The evaluation of 3D printed and designed composite based restorations in patients with dental implants

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To evaluate the performance of patients with dental implants that have been restored with CAD CAM 3D printed resin/polymer screw retained crowns on Straumann dental implants. As no clinical study has been carried out on these materials up till now…

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

Summary

ID

NL-OMON47615

Source
ToetsingOnline

Brief title
In vivo behaviour of 3D printed crowns on implants

Condition

- Other condition

Synonym
tooth replacement with crowns on implants

Health condition

kauwstelsel

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Acta Dental Research

Intervention

Keyword: 3DPrinted, Crowns, Implants, Wear

Outcome measures

Primary outcome

Failure of the restauration

Secondary outcome

discoloration

Plaque retention of the restoration

condition of soft tissue surrounding the restoration

Study description

Background summary

One of the treatment options to replace a missing tooth, is the insertion of a dental implant. Dental implants are available in various surface characteristics, lengths, shapes and design. The ultimate goal of any design of dental implants is to simulate the function of a dental root. It is of course a compromise as it will support a superstructure replacing the natural crown. Dental implants are a predictable long-term method for the replacement of the roots of teeth. Both soft- and hard-tissue are important factors in bone-healing and thus in successful long-term integration. In the osseointegrated period various factors have been described to contribute to long term success. Superstructures placed in and on these implants could also contribute to this long term success. Stresses in the prosthesis have been linked with marginal bone loss and implant failure. The misfit of the superstructure may also lead to biological complications or mechanical complications such as screw loosening of the implant abutment, fracture of the screw, the abutment and/or the implant. The biological complications can cause

an adverse reaction of soft/hard tissue, which can play a role in plaque accumulation and bacterial overload. The materials used to fabricate crown and bridgework on dental implants have shown a rapid development during the last 2 decades.. We have gone from cast frameworks with porcelain fused to metal to milled frameworks from resin structures and ceramics such as zirconia to now 3D printed structures. Recent development and advancement in digital tools allow numerous options for restorative dentistry. Digital fabrication technologies involve CAD/CAM techniques through either subtractive (milling) or additive (3D printing) manufacturing (AM).
Additive manufacturing has a unique advantage over conventional milling production methods; it has practically no waste material, no restriction in geometric shape of the products and tolerance of milled parts is no longer an issue [1,2]. This allows the AM technologies to be a key component in the mass production of parts with special geometrical requirements [2]. Relevant to this is the fabrication of fixed dental crown and bridge restorations with their unique buccal, lingual, mesial and distal contours as well as the sophisticated occlusal outlines.
Among the various additive-manufacturing techniques, DLP (direct laser projection) is gaining increased popularity in the production of dental parts [3-5]. In a DLP build process a highly complex structure is fabricated on a layer-by-layer basis directly from 3D data, whereby consecutive liquid photo-activated monomer layers are exposed to UV light and cured based on the final shape of the required product. The DLP process involves a digital micromirror device (DMD) that is used to dynamically define a mask image that is projected on the resin surface [6-9]. DMDs, consist of hundreds of thousands of individually moving micromirrors, that control the reflection path of light. Each pixel of the image corresponds to an individual micromirror, the orientation of which can be switched between several degrees based on the geometry of the part to be printed [9,10].
Next Dent (Vertex-Dental) has successfully developed resin/polymer materials for 3D printing that have been tested on various biocompatibility properties and have also been clinically tested. They have been registered as a biocompatible material for crowns and dentures that can be used in the mouth indefinitely.
In order to evaluate the possible influence of the printing material the submucosal bmicrobiome of the patients will be evaluated for change before, 6 and 12 months after the prosthetic procedure. This will be carried out by collecting submucosal plaque samples with the paperpoint technique. The submucosal microbiome will be sequenced by Illumina
New dental impression technologies have been developed which claim to be more accurate and ensure a passive fit of crowns on natural teeth and implants. Apart from the traditional way of impression taking using elastomers, there is an alternative, namely digital intra-oral scanning. This may be combined with CAD/CAM to produce crowns and fixed partial dentures. These have been developed to achieve a higher accuracy than traditional impression methods and to make a full digital workflow possible. Various methods of CAM of superstructures exit nowadays. Mostly larger discs of metal or zirconium are designed and milled

