Digital workflow to produce CAD/CAM fixed prosthesis (Lava Plus) on dental implants (Straumann) with the use of CBCT based (flapless) Guided surgery (coDiagnostix) and Intra-oral Scanning (True Definition Scanner - 3M)

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

Summary

ID

NL-OMON38606

Source
ToetsingOnline

Brief title
3D in implantology - *from planning to scanning*.

Condition

- Other condition

Synonym
Missing teeth / diasthema

Health condition

Ontbrekende gebitselementen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Centrum Tandheelkunde Amsterdam
Source(s) of monetary or material Support: Ministerie van OC&W,3M ESPE,De wereldwijde beroepsvereniging voor implantologen ITI (non profit),Straumann

Intervention

Keyword: Digital Workflow, Guided Surgery, Implantology, Intra-Oral Scanning

Outcome measures

Primary outcome

The clinical fit of CAD/CAM supra-structures based on conventional- or digital impressions will be judged by the restorative dentist who places the crown or bridge. For that reason, the dentist fills in a questionnaire on the fit not knowing to which group the supra-structure belonged.

- Three outcomes are possible: perfect fit, acceptable fit and non-acceptable fit.

Secondary outcome

1. The accuracy of computer guided surgery. Measured by superimposing the implant positions from the planning software with the positions gathered by the intra-oral scan made 3 months after implant insertion.

- Outcomes: deviation at implant apex (in mm), deviation at implant entry point (in mm), and angular deviation (in °).

2. Analyzing the dimensional changes in the treated area during the entire

treatment period. With digital subtraction of all intra-oral scans of one

patient the differences can be quantified in mm3.

3. Describing implant survival, surgical- and prosthetic complications up to

one year after restoring the implants. The clinical use of CAD/CAM restorations

on dental implants is thus quantified.

Study description

Background summary

In modern oral implantology digital technologies are applied incriesingly. Since the introduction of CAD/CAM, dentistry has changed dramatically. Whereas it was initially primarily used in dental laboratories this is changing rapidly and shifting to the dental practice, especially since several manufacturers are offering devices for digital intra-oral impressions. One of the major advantages of these developments is that once the digital image of a tooth or implant is saved, the chances of mistakes due to technical errors in the production process are minimal. Shrinkage, expansion, fracture, transportation and storage of dental casts are eliminated. The success of this digital workflow is thus entirely dependent on the accuracy of these scans. With dental implants this is even more critical than with natural teeth because they lack the resilience of the periodontal ligament.

Digital planning and guided surgery based on CBCT is another recent development. This digital planning makes implantology more predictable and surgery time shorter9. Additionally, extensive surgical interventions can be avoided because of flapless approaches. Combining all these new techniques, it should be possible to completely digitize the implantology workflow from planning to production of the supra-structures.

In addition the intra-oral scans are used to evaluate volumetric changes in the implanted area. For this purpose a partial intra-oral scan are taken from the implanted site in each session. These files can be superimposed digitally and volumetric changes will be observable very accurately. With the information obtained with this method, it might be feasible to make guidelines of expected volume loss in certain situations. With this information clinicians can anticipate on signals that indicate future problems. This method is rather new

and there are no studies so far with volumetric data compared in each session.

Study objective

The main purpose of the studies suggested in this proposal is to scientifically test the digital workflow in implant dentistry. The following primary and secundary goals are pursued:
Primairy:
1. Assessment of the clinical use of intra-oral scanning of dental implants and comparing it with conventional impression methods. Comparing these methods on *m-level is performed in another in-vitro experiment.
Secundary:
2. Testing the accuracy of computer guided implant placement with tooth-supported drill guides produced with rapid prototyping.
3. Assessment of dimensional changes around implants evaluated during the entire treatment phase.
Producing prosthetics on implants in fully digital (CAD/CAM) workflow. Preferably without the use of a model of any sort.
4. Implant survival, surgical- and prosthetic complications are recorded up to one year after restoring the implants. The clinical use of CAD/CAM restorations on dental implants is thus quantified.

Study design

In general this study is a Double-blind randomized clinical trial. This double blind qualification concerns the random selection of the produced supra-structure. However remarks have to be made, since the randomization is done after the applying both methods to the same patient. Furthermore the methods itself are not interventions but (diagnostic) registrations on which an intervention (placing the supra-structures) is based. The interventions itself are more or less equal; both groups receive the same kind of supra-structures and are subjected to the same restoration fit assessment.

The actual fit-checking is the primary outcome of this study. This assessment is performed with a questionnaire on the fit which is filled in by the dentist who performs all supra-structure placements. In addition a second dentist will independently perform the fit check. If any disagreement is present a third reviewer (the head of the department) will make the final decision on the quality of the fit.

Intervention

In this study titanium implants are inserted in the jaw bone. This is done with a widely used and well documented implant type. This is thus not considered an experimental intervention. De supra-structures, which will be placed on these implants four months after insertion, are all made of zirconia-oxide; a widely

used and well docuemented restorative material in dentistry.

This application focuses primarily on applying an extra (non invasive) measurement tool: the intra-oral scanner. De images gathered with this scanner are used in half the patients to design the above mentioned zirconia-oxide supra-structures. The fit of these supra-suprastructures is thoroughly tested before they are finally attached. This is a regular procedure when placing supra-structures. The chance of problems is thus not larger than with any other conventionally produded suprra-structures. In addition to that, a supra-structure is a reversible construction (it is not introduced into the body). When problems or complaints do occur such a structure can relatively easily be removed.

In our opinion this is not a study on an intervention per se, but a on a (diagnostic) measurement tool used to do an intervention.

Study burden and risks

The additional risks for patients participating in this research are very little. The implants and restorative materials used in this study are a well known and thoroughly researched instruments. Although half the supra-structures are designed based on a relatively new method (intra-oral scanning of dental implants), a proper fit is guaranteed by a thorough clinical control before the restoration will be installed definitively. If by any chance a restoration is insufficient or fails a new restoration will be made based on a conventional impression. This will obviously be free of charge for the patient. The most significant effort for the patients are the extra intra-oral scans made at each session (no radiation involved). These scans are in addition to the three regular plaster models (conventional impressions) taken during such a treatment protocol. The total extra time needed for these scans during the 15 months period is estimated as 78 minutes. The patients do not need to bring extra visits to our clinic. However it is expected that patient follow a, more or less, strict time schedule. This time schedule (or planning) will be made in conjunction with the patient and is important to make every treated patient comparable.

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

- Patients requiring dental implants for the support of fixed crowns and/or bridges in the resorbed posterior area.
- Good general Health (ASA Score 1&2)
- If additional bone augmentation is required this will preferably be done before the patient is included in the study.

Exclusion criteria

- Patients under the age of 18.
- Women pregnant at intake (because of CBCT taken during diagnostic phase).
- Implant placement wanted on incisor locations.
- Implant sites certainly requiring bone augmentation during implant placement

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2013
Enrollment:	82
Type:	Anticipated

Medical products/devices used

Generic name:	supra-structures on previously inserted dental implants
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-12-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL43489.029.13