A Randomised Controlled Clinical Trial comparing the results of the Immediate Loading (within 48 hours) of Mandibular Overdentures supported by either 2 standard Straumann dental implants or 4 Mini Dental Implants (MDIs).

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

Summary

ID

NL-OMON38808

Source
ToetsingOnline

Brief title
RCT on 2 different immediate loading protocols to support overdentures

Condition

- Other condition
- Head and neck therapeutic procedures

Synonym
edentulous mandible (lower jaw)

Health condition

de edentate mandibula (prothese met weinig retentie)

Research involving
Human

Sponsors and support

Primary sponsor: ACTA DENTAL RESEARCH BV
Source(s) of monetary or material Support: 3M ESPE

Intervention

Keyword: DENTAL IMPLANTS, IMMEDIATE, LOADING, MINI

Outcome measures

Primary outcome

The primary outcome of the study is to analyse the marginal bone loss around immediately loaded standard Straumann implants and Mini Dental Implants used to support mandibular overdentures.

Secondary outcome

1.Clinical parameters related to implants

*plaque index

*bleeding index

*probing depth

*assessment of soft tissue.

2.The level of satisfaction of the patients in terms of function, aesthetics, phonetics, mastication, retention of the dentures anchored with the different implant types and the overall quality of life before and after treatment will

be also investigated.

3.Frequency and type of technical complications of the superstructure

4.Cumulative implant success rate

Success will be based on clinical and radiographic criteria to describe implant performance as defined by Albrektsson et al. 1986 and adapted by Buser et al. 1997 as well as Karoussis et al. 2004, Roos-Janseker et al. 2006a, b, and Renvert et al. 2007:

*Absence of persistent subjective complaints (pain, foreign body sensation and/or dysaesthesia)

*Absence of recurrent peri-implant infection with suppuration

*Absence of mobility

*Absence of a continuous radiolucency around the implant

*No PPD * 5mm and bleeding on probing (POB)

*Peri-implant bone loss *1.5 mm during the first year of function. After the first year of service, the annual vertical bone loss should not exceed 0.2 mm (mesially or distally)

5.Cost analysis

Study description

Background summary

Implant-retained overdentures are an established treatment option to improve oral health-related quality of life in edentulous patients. (1-5). The most common protocol used is the implant-retained overdenture treatment which includes placement of 2 implants in the anterior region of the mandible. There is now overwhelming evidence that 2 implants splinted with a rigid interconnected bar that incorporates an attachment mechanism for the retention of the overdenture is a viable option for rehabilitation of the edentulous mandible (6-12). Immediate loading with mandibular overdentures is a protocol in which implants are connected to the prosthesis within 1 week after implant placement (4th ITI Consensus Conference).The immediate loading of implants with overdentures was first reported by Ledermann (13,14), where 4 implants supported an overdenture.

The initial treatment protocols were based on several prospective studies that have been published on immediate loading of implants supporting overdentures in the edentulous mandible, most of them related to four or more implants (15-20). The proposed advantages for such loading protocols with shorter healing times prior to implant loading are a reduction in the number of surgical and prosthodontic procedures, associated clinical time, healing periods, treatment costs and an improvement of the patients quality of life. Immediate or early loading of 2 implants in the edentulous mandible to support an overdenture has also been investigated in the literature (21-26). Stoker and Wismeijer (27) describe in a recent article an immediate loading protocol where the overdenture is inserted within 48 hours after implant surgery. The implant survival rate in these studies is more than 95%. An alternative to standard or narrow diameter implants in the edentulous mandible is the use of Mini Dental Implants (MDIs). The MDI is a one-piece implant that does not require a separate abutment. This simplifies the restorative phase resulting in reduced costs for the patient. Although initially MDIs were used for temporary prosthetic stabilization during the healing phase of standard implants (28-30) their reproducible success has expanded their use. Recently they have been used for long term fixed and removable prosthetics (31). Griffitts et al. 2005 (32) placed 116 MDIs in the anterior zone of the mandible. The reported success rate for the implants was 97.4% whereas a great improvement was mentioned by the patients with regard to retention of the prosthesis, chewing ability, comfort in a comparison of questionnaires completed pre-operatively and at five months post-operative. In a cost benefit analysis the authors concluded that the cost of four (4) MDIs was equivalent to one conventional implant. Shatkin et al. (33) have placed 2514 MDIs over a period of 5 years with an overall survival of 94.2%. The literature review shows that the *Mini Dental Implant* has the potential of substituting the current standard care for the edentulous mandible (2 implant overdenture) and can be a viable alternative to the current treatment. In case of narrow ridges the alternative to mini implants is an augmentation of the ridge in order to provide adequate bone width for placement of conventional implants (34). Compared to an augmentation procedure, the use of MDIs is a significantly less invasive procedure resulting in reduced bleeding, decreased postoperative discomfort and shortened healing time. If the research outcome shows that this treatment is viable then it might be a

