An open, prospective, multicenter investigation to evaluate the clinical outcome of PrimeTaper EV implant in extraction sockets and healed ridges - A 5 year follow-up

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1. Primary objectiveThe primary objective of this clinical investigation is to evaluate implant survival rate 1 year afterpermanent restoration (PR), i.e. implant in place 1 year after PR, Yes/No.2. Secondary objectivesThe secondary objectives are...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON51681

Source
ToetsingOnline

Brief title
C-PT-21-001

Condition

- Other condition
- Bone and joint therapeutic procedures

Synonym
missing teeth, partial edentulous

Health condition

herstel dentitie

Research involving
Human

Sponsors and support

Primary sponsor: Gulje Mondzorg bv
Source(s) of monetary or material Support: DENTSPLY IH AB d.b.a. Dentsply Sirona

Intervention

Keyword: bone-level, gingiva, implant, PrimeTaper

Outcome measures

Primary outcome

The primary objective of this clinical investigation is to evaluate implant

survival rate 1 year after

permanent restoration (PR), i.e. implant in place 1 year after PR, Yes/No.

Secondary outcome

The secondary objectives are to evaluate:

* Implant survival rate 2, 3, 4 and 5 years after PR.

* Implant stability at implant placement and at PR.

* Insertion Torque Value (ITV) and torque build-up at implant placement.

* The surgeon*s perception of implant stability and confidence at implant

placement.

* Maintenance of Marginal Bone Levels (MBL).

* Condition of the periimplant mucosa (bleeding on probing (BoP), probing

pocket depth

(PPD) and plaque).

* Implant success (adapted Albrektsson et al 19866).

Study description

Background summary

Tapered dental implants are well-established medical devices which are available in a range of
different sizes pending the anatomical context at hand. There is clinical proof for their successful
application in immediate installation, immediate loading as well as in different bone qualities.
There are also reports on potential advantages of the tapered shape regarding available space
at the insertion site, and also regarding reduced risk of bone fracture.
The motivation behind the development of the tapered implant design is mimicking the natural
shape of tooth roots of non-molars as it is deemed advantageous to fit extraction sockets and
provide increased stability and adequate stress distribution.
Based on practicing dental expert point of view, tapered implants might often be preferred
because of their better fit in the edentulous space and the perception of achieving a higher
primary stability as compared to cylindrical implants.

Study objective

1. Primary objective
The primary objective of this clinical investigation is to evaluate implant survival rate 1 year after
permanent restoration (PR), i.e. implant in place 1 year after PR, Yes/No.

2. Secondary objectives
The secondary objectives are to evaluate:
* Implant survival rate 2, 3, 4 and 5 years after PR.
* Implant stability at implant placement and at PR.
* ITV and torque build-up at implant placement.
* The surgeon*s perception of implant stability and confidence at implant placement.
* Maintenance of Marginal Bone Levels (MBL).
* Condition of the periimplant mucosa (bleeding on probing (BoP), probing pocket depth
(PPD) and plaque).
* Implant success (adapted Albrektsson et al 19866).

Study design

The PrimeTaper clinical investigation is an open prospective, single-arm, multicenter,
international clinical investigation with a 5-year follow-up period. The primary objective is to
evaluate implant survival 1 year after Permanent Restoration (PR). Partially edentulous subjects
in need of one implant in the maxilla or mandible (2nd and 3rd molars excluded) will be included
using competitive recruitment until 137 subjects/implants are reached at 6 centers (including
20% drop-out rate to assure 109 fully evaluable subjects at 1 year after PR), and until at least
13 subjects have received one implant in length 6.5mm (including 20% drop-out rate to assure
10 fully evaluable subjects).
The implant can be placed in all bone qualities with a one- or two-stage surgical protocol as per
the investigator*s preference. The timing of implant placement7 is divided into:
* Immediate implant placement
- Implant placed in a fresh extraction socket just after tooth extraction
* Immediate-delayed implant placement
- Implant placed in an extraction socket within 8 weeks after tooth extraction
* Delayed implant placement
- Implant placed at least 2 months after tooth extraction
NB! Tooth extraction made within the clinical investigation should preferably be deemed
suitable for either immediate or immediate-delayed implant placement (i.e. within 8 weeks).
Delayed implant placement in the PrimeTaper clinical investigation is mainly aimed for subjects
edentulous for more than two months at time of inclusion.

Loading protocol can be chosen as per the investigator*s preference:
* Immediate loading
- Implant connected to the prosthesis within 2 days from implant placement
* Early loading
- Implant connected to the prosthesis between 3 days to 8 weeks after implant placement
* Conventional loading
- Implant connected to the prosthesis more than 8 weeks up to 6 months after implant
placement
For all of the above, either temporary restoration (Temp Abutment EV) or PR (TiDesign EV) can
be chosen as per the investigator*s preference:
* Temporary restoration
- Implant connected to prosthesis held out of occlusion with the opposing arch.

* Permanent restoration
- Implant connected to prosthesis in balanced occlusion with the opposing arch. However, the final crown (cement- or screw retained, full contour Zirconia) must be in place no
later than 6 months after implant placement. PR will be baseline for the follow-up visits.
Radiographic examinations will take place before surgery for treatment planning, at implant
placement, at PR and 6 months, 1 year, 2 years, 3 years and 5 years after PR. ITV and primary
stability (ISQ) will be recorded at implant placement and the surgeon*s perception of the implant
installation will be collected. Analogue impression technique will be used. ISQ will be recorded
also at PR. PPD and BoP will be recorded at PR and at all follow-up visits. Plaque will be
recorded at all follow-up visits after PR. Implant success will be evaluated 1, 2, 3 and 5 years
after PR and safety assessments will take place throughout the clinical investigation.
11 standard visits are planned for each subject. Depending on the treatment chosen additional
visits may be scheduled at the discretion of the investigator.

Study burden and risks

RISKS FOR PARTICIPATING SUBJECT
LIKELIHOOD CONSEQUENCES
MITIGATION

Investigational medical device
Low N/A. There are
no N/A

additional risks or

disadvantages

foreseen with

PrimeTaper EV

implants

compared to

other implants on

the market

Radiographic exposure
Low There are
no All attempts to limit X-ray

additional
X-rays exposure will be made

taken
compared during the clinical

to normal
routine investigation, including

proper shielding.

Processing of subjects*
Low
Potential Risks related to the
personal
data
exposure of
processing of subjects*

personal
data personal data, and in

particular data concerning

health, will be mitigated by

use of pseudonymization,

whereby the personal data

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

For inclusion in the clinical investigation subjects must meet all of the following criteria:
1. Adult aged 18-75 years.
2. Willing and able to sign and date the informed consent form.
3. In need of an implant in position 16 to 26 or 36 to 46, and each subject can only receive one
implant.
4. Deemed by the investigator as likely to present with an initially stable implant situation.
5. A stable occlusion, i.e. an opposing natural dentition, a crown, an

implant-supported fixed or
removable prosthesis, a partial removable prosthesis or a full denture.
6. An adjacent tooth (root with natural or artificial crown) or an
implant-supported crown
mesially and distally. Exemption: If the planned implant is in the first molar
position, an
edentulous space is accepted distally.

Exclusion criteria

Exclusion criteria
All exclusion criteria apply at inclusion with a final eligibility verification
prior to implantation, but
exclusion criteria number 4 also applies during the entire clinical
investigation period.
Any of the following is regarded as a criterion for exclusion from the clinical
investigation:
1. Not willing to participate in the clinical investigation or not able to
understand the content of
the clinical investigation.
2. Unlikely to be able to comply with clinical investigation procedures
according to
investigator*s judgement.
3. Unable or unwilling to return for follow-up visits for a period of 5 years.
4. Severe non-compliance to CIP as judged by the Investigator and/or Dentsply
Sirona.
5. Known allergy or hypersensitivity to titanium and/or stainless steel.
6. Uncontrolled pathological process in the oral cavity, e.g. untreated rampant
caries and
uncontrolled periodontal disease.
7. Uncontrolled para-functional habits, e.g. bruxism.
8. Current need of any Guided Bone Regeneration (GBR) procedure in the planned
implant
area (gap filling at immediate placement and soft tissue grafting are allowed).
9. Systemic or local disease or condition that would compromise post-operative
healing and/
or osseointegration.
10. Immunosuppression, use of corticosteroids, per-os or intravenous
bisphosphonate use, or
any other medication such as anti-resorptive therapy or monoclonal antibodies
that could
compromise post-operative healing and/or osseointegration.
11. Any other condition that would make the subject unsuitable for
participation, including but
not limited to;

* History of radiation therapy in the head and neck region.
* History of chemotherapy within 5 years prior to surgery.
* Present alcohol and/or drug abuse.
* Ongoing psychiatric illness.
* Current smoking/use of tobacco, including e-cigarettes.
12. Any ongoing disease that would make the subject unsuitable for participation, including but
not limited to;
* Recent myocardial infarction (< 3 months*).
* Recent cerebrovascular accident (< 3 months*).
* Recent cardiac-valvular prosthesis placement (< 3 months*).
* Hemorrhagic diathesis.
* Severe liver dysfunction.
* Known or suspected current malignancy.
* Uncontrolled diabetes mellitus.
* Florid infection.
13. Pregnant or breastfeeding females. (Pregnancy tests will be performed as per local
requirements).
14. Previous enrolment in the present clinical investigation.
15. Involvement in the planning and conduct of the clinical investigation (applies to both
Dentsply Sirona staff and the clinical investigation site).
16. Simultaneous participation in another clinical investigation, or participation in a clinical
investigation during the last 6 months that may interfere with the present clinical
investigation.
* < 3 months is a strict exclusion criterion. After 3 month it is up to the investigator to judge whether the subject is considered suitable for participation or not.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-05-2022
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	28-03-2022
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL80094.028.21