Anchor Peg - RSA study: stability of a glenoid component

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The purpose of this study is to evaluate whether the Anchor Peg Glenoid provides adequate stability in the first en second year after surgery. Therefore, the migration pattern is determined after 3, 6. 12 and 24 months. The correlation with...

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

Summary

ID

NL-OMON33888

Source
ToetsingOnline

Brief title
Anchor Peg RSA

Condition

- Bone and joint therapeutic procedures

Synonym
osteoarthritis, shoulderprosthesis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Johnson & Johnson

Intervention

Keyword: Glenoid, RSA, Stability, Total shoulder arthroplasty

Outcome measures

Primary outcome

The main study parameter is stability as measured with Radio Stereometric

Analysis (RSA)

Secondary outcome

The secondary study parameters are:

radiographic evaluation

radiolucency, scored through a modification for pegged components of the

Franklin system, grading radiolucent lines bordering keeled components grade of

glenoid component seating

pain, scored through 10-cm Visual Analog Scale (VAS)

functional outcome, scored through Constant-Murley Score, Nederlandse Schouder

Test, DASHscore

Study description

Background summary

A painful shoulder is a symptom of diseases such as osteoarthritis and rheumatoid arthritis. These conditions are characterized by degeneration of articular cartilage and subchondral bone with diminished glenohumeral joint space. It can significantly decrease the functional capacity of these patients and even lead to the patient*s becoming fully dependent on others.
The goals of treatment include reduction of pain and improvement of function. Optional treatments for these patients are conservative treatment (analgesics) and Shoulder Arthroplasty. With regard to shoulder arthroplasty, the most important goals are the stability of the joint, pain free movement, and sufficient range of motion (ROM) for activities of daily living (ADL). The

primary benefit from such surgery is pain reduction. The principle disadvantage of treatment with a total shoulder arthroplasty is the possible loosening due to wear particles or contact stresses on the glenoid component.
Radiolucent lines on plain radiographs are not reliable for early loosing. When traditional radiographs are used for assessment, the rate of early loosening is underestimated. Radiostereometric analysis (RSA) is recommended to be used for this. [1,2,3]
The Anchor Peg Glenoid (DePuy International Ltd.) is an all-polyethylene, minimally cemented, pegged glenoid prosthesis. It features a circumferentially fluted, central, interference fit peg for tissue integration and three small, cemented, peripheral pegs. This glenoid is designed to improve fixation, compared to conventional all-polyethylene keeled and pegged glenoids.

Study objective

The purpose of this study is to evaluate whether the Anchor Peg Glenoid provides adequate stability in the first en second year after surgery.
Therefore, the migration pattern is determined after 3, 6. 12 and 24 months.
The correlation with radiolucency iwill be evaluated, scored on regular X-rays.
Clinical functioning is registered.

This study intends to answer the following questions:
What is the migration pattern of the Anchor Peg Glenoid ?
Is the design sufficient to guarantee stability and good clinical performance ?

Study design

Prospective, observational (cohort) RSA study

Study burden and risks

Patients visit the clinic 6 times in 2 years. The intervantion is th usual (standard) procedure with foloow ups and measures. The only difference is the RSA. The RSA is used to follow the process of migration and states the risc for early loosening.

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

· Patient presents with shoulder osteoarthritis and requires a TSP.
· Patient reports moderate to severe pain in affected shoulder.
· Patient is 18 to 80 years of age.
· Patient is in stable health and is free of or treated and stabilized for cardiac, pulmonary, hematological, or other conditions that would pose excessive operative risk.

Exclusion criteria

· Patient diagnosed with posttraumatic osteoarthritis of the shoulder.
· Patient has an active, local infection or systemic infection.
· Patient has a BMI >35.
· Patient has physical, emotional or neurological conditions that would compromise the patient*s compliance with postoperative rehabilitation protocol follow-up (e.g.: drug or alcohol abuse, serious mental illness, or general neurological conditions such as Parkinson, Multiple sclerosis, etc.).
· Patient is pregnant or plans to become pregnant during the course of the RSA study.
· Patient suffering postoperative complications such as infections, recurrent luxations, non compliance with normal postoperative care /

rehabilitation program.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2009
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	IRB Nijmegen: Independent Review Board Nijmegen (Wijchen)

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	NL21091.072.09