A multi centre randomized controlled clinical trial comparing conventional loading of an overdenture on two implants with a bar to immediate loading of an overdenture on two implants with a bar.

Published: 07-11-2008
Last updated: 08-05-2024

There is no long term prospective clinical research based on the principle of direct loading (within 24 hours) of overdentures on 2 implants with a bar in the mandible. Recently, for the period of 12 months, a pilot study has been carried out...

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

Summary

ID

NL-OMON31470

Source
ToetsingOnline

Brief title
Active in one day

Condition

- Other condition

Synonym
Oral implantology in edentulous patients

Health condition

Edentate proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Ministerie van OC&W,Straumann AG (CH) 30%

Intervention

Keyword: - 2-Implant overdentures, - Immediate loading, - multi centre study, - randomized controlled clinical trial

Outcome measures

Primary outcome

During several points in time, the following parameters are registered:

- patient satisfaction

- total treatment costs

- total treatment time

- total prosthetic aftercare

- bone level around implants by the use of standardized x-rays

- periodontal parameters

- implant stability

Secondary outcome

Microbiolologic annd genetic factors that might play a role in the etiology of

peri-implant infection.

Study description

Background summary

Recent literature shows that implant supported prostheses are a significant improvement when compared to conventional prostheses. A lower jaw with severe resorption frequently causes problems, functionally as well as socially.
Several authors describe treatment concepts for the edentulous mandible, such as an overdenture on two implants, attached by balls or by a bar. In addition, an overdenture on 4 implants attached by a bar and a rigid bridge on 4 or more implants are described. There is an agreement in literature that the use of overdentures on 2 implants is a reliable treatment modality in the edentulous mandible.
Overdentures on 2 implants interconnected by a bar are an improvement in patient satisfaction and quality of life when compared to full conventional prostheses. Moreover, these overdentures seem to be a financially favorable treatment option when compared to the alternative options mentioned above. A number of authors even have the opinion that this option is to be preferred when treating the edentulous mandible.
For a long period, an osseointegration phase of 3 to 6 months was considered to be essential to accomplish predictable treatment outcomes. Recent clinical and experimental research regarding early and direct loading have actually revealed that successful osseointegration can be accomplished. Furthermore, a lot has been published about topography and chemical additions of the implant surface. Both aspects are able to enhance osseointegration. Certain surfaces, such as those of SLActive implants, have a positive effect on primary implant stability. Possible advantages of shorter healing times prior to implant loading are a reduction in treatment time, lower costs and higher patient satisfaction. However, there is still no consensus because of a lack of long term prospective research.

Study objective

There is no long term prospective clinical research based on the principle of direct loading (within 24 hours) of overdentures on 2 implants with a bar in the mandible. Recently, for the period of 12 months, a pilot study has been carried out including 64 healthy adults. No complications were revealed.
The good results of the pilot have been the motivation to start a multi centre randomized controlled clinical trial. Conventional loading (after 6 weeks) of an overdenture on 2 standard SLA implants with a bar are compared to direct loading of the similar construction on 2 SLActive implants.
In addition, microbiological and genetic factors are studied that might play a role in the etiology of peri-implant infections.

Study design

A multi centre randomized controlled clinical trial

Study burden and risks

After selection based on determined criteria, 92 patients are allocated at random in 2 treatment centres. During several points in time, the following parameters are registered:
- patient satisfaction
- total treatment costs
- total treatment time
- total prosthetic aftercare
- bone level around implants by the use of standardized x-rays
- periodontal parameters
- implant stability

The estimated extra time amounts to 1 hour a year.

Contacts

Public
Vrije Universiteit

Louwesweg 1
1066 EA Amsterdam
NL
Scientific
Vrije Universiteit

Louwesweg 1
1066 EA Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

1) The study object must be fully edentulous for a minimal period of 1 year.
2) The study object must have a minimal intraforaminal bone height of at least 8 mm measured on a lateral cephelometric radiograph.
3) The study object must agree to a treatment allocation in any of the two groups.
4) The study object must have suitable bone quality as assessed radio graphically (Lekholm & Zarb 1985).
5) The implants must be initially stable and inserted with at least 35 ncm torque.

Exclusion criteria

1) Physical and mental disabilities which interfere with the maintenance of implants;
2) Severe skeletal jaw discrepancies
3) Severe clenching habits
4) Those that have already received or lost implants
5) Those who abuse drugs or alcohol
6) Having received radiotherapy to the head and neck region for malignancies
7) Heaving smokers (more than a packet a day)
8) Undergoing chemotherapy
9) Systemic and local bone disorders and pathology
10) Immuno-compromised patients, including those with HIV

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-11-2008
Enrollment:	92
Type:	Actual

Ethics review

Approved WMO Date:	07-11-2008
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	NL16723.029.07