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Use of 3D replicas as surgical guides for dental autotransplantation (movement of a tooth from one position to another)

Submission date
06/11/2022

Recruitment status
No longer recruiting

Registration date
30/11/2022

Overall study status
Ongoing

Last Edited
07/11/2024

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[X] Individual participant data

Plain English summary of protocol

Background and study aims
Tooth loss is mainly solved by prosthetic rehabilitation or dental implants. However, these solutions are expensive and may not be affordable for the entire population. As a biological and less costly alternative, autotransplantation (i.e. using a tooth extracted from the same patient, usually a third molar, to replace a tooth that has to be extracted, usually due to tooth decay), has shown an effectiveness of 80-95%. One factor that explains the difference in survival of the auto-transplanted tooth is the time that elapses between when the tooth is extracted and re-implanted. Traditionally, when the tooth is extracted, it is used as a mould to adapt the bone site that will receive it. Adaptation of the receptor alveolus (tooth sockets) requires time and surgical skill. A surgical guide could reduce the surgical time and improve the survival results of the auto-transplanted tooth, considering that it would reduce the time it remains outside the socket. This study aims to explore the effect of using 3D replicas of the tooth to be auto-transplanted to reduce surgical time and improve the results of autotransplantation. For this purpose, a 3D cone-beam scanner is taken in selected patients to evaluate the anatomy of the tooth to be transplanted. A 3D model is then generated and printed, generating a replica that allows it to be used for the surgical adaptation or grinding of the recipient site without having to extract the donor tooth until the moment before the autotransplant, thus reducing the time it remains outside an alveolus.

Who can participate?
Patients under the age of 25 years who require the extraction of a permanent tooth, molar or premolar and who have at least one third molar

What does the study involve?
A surgeon will ask for a 3D scan of the patient's jaw to make a model of the tooth to be transplanted. Then, during the extraction of the decayed tooth, the model will be used to ensure that the self-transplanted third molar will fit snugly in place of the extracted tooth. Patients in the control group will receive conventional autotransplantation, i.e. without using a 3D replica. Each patient will be monitored at 6, 12 and 24 months.

What are the possible benefits and risks of participating?
Using one of the patient's teeth is cheaper and more biological than using dentures or dental implants. The expected adverse effects are failure of autotransplantation due to infection and pain after the surgery.

Where is the study run from?
Riga Stradins University (Latvia)

When is the study starting and how long is it expected to run for?
January 2019 to June 2026

Who is funding the study?
1. Riga Stradins University (Latvia)
2. Horizon 2020

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
23.07.2022, Nr.6-1/08/12, RSU

Study information

Scientific Title
Effect of the use of 3D printed replicas on the surgical time of autotransplantation: a controlled clinical study

Acronym
3DATT

Study objectives
Hypothesis 1: The use of 3D-printed replicas decreases operative surgical time during autotransplantation.
Hypothesis 2: The use of 3D-printed replicas improves the survival of auto-transplanted teeth.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/07/2022, Research Ethics Committees of Riga Stradins University (Rīga Stradiņš University Main Building, 16 Dzirciema iela, Rīga, LV-1007, Latvia; Tel: not available; pek@rsu.lv), ref: 6-1/08/12. The ethics committee's permission indicated the possibility of including patients as historical controls, so they included patients from August 2019 onwards.

Study design
Non-randomized controlled clinical study

Primary study design
Interventional

Secondary study design
Non randomised study

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
Tooth extraction due to extensive tooth decay

Interventions
Patients assigned to the procedure will have a maxillary cone-beam CT radiographic examination. The third molar or tooth to be transplanted with the imaging volume will be modelled to create a 3D-printed model. Subsequently, during surgery, the affected tooth will be extracted and the 3D model will be used to adjust the socket to receive the tooth transplanted. Once the extracted tooth's socket is adapted, the tooth to be auto-transplanted will be extracted and proceed as usual. Patients in the control group will receive conventional autotransplantation, i.e. without using a 3D replica. Patient allocation will be sequential, not randomised, and the surgeon in charge will be aware of the group assigned to the patient (it will be unblinded). Each patient will be monitored at 6, 12 and 24 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Survival of the auto-transplanted tooth measured in months or years