solution particularly suited for medically compromised patient. That means patients who would otherwise be excluded as a result of health problems that preclude extensive surgical procedures can benefit from implant treatment resulting in an improvement in the quality of their lives. Naturally further research will be necessary to prove this. Clinical and radiographic outcomes of immediately loaded MDIs used for long term stabilization of overdentures as an alternative to standard sized implant overdentures have been already published in the literature (35,36).

The cumulative survival and success rates of MDIs were 96.4% and 92.9% respectively. Although the mini dental implant has a reduced surface area compared with a conventional dental implant histology has shown that the percentage bone to implant contact for MDI is comparable to conventional implants. The narrow diameter of the MDI allows a simplified insertion technique involving placement without raising a flap (43). To summarize, the benefits of providing an implant overdenture on mini implants include the fact that the treatment is cheaper (of course the cost is not relevant with regards to The Nederlands because the insurance will cover the cost, but in other countries this can be a significant advantage) and it is simpler (the prosthetic part requires less appointment and of shorter time). If we prove that their clinical performance is as good as the clinical performance of the standard treatment, then the MDIs can be a viable alternative because of the aforementioned extra advantages. However, a Randomised Controlled Clinical Trial to compare the clinical performance of MDIs with an already well documented treatment modality has not yet reported in the literature.

Study objective

In this randomized controlled clinical trial we aim to apply the-already investigated-concept of immediate loading protocol and examine the performance of implant-retained overdentures using 2 SLAactive Straumann implants connected by bar (Contol Group), versus 4 MDIs with ball attachments (Test Group) in comparable situations. To be able to randomize both treatment modalities, a minimum width of 5.5mm of residual ridge is required with regard to surgical requirements to accommodate the wider diameter Straumann implants (3.3mm) in both the control and the test group.

Study design

Following comprehensive discussion about the aims and objectives of the study, risks-cost/benefits, advantages and disadvantages of each treatment option an informed consent will be signed and each patient will undergo a complete dental examination.
Patients who are deemed eligible for the study after this initial screening will be asked to undergo a more detail examination by the investigator. An overview of the 6 phases of the study procedures is shown in the flow chart of

study procedures.

1.EXAMINATION OF THE PATIENT
A summary of these procedures is shown in the flow chart of the examination of the patient.
a.Comprehensive History A thorough and systematic history and examination of the patient will ensure that all relevant information is recorded. History will include:
*History of the present complaint
*Dental History
*When the natural teeth were extracted
a.The reasons for the extractions
b.The occurrence of any surgical complications
c.The number of dentures that have been worn subsequently
d.The degree of success or failure of the dentures
e.The degree of adaptation of the patient
*Medical History
*Social History
The patients will be presented with self administered questionnaires of the VAS type on denture functioning, satisfaction, speech, aesthetics, retention, mastication and social functioning. They will also be presented with questionnaires on somatisation and depression, parafunction activities, and overall quality of life before and after treatment. These questionnaires will be presented again 3 months after the dentures have been placed and again after 1, 2 and 4 years.

