Immediate Loading and Fully Guided Surgery: Single Implants

NCT04061694

Includes: ***Study protocol, English short version translation from Swedish.***

Date of ethical approval: 2015-11-13

Study protocol approved 2015-11-13.

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Study protocol

Prospective non-randomized clinical trial to be conducted in accordance with the Helsinki declaration of 1975 as revised in 2000.

Study protocol to be sent to was approved by the Regional Ethical Review Board in Lund, Sweden (Dnr 2015/671).

Patients referred to the Centre of Dental Specialist Care, Malmö to be consecutively considered for inclusion.

The control group (IL) inclusion of at least 20 patients.

Digital planned, fully guided-surgery and immediate loading group (DIL) inclusion of at least 20 patients.

Power calculation: 80.6%, group size 20.

Inclusion criteria as follows:

1. At least 18 years old.
2. In need of a single-tooth replacement of an incisor, canine or pre-molar in the maxilla.
3. Signed informed consent.

Exclusion criteria as follows:

1. General health contraindications for oral surgery.
2. Inadequate oral hygiene, defined as a full-mouth plaque score of above 25%.
3. In need of bone grafting or ridge augmentation

Immediate loading group (IL)

The control group (IL) 25 immediately loaded (IL) dental implants. Treatment included conventional surgery, dental implants (Tapered Internal, BioHorizons, Birmingham, AL), immediate loading with temporary restorations that are fabricated manually immediately after surgery and final restorations in situ 2 months after surgery.

Digital planned, fully guided-surgery and immediate loading group (DIL)

The DIL group to be subjected to an intraoral scanning of the maxilla and antagonist arch performed with an IOS (Trios 3, 3Shape A/S, Copenhagen, Denmark). Cone beam computed tomography (CBCT) (ProMax 3D, Planmeca Oy, Helsinki, Finland) of the implant site.

Guided surgery: Guided surgery software (Implant Studio, 3Shape, Copenhagen, Denmark). The implants to be positioned optimal in relation to a predesign of the prosthetic restoration and thereafter the appropriate implant diameter and length selected for each individualy.

The surgical guides (E-Shell 600 Clear, Deltamed GmbH, Friedberg, Germany), made with additive technology, using a digital light processing (DLP) 3D printer (Vida, EnvisonTEC GmbH, Gladbeck, Germany). Master cylinder sleeve (BioHorizons, Birmingham, AL) incorporated into each surgical guide. The surgical guides to be submitted to cold sterilization according to the material suppliers' guidelines.

The temporary restorations finalised (Dental Designer, 3Shape, Copenhagen, Denmark) according to the intended prosthetic design and 3D printed (E-Dent 400, EnvisonTEC GmbH, Gladbeck, Germany).

Surgery protocol DIL

Implant should be placed into healed bone (at least 4 months after tooth loss) in sites that are free from clinical signs of inflammation/infection.

Prior to surgery a single-preoperative dosage of 2 g amoxicillin.

Installed using a guided surgery kit (BioHorizons, Birmingham, AL), mucosal tissue at the implant site removed with a soft tissue punch from the guided surgery kit, no mucoperiosteal flaps.

The installation torque to be registered for each implant and resonance frequency analysis (RFA), measured as the implant stability quotient (ISQ).

The temporary restorations to be immediately mounted onto the dental implants. Adjust to light centric contact and free from eccentric contacts, make necessary adjustments to approximal contacts points.

Postoperatively: 0.2% chlorhexidine for 14 days.

Definitive prosthesis procedure DIL

Two months after surgery, intraoral scanning (Trios 3, 3Shape A/S, Copenhagen, Denmark).

The final screw-retained single implant crown: Titanium base abutment (BioHorizons, Birmingham, AL) and a zirconia crown (BruxZir, Glidewell Labratories, Newport Beach, CA).

All laboratory procedures to be performed by the same team of dental technicians and all prosthetic procedures to be performed by one person.

Assessments

DIL and IL baseline and follow-up examinations (3 and 12 months) to be conducted by the same person responsible for the prosthetic treatment

Subsequent assessments of radiographs and aesthetics to be performed by an examiner not involved in patient treatment and blinded to patient group allocation.

Radiographic and soft tissue

Marginal bone loss (MBL) at baseline and 12 months.

Digital intra-oral periapical radiographs (Schick Digital X-ray Sensor, Sirona, Salzburg, Austria) using the long-cone parallel technique.

The marginal bone level measurements to be calibrated using the inter-thread distance of the dental implants (1.00 mm). The Image J software (National Institute of Health, Bethesda, MD) to be used for all measurements.

Implant success and survival evaluated according to Albrektsson et al. 1986/1993 after 12 months.

The gingival index (GI) by Löe and Silness 1963, baseline, 6 and 12 months.

The papilla index by Jemt 1997, baseline, 6 and 12 months.

Change in gingival zenith position and papilla levels measured from intraoral scanning's acquired following delivery of the temporary restoration, completion of the final restoration, and at the 3 and 12 months follow-up visits for DIL. Photographic measuring technique used for the IL group has been described by Gjelvold et al. 2017.

Aesthetics

Photographs (Nikon D7000, Nikon Corporation, Tokyo, Japan) are to be taken at definitive crown placement and at the 3 and 12 months follow-up appointments.

Pink esthetic score (PES) according to Fürhauser et al. 2005.

White esthetic score (WES) according to Belser et al. 2009.

Perfect outcome and aesthetic failure considered according to Cosyn et al. 2012.

Patient-centred considerations

The validated Swedish version of the Oral Health Impact Profile (OHIP-14) according to Hägglin et al. 2007. Recorded at the following appointments: pre-surgery visit; after two months with the temporary crown; on the 12 months follow-up. The additive score to be used.

Visual analog scales (VAS) used to assess patient perceived aesthetic satisfaction, pain and discomfort. The aesthetic outcome scored by the patients at the same appointments as OHIP-14. Pain

and discomfort scored after the surgery and impression appointments. The patients to mark their decision on a non-numerical 100 mm line ranging from "not at all satisfied, severe pain and severe discomfort = 0” (left) to “very satisfied, no pain and no discomfort = 100" (right). Each response then to be given a numerical value by measuring in millimeters the distance from the left end of the line.
For OHIP-14 and VAS the patient are to be given the same oral and written information and then left alone to complete the questioners in private.

Implant deviation from the planned implant position

For the DIL group datasets from guides surgery software and intraoral scans after fixture installation to be used to measure implant deviation. The following parameters are to be calculated: deviation at entry point, measured at the center of the implant (in mm); deviation at apex, measured at the center of the implant apex (in mm); angular deviation (in degrees); deviation in vertical implant position (in mm, + deviation in coronal direction); and deviation in horizontal implant position (in mm).