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Evaluation of gum and bone changes after immediate dental placement with two different surgical techniques

Submission date
22/07/2020

Recruitment status
No longer recruiting

Registration date
23/07/2020

Overall study status
Completed

Last Edited
23/07/2020

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The introduction of dental implants as an option to replace missing teeth was considered one of the most revolutionary developments in modern dentistry. However, one of the main drawbacks with the first dental implants was the time required for the treatment to be completed. One of the stages that delayed the overall treatment considerably was the waiting time for the gum and the bone to heal once a tooth had been extracted (3-6 months) before a dental implant could be placed. Quite recently, a new approach was described in which a dental implant was placed immediately in the socket left after a tooth was removed. This proved to be a very valid modality of treatment that reduced considerably the time needed to place an implant. As surgical techniques evolved, it was noticed that the less trauma caused during the immediate implant placement, the better the healing was. This led to the consideration of placing immediate dental implants without lifting the gums due to the potential advantages this may have for the healing of the gum and the bone afterwards. At the present, there are not many studies looking into this surgical aspect of immediate dental implants, so the aim of this study is to compare the gum and bone healing in immediate dental implants placed with and without gum lifting/flap.

Who can participate?
Patients aged over 18 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 immediate dental implants placed with and without gum lifting/flap. Both groups will receive hard and soft tissue grafting as part of the procedure. Dental implant survival and success are measured after 1 year.

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 modality that would not suit their needs or may have a negative impact in neighbouring teeth, such as fixed dental prosthesis. The potential risks

associated with this treatment modality 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 items 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 cause 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?
October 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 Ruben Garcia
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Contact information

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Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
1738/2017

Study information

Scientific Title
Evaluation of soft and hard tissue remodelling in post-extraction immediate dental implants placed with a flap and flapless approach in the aesthetic region. Clinical and radiographic prospective evaluation at one year.

Study objectives
The aim of this study is to test the main null hypothesis that there are no differences in survival /success rate in a group of patients requiring single immediate DI in the anterior maxillary region treated with a flapless vs. flap approach against the alternative hypothesis of a difference. For the secondary outcomes, the study tests the null hypotheses that there are no differences in "Pink aesthetic score (PES)", cortical plate resorption and "patients' reported outcomes (PROMS)" in a group of patients requiring single immediate DI in the anterior maxillary region treated with a flapless vs. flap approach against the alternative hypothesis of a difference.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/03/2018, 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: 1738/2017

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

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Soft and hard tissue remodelling in post-extraction immediate dental implants

Interventions
Patients requiring single tooth extraction in the anterior and premolar areas were recruited for this study. Self-tapping, screw-shaped Biomimetic OCEAN, Avinent® implants of different lengths and diameters were immediately placed after dental extraction. In the control group, implant placement was performed with the elevation of a mucoperiosteal flap whereas in the test group this was performed flawless. In all study cases, test and control, discrepancies between the extraction socket and the implant surface were filled with a mix of bone replacement graft (Gen-Os, Osteógenos s.r.l.) and autologous bone, covered with a collagen membrane (Evolution, Osteógenos, s.r.l). In addition, soft tissues were augmented by the use of autogenous connective tissue graft.

Randomization was done by balanced block randomization using a computer-generated table with random numbers. Treatment assignment was concealed to the treating surgeon by opaque envelopes that were opened only after completion of tooth extraction and final assessment of the feasibility of immediate implant placement. Clinical/radiographic measures, aesthetic evaluations and statistical analyses were performed blind with respect to treatment assignment.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Dental implant survival, defined as percentage of dental implants that presented successful osseointegration, lack of complications and bone loss less than 0.2 mm/year after loading at 1-year post-loading
2. Dental implant success, defined as percentage of implants that survived and the pink aesthetic score was above 7 and the white aesthetic score was above 5 at 1-year post-loading

Key secondary outcome(s))
1. Aesthetic of gums measured using the pink aesthetic index at 1-year post-loading
2. Aesthetic of false tooth measured using the white aesthetic index at 1-year post-loading
3. Buccal plate resorption measured using cone-beam CT at 1-year post-loading
4. Patients' reported outcomes measured using questionnaire and visual analogue scale at 1-year post-loading

Completion date
22/05/2020

Eligibility

Key inclusion criteria
1. Healthy individuals above 18 years who underwent immediate implant placement following single tooth extraction and were intended to receive implants
2. Non-smokers
3. Enough quantity of native bone to achieve primary stability
3. Patient has adequate mesiodistal space for implant placement
4. Patient available for follow-up according to protocol for 12 months post-loading to be able to assess the results of the proposed investigation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
28

Key exclusion criteria
1. Medically compromised patients
2. Smokers
3. Presence of active periodontal disease
4. Symptomatic apical pathology before extraction

Date of first enrolment
20/04/2018

Date of final enrolment
29/05/2019

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Murcia
Universidad de Murcia Hospital Morales Meseguer
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Sponsor information

Organisation
Hospital General Universitario Morales Meseguer

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
Avinent

Funder Name
Osteógenos s.r.l.

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes