Comparing cooling and non cooling of burs during placement of dental implants.

Published: 26-06-2020
Last updated: 10-04-2024

Primary objective: The primary goal of this research is to compare peri-implant hard tissue around implants placed using a modified drilling protocol, i.e. a reduced drilling speed without cooling and around implants inserted using a default...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49841

Source
ToetsingOnline

Brief title
Cooling versus non Cooling

Condition

- Other condition

Synonym
cooling burrs, Implantology

Health condition

Tandimplantaten

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Oral Reconstruction Foundation

Intervention

Keyword: - Burring protocol, - Cooling, - Implant

Outcome measures

Primary outcome

Peri-implant hard tissue around implants

Secondary outcome

Periodontal parameters (PD, BoP)

Precision of guided implant insertion in practice by superimposing volumetric

3D models.

3D soft tissue contour comparison

Patient reported outcomes

Evaluation of the used drills in each drilling method

Study description

Background summary

During osteotomy preparation, the exposure of bone to a temperature of 47 °C for one minute can cause bone resorption and necrosis (Eriksson & Albrektsson, 1983; Eriksson & Albrektsson, 1984). But when using computer aided implant surgery (CAIS), cooling never find its way to the drills, since the surgical guides are often close structures supported either on teeth, mucosa or bone. Recently, the thermal osteonecrosis and drilling parameters are revisited and it has been demonstrated that osteotomy preparation can be performed in all types of bone without external or internal irrigation (Flanagan, 2010). An advantage of avoiding this aqueous irrigation is that bone chips will remain attached to the drill flukes during the implant osteotomy preparation. Tabassum et al. (IJOMI accepted 20191) demonstrated that the osteogenic efficacy of

autogenous bone particles collected using low-speed drilling without cooling was superior compared with standard drill samples.

It is possible to avoid aqueous irrigation without detrimental effects on bone by adopting a low-speed drilling protocol which does not produce heat exceeding 47°C due to less frictional heat generation (Anitua, Carda, & Andia, 2007; Anitua, Prado, & Orive, 2009; Giro et al., 2011;). Augistin et al. demonstrated that the temperature range without external irrigation at 188 rpm was 31.4 - 36.9°C and at 462 rpm was 35.2 - 43.0°C (2008). Therefore, nowadays low-speed drilling is commonly employed during osteotomy preparation without saline irrigation.

Study objective

Primary objective:
The primary goal of this research is to compare peri-implant hard tissue around implants placed using a modified drilling protocol, i.e. a reduced drilling speed without cooling and around implants inserted using a default drilling protocol.

For this purpose, the marginal bone level around implants of both groups will be compared using CBCT radiography.

Secondary objectives:
Evaluation of the Periodontal parameters (PD, BoP)
Evaluation of the precision of guided implant insertion in practice by superimposing volumetric 3D models.
3D soft tissue contour comparison
Patient reported outcomes measurements
Evaluation of the used drills in each drilling method

Study design

The study design is a prospective randomized controlled clinical trial (RCT). Patients with one of the following indications and who fulfil the inclusive/exclusive criteria (paragraph 3.1.1.), will be enrolled in the study:
One single implant in the (pre) molar maxilla or mandible [#4-#7]
two non-adjacent (single) implants in the (pre)molar maxilla and/or mandible [#4-#7]
In all indication the proximal part of the (proximal) implant must be adjacent to a natural tooth.
Randomization will allocate patients into two groups: the test group with a modified drill protocol (TG) and (2) the control group with a default drill protocol (CG).

Implant success/survival will be analyzed and followed up until 1 year after

implant loading.

Intervention

Control Group:
Default drillings protocol according to the manufacture recommendation.

Test Group:
Modified drillings protocol:
Drillings speed limited to 200 RPM
No drill cooling is applied

For both study groups: Included patients will be operated by 3 surgeons (researchers 1, 3, 4; researcher 1 present in all the surgeries).
The following medication will be prescribed to the patients: Chlorhexidine mouth rinse (Perio Aid, Dentaid, Benelux), starting 2 days prior to surgery and extended for 2 weeks after surgery; antibiotic prophylaxis, Amoxicillin 2g 1 hour prior to surgery (in case of hypersensitivity to Amoxicillin, 600mg of Clindamycin 1 hour prior to surgery) and analgesic, Ibuprofen 600mg 3/day for 3 days, or in case of hypersensitivity to Ibuprofen 1000 mg of Paracetamol 4-6/day for 3 days.
After administering local anesthetics (Septanest SP, 40 mg/nml Articaine hydrochloride + 10 µg/ml Adrenaline tartrate), a minimal mid-crestal flap will be elevated with the purpose to conserve keratinized gingiva on the buccal side of the implant. The surgical template will be placed. For the control group, the drilling protocol will be used according to the manufacturer*s recommendations (CAMLOG, Germany) after which the planned implant (table 3) will be inserted guided, 2 mm apical to the planned cervical margin, according to prosthetic plan. For the test group, the drilling sequence will be followed according the manufacture*s recommendation except the drilling speed which is limited to 200 RPM and where no drill cooling is applied, after which the planned implant (table 3) will be inserted guided, 2 mm apical to the planned cervical margin, according to prosthetic plan.
Implant placement has to be implemented with minimal 20N insertion torque force. To control this parameter, the torque in the Implant hand-piece motor will be established at 20N, and it has to get stuck before completion of implant insertion.

Before suturing, a healing abutment will be placed. Suturing will be completed with mesial and distal double sling sutures using Ethicon, coated, Vicryl Rapide 3.0, Polyglactin 910. To ensure maximum approximation of the flaps without tension, semi-lunar thinning of the lingual flap can be done, according to case specific demands.
Light pressure with a gauze damped in chlorhexidine will be applied over the surgical site for 1 min. Oral and written instructions will be given to the patient concerning post- surgical care (table 5).
For each a group, a different surgical set will be used. At the end of the

surgical phase i.e. when all patients have received their planned implants, the drills will be analysed (REM).

Study burden and risks

Completing of a questionnaire (during follow up, 4 times in total)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. At least 20 years old
2. In need of a single or more implant(s) in the (pre)molar region
3. Healed site; defined by a surgical site with restored gingiva, that is free

of inflammation and scar tissue (Zuhr, Hurzeler 2012. Book), with a keratinized band of 3 mm from crest to muco-gingival junction, and sufficient osseous architecture to receive an implant (Koutouzis 2013) with a minimal diameter of 3.8 mm and a length of 9 mm.
5. At least one neighbouring element present.
6. Absence of visible active inflammation.
7. Adequate oral hygiene: FMPI< 20%, FMBoP< 20%.
8. Sufficient occlusal units, including the diastema to be restored: 4 occlusal units.

Exclusion criteria

1. Medical condition that contraindicates surgery; ASA II
2. Presence of inflammation expressed by PPD >4mm and BoP on adjacent teeth.
3. History of radiotherapy in the head and neck region.
4. History of Bisphosphonate medication.
5. Medium smokers: >10 cigarettes per day.
6. Patients unwilling or incapable of understanding and signing the informed consent.
7. Root canal treatment performed < 4 months previous to planned implant insertion.
8. Periapical radiolucency on neighbouring tooth to future implant.
9. Insufficient restorative space.
10. Active caries
11. Bone augmentation within 6 months previous to the implant treatment
12. Unhealed extraction sites (less than 6 weeks post extraction of teeth in intended sites)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2019
Enrollment:	48
Type:	Anticipated

Ethics review

Approved WMO

Date:	26-06-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL71259.078.19