b.Clinical examination

Extraoral Examination
*TMJ pain or discomfort
*Skeletal relationship
*Occlusal Vertical Dimension (OVD)
*Dental appearance (during speaking, smiling)
*Extra-oral lesions (inflammation, angular stomatitis)
*Intolerance or other difficulties with the dentures

Intraoral examination:
The broad objectives of this part of the examination are to determine:
*Any pathology such as mucosal inflammation, ulceration, hyperplasia, herostomia
*The shape and size of ridges and hard palate
*The depth and width of the sulci, including the presence of prominent frena
*The degree of compressibility of the denture-bearing mucosa determined by palpation

c. Examination of the dentures
Each denture will be examined in the mouth separately for:

*Retention
*Stability
*Border extension
The dentures are then examined together to assess the:
*Occlusion
*Occlusal vertical dimension
*Appearance

d.Radiographic examination Preliminary radiographic examination (OPT) which will provide some general information for evaluating residual lesions and the amount of bone available.

2.FABRICATION OF NEW DENTURES
Before proceeding with the fabrication of the new dentures any inflammation of the denture-bearing mucosa will be treated.
Stages:
1.Preliminary impressions will be taken with alginate using metal trays
2.Master impression will be taken using customized trays (light cured acrylic resin will be used) for the particular patient after border moulding. The impression material will be an addition-cured silicone material
3.Jaw relations recording. We will make sure that:
*The rims are stable
*There is adequate freeway space
*An consistent retruded jaw relationship is established
*There is even occlusal contacts
*There is a pleasing appearance with the rims in the mouth and the lips brought together
4.Choice of teeth (colour, shape and size of the artificial teeth)
5.Try-in stage to ensure that the patient is happy with appearance, phonetics, function. The type of occlusion provided will be lingualised occlusion
6.Provision of final dentures. In the prosthesis an radiological marker will be incorporated for future radiographic reference.
7.Review appointment.
8.Dental Hygiene Instructions
The need for meticulous cleaning will be explained to the patient and the methods for carrying it out will discussed, demonstrated and subsequently monitored both at this and consequent stages.

A period of at least 3 weeks will be allowed prior to surgery for overall evaluation of the prostheses by both the patient and the clinician and also to let patients adapt to their new prosthesis.

3.PRESURGICAL PROCEDURES
Under local anesthesia the thickness of the mucosa will be measured, using a modified UTC 15 modified probe. Due to the limitation of OPTs in accurate treatment planning (e.g. distortion) we intend to make a CBCT for each patient prior to implant placement which will facilitate a precise radiographic

diagnosis.
The new mandibular denture will be copied and a diagnostic template using radiopaque teeth will made which the patient will wear during the CBCT. In this way the exact amount of bone and shape of the ridge in the planned implant position will be calculated. This is in accordance with the EAO guidelines (Cone Beam CT for dental and maxillofacial radiology, Evidenced Based Guidelines 2011). Although the relative risk of exposure to radiation during the period of the study is extremely low, in order to reduce even further the exposure of the patient to radiation, we intend to narrow the field of view in the intraforaminal region, since this localized part of the lower jaw is our region or interest. The patient will be then allocated randomly in Control and Test treatment groups.

4.SURGICAL PROTOCOL
A summary of these procedures is shown in the flow chart of the surgical protocol.

Control Group .(3.3mm Straumann Implants)
A crestal incision in the mandible will be made. The mucoperiosteum will be elevated and the bone gently drilled to prepare osteotomy sites for the implants. Where appropriate, the crestal jawbone will be trimmed to provide an adequate site for implant placement. Two SLActive straumann implants of 3.3 mm diameter will be placed tightened with a torque of at least 35 Ncm. The distance between the 2 implants will be approximately 20 mm to allow fabrication of a bar superstructure.
ISQ measurements will be made at the levels of the implant and the abutment using an Osstell Mentor device and a Smartpeg (type 4; ref. 100350) (Osstell AB, Göteborg, Sweden). The ISQ measurements will be made parallel and perpendicular to the bone crest in the buccolingual direction, and parallel to the bone crest in mesial*distal direction, as advised by Osstell.
Themucoperiosteal flaps will be sutured in place with non resorbable sutures.

