Long-term follow-up after Instrumented Bone Preserving (IBP) total elbow arthroplasty using RadioStereometric Analysis (RSA).

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The purpose of this study is to determine the survival rates of the IBP total elbow prosthesis, to give insight into the migration pattern of the IBP prosthesis and to evaluate the predictive value of early migration for future revision, loosening...

Ethical review	Approved WMO
Status	Pending
Health condition type	Bone and joint therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON43113

Source
ToetsingOnline

Brief title
Long-term follow-up IBP prothesis using RSA

Condition

- Bone and joint therapeutic procedures

Synonym
elbow arthroplasty, elbow prosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: eigen middelen Sint Maartenskliniek

Intervention

Keyword: elbow, IBP prothesis, RSA

Outcome measures

Primary outcome

The main study outcome is the survival rate of the IBP elbow prosthesis.

Micromotion of the implant will be evaluated using RSA. The migration values

obtained at two years follow-up will be used to investigate the relation

between early migration (first two years postoperatively) and revision,

loosening and pain

Secondary outcome

Secondary endpoints include range of motion, Elbow Function Assessment, Elbow

Functional Rating Index, Oxford Elbow Score and VAS satisfaction.

Study description

Background summary

Radiostereometric Analysis (RSA) enables measurement of micromotion of orthopaedic implants. A relation between early micromotion and future aseptic loosening has been demonstrated for total hip and knee prostheses. Regarding the elbow joint four RSA studies have been performed presenting short-term results. Unfortunaletly long-term results are lacking and a predictive value of early migration is not yet known. Between 2003 and 2006 16 IBP elbow prostheses analysed using RSA, were described with a follow up time of two years. In the present study we will investigate the long-term results (> 10 year follow-up) of this cohort. The results are of great importance for the evaluation of elbow prosthesis in the long-term and further evaluation of the role of RSA and the investigation of the predictive value of early migration in the elbow joint.

Study objective

The purpose of this study is to determine the survival rates of the IBP total elbow prosthesis, to give insight into the migration pattern of the IBP prosthesis and to evaluate the predictive value of early migration for future revision, loosening and pain. The secondary objective is to present the clinical and functional outcomes 10 years after implantation of the IBP total elbow prosthesis.

Study design

This follow-up study is a prospective study of a historic cohort.

Study burden and risks

Patients are asked to visit our clinic once, prior to a regular follow up appointment. The extra amount of time that a patient invests in the study is about 1 hour. Prior to the visit patients are asked to fill in the questionnaires. During the visit RSA radiographs will be taken and a physical examination will be performed. The questionnaires and physical examination will not bring any additional burden for the patient. The total amount of radiation of the RSA radiographs fall within the limits of the International Commission of Radiological Protection (ICRP).

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

- Received an IBP total elbow prosthesis between June 2003 and February 2006.
- Participated in the study assessing the short-term results of the IBP total elbow prosthesis
- Sign informed consent for the proposed study.

Exclusion criteria

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Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-10-2016
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO

Date:	25-10-2016
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL59132.048.16