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The performance of a two-unit bridge supported by one implant in the lateral part of the upper and lower jaw

Submission date
10/03/2021

Recruitment status
No longer recruiting

Registration date
14/03/2021

Overall study status
Completed

Last Edited
20/08/2021

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Sometimes it is impossible or undesirable to place two adjacent dental implants in a diastema (the space or gap between two teeth) to replace two teeth. Several factors could play a role like a shortage of bone, a shortage of the length of the diastema or financial constraints. There is a lack of evidence for this treatment. Besides, no study has ever reported on patient satisfaction with this treatment to the best of the researchers' knowledge. Therefore, the aim of this study is to evaluate survival, clinical performance, complications and patient-reported outcomes of single implant-supported two-unit cantilever fixed partial denture in the posterior region of the mouth.

Who can participate?
Patients who received a single implant-supported fixed partial denture with a cantilever in the posterior region between January 2004 and February 2018

What does the study involve?
The survival rate of the implants and the fixed partial dentures and data regarding the marginal bone level, presence of plaque, calculus (hardened plaque), bleeding on probing, mucosal health, pocket probing depth and patient satisfaction are collected during an evaluation visit. Complications are recorded from their medical records.

What are the possible benefits and risks of participating?
All patients were scheduled for a regular check-up (care as usual). The patients were able to give their opinion on the treatment and results (retrospectively) by filling in two questionnaires. No risks were involved.

Where is the study run from?
University Medical Center of Groningen (Netherlands)

When is the study starting and how long is it expected to run for?
September 2018 to July 2019

Who is funding the study?
University Medical Center of Groningen (Netherlands)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
METc UMCG RR201800656

Study information

Scientific Title
Single implant-supported two-unit cantilever fixed partial dentures in the posterior region: a retrospective case series with a mean follow-up of 6.5 years

Study objectives
The aim of this retrospective study is to evaluate survival, clinical performance, complications and patient-reported outcomes of single implant-supported two-unit cantilever fixed partial dentures (FPD) in the posterior region.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Medical Ethical Committee of the University Medical Center Groningen considered this retrospective case series study not to be subject to the Medical Research Involving Human Subjects Act (METc RR-Number 201800656)

Study design
Retrospective case series

Primary study design
Observational

Secondary study design
Case series

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Evaluation of the functioning of implant-supported cantilever fixed partial dentures

Interventions
Patients who received a single implant-supported fixed partial denture with a cantilever in the posterior region between January 2004 and February 2018 are included. The survival rate of the implants and the fixed partial dentures and data regarding the marginal bone level, presence of plaque, calculus, bleeding on probing, mucosa health, pocket probing depth and patient satisfaction are collected during an evaluation visit. Complications are recorded from the medical records. The average follow-up period of this particular retrospective study is 6.5 ± 4.8 years at the time of data collection.

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Survival rate of implants assessed using clinical examination at the follow-up evaluation

Secondary outcome measures
1. Marginal bone level (MBL) measured using radiographic assessments at baseline and during the follow-up evaluation

2. Clinical assessments by one examiner at the follow-up evaluation:
2.1. Plaque assessed per implant using the modified plaque index
2.2. Presence of calculus observed during clinical examination
2.3. Bleeding assessed per implant using the modified sulcus bleeding index
2.4. Gingival health assessed per implant using the gingival index
2.5. Probing depth assessed at four sites per implant using a manual standardized pressure periodontal probe (Click-Probe®, Kerr, Bioggio, Switzerland) measuring to the nearest 1 mm
3. Complications recorded from medical records at the follow-up evaluation
4. Patients' satisfaction measured using OHIP-NL49 and VAS questionnaire at the follow-up evaluation

Overall study start date
01/09/2018

Completion date
01/07/2019

Eligibility

Key inclusion criteria
All patients treated with a single implant-supported two-unit cantilever FPD in the posterior region of maxilla or mandible between the period January 1st, 2004 and January 1st, 2018 in a private referral practice in Apeldoorn, The Netherlands. The inclusion criteria for the study are:
1. One dental implant restored with a crown with one cantilever unit positioned mesially or distally, in the posterior region of maxilla or mandible
2. Presence of antagonistic teeth
3. Follow-up period at least 1 year after placement of the restoration
4. Presence of a radiograph taken directly after placement of the implant

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
25

Total final enrolment
23

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
01/10/2018

Date of final enrolment
01/04/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Private referral practice in Apeldoorn: "De Mondhoek"
Zwolse Binnenweg 5
Apeldoorn
Netherlands
7315 CA

Sponsor information

Organisation
University Medical Center Groningen

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.umcg.nl/EN

ROR
https://ror.org/03cv38k47

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/10/2021

Individual participant data (IPD) sharing plan
Data will be shared on a personal basis. If a researcher is interested in the data they can contact Dr C Jensen-Louwerse (c.jensen@umcg.nl). Patients were informed verbally and in writing about the study and signed the informed consent form. All data is stored in Red Cap and processed anonymously.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/08/2021	20/08/2021	Yes	No