Secondary outcome measures
1. Surgical time used, measured in minutes from the first incision to the end of the last suture
2. Donor extra alveolar socket time(s), measured in minutes. The extracted tooth was fitted into the recipient’s socket in the control group. For extra-alveolar time in the control group, only the time that it was outside the original socket was registered.
3. Donor fitting times, measured in minutes. Fitting into the recipient socket attempts was recorded. If the socket had to be adjusted, then extracted donor's tooth was gently replaced back in the original socket.
4. Success and survival rate at 1, 3, 6, 12 and 24 months after autotransplantation. Survival will be considered as the permanence of the auto-transplanted tooth, in the absence of infection or pain and with radiographic evidence of the absence of adjacent bone problems.
5. Infection/alveolitis rate, defined as the proportion of sites that had a clinical diagnosis of alveolitis after the surgery or required antibiotic therapy at any moment after the surgery
6. Any other adverse effects reported in addition to infection, swelling or pain at 6, 12 and 24 months

Overall study start date
01/01/2019

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. Patients under the age of 25 years
2. One or more missing teeth or irreversible dental damage
3. Seeking help at the RSU Institute of Stomatology for the restoration of dental row defects
4. Have indications for autotransplantation of third molars
5. Understand the nature of the procedure and give informed consent
6. The third molars have not erupted
7. Clinically healthy
8. Good oral hygiene
9. Non-smokers

Participant type(s)
Patient

Age group
Mixed

Upper age limit
25 Years

Sex
Both

Target number of participants
A total of 49 patients will enter this two-treatment parallel-design study. The probability is 80% that the study will detect a treatment difference at a two-sided 5.0% significance level (0.05) if the true hazard ratio is 2.732. This is based on the assumption that the accrual period will be 1 year, the follow-up period will be 2 years, and the median survival is 1 year. The total number of events will be 29.

Total final enrolment
46

Key exclusion criteria
1. Unsuccessful extraction of the donor's tooth
2. Insufficiently formed roots of third molars
3. Patients with chronic diseases
4. Pregnancy
5. The patient does not attend control visits

Date of first enrolment
14/08/2019

Date of final enrolment

01/06/2025

Locations

Countries of recruitment
Latvia

Study participating centre
RSU Stomatologijas Instituts
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Sponsor type
University/education

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ROR
https://ror.org/03nadks56

Funder(s)

Funder type
University/education

Funder Name

Rīgas Stradiņa Universitāte PhD minimal scholarship- 17-5/2022/13933

Alternative Name(s)
Rīga Stradiņš University, Rīga Stradiņš University, Universitas Rigensis Stradina, Riga Medical Institute, Medical Academy of Latvia, RSU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Latvia

Funder Name
Horizon 2020 grant agreement No 857287

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 04/11/2024:
Technical efficacy results published: https://pubmed.ncbi.nlm.nih.gov/37915275/
Clinical efficacy results paper accepted for publication Dental Traumatology Journal

Previous publication and dissemination plan:
Preliminary results will be presented at conferences and seminars in the field. The results will be summarised in at least one peer-reviewed publication in an international journal.

Intention to publish date
01/12/2022

Individual participant data (IPD) sharing plan
The data of the study will be published in the RSU data repository (https://dataverse.rsu.lv/). Access will be restricted.
The name of the repository: RSU Dataverse

A persistent weblink (if applicable): the final dataset has not yet been generated
The type of data stored: the repository will contain a dataset with anonymised patient data in CSV format, the statistical analysis script in r format and the output of the statistical analysis in HTML format.
The process for requesting access (if non-publicly available): the data will be made publicly available under CC Attribution 4.0 International (CC BY 4.0) license.
Timing for availability: data expected to be available from January 2025
Whether consent from participants was required and obtained: all participants provided written consent to participate in the study.
Comments on data anonymization: the data were anonymised using the R Anonymizer package (Paul Hendricks (2015). anonymizer: Anonymize Data Containing Personally Identifiable Information. R package version 0.2.0. https://github.com/paulhendricks/anonymizer). Only the principal investigator has access to the code that identifies each patient.
Any ethical or legal restrictions: only those applicable to the CC Attribution 4.0 International (CC BY 4.0) licence.

IPD sharing plan summary

Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Dataset			05/06/2023	No	No
Results article		01/11/2023	02/11/2023	Yes	No
Results article		06/11/2024	07/11/2024	Yes	No