Single implant restorations with a cantilever in the (pre)molar region: a prospective case-series study after a 3 year observation period

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26100

Source
Nationaal Trial Register

Brief title
Cantilever bridge on one implant

Health condition

Missing (pre-) molars in the lateral part of the maxilla or mandible and a compromised oral function as a consequence.

Sponsors and support

Primary sponsor: Oral Recontruction Foundation
Source(s) of monetary or material Support: Oral Reconstruction Foundation (ORF42110)

Intervention

Outcome measures

Primary outcome

Primary outcome parameter
The primary outcome variable is the mean marginal bone loss, for which the Marginal Bone Levels (MBL) between placement of the restoration (T0) and after 3 years (T3) are determined from standardized, long cone intraoral radiographs, by measuring from the edge of the implant to the bone-to-implant contact, both mesially and distally.

Secondary outcome

Secondary outcome parameters
- Survival of the implant (Isur) defined as the presence of the implant at any moment of observation is noted and presented according to Kaplan Meier;
- Survival (Rsur) and success (Rsuc) of the restoration defined as the presence of the restoration at any moment of observation (Rsur), without any complications or interventions (Rsuc).
- Patient reported outcome: This is determined by means of a validated questionnaire that measures people's perceptions of their quality of life related to their oral health (OHIP-NL 49)(7) and a Visual Analogue Scale (VAS) on general satisfaction with the function of their cantilever bridge (range 0-100);
- Clinical parameters indicative for peri-implant soft tissue health include Probing Pocket Depth (PPD), recession (REC), Gingival Index (GI), Plaque Index (PI) and Bleeding On Probing (BOP) is assessed at 4 sites per implant (8,9);
- All subjects are continuously monitored during the course of the trial for adverse events. These will be recorded, as well as detailed post-insertion maintenance and restorative complications

Study description

Background summary

The aim of this prospective case-series study is to evaluate and document the clinical performance, complications and patient-reported outcomes of single implant-supported two-unit cantilever restorations in the posterior region. A total of 20 consecutive patients will be treated with a single implant in the (pre-) molar region. After an osseointegration period of 3 months a single crown with a mesial cantilever is provided. All data will be collected beforehand, after providing the restoration and yearly during a follow-up period of 3 years.

Study objective

The single implant-supported two-unit cantilever restorations in the posterior regio will be a favourable in selected cases, regarding clinical and patient-based outcome measures

Study design

Tbaseline

T 1 year result
T 3 year result

Intervention

mplant placement
Implant treatment consists of the placement of a single implant (Conelog Progressive-Line, Promote Plus 4.3mm with a minimal length of 11mm, Camlog Biotechnologies GmbH, Basel, Switzerland) under local anesthesia. Implant placement will be conducted in accordance with the manufacturers' recommendations and is based on a digital planning and drill guide. It is performed by two experienced implant specialists. A protocol for antibiotic prophylaxis consisting of amoxicillin (2 grams, intraorally, 1 hour prior to surgery) and a mouth rinse (for two weeks, 0.2% Chlorhexidine, 2 times a day, starting 1 day prior to surgery) will be followed. A cover screw will be placed and de wound will be closed primarily for an uncompromised healing.

Restorative procedure
After a minimum of 3 month the implant is uncovered and a healing abutment is placed. Restorative treatment commences a week after uncovering the implant. A digital impression is made. A screw retained crown luted to an individual titanium abutment and with a cantilever is provided according to standard restorative procedures. Occlusion is checked meticulously and oral hygiene instruction is provided. Recall visits are scheduled.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria

- Patients older the 18 years old, in good physical, mental and periodontal health;
- A diastema in the premolar of molar area of the maxilla or mandible between 10-16 mm wide (2 premolars);
- Ample bone volume and height to place a single implant of at least 4.1 mm in diameter and 8 mm in length at the posterior end of the diastema;
- Natural teeth as antagonist.

Exclusion criteria

Exclusion criteria
- Radiotherapy involving the implant area;
- Current smoking habit that exceeds 5 cigarettes a day;
- Evidence of bruxism or other parafunctional habits.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	09-10-2021
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL9800
Other	METc UMCG : METc 2021/613

Study results