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Comparing the esthetic results and efficiency of 2 treatment protocols: the conventional approach using provisional crowns to sculpt the soft tissue before fabrication of the final crown, and a faster protocol, in which the final crown is finished directly without provisional crown phase.

Submission date
30/08/2017

Recruitment status
No longer recruiting

Registration date
21/11/2017

Overall study status
Completed

Last Edited
21/11/2017

Condition category
Oral Health

[X] 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 use of single implant crowns to restore a missing tooth in the mouth has become standard procedure. With the aim to improve the esthetic (looks) outcome, an additional treatment phase referred to as “soft tissue conditioning” is carried out before the final crown is fabricated and placed on the implant. This phase involves the fabrication, placement, and modified in several steps, of a provisional single implant crown made out of composite, which can be easily modified. The rational to do this is to push and sculpt the soft tissue around the final implant crown, with a modifiable crown, until we reach a “soft tissue framework” that we are satisfied with, therefor guarantying and improved esthetic outcome than if we do not carry out this phase. The issue is that the esthetic benefit of this extra tedious phase is not proven in the available literature. There are very few randomized control clinical trials evaluating this issue. The evidence seems to point out that after 2 years, the initial benefit of having conditioned the tissues to an improved framework disappear. As the soft tissue around an implant crown will settle and improve to where it can improve, depending on the onsite anatomical characteristics, for example; bone level at the neighboring teeth, implant correct position, soft tissue thickness, crown design, etc. The aim of this study is to evaluate the esthetic results around single implant crowns, with and without a previous phase of soft tissue conditioning.

Who can participate?
Adults aged 22 and older require a tooth.

What does the study involve?
Participants with a single missing tooth and an implant already placed in the anterior region are randomly allocated to one of two groups. Those in the first group receive a provisional implant crown, which is modified a couple of times by adding composite or removing composite, to shape the soft tissue around the implant, with the aim to create the most beautiful sculpted soft tissue around the implant possible. This procedure is called soft tissue conditioning. It is widely recommended and used, in order to optimise aesthetic results, yet it is not proven in the available evidence that there is an aesthetic difference 2 years after crown placement, as the soft tissue may improve alone without the use of this conditioning phase. Those in the second group do not have a provisional crown and conditioning, but will receive the final crown immediately after second stage surgery.
Both groups will receive the same the type of final crown, the only difference is one will have a tissue conditioning phase, with 5 extra appointments (5 months extra in total), while the other group will have directly the final crown placed (with less efforts to achieve an aesthetic result). Both groups are followed up for three years, to evaluate if the aesthetic outcomes, and the biologic results differs between both groups.

What are the possible benefits and risks of participating?
Participants may benefit from having the cost of the treatment covered. They may also benefit from esthetic improvements. There are normal risks with the implant crowns procedure however the success rate for this procedure is high. There are no extra risks with participating in this study.

Where is the study run from?
1. Université de Genève (Switzerland)
2. Smart Dental Concepts (Germany)

When is the study starting and how long is it expected to run for?
September 2017 to November 2022

Who is funding the study?
Oral Reconstruction Foundation (Switzerland)

Who is the main contact?
Ms Cristina Zarauz

Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
ORF41703

Study information

Scientific Title
Clinical, esthetic outcomes and efficiency of the one crown one time concept compared to the conventional approach encompassing soft tissue conditioning for the fabrication of single implant crowns: a pilot randomized controlled multicenter clinical trial

Study objectives
1. No differences will be found between test group and control group with respect to the esthetic outcomes, biological and technical results.
2. Yet, a difference is expected in regards of treatment efficiency, i.e. less time, less efforts and less costs will be needed for the test group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Randomised controlled clinical trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Missing single tooth

Interventions
Participants with a single missing tooth and an implant already placed in the anterior region are randomly allocated to one of two groups:

Control group: Participants receive a provisional implant crown, which is modified a couple of times by adding composite or removing composite, to shape the soft tissue around the implant, with the aim to create the most beautiful sculpted soft tissue around the implant possible. This procedure is called soft tissue conditioning. It is widely recommended and used, in order to optimise aesthetic results, yet it is not proven in the available evidence that there is an aesthetic difference 2 years after crown placement, as the soft tissue may improve alone without the use of this conditioning phase. This is why we want to do this study, to test a conditioning group with a non- conditioning group (test group).

Test group: Participants do not have a provisional crown and conditioning, but will receive the final crown immediately after second stage surgery.
Both groups will receive the same the type of final crown, the only difference is one will have a tissue conditioning phase, with 5 extra appointments (5 months extra in total), while the other group will have directly the final crown placed (with less efforts to achieve an aesthetic result).

Both groups are followed up for three years, to evaluate if the aesthetic outcomes, and the biologic results differs between both groups.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Esthetic outcome is measured using the "PES/WES": which is an esthetic index described by Belser in 2009 which is done by taking photographs (the photographs are examined and given points to different parameter, such as papilla fill, texture of soft tissue, volume, or color of soft tissue) at each follow up appointment
2. Volumetric changes is measured using digital models of the site of interest through the intraoral impression system

Key secondary outcome(s))
1. Biologic soft tissue outcomes is measured by registering the PPD (periodontal pocket depth), bleeding, and plaque around the implant crown at the follow up visit, which we would do anyway in routine control visits after crown placement
2. Biologic hard tissue outcomes is measured by registering the bone level changes: a small periapical radiograph is taken to evaluate bone level changes around the implant crown at the follow up visit
3. Efficiency comparison of the 2 protocols measured registering the time it takes in each procedure, and adding the time for all the procedures in the same protocol group. After, once the esthetic outcomes have been summed up, we may discus if the higher efforts of the control group was worth it.

Completion date
30/11/2022

Eligibility

Key inclusion criteria
1. Older 22 years old
2. Patients with Conelog Implants placed in the anterior and premolar region in the maxilla or mandible.
3. These implants should:
3.1. Allow for a screw retained reconstruction
3.2. Be submerged (second stage surgery is the 1st study appointment)
4. Two neighboring teeth are present, or one tooth and one implant
5. Capable of providing written informed consent
6. Obtained informed consent from the patient
7. 2mm band of keratinized mucosa at implant site
8. Patients with adequate oral hygiene Plaque Index < 20% or persistent intraoral infection BoP < 20%

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Medical condition that contraindicates surgery: ASA -score ≥ III
2. History of radiotherapy in the head and neck region
3. History of bisphosphonate medication
4. Women of childbearing potential with a positive urine pregnancy test
5. Medium smokers ≥ 10 cigarettes per day
6. Patients unwilling or incapable of understanding and signing the informed consent
7. Pronounced esthetic expectations
8. Severe bruxism or clenching habits

Date of first enrolment
30/11/2017

Date of final enrolment
30/06/2019

Locations

Countries of recruitment
Germany

Switzerland

Study participating centre
Université de Genève
Division de Prothèse Fixe et Biomatériaux
Clinique universitaire de Médecine Dentaire
CUMD - 19, Rue Lombard
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Study participating centre
Smart Dental Concepts
Dr. Happe und Kollegen Private dental practice

Schützenstr. 2
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Sponsor information

Organisation
Oral Reconstruction Fundation

ROR
https://ror.org/0178qr782

Funder(s)

Funder type
Charity

Funder Name
Oral Reconstruction Foundation (Switzerland)

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

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