Test group (MDIs)
All surgeries will be carried out under Local Anesthesia.
*4 implants with diameter 2.1 mm (3M ESPE Mini Dental Implant) will be placed interforaminal.
*Immediate loading with metal housing only if primary stability is above 35 Ncm.
*The selection of the implant would depend on the thickness of the mucosa.
If > 2mm the collared type implant will be used
If <2mm the non collared type implant will be used
*In the test group where the ridge has sufficient width a flapless, transgingival technique for the pilot drill will be used. In case of mobile mucosa the 1.5 mm tissue punch is going to be used prior to using the pilot drill. The MDI implants will be placed into the bone by a self tapping compression technique.
*Small modifications on the surgical preparation of the MDI implant bed will be

made dependent on the density of the bone at the surgical site, according to the manufacturer recommendations.

All implants will be inserted in the symphysial area under local anesthesia. The new dentures will act as a drilling template.

5.RESTORATIVE PROTOCOL

Immediately after surgery the existing mandibular dentures will be hollowed out. Following confirmation of impression copings seating, a pick up impression will be made with the denture serving as a customised tray. This will be sent to the laboratory and the impression will be poured in dental stone.

The patient will be administered paracetamol as an analgesic and sent home to return later in the day or the day after for the insertion of the bar and the overdenture.

An egg shaped Dolder bar (CMST53012P20, Cendres et Métaux SA, Biel, Switzerland) will be fabricated and returned to the clinic at the same day. The SynOcta gold copings (048.204, Straumann AG) will be soldered and the retention clip mounted in the lower denture.

After passive fit of the bar is confirmed in the patient*s mouth, the overdenture will be inserted. In the test group the new denture will be fitted with the O-ring attachments following the prescribed protocol within 48 hours after implant placement. The overdenture will be adjusted following a relining procedure in the laboratory.

Postoperative Instructions

During the first night, the patient will be instructed to wear the overdenture, which acts as a pressure bandage for optimal wound healing. For the following 3 weeks, the patient will be instructed not to wear the overdenture at night. The patient will be permitted to eat with the overdenture in place, but will be advised to avoid biting hard food. No further restrictions will be imposed. On the first postoperative day, a control visit will be planned to check for possible denture problems and wound healing. The patient will be instructed how to remove the overdenture and how to disinfect the mouth, the wound, and the superstructure with 0.12% chlorhexidine (4 times a day for 5 days). The patient will be advised to begin brushing the bar twice daily after 3 days. One week after surgery, the sutures will be removed.

6.FOLLOW UP

*Standardised per apical X-rays will be taken at implant insertion, after 12, 24 and 36 months. Standardized periapical radiographs will be obtained with the long-cone technique and a standardized jig locator at a 10cm film to cone distance.

Test group: for standardisation of radiographic film position in relation to the beam during subsequent film exposures, an acrylic resin bite registration record with compound rim will be constructed over the resultant cast on which the denture will be rebased to capture the matrices. The maxillary denture teeth indentations on the compound rim will be used for future orientations of

the film holder. The film holder will be attached to the record base with self-cure acrylic resin to obtain standardised intraoral radiographs.
Control group: radiographs will also be obtained with appropriate aiming devices for standardised images for marginal bone level follow-up in the transversal plane.
All radiographs will be exposed using the same X-ray unit with an exposure factor of 70 kvp, 8 mA, and 0.25 exposure time. All films will be processed using an automatic machine.
For the radiographic analysis we will use the subtraction technique.

*Periodontal parameters will be documented in a standardized method evaluating the scenario of the treatment at three months, six months, one year and at yearly intervals thereafter. These parameters are:
oPlaque and bleeding index according to Mombellli et al.
oMarginal bone height
oProbing depth. These are all measured at the buccal, distal, lingual and mesial postion around the implant.
Using the Ostell mentor Resonance Frequency Analysis device the ISQ value of the implants will be tracked over time (1, 6 weeks after surgery and then at 3, 6, 12, 24, 36 months). In all groups the measurements will be done at abutment level. The measurements that will be made at weeks 1 & 6 will be performed only at the abutment level to avoid the risk of rotating the implant when dislodging the abutment. A percussion-sounding or implant-sounding test will be used as a subjective control. Twelve weeks after surgery, the ISQ measurements will be made at both the implant and the abutment level. The SynOcta abutment will be retightened at 35 Ncm.
An independent colleague will evaluate the patients (will perform the periodontal measurements, record the ISQ values and register the results of the questionnaires into the computer).

Intervention

Immediate loading (within 48 hours) of two interconnected implants with an overdenture (Control group) Immediate loading (within 48 hours) of 4 mini implants and an overdenture in patients with adequate bone width (test group).

Study burden and risks

As any other type of oral rehabilitation the provision of implant-retained overdentures requires a regular and ongoing maintenance program to ensure long term clinical success. This requires patient*s understanding, compliance and commitment during the whole study period. The surgical risks involved in the aforementioned treatment modalities provided will not exceed those of other conventional surgical procedures in the same region of the oral cavity. Some minor postoperative pain and discomfort will be expected in both the control and the test group. The most severe complication during surgery is the

perforation of the lingual plate and subsequent damage of the lingual artery. The literature shows that this complication is extemely rare(*0,1%), , and the possibility of this occurring will be even lower due to the comprehensive clinical and radiographic examination. Altered sensations of the mental nerve caused by the surgery is also another complication that might occur. These complications are also rare. The meticulous and thorough clinical and radiographic planning will reduced further the chance of this happening. Early complications after surgery include lack of osseointegration and loss of the implant. The literature has shown that the 5 year success rate of the implants in the edentulous mandible is well above 95%. Later complications can be either biological (e.g. peri-implant diseases) or technical complications. Every care will be taken to minimize these complications to occur. The patients however will be informed of the fact that a strict maintenance protocol is important to detect potential complications at an early stage.
A vast improvement in terms of function, mastication, retention and overall quality of life is expected for the treated patients. For the patients allocated to the test group, the procedure is potentially less invasive and the pain and discomfort may be reduced. The patients will be placed in a maintenance program for several years, in an academic environment in which a high level of care is provided. *

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 that have been completely edentulous for at least 6 months.
*Patients that have a maladaptive mandibular denture
*Patients that have enough bone volume for an implant length of at least 10 mm and diameter of 3.3 mm measured on a CBCT
*Presence of a maxillary complete denture
*Presence of keratinised tissue around the proposed implant site
*Presence of suitable bone quality (type 1-3) as assessed radiographically (Lekholm & Zarb classification)
*The patient agrees to a treatment allocation in any of the two groups
*The patient is willing and able to give informed consent

Exclusion criteria

*Insufficient bone volume (<5,5mm).
*Presence of local inflammation of the mucosa
*Presence of oral mucosal diseases
*Active intraoral infections
*History of bruxism
*Physical and mental disabilities which interfere with the maintenance of implants
*Smokers (more than 1 cigarette per day)
*Abuse of drugs or alcohol
*Patients who have already received or lost implants
*Patients who received radiotherapy to the head or neck region for malignancies
*Patients who undergo chemotherapy
*Patients on long term steroids, immunosuppressants, or bisphosphonates
*Insulin dependent diabetic patients and uncontrolled onset diabetic patients as diagnosed by their doctor
*Patients affected by chronic renal or liver diseases
*Systemic and local bone disorders and pathology
*Serious cardiac and pulmonary disorders
*Patients with haemophiliac disorders who are susceptible to increased bleeding and tendency for post-operative infections
*Patients at risk of developing bacterial endocarditis
*Immuno-compromised patients, including those with HIV

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2013
Enrollment:	64
Type:	Anticipated

Medical products/devices used

Generic name:	Mini Dental Implants (MDIs) and Straumann dental implants which are placed in the edentulous mandibl
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-09-2013
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	NL45037.029.13