published. The data available will be all of the individual participant data collected during the trial, after deidentification. This data will be available 3 months after publication and ending 5 years following article publication. This data will be shared with investigators whose proposed use of the data has been approved by an independent review committee identified for this purpose. The data will be shared to achieve the aims in the approved proposal. Proposals should be directed to Dr Guillermo Pardo Zamora (gparza@um.es). To gain access, data requestors will need to sign a data access agreement.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		19/01/2024	19/01/2024	No	No
Statistical Analysis Plan		19/01/2024	19/01/2024	No	No