Masticatory performance, maximum bite force and maximum mouth opening in patients treated with Biomet microfixation total joint prostheses: a cross-sectional study

Published: 24-04-2018
Last updated: 12-04-2024

The main aim of this study is to get insight in postoperative clinical results such as masticatory performance, maximum bite force, maximum mouth opening, pain, mandibular function and patient satisfaction in patients with an alloplastic TJR TMJ (...

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

Summary

ID

NL-OMON46696

Source
ToetsingOnline

Brief title
Oral function in patients treated with a total joint prosthesis

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
Biomet microfixation total joint prosthesis, jaw joint prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Oral function, total joint prosthesis

Outcome measures

Primary outcome

The masticatory performance will be measured by the mixing ability test. It measures how well a subject can mixe a red-blue wax tablet (size of a peppermint) by chewing on it.

Secondary outcome

(1) The bite force transducer will be used to measure the maximum bite force (MBF).

(2) To measure the maximum active and passive range of motion of the jaw opening, participants will be asked to open their mouth to the maximum and all measured values will be recorded between the front teeth with a metal ruler.

(3) The Visual Anologue Scale (VAS) will be used to assess the pain level from score 0 mm 'no pain' to score 100 mm 'worst imaginable pain'. Before measurements and during chewing, maximum bite force, and maximum mouth opening.

(4) Patients satisfaction with the replacement will be determined using a VAS. This will be rated between 0 mm 'absolutely dissatisfied' and 100 'completely satisfied'.

(5) To evaluate subjective impression of daily oral function the mandibular function impairment questionnaire (MFIQ) will be used.

Study description

Background summary

Patients with temporomandibular dysfunction (TMD) are normally treated with conservative, non-surgical methods. However, if intra-articular disorders are not responding to conservative therapies, and patients suffer from severe, chronic temporomandibular joint (TMJ) pathology*s, patients may benefit from surgery. One of the surgery options that is becoming more popular worldwide is an alloplastic total joint replacement (TJR) of the TMJ. An alloplastic TJR TMJ is a surgical option that involves reconstruction of both the mandibular condyle and temporal bone fossa. Important goals of this surgery include improvement of mandibular function, reduction of pain and suffering and also improvement of masticatory performance. Promising results have been documented including subjective data related to pain, quality of life, the perception of mandibular function and diet consistency and also about objective data such as maximum mouth opening (MMO) and maximum voluntary bite force. A recent study indicated that to the year 2030 there will be an increasing demand for the use of TJR devices in the United States. Also in Europe there is an increased demand for the use of TJR TMJ devices. Thus making the outcomes of this intervention worthy for further evaluations.
To our knowledge objective masticatory performance has not been evaluated in the literature. Patients with end-stage TMJ pathologies commonly suffer from impaired masticatory performance and an allplastic TJR TMJ might change this. Therefore, it is important to evaluate the objective masticatory performance, to determince how an alloplastic TJR TMJ influences the masticatory system.

Study objective

The main aim of this study is to get insight in postoperative clinical results such as masticatory performance, maximum bite force, maximum mouth opening, pain, mandibular function and patient satisfaction in patients with an alloplastic TJR TMJ (Biomet Microfixation systems). The second aim is to determine if masticatory performance can be explained by maximum bite force, maximum mouth opening, pain, and/ or patient satisfaction. It is important to investigate these outcomes, because it may contribute to a better understanding of the results and management after replacing the temporomandibular joint.

Study design

Cross-sectional study

Study burden and risks

The objective tests will take at maximum 20 minutes, 5 minutes per objective

test (chewing, maximum bite force, and passive and active maximum mouth opening). The burden of these tests are minimal for the participents; chewing 20 times on wax, clenching four times as hard as you can on a biteforce transducer, and to open twice your mouth as wide as possible. The subjective tests will take at maximum 30 minutes (MFIQ and VAS scales). So in our opinion the burden is minimal. There are no specific advantages or risks for the participants in this study, because the physical burden is minimal and so the consequences for the participants are nihil.

Contacts

Public
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
's Hertogenbosch 5223 GZ
NL
Scientific
Jeroen Bosch Ziekenhuis

Henri Dunantstraat 1
's Hertogenbosch 5223 GZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(1) unilateral or bilateral total joint reconstruction of the temporomandibular joint
(2) absence of postsurgical trauma

(3) signed an informed consent

Exclusion criteria

(1) edentate
(2) patients who don*t speak and understand Dutch or English.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-07-2018
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2018
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL65072.028.18