down to a fitting proportion. In this way a lot of material gets lost. Furthermore, due to limitations of the milling machines not every design is possible.
The new possibilities of 3 dimensional printing could eliminate the loss of these precious materials.
Objective of the study:
To evaluate the performance of patients with dental implants that have been restored with CAD CAM 3D printed resin/polymer screw retained crowns on Straumann dental implants. As no clinical study has been carried out on these materials up till now we want to evaluate their function in the oral cavity after a year. The primary outcome of this research is the failure of the restoration.
As secondary outcome dDiscoloration, mechanical wear, changes in the surface structure, adhesion of plaque and debris as well as patient-centred satisfaction with the aesthetic and functional treatment outcome will also be evaluated.
Study design:
A virtual crown restoration will be designed on the individual implant using the 3-Shape Dental System TM CAD solution. The crown design will fit the desired occlusion and articulation requirements of the individual patient as well as the tie-base that is to be fitted to enable the screw retention on the dental implant. The crowns will be printed using Rapid Shape D30 DLP printer (Rapid Shape GmbH, Germany) with each series of 4 crowns being fabricated at the center of the build platform. The DLP printer involves an LED light source, DMD device/chip, lens, resin vat, building platform that is moving in Z-axis .The DMD device is composed of several micromirrors that dynamically reflect the light either toward the vat (on) or away from it (off) to create light or dark pixels respectively. The LED light used has a wavelength of 405 nm (narrow spectrum wavelength of 390-420 nm) and 10,0 W/m2 energy output. The build platform size is 110*62 mm and the power of resolution was 1080 *1920 pixels. The pixel size is 0.058 mm and the layer thickness is 30µm. The x-y accuracy of this DLP system as reported by manufacturer is ±29µm [13]. Fig 1 shows a schematic drawing of DLP printing technology. All crowns will be printed using NextDent C&B material (NextDent C&B MHF* Shade: N1 * N1.5 * N2 * N2.5 * N3 * BL * T1) with similar printer settings with similar printer settings. The material properties as reported by the manufacturer are presented in Table 1. After printing, all specimens will be cleaned with 96% alcohol for five minutes and post-cured for 30 minutes using ultraviolet curing unit LC 3DPrint Box (Next Dent B.V. Netherlands) following the manufacturer*s instructions [14].
All the crowns will be fitted with a Straumann Tie base. The luting agent that will be used for this is panavia R.
Two crowns will be stored in a lightproof box. One will be tested after a year. The second will replace the test crown when this is unscrewed and presented for laboratory analysis. The 3rd crown will be stored under comparable circumstances as in the mouth in a laboratory environment.

Prior to storage / placement all 3 specimens per patient will be digitally

scanned using a high-resolution optical surface scanner (IScan D104i; Imetric; Courgenay, Switzerland). Prior to scanning, the scanner will be calibrated according to the manufacturer*s instructions. The specimens will be examined for any manufacturing defects and sprayed with a thin layer of anti-reflective powder (Helling 3D Scan Spray, Helling GmbH, Germany).
The accuracy of the printed crowns will then be evaluated using a digital subtraction technique. The STL files of the three scanned printed crowns [test model] and that of the designed crown [reference model] were exported in Geomagic® studio (3D Systems, Rock Hill, SC, USA; 2014). The exported files will be aligned to have the same coordinate systems. The alignment will be further refined using automatic best-fit alignment that is based on the closest point algorithm (ICP) system. Prior to alignment process, the support structure will be virtually removed to eliminate any potential error during the procedure. The accuracy will then then evaluated through root mean square estimate values (RMSE) and deviation patterns on color maps. All specimens will be scanned and analyzed by two trained operators.
Intra-observer reliability will be assessed using Interclass correlation coefficient. To assess the observer bias, measurements will be taken twice by one observer within a 15 days interval between the two measurements. Furthermore, possible errors from optical scanning will be excluded by assessing the repeatability of the measurements six times.
After 12 months the removed crowns will be analysed. Colour stability will be measured using a spectrophotometer.
The change of the surface will be measured using an electron microscope (SEM).
Mechanical wear will be analysed using a scanning and subtraction technique.

Before, 6, 12 and 24 months after the surgical procedure submucosal fluid and plaque samples will be collected from the sulci around the implants using the paper point technique before, 6 and 12 months after the prosthetic procedure .
The submucosal microbiome will be sequenced by Illumina.
Patient centered satisfaction will be assessed by treatment outcome, and quality of life (VAS, OHIP-49) after 12 months or earlier if the restoration fails.
To evaluate clinical parameters [pocket probing depth (PPD), bleeding on probing (BoP) will be recorded.

A nutrition diary will assist in understanding the erosive and discoloration potential of the patient*s diet. Patients will be asked to fill this out during month 1 , month 6 and month 12. The researcher responsible for the evaluation will send the patients the list on line or on paper depending on the patient*s wishes.

Follow-up per patient: Total treatment time: 1 year
Duration of intervention per patient: 1 year
Study population:
80 Patients treated with Straumann implants

Primary study parameters/outcome of the study:
Failure of the restaurationrestoration
Secundary Secondary study parameters/outcome of the study (if applicable):
discoloration
Plaque retention of the restoration
condition of soft tissue surrounding the restoration
Nature and extent of the burden and risks associated with participation, benefit and group relatedness (if applicable):
Burden consists of time involved. Procedure is identical to golden standard so no higher risk involved. No direct benefit for participants.

Study objective

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Follow-up per patient: Total treatment time: 1 year
Duration of intervention per patient: 1 year

Intervention

A 3D printed crown will be placed on a dental implant and stay in the mouth for one year

Study burden and risks

Burden consists of time involved. Procedure is identical to golden standard so no higher risk involved. No direct benefit for participants.

Contacts

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ADR

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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 that received a Straumann implant at the dental school as part of graduate students training and education are also prosthetically restored by students and one specific member of staff at ACTA. Patients with an implant in (pre)molar sites will be included for this study. ;These patients will all receive a 3D printed crown (Next Dent material) which they will have in their mouth for 12 months. After 12 months this crown will be unscrewed and replaced by another.

Exclusion criteria

Only patients who do not agree to participate or who are not willing or able to fill in the evaluation forms will be excluded from this study.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	80
Type:	Anticipated

Medical products/devices used

Generic name:	Crown/ fixed partiel denture
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-06-2018
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	NL61750.029.17