

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

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| Submission date 10/03/2021 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 14/03/2021 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 20/08/2021 | Condition category Oral Health | <input type="checkbox"/> 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?
Dr C Jensen-Louwerse
c.jensen@umcg.nl

Contact information

Type(s)
Scientific

Contact name
Dr Charlotte Jensen-Louwerse

ORCID ID
<https://orcid.org/0000-0002-3483-5220>

Contact details
Antonius Deusinglaan 1
Groningen
Netherlands
9713AV
+31 (0)50 3616274
c.jensen@umcg.nl

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

ROR

<https://ror.org/03cv38k47>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |