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Evaluation of the residual bone level around explanted implants: local and systemic risk factors

Submission date
03/12/2023

Recruitment status
No longer recruiting

Registration date
05/12/2023

Overall study status
Completed

Last Edited
17/07/2025

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Peri-implantitis is an inflammatory disease with bacterial origin which affects the tissues surrounding the dental implants and it is characterized by bone loss around the affected implant. In absence of treatment, it can lead to implant loss with functional, biological and psychological consequences for the patient.
The peri-implant treatment can stabilize the disease in a long-term basis; however, the treatment outcomes of this disease are correlated to baseline situation and in cases with bone loss reaching more than 50% of the implant length, the explantation has been recommended. On the other hand, although the treatment of these situations is less predictable, the survival of dental implants after surgical treatment of advanced peri-implantitis has reached about 60% of cases.
The aim of the study is to analyze retrospectively the radiographic bone level of the implants explanted in a dental clinic group from 2005 to 2021. Moreover, the impact of other factors, such as dental status, prosthetic factors or systemic conditions, is analyzed.

Who can participate?
Data relating to adult patients with an explanted dental implant (osseointegrated and non-osseointegrated) between January 1, 2005 and December 31, 2021.

What does the study involve?
Analysis of the data gathered.

What are the possible benefits and risks of participating?
The main benefit of this study is to assess the risk profile of patients where dental implants were explanted. This could promote preventive therapies in those groups of patients and improve the understanding of the decision-making process for implant explantation.

Where is the study run from?
University of Geneva (Switzerland)

When is the study starting and how long is it expected to run for?
January 2022 to August 2024

Who is funding the study?
University of Geneva (Switzerland)

Who is the main contact?
Professor C. Giannopoulou, Ekaterini.Giannopoulou@unige.ch

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Assessment of the radiographic residual bone level around explanted implants and the influence of implant, prosthetic and systemic factors.

Study objectives
The clear hypothesis is that peri-implantitis is the first reason for implant explantation and that it is carry out when the bone loss reaches more than 60% of the implant. Other reasons of implant explantation are (in order of prevalence) primary failure, aseptic loosening and fractures. Another clear hypothesis is that there is an increase of the number of explantations in the last 15 years.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 02/03/2022, Commission cantonale d'éthique de la recherche CCER (Rue Adrien-Lachenal 8, Geneve, 1207, Switzerland; +41 22 546 51 01; ccer@etat.ge.ch), ref: 2022-00151

Study design
Single-center observational retrospective cohort

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Radiographic bone level around explanted implants

Interventions
This observational retrospective study analyzes retrospectively the radiographic data available in the files of patients treated in 13 dental clinics of a Swiss Dental Clinic Group (Ardentis Cliniques Dentaires, Switzerland) for implant explantation between years 2005 and 2021.

Medical records from about 500 potential candidates retrieved by billing data, is screened.

The following data is recorded when available:
- Demographic data: Age, gender, implant position.
- Implant related data: Implant lifespan, type of implant, implant placement surgery data (graft, dehiscence, sinus procedures, biomaterials), reason for explantation, peri-implant bone loss (mm and %), type and severity of bone defect, proximity of anatomical structures (adjacent teeth,

sinus, lower alveolar nerf).
- Periodontal conditions (periodontal diagnosis, mean pocket depth, number and percentage of shallow and deep periodontal pockets, history of periodontal treatment, scaling frequency, radiographic bone loss, bone loss/age ratio)
- Dental status (missing teeth, number of implants, DMFT index)
- Prosthetic data (Type of prosthesis, splinted implants, position of cantilevers, radiographic misfit of the prosthesis, number of implants, emergence profile and angle, antagonist).
- Medical data (systemic diseases, allergies, medication, tobacco consumption)

Descriptive statistics will include calculating means and standard deviations for continuous data or evaluating frequency distributions for categorical data. The p values for the differences between the subgroups (early and late failures; history of periodontitis or not; type of prosthesis, etc.) will be obtained via t tests for normally distributed continuous variables, Wilcoxon tests for variables non-normally distributed continuous and chi-square tests for categorical variables. A multivariate linear regression will be calculated to assess the influence of local and systemic factors.

The hypothesis to be confirmed is that explanted implants have bone loss close to 65% in agreement with the literature (Wentorp et al, Clin Oral Implant Res, 2021) and that the frequency of explants due to peri-implantitis has increased in in recent years, as has the prevalence of this disease (Elani et al, J Dent Res, 2018). Different factors such as a history of periodontitis could increase the risk of implant failure.

The standard error for assessing bone loss is between 0.5 mm (Derks et al, J Dent Res, 2016) and 1 mm (Serino et al, Clin Oral Implant Res, 2021). This is equivalent to 5% of the length of a standard 10 mm implant. A recent study included 66 patients for the calculation of bone level during explantation (Wentorp et al, Clin Oral Implant Res, 2021) taking into account that a sample size of 62 would achieve a power of approximately 90% for detect a difference of -20%. Given these data, our initial population of approximately 500 patients could produce a final representative sample with generalizable concrete conclusions. Likewise, our cohort would allow the analysis of the influence of other factors such as prosthesis, history of periodontitis, number of teeth/implants, etc. which has been a limitation for previous research on the subject (Wentorp et al, Clin Oral Implant Res, 2021).

The results of this research will be reported according to the STROBE recommendations for observational epidemiological studies.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Radiographic residual bone levels (mesured as percentage of the implant length) at the moment of explantation

Key secondary outcome(s))
Measured using patient records:
1. Implant position, demographic data (such as age) and life of the implant at the explantation.
2. Is implant loss associated with poor periodontal conditions (such as history or diagnosis of periodontitis, number of pockets, radiographic bone loss, bone loss/age ratio, scaling visits frequency)?
3. Is implant loss associated with poor prosthetic reconstructions (such as inadequate

emergence angle, cantilever presence, number of implants, prosthetic misfit, type of antagonist)?
4. Is implant loss associated with medical conditions, drug intake and/or tobacco consumption?
5. Is implant loss associated with any of other analyzed factors?
6. Tendency of the number of explantations in the last 15 years

Completion date
31/08/2024

Eligibility

Key inclusion criteria
1. Data relating to adult patients with an explanted dental implant (osseointegrated and non-osseointegrated) between 1 January 2005 and 31 December 2021.
2. Radiographic data available in the file.
3. Reason for explantation available.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
494

Key exclusion criteria
1. Data relating to patients whose reason for explantation is unsure.
2. Incomplete data (radiographs unable to measure the entire implant or not usable due to exposure/distortion, etc).
3. Implants placed for orthodontic reasons or temporary implants.
4. Document attesting to a consent refusal.

Date of first enrolment
14/03/2022

Date of final enrolment
10/10/2024

Locations

Countries of recruitment
Switzerland

Study participating centre
Division de médecine dentaire régénérative et de parodontologie. University of Geneva
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Sponsor information

Organisation
University of Geneva

ROR
https://ror.org/01swzsf04

Funder(s)

Funder type
University/education

Funder Name
Université de Genève

Alternative Name(s)
University of Geneva, UNIGE

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Switzerland

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from R. Martin Cabezas (rmartincabezas@gmail.com)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/07/2025	17/07/2025	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes