

# RESEARCH PROTOCOL

## **Hybrid versus poly-ethylene glenoid in stemless anatomical shoulder arthroplasty: A multicentre, prospective, non-inferiority randomized controlled trial.**

Short Title: poly versus hybrid glenoid in stemless aTSA

Protocol ID:

Date/Version 01-11-2024, version 5

Tjarco Alta: Orthopaedic Surgeon  
Michel van den Bekerom: Orthopaedic Surgeon  
Guus Janus: Orthopaedic Surgeon  
Paul Kuijer: Human Movement Scientist\  
Joost Willems: Orthopaedic Surgeon  
A. Akchi Masjediy: Coordinating Investigator  
Olivier van der Meijden: Orthopaedic Surgeon  
Arthur van Noort: Orthopaedic Surgeon  
Marjolein Schager: Research Coordinator  
Inger Sierevelt: Clinical Epidemiologist

### **Sponsor**

Spaarne Gasthuis,  
Spaarnepoort 1  
2134 TM  
Hoofddorp

### **Financial support**

Limacorporate spa  
Via Nazionale 52  
33038 Villanove di San Daniele (Udine), Italy

**PROTOCOL TITLE**

A randomised, multicentre, prospective, non-inferiority clinical study analysing outcomes of a cemented pegged polyethylene glenoid component versus a hybrid polyethylene and trabecular titanium glenoid component in patients with osteoarthritis treated with an anatomical SMR stemless shoulder arthroplasty

<b>Protocol ID</b>	<b>A randomised, multicentre, prospective, non-inferiority clinical study analysing outcomes of a cemented pegged polyethylene glenoid component versus a hybrid TT glenoid component in patients with osteoarthritis treated with an anatomical SMR stemless shoulder arthroplasty</b>
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<b>Coordinating investigator/project leader</b>	<i>Joost I.P. Willems MD</i> <i>p/a Medische Kliniek Velsen</i> <i>Leeghwaterweg 1b</i> <i>1951 NA Velsen Noord</i> <i>Tel. 085 - 0600855</i>
<b>Principal investigator (in Dutch: hoofdonderzoeker/uitvoerder)</b>	<i>A. van Noort MD PhD</i> <i>p/a Spaarne Gasthuis</i> <i>Spaarnepoort 1</i> <i>2134 TM Hoofddorp</i> <i>Tel. 023 – 224 64 59</i>
<b>Independent expert</b>	<i>J. van Aken MD</i> <i>Rheumatologist</i> <i>Spaarne Gasthuis</i> <i>jvanaken@spaarnegasthuis.nl</i>

**PROTOCOL SIGNATURE SHEET**

<b>Name</b>	<b>Signature</b>	<b>Date</b>
<b>For non-commercial research</b> <b>Head of Department:</b> <i>P.A. Nolte MD PhD</i> <i>p/a Spaarne Gasthuis</i> <i>Spaarnepoort 1</i> <i>2134 TM Hoofddorp</i> <i>Tel. 023 – 2246453</i>		
<b>Principal investigator:</b> <i>A. van Noort MD PhD</i> <i>p/a Spaarne Gasthuis</i> <i>Spaarnepoort 1</i> <i>2134 TM Hoofddorp</i> <i>Tel. 023 – 224 64 59</i>		
<b>Coordinating investigator/project leader</b> <i>J.I.P. Willems MD</i> <i>p/a Medische Kliniek</i> <i>Velsen</i>  <i>Leeghwaterweg 1b</i> <i>1951 NA Velsen Noord</i> <i>Tel. 085 – 060 0855</i>		

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**LIST OF ABBREVIATIONS AND RELEVANT DEFINITIONS**

<b>ABR</b>	<b>ABR form, General Assessment and Registration form, is the application form that is required for submission to the accredited Ethics Committee (In Dutch, ABR = Algemene Beoordeling en Registratie)</b>
<b>AE</b>	<b>Adverse Event</b>
<b>AR</b>	<b>Adverse Reaction</b>
<b>aTSA</b>	<b>Anatomic Total Shoulder Arthroplasty</b>
<b>CA</b>	<b>Competent Authority</b>
<b>CCMO</b>	<b>Centrale Commissie Mensgebonden Onderzoek</b>
<b>CMS</b>	<b>Constant Murley Scale</b>
<b>CV</b>	<b>Curriculum Vitae</b>
<b>EU</b>	<b>European Union</b>
<b>EQ-5D</b>	<b>Euro Qol</b>
<b>GCP</b>	<b>Good Clinical Practice</b>
<b>HADS</b>	<b>Hospital Anxiety and Depression Scale</b>
<b>IC</b>	<b>Informed Consent</b>
<b>METC</b>	<b>Medical research ethics committee (MREC); in Dutch: medisch ethische toetsingscommissie (METC)</b>
<b>OSS</b>	<b>Oxford Shoulder Score</b>
<b>(S)AE</b>	<b>(Serious) Adverse Event</b>
<b>SSV</b>	<b>Subjected Shoulder Value</b>
<b>SUSAR</b>	<b>Suspected Unexpected Serious Adverse Reaction</b>
<b>VAS</b>	<b>Visual Analog Scale</b>
<b>Wbp</b>	<b>Personal Data Protection Act (in Dutch: Wet Bescherming Persoonsgegevens)</b>
<b>WMO</b>	<b>Medical Research Involving Human Subjects Act (in Dutch: Wet Medisch-wetenschappelijk Onderzoek met Mensen)</b>
<b>WORQ-UP</b>	<b>Work-Related Questionnaire for UPper extremity disorders</b>
<b>WAS</b>	<b>Single-item Work Ability Score</b>

## 1. INTRODUCTION AND RATIONALE

Shoulder arthroplasty is a proven procedure for the treatment of severe glenohumeral osteoarthritis to relieve pain and restore shoulder function. Anatomic total shoulder arthroplasty (aTSA) is the preferred treatment in patients with symptomatic osteoarthritis and an intact rotator cuff. The weakest link in total shoulder arthroplasty is the glenoid component. Despite the fact that good functional long-term outcomes have been described with cemented polyethylene glenoid components as the gold standard, complications related to these components are frequent, with (aseptic) loosening as a very common inevitable complication in the long term.<sup>1-3</sup> There is an urgent necessity to improve the survival of these glenoid components and therefore new designs and fixation methods were developed. The uncemented metal back glenoid component was used in an attempt to address this problem using a coated back side combined with additional screw fixation. However, multiple studies have shown there is an unacceptable high failure rate when compared to polyethylene glenoids, which created a shift back to using cemented polyethylene implants.<sup>4-7</sup> In an attempt to overcome the high glenoid loosening rates in cemented polyethylene glenoids, several companies have developed a hybrid glenoid component, which in most cases consists of a polyethylene glenoid with a porous metal central peg which promotes bony ingrowth. In the short term, hybrid glenoid components result in excellent improvements in ROM and patient-reported outcomes with complication and revision rates comparable to all-polyethylene glenoid component.<sup>8,9</sup> The aim of this study is (1) to assess clinical and radiographic outcomes after an anatomic SMR stemless prosthesis with either a cemented polyethylene pegged glenoid component, or a hybrid Trabecular Titanium (TT) glenoid component; (2) to report failure rates and complications; and (3) to identify possible risk factors that may lead to failure. Our primary hypothesis is that a hybrid TT glenoid component shows good clinical

and radiological outcome when compared to a standard cemented pegged all polyethylene glenoid. Our secondary hypothesis is that the hybrid TT glenoid improves the longevity of the implant by reducing failure and loosening rates.

## **2. OBJECTIVES**

### Primary Objective:

The primary objective of this study is to evaluate the difference in functional outcome, measured by the Constant Murley score in the short, medium and long term after treatment with a SMR stemless humeral part of an aTSA combined with a cemented pegged polyethylene glenoid component - versus a SMR TT hybrid glenoid component of an aTSA in patients with osteoarthritis of the shoulder.

### Secondary Objective:

Secondary outcome measures to measure the primary objective are the range of motion, OSS, SSV, VAS (pain), EQ-5D, HADS, WORQ-UP, WAS, return to work, and difference in implant survival in the mid and long term between both groups. Standardised radiologic measurements will be used to evaluate any signs of loosening or implant failure. Complication and revision rates will be compared.

### **3. STUDY DESIGN**

This study is designed as a randomized controlled trial to evaluate the difference in functional and radiographic outcome after operative treatment using a stemless total shoulder arthroplasty system with either a cemented polyethylene glenoid component (group 1) or a hybrid TT component (group 2) and identify possible risk factors that may lead to failure. The inclusion and first evaluation will be performed by the orthopaedic surgeon at any of the three participating hospitals located in the Netherlands. After informed consent is obtained, the patients will be randomly allocated into one of the two groups. Both groups will follow a standardized physical therapy program after the intervention. Randomisation will be done using the randomisation computer programme Research manager. At baseline, 6 weeks, 3 months, 1y, 2y, 5y, 7y and 10 y, postoperatively, relevant outcome data are collected through clinical evaluation performed by the orthopaedic surgeon or physician assistant. Standard radiographs of the shoulder are made at baseline, and during the above-mentioned control moments. Both the patient and the researcher present during follow-up will be blinded to the type of prostheses implanted and the results of the outcome scores.

### **3.1 Research team**

- Principal investigator: A. van Noort, MD PhD, orthopaedic surgeon
- Coordinating investigator: J.I.P. Willems, MD, orthopaedic surgeon
- Co-author: A. Akchi Masjediy, medical student.
- Co-author: M.P.J. van den Bekerom, MD PhD, orthopaedic surgeon
- Co-author: T.D.W. Alta, MD PhD, orthopaedic surgeon
- Co-author: G. Janus, MD PhD, orthopaedic surgeon
- Co-author: O. van der Meijden, MD PhD, orthopaedic surgeon
- Co-author: I. N. Sierevelt, MSc, clinical epidemiologist
- Co-author: P.P.F.M. Kuijer, MSc PhD, human movement specialist work
  
- Ms. M. Schager, Mth, research coordinator
- Mrs. N. Miedema, nurse practitioner / Mr. P. Spruit, physician assistant

## **4. STUDY POPULATION**

### **4.1 Population (base)**

The study population consists of a maximum number of 94 treated patients to be recruited during an enrolment period of 36 months. Patients will be selected for recruitment into the study requiring a primary anatomic shoulder arthroplasty, due to symptomatic painful degenerative joint disease (primary osteoarthritis) with sufficient bone stock and an intact rotator cuff. A subject is considered to be enrolled in the study, if compliant with inclusion/exclusion criteria and agrees to sign the informed consent. Subjects who do not meet the inclusion criteria or meet any exclusion criteria are excluded from the study participation. These subjects will nevertheless be registered in order to assess potential selection bias. It is required to properly report all subjects enrolled in the study on the Screening & Enrolment Log.

Only patients withdrawn within the enrolment period because of revoking consent or because the investigator deems it necessary due to the clinical condition may be substituted.

### **4.2 Inclusion criteria**

In order to be eligible to participate in this study, a subject must meet all of the following criteria:

1. Both genders;
2. Age  $\geq$  18 years old;
3. Life expectancy over 5 years;
4. Patient has symptomatic shoulder osteoarthritis for more than 1 year and is submitted to previous conservative non-surgical treatments;

5. Patient is requiring primary unilateral or staged bilateral anatomic arthroplasty based on physical examination, medical history and X ray examination. (In cases where bilateral aTSA's are indicated, the patient will be included for the second aTSA again when the patient meets the inclusion criteria);
6. Good bone quality evaluated by the investigator on the basis of a risk factors analysis and the intraoperative estimation;
7. A diagnosis in the target shoulder of osteoarthritis; according to the classification of Walch, the glenoid should be a type A1, A2 or B1. Retroversion should not exceed 15 degrees.
8. Patient is willing and able to complete scheduled follow-up evaluations as described in the Informed Consent;
9. Patient has participated in the Informed Consent process and has signed the Informed Consent form previously approved by the Ethics Committee.

#### **4.3 Exclusion criteria**

1. Patient requiring revision shoulder arthroplasty;
2. Osteoporosis with a history of non-traumatic fractures;
3. Steroid injections within the previous 6 months;
4. Contralateral shoulder replacement within the previous 3 months;
5. Meta-epiphyseal bony defect (including large cysts);
6. Significant proven or suspicious infection of the target shoulder or any serious infectious disease
7. Significant neurological or musculoskeletal disorders that may compromise functional recovery;
8. Known or suspicious hypersensitivity to the metal or other materials of the implant;

9. Unwillingness or inability (i.e. alcoholism, infirmity) to comply with rehabilitation and to return for follow-up visits and any psychiatric illness that would prevent comprehension of the details and nature of the study;
10. Any systemic disease which may affect outcome.
11. Active or metastatic neoplastic disease
12. Chemotherapy and/or radiotherapy within the last 6 months
13. Previous organ transplant
14. Participation in any clinical research study that may interfere with this study
15. A current or prior DSM-5 diagnosis of schizophrenia, delusional disorder, schizoaffective disorder, psychotic disorder or bipolar disorder.
16. Current substance use disorder (excluding nicotine/tobacco use disorder) or moderate or severe alcohol use disorder.
17. Imminent suicide risk.
18. Any other psychiatric condition that renders the individual unsuitable for the study according to the study physicians judgment

#### **4.4 Sample size calculation**

In this non-inferiority study the Constant Murley score will be used as the primary outcome measure. Based on a previous reported minimal clinically important difference (MCID) of  $12.8 \pm 2.5$  points in anatomic shoulder arthroplasty at a mean 3.5 years follow-up, as reported by Simovitch et al.<sup>10</sup>, the non-inferiority limit of the difference between the two designs was set at 10 points. If non-inferiority is proven, secondary testing for superiority will be performed.

When the sample size in each group is 42 participants, a two group one-sided 0.025 significance level t-test will have 80% power to reject the null hypothesis that the hybrid glenoid and poly-ethylene glenoid are not non-inferior (the difference in means is 10 or farther from zero in the same direction) in favour of the alternative hypothesis that the means of the two groups are non-inferior, assuming that the expected difference in means is 0 and the common standard deviation is 16.<sup>11,12</sup>

When considering a dropout of 10%, this will add up to a total of 94 patients (47 per group).

There is a slight possibility that patients may require intraoperative conversion to a reverse total shoulder arthroplasty if a significant cuff lesion is present. However, this risk is minimal due to a thorough preoperative clinical and radiologic assessment. It's important to note that this potential risk is already considered in the expected 10% dropout rate.

## **5. TREATMENT OF SUBJECTS**

### **5.1 Investigational treatments**

The surgical procedure is conducted by an orthopaedic surgeon qualified by training, with a vast experience in primary shoulder arthroplasty, and familiar with the appropriate use of the components involved in this clinical evaluation. Before conducting this study, all surgeons were trained with the use of the SMR stemless prosthesis including the hybrid glenoid and are sufficiently experienced.

Whether the patient is deemed eligible for a stemless anatomic prosthesis is decided by the investigator, and is dependent on patient's pathology and comorbidities. It is decided during preoperative planning; however, it can be modified at any time before or during the surgery if the investigator notices any clinical condition or complication not related to the investigational device. This decision is independent and clearly differentiated from the decision to include the patient in the study. If a decision is made to exclude a patient, it will be recorded and mentioned separately.

Once a patient is included in the study according to the eligibility criteria, they are submitted to primary shoulder arthroplasty as described below.

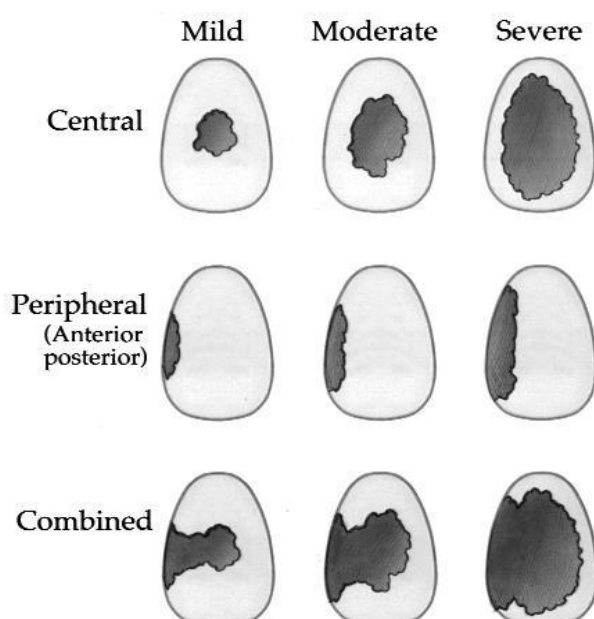
All the operations in each center will be performed by the same surgeons, and according to proper standardized surgical technique.

Type of anaesthesia, postoperative pain management, prophylactic antibiotics, the use and dose of tranexamic acid, surgery time and surgical approach will be provided as instructed by the investigators, according to the standard practice and will be documented.

### Surgical technique

All procedures are performed through a deltopectoral approach. The choice of subscapularis management is made by the investigator and recorded. Following standard exposure, the humeral and glenoid implants are placed with use of the implant specific instruments provided. After the humeral bone cut, the proximal humeral bone quality will be assessed and in case of clear insufficient bone quality, the patient will receive a stemmed implant and will be excluded from the study. At the glenoid side, cement is used for all pegs of the all-polyethylene glenoid component and for the 2 peripheral pegs of the TT hybrid component . Post-operatively, all patients will receive a sling and are required to participate in a rehabilitation protocol as prescribed by their surgeon. The physiotherapy treatment protocol is adapted to the national guideline.

Intraoperatively, glenoid bone loss will be classified on the basis of location and severity. Based on the location, the defects are categorized as central, peripheral (anterior or posterior), or combined (central and peripheral) deficiencies. Based on the severity, deficiencies are classified as mild if they involved less than one third of the glenoid rim or surface, moderate if they involved between one third and two thirds, and severe if they involved more than two thirds (Figure 1).



**Figure I.** Glenoid bone loss according to Antuna et al. <sup>13</sup>

## **6. METHODS**

### **6.1 Study parameters/endpoints**

#### **6.1.1 Main study parameter/endpoint**

The main study parameter is the shoulder function as measured by the Constant Murley Score. Both the absolute value and the gender and age adjusted value is recorded. An analysis for the primary endpoint will be conducted during the 1-year follow-up.

#### **6.1.2 Secondary study parameters/endpoints**

The remaining follow-up moments shall be analysed in hierarchical order and regarded as secondary. Secondary study parameters are the range of motion, Oxford Shoulder Score (OSS), Subjected Shoulder Value (SSV), Visual Analog Scale (VAS), Euro Qol 5 Dimensions questionnaire (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Work-related questionnaire for upper extremity disorders (WORQ-UO), Single-item Work Ability Score (WAS) and implant survival. Regarding subjective assessment of function and pain, two questions were included. Both questions are a 7-scale assessment of general daily function and pain complaints when compared to the preoperative status (very much worse, much worse, a little worse, unchanged, a little improved, much improved, very much improved). In order to assess any evidence for subsidence or loosening of the implant, thorough radiologic measurements will be performed at the periodic follow up, starting immediately postoperatively (baseline) and ending at 10 years postoperatively. The endpoint for survival is the detection of loosening of the prosthesis on radiological imaging. Any complications, whether related or unrelated to the implant, will be recorded and assessed.

#### **6.1.3 Other study parameters/endpoints**

Other study parameters that are recorded are demographic data (gender, age, BMI, operated side, ASA classification, smoking, workers compensation), type of profession and type of sports if applicable. Preoperative use and type of painkillers and/or antidepressants are recorded.

Additionally, the level of return to work is recorded (not able, partial/with adaptations, fully able) and the number of hours at work per week as compared to the preoperative hours and premorbid hours. First day of RTW is defined as: time in days from surgery to the first day of returning to work, regardless of the number of working hours, adaptations or tasks performed. Fully RTW is defined as: time in days from surgery to the first day of the week a patient works the number of hours stated in his or her employment contract. For self-employed patients, fully RTW is defined as: the first day of the week a patient works the number of hours equal to the number of hours he or she worked before surgery.

### ***Outcome measures***

#### **Constant Murley Score (CMS)**

The CMS evaluates four aspects of the shoulder; two subjective: pain and activities of daily living and two objective: range of motion and strength.<sup>14</sup> The patient self-reported section can score up to 35 points and the objective section used by medical professionals can score up to 65 points, both adding up to a maximum of 100 points (best function). An adjustment to the score was described by Katolik et al. to incorporate any differences related to gender and age.<sup>15</sup> This adjusted CMS is described as a percentage, 100% being the highest possible score. Both values will be recorded.

#### **Range of motion**

Active and passive range of motion (ROM) will be recorded in degrees for:

- Forward elevation;
- abduction;
- external rotation with arm at the side;
- external rotation in 90° of abduction;
- internal rotation with arm in neutral abduction;

- internal rotation with arm in 90° of abduction.

### **OSS score**

The Oxford Shoulder Score (OSS) is a 12-item patient-reported outcome specifically designed and developed for assessing outcomes of shoulder surgery.<sup>16</sup> A total score of 12 (best) to 60 (worst) can be obtained. It has been designed and developed by the Health Services Research unit in association with surgical colleagues at the Nuffield Orthopaedic Centre, part of the Nuffield Department of Population Health at the University of Oxford, who also created the Oxford Hip and Knee scores, which are used for assessment of all NHS hip and knee surgeries (approximately 120,000) since April 2009. The OSS has been tested in a surgical context with patients and shown to be reliable, valid and responsive. First published in 1996, the OSS has gradually been adopted as an outcome measure, validated in the Dutch language and is now widely used in clinical studies.<sup>17</sup>

### **SSV**

The Subjective Shoulder Value was developed by Gerber whom first reported using this value in 2000.<sup>18</sup> It is a single self-reported value, which is an estimation by the patient of the operatively treated shoulder as a percentage of the value for an entirely normal shoulder (that is, 100 percent).

### **VAS**

The Visual Analogue Scale is first developed by Freyd in 1923.<sup>19</sup> Since then it has been a popular measure for analysing the level of pain the patients experience at that particular moment. It is a self-reported patient reported scale from 0-10, 0 resembling no pain and 10 resembling the worst pain imaginable.

### **EQ-5D**

EQ-5D (EuroQol Research Foundation) is a standardised 5-item measure for overall health status developed by the EuroQol Group, which was formed by the UK, the Netherlands, Finland, Sweden and Norway, as a measure to quantify quality of life with a single numeric value.<sup>20</sup>

The EQ-5D contains 2 parts: the first part is the EQ-5D-5L descriptive system, consisting of questions regarding mobility, self-care, usual activities, pain/discomfort and anxiety/depression. The respondent can answer these by ticking a box in one of 5 possible answers, being: no problems, slight problems, moderate problems, severe problems, and extreme problems. The second part is the EQ Visual Analogue Scale (EQ-VAS) which records the respondents self-rated health on a 20 cm, visual analogue scale with endpoints labelled 'the best health you can imagine' and 'the worst health you can imagine', which corresponds to a grading of 0-100.

## **HADS**

The Hospital anxiety and depression scale (HADS) is developed by Zigmond in 1983.<sup>21</sup> The HADS is a self-assessment mood scale specifically designed for use in non-psychiatric hospital departments. The 14-part questionnaire distinguishes between the concepts of anxiety and depression, with each composing 7 questions. The overall severity of anxiety and depression are rated on a four-point Likert scale (0-3), with a maximum score of 21 for both subsections. The subscale scores are 0-7 (no anxiety or depression), 8-10 (possible anxiety or depression) and 11-21 (probable anxiety or depression). The Hospital Anxiety and Depression Scale (HADS) is included because psychological distress can significantly impact pain perception and hinder recovery due to factors like catastrophizing and an exaggerated negative focus on symptoms.<sup>33</sup> To improve the efficiency of the estimation of the primary endpoint in the presence of severe psychiatric symptoms in participants, the following measures will be implemented:

1. We will exclude patients with severe psychiatric conditions, including schizophrenia spectrum disorders, bipolar disorders, acute suicidality, and severe substance use disorders.
2. We will administer the HADS at both baseline and follow-up assessments, without using clinical cut-off scores as exclusion criteria. If group differences in HADS scores are observed, these scores will be included as covariates in the statistical analysis.

This approach allows us to effectively monitor psychological factors and analyze their impact on treatment outcomes without unnecessarily limiting the inclusivity of the study population. By doing so, we preserve a significant degree of the study's generalizability and validity while accounting for important psychological influences on recovery and pain perception.

We will advise participants scoring above the clinical cut-off on the HADS (11 or higher) to seek assistance from their general practitioner (GP). With the participant's consent, we may also facilitate communication by providing the GP with relevant information

## **WORQ-UP**

The Work-Related Questionnaire for Upper extremity disorders (WORQ-UP) was developed in 2018 by Aerts et al. in order to measure to what extent patients with upper extremity musculoskeletal disorders experience limitations in their ability to work<sup>22</sup>. It comprises of 17 items which reflect work-related activities that can be limited by upper extremity disorders. Each item can be answered using a 5-point scale by the difficulty of the respondent to perform each item (1 being no difficulty at all, 5 being not possible to perform). If a patient did not perform an activity in their job, a score of 0 could be used (not applicable). The highest score that can be achieved is 85.

**Work Ability Score**

The Work Ability Score (WAS) is a single question score, which is the first question from the Work Ability Index questionnaire, originally developed in the 1980s at the Finnish Institute of Occupational Health (FIOH) as a tool to measure work ability.<sup>23</sup> It is a self-assessment of current overall work ability level (range 0–10) in comparison to lifetime best. A score of 0 to 5 is considered poor, 6 to 7 moderate, 8 to 9 good and 10 is considered excellent.<sup>24,25</sup>

## Radiographic Evaluation

In the preoperative analysis, radiological assessment includes standard views of the affected shoulder:

- true antero-posterior (AP) view with arm at side in neutral rotation (Grashey's view);
- axillary "truth" view. In this view, the patient's arm is elevated in the plane of the scapula while the beam is oriented in the plane of the scapula. Proper orientation is confirmed by visualizing the "eye" of the spinoglenoid notch (figure 2: blue arrow)



Figure 2. Axillary "truth" view

In order to assess and document the status of the cuff musculature, complementary imaging exams using either MRI or CT combined with ultrasound will be used. The choice of preferred imaging modality is at the discretion of the treating surgeon. Presence of any tears, degree of fatty infiltration or atrophy is carefully documented.

## Analysis and reporting of radiologic studies

### Preoperative:

There are inadequate objective metrics to evaluate bone quality sufficient for fixation of stemless shoulder arthroplasty preoperatively. Final implant selection is determined by intraoperative assessment of bone quality by using the thumb test (or index finger test), which implies putting gentle pressure of the thumb or index finger on the cut surface of the humerus to assess metaphyseal bone quality. If the thumb or index finger is easily pressed into the bone, the quality is deemed insufficient for implantation of a stemless implant.

Preoperative DTI has been determined by good ability (AUC of 0.86) to categorize patients as appropriate for stemless TSA.<sup>26</sup> DTI will be determined preoperatively on true antero-posterior (AP) view with arm at side in neutral rotation (Figure 3).

	View	Measurement	Formula	Cut-off Value	Diagnostic Accuracy	Condition
<b>Tingart Measurement</b>	AP	Two levels: where the proximal cortices first become parallel & 20 mm distal	$(A-B + C-D) \div (2)$	< 6	93% sensitivity, 52% specificity, 95% negative predictive value	Osteoporosis
<b>Deltoid-Tuberosity Index</b>	AP with IR	One level: just proximal to the deltoid tuberosity	$F \div G$	< 1.4	88% sensitivity, 80% specificity	Low-Humeral Bone Density



**Figure 3.** Deltoid tuberosity index

A. Glenoid morphology: Using the modified Walch classification.

*Glenoid morphology* is described according to the classification which was primarily proposed by Walch et al.<sup>27</sup>, which was later modified by Bercik et al.<sup>28</sup> (Figure 4):

Type A: the humeral head is centered, and the resultant strengths are equally distributed against the surface of the glenoid.

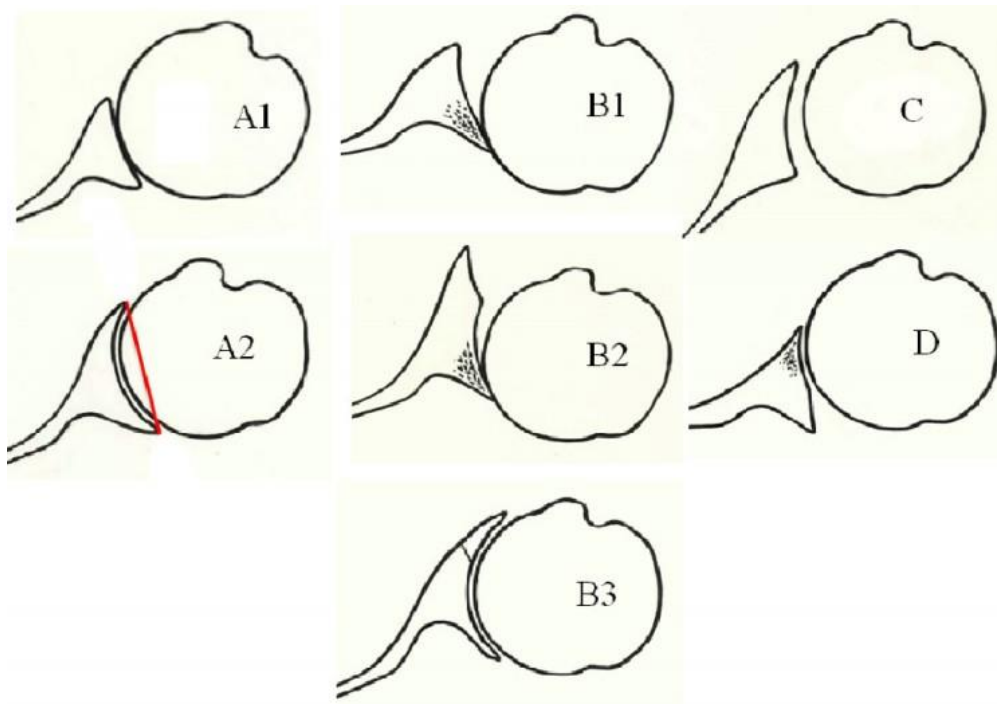
- Type A1: There is minor erosion.
- Type A2: Major erosion is present, which is only the case when a line drawn from the anterior to posterior rim transects the humeral head

Type B: the humeral head is posteriorly subluxated, and the distributed loads are asymmetric.

- Type B1 is characterized by a narrowing of the posterior joint space, subchondral sclerosis, and osteophytes.
- Type B2 presents a posterior cupula that gives a biconcave aspect of the glenoid.
- Type B3 glenoid is monoconcave and posteriorly worn, with at least 15° of retroversion or at least 70% posterior humeral head subluxation, or both.

Type C: has a dysplastic origin, humeral head is well centered or slightly subluxated posteriorly. At least 25° of retroversion is present, not caused by erosion.

Type D: A glenoid with any level of glenoid anteversion or with humeral head subluxation of less than 40% (i.e., anterior subluxation)



**Figure 4** Glenoid morphology according to the modified Walch classification<sup>27,28</sup>

- B. Glenohumeral osteoarthritis: OA recorded as being primary or secondary. Secondary causes such as post-traumatic, instability, inflammatory arthritis, osteonecrosis, neuropathic, cuff tear arthropathy. Additionally, the presence of osteophytes, subcortical cysts, osteochondral lesions, intraarticular bodies are recorded.
- C. AC joint and acromial arch: Record presence of ACJ OA and acromial bone spurs
- D. Fractures: Record the presence of acute and/or chronic fractures
- E. Measurements: Record neck-shaft angle, humeral head offset (HHO) between head and greater tuberosity, lateral glenohumeral offset (LGHO) between medial border coracoid and greater tuberosity.
- F. Prior surgeries: Record the presence of any current or previous orthopedic implant or procedure, including nails and screws, plates, wires, cement, or others.
- G. Rotator cuff status, evaluated using CT or MRI as:
- intact;
  - attenuated;

- minor tear (< 2 cm);
- large tear (2-5 cm)
- massive tear (> 5 cm).

Whenever possible, rotator cuff compromise is defined according to the Goutallier classification on preoperative images.<sup>29</sup> Rupture of the shoulder cuff tendons can induce a degeneration of cuff muscles, characterized by an infiltration of these muscles by areas of fat.

A grading of this so-called fatty degeneration was proposed in five stages:

- stage 0 corresponds to a completely normal muscle, without any fatty streak;
- in stage 1 the muscle contains some fatty streaks;
- in stage 2 the fatty infiltration is important, but there is still more muscle than fat;
- in stage 3 there is as much fat as muscle;
- in stage 4 more fat than muscle is present.

H. Others: Record the presence of deformities, bone lesions including tumors (benign or otherwise) and bone infarcts, and any other feature observed in the preoperative radiographs that may be relevant for preoperative evaluation.

#### Postoperative:

- I. Implant position/size, defined by the following parameters, and compared to pre-operative measures whenever applicable.
- humeral neck-shaft angle, measured using the method described by Beck et al<sup>30</sup>;
  - center of rotation measurements using the best fit circle method<sup>31</sup>;
  - humeral head offset (HHO), measured between head and greater tuberosity;
  - lateral glenohumeral offset (LGHO), measured between medial border coracoid and greater tuberosity;

## J. Radiolucent lines or osteolysis

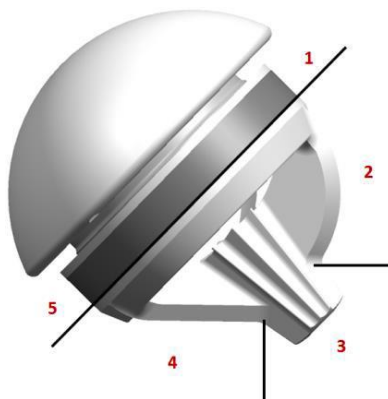
Presence and progression of glenoid and humeral component radiolucent lines or osteolysis.

Radiolucent lines are graded as follows:

- None
- 1 mm thickness
- 2 mm thickness
- >2 mm thickness

The location of radiolucent lines around the humeral head is described as follows (figure 5):

- Zone 1: Proximal area around the superior part of the trabecular structure of the taper
- Zone 2: Area superior to the curved fins
- Zone 3: Distal area around the mini-stem
- Zone 4: Area inferior to the straight fin
- Zone 5: Proximal area around the inferior part of the trabecular structure of the taper

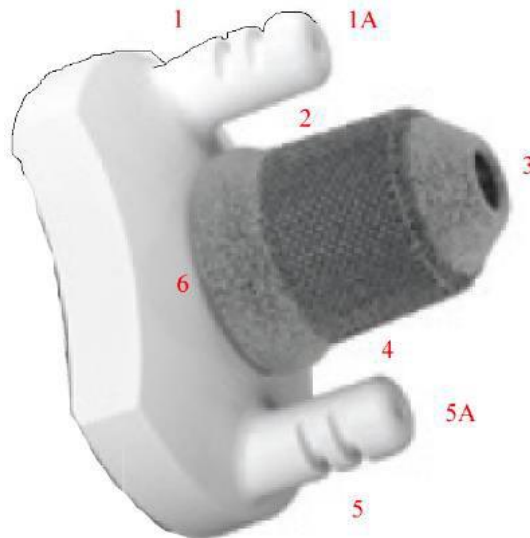


**Figure 5** Zones for radiolucent lines evaluation of the humeral component.

The location of radiolucent lines around the hybrid TT and polyethylene glenoid component is described as follows (figure 6a and 6b):

- Zone 1: Superior part of the base plate
- Zone 1A: Area surrounding the superior peg
- Zone 2: Superior part of the central peg

- Zone 3: Distal part of the central peg
- Zone 4: Inferior part of the central peg
- Zone 5: Inferior part of the base plate
- Zone 5A: Area surrounding the inferior peg
- Zone 6: Area around the central part of the base plate



**6a:** Evaluation of glenoid radiolucent lines of the hybrid TT glenoid component.

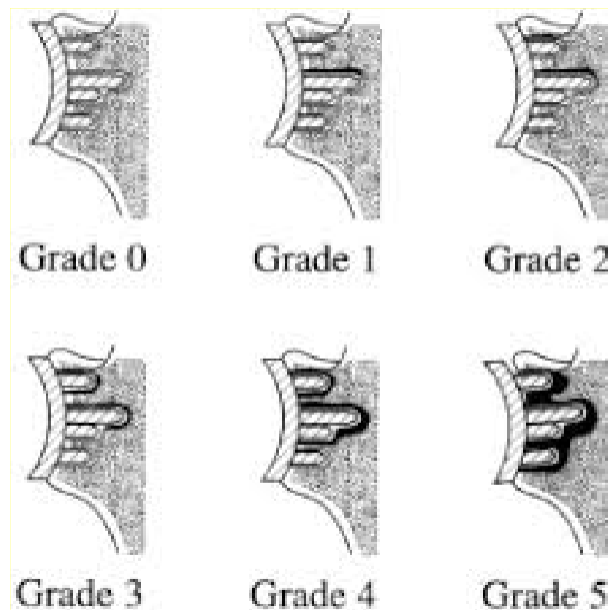


**6b:** Evaluation of glenoid radiolucent lines of the polyethylene glenoid component.

Additionally, at the glenoid side, RLLs are graded according to the Lazarus classification<sup>32</sup> (Figure 7).

- Grade 0: No radiolucency
- Grade 1: Incomplete radiolucency around one or two pegs

- Grade 2: Complete radiolucency ( $\leq 2$  mm wide) around one peg only, with or without incomplete radiolucency around one other peg
- Grade 3: Complete radiolucency ( $\leq 2$  mm wide) around two or more pegs
- Grade 4: Complete radiolucency ( $> 2$  mm wide) around two or more pegs
- Grade 5: Gross loosening



**Figure 7** The Lazarus radiologic classification of glenoid radiolucency.<sup>32</sup>

The seating grade, also developed by Lazarus et al, will be used in order to classify the seating of the glenoid (Figure 8).<sup>32</sup> The grades are as follows:

- Grade A: Complete component seating
- Grade B:  $< 25\%$  incomplete contact, single radiograph
- Grade C:  $25\text{--}50\%$  incomplete contact, single radiograph
- Grade D:  $< 50\%$  incomplete contact, both radiographs
- Grade E:  $> 50\%$  incomplete contact, single radiograph

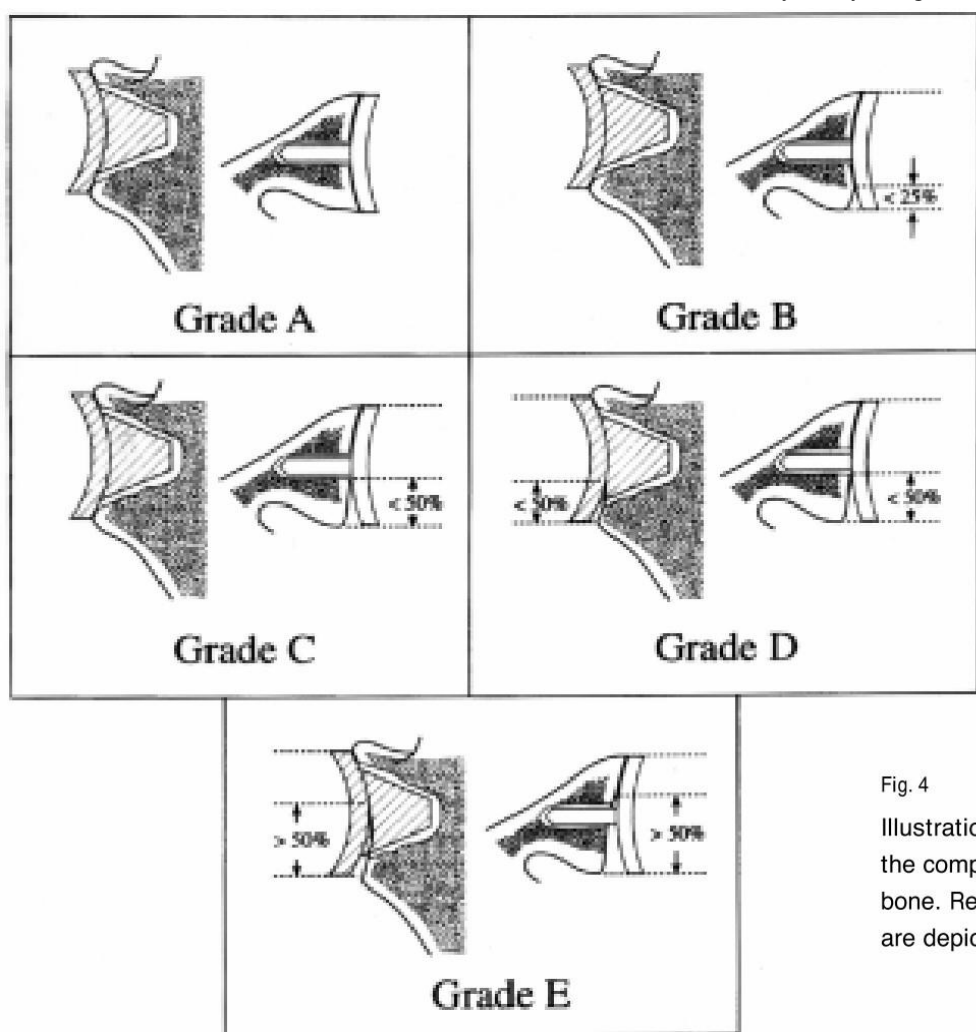


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**Figure 8** Classification of glenoid seating according to Lazarus et al.<sup>32</sup>

- K. Any change of implant position/subsidence: Using the radiographs, implant position and any abnormalities such as subsidence/migration, dissociation of components or subluxation/dislocation are described.
- L. Glenohumeral subluxation or dislocation, described using the axillary view, is classified as follows:
- None
  - Mild ( $< 25\%$  translation)
  - Moderate (25 - 50% translation)
  - Severe ( $> 50\%$  translation)

M. Risk of loosening: A component is considered to be radiologically at risk for

loosening in case of:

- Circumferential radiolucent line of at least 2 mm around the entire component (Lazarus grade 5);
- Grossly inadequate seating of the component (grade E);
- progression of radiolucent lines on serial radiographs;
- or component migration/dislocation.

N. Presence of fractures

O. Presence of other implants (nails, plates, rings, wires), these may be an indication of intraoperative or postoperative complications/adverse events

P. Presence and location of heterotopic ossification and other calcifications

The total radiation dose used in the context of the study has been calculated by the clinical physicist, Mr. Hugo Spruijt. In the standard situation, a total of 1 CT scan and 6 shoulder X-rays are taken. As part of the study, 2 additional shoulder X-rays are taken after 2 and 7 years. The radiation calculation utilized the international calculator (Radiation risks from medical x-ray examinations as a function of the age and sex of the patient, BF Wall et al., HPA-CRCE-028 (2011), [www.hpa.org.uk](http://www.hpa.org.uk)). The conversion factor the calculator uses for Shoulder AP is 0.064 (for Shoulder (axial), it is 0.046). Therefore, in the worst-case scenario, a patient receives 50 microGy.cm2 for a shoulder series, adjusted with the conversion factor for Shoulder AP, resulting in 0.032 mSv or 32 microSievert of ionizing radiation dose. The background radiation due to Earth and cosmic radiation in the Netherlands is approximately 6.8 microSievert per day. So, in a worst-case scenario, a series of shoulder X-rays adds an extra radiation exposure of about 5 times the background radiation in a day. This means that participation in the study results in an additional burden of 64 microSievert over 10 years. This amount is negligible and can be

compared to the background radiation exposure in 10 days to which every individual is naturally exposed.

## **6.2 Randomisation, blinding and treatment allocation**

To reach similar distribution of the experimental and control prostheses among the participating sites, stratified block randomization with variable block sizes will be applied, using the randomisation tool from Research Manager (Nova Business Software). Additionally, using this technique, the distribution in time is more equal between both groups. This software system is designed to facilitate clinical trials. The allocation to each group will be concealed and performed by the research assistant.

## **6.3 Study procedures**

Of the patients with clinical signs of osteoarthritis of the shoulder presenting at the orthopaedic outpatient clinic of the participating hospitals, the general history is acquired and standard radiographs are made. When the diagnosis primary osteoarthritis is made, and all inclusion criteria are met, patient information (written and oral) concerning this trial is provided to the patients. The patient will be given a week to consider participation. After one week the patient will be contacted by an independent research nurse and asked whether they wish to participate or not. After signing the informed consent, patients will be planned for surgery. Allocation of the patients to one of the two treatment groups will be done using Research Manager (Nova Business Software), and will be performed in the two weeks prior to the procedure. An attempt is made for all patients to plan for surgery within three months after inclusion in the study. If surgery is delayed for any reason beyond six months, repeat X rays will be made to assess if significant changes have occurred, and patients will be reassessed if the inclusion criteria are still met. Both groups will follow a standardized physical therapy program after the intervention consisting of physiotherapy sessions according to the national guideline including

active and passive exercise mobilization techniques to increase power and range-of-motion and prevent muscular deficit or imbalance. Aggressive range of motion and subcapularis stretching exercises are in any case avoided during the first 6 weeks.

Follow-up for the study will be at 6 weeks, 3 months, 6 months (only by telephone), 1y, 2y, 5y, 7y and 10y post-surgery. From 6 weeks postoperatively onwards, the patients are asked to fill out the various PROMS, the CMS score is calculated at each follow up moment from 3 months onwards. Several factors may influence pre – and postoperative PROMS. Use of medication will be recorded at every follow-up visit. A medical status will be recorded regarding complications and adverse events. Radiographs are made at each follow up moment. See table 1 for an overview of events.

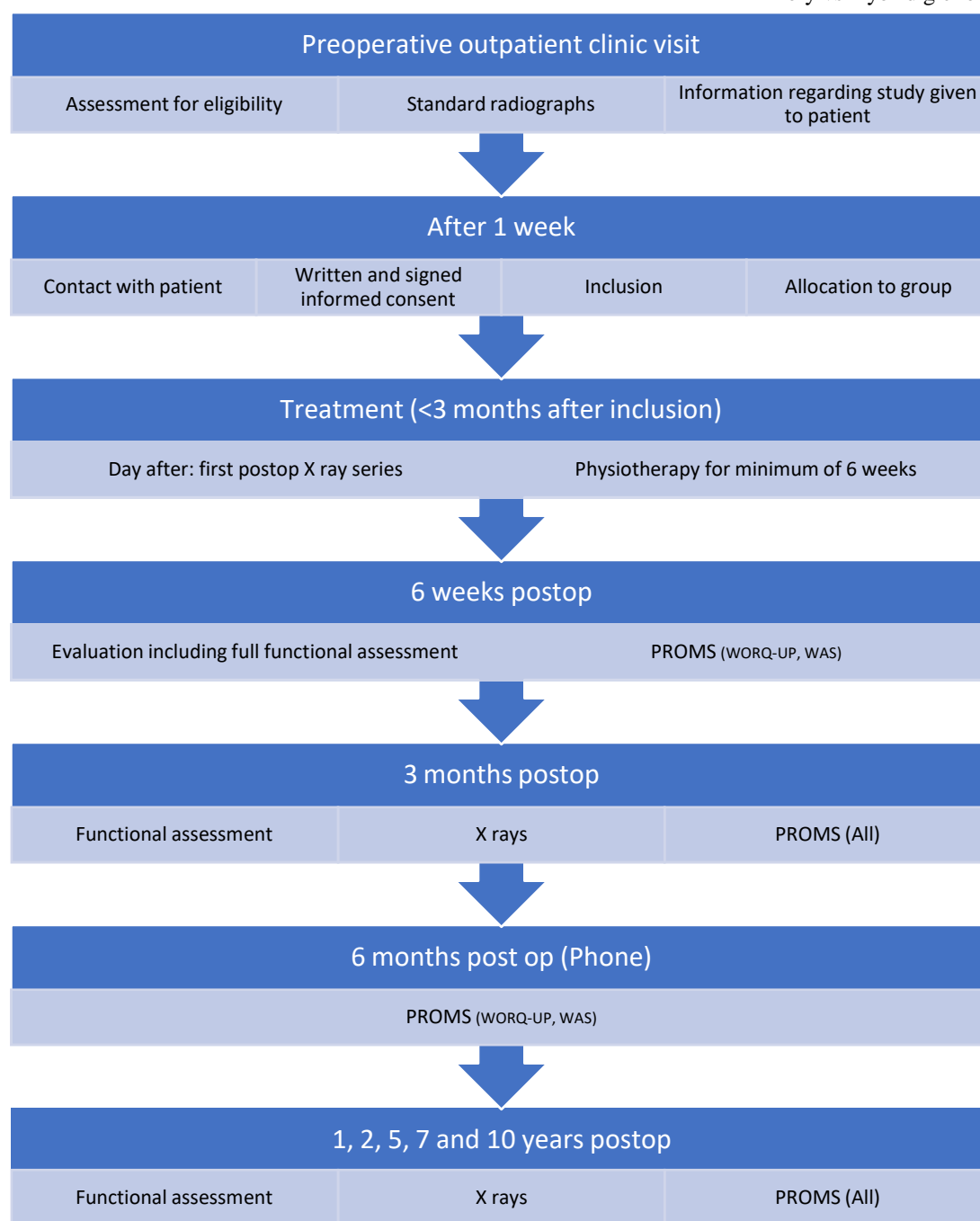


Table 1. An overview of the events.

The X-rays at 1, 5, and 10 years are part of standard care.

The X-rays at 2 and 7 years are conducted as part of the study.

#### **6.4 Withdrawal of individual subjects**

Subjects can leave the study at any time for any reason if they wish to do so without any termination consequences. The investigator can decide to withdraw a subject from the study for urgent medical reasons. Per Protocol and Intention To Treat analysis will be applied.

#### **6.5 Replacement of individual subjects after withdrawal**

Patients who withdraw will not be replaced. Data that are collected up to withdrawal will be used for analysis.

#### **6.6 Follow-up of subjects withdrawn from treatment**

Patients who withdraw will be treated according to the centre standard protocol.

#### **6.7 Premature termination of the study**

The study will be prematurely terminated if for any reason one of either treatment methods can no longer be performed in the participating institutes or if the participating clinicians is not able to continue to perform one of either method. Lima Corporate reserves the right to withdraw their funding. This will not affect the continuation of the study itself, which will proceed without interruption thanks to stable funding from Spaarne Gasthuis. In this case, the specific funding for the PhD candidate would be discontinued. However, this can be supplemented by other available resources, such as those from the Spaarne Gasthuis Academy, to ensure continued support for the PhD candidate.

## **7. SAFETY REPORTING**

### **7.1 Section 10 WMO event**

In accordance to section 10, subsection 1, of the WMO, the investigator will inform the subjects and the reviewing accredited METC if anything occurs, on the basis of which it appears that the disadvantages of participation may be significantly greater than was foreseen in the research proposal. The study will be suspended pending further review by the accredited METC, except insofar as suspension would jeopardise the subjects' health. The investigator will take care that all subjects are kept informed.

### **7.2 AEs, SAEs and SUSARs**

#### **7.2.1 Adverse events (AEs)**

Adverse events are defined as any undesirable experience occurring to a subject during treatment which may or may not be considered related to the intervention. All adverse events reported spontaneously by the subject or observed by the investigator or his staff will be recorded. This also includes planned procedures.

#### **7.2.2 Serious adverse events (SAEs)**

A serious adverse event is any untoward medical occurrence or effect that:

- Results in death;
- Is life threatening (at the time of the event);
- Requires hospitalisation or prolongation of existing inpatients' hospitalisation;
- Results in persistent or significant disability or incapacity;
- Any other important medical event that may not result in death, be life threatening, or require hospitalization, may be considered a serious adverse experience when, based upon appropriate medical judgement, the event may jeopardize the subject or may require an intervention to prevent one of the outcomes listed above.

All the SAEs will be reported through the web portal *ToetsingOnline* to the accredited METC that approved the protocol.

SAEs that result in death or are life threatening should be reported expedited. The expedited reporting will occur not later than 7 days after the responsible investigator has first knowledge of the adverse reaction. This is for a preliminary report with another 8 days for completion of the report.

### **7.3 Follow-up of adverse events**

All AEs will be followed until they have abated, or until a stable situation has been reached. Depending on the event, follow up may require additional tests or medical procedures as indicated, and/or referral to the general physician or a medical specialist.

SAEs need to be reported till end of study within the Netherlands, as defined in the protocol.

## **8. STATISTICAL ANALYSIS**

### **8.1 Descriptive statistics**

All data will be analysed in an encoded fashion in the Spaarne Gasthuis Hoofddorp, the Netherlands. We will form a digital database with the obtained data and the two treatment groups will be compared. Analysis will be performed by use of SPSS statistical package (version 26.0; SPSS, Chicago, Illinois).

### **8.2 Analysis**

Patient demographics, clinical characteristics and radiographic outcome scores will be described according to their distributions. The SMR TT Hybrid Glenoid is the experimental procedure. The All Poly 3-pegs Cemented Glenoid is the control procedure.

Continuous variables will be described as means with standard deviations (SD) in case of normal distribution, otherwise medians and interquartile ranges (IQR) will be used.

Categorical variables will be described using frequencies with accompanying proportions.

As this study has a non-inferiority design, analyses will be performed both Per Protocol (PP) and conform the Intention to Treat (ITT) principle.

Primary non-inferiority analysis of the absolute CMS (defined as change from baseline) will be performed using linear regression analysis at the follow up moment of interest. In case of confounding (potential confounders: gender, age, BMI, dominance, workers compensation, smoking, ASA grade, HADS score), adjustment will be performed by use of multivariate linear regression analysis. Non-inferiority analysis of the gender and age adjusted CMS (defined as change from baseline) will be performed in the same manner. In case of confounding (potential confounders: BMI, dominance, workers compensation, smoking, ASA grade, HADS score), adjustment will be performed by use of multivariate linear regression analysis. Crude as well as adjusted differences between the treatment groups will be presented with 95% CI. In case the

inferiority limit of -10 falls outside the lower bound of the 95%CI of the difference between the experimental and control group, non-inferiority is confirmed.

Additional mixed model analysis will be performed in case of repeated measurements, adjusted for confounders where necessary. A one-sided significance level of 0.025 will be considered significant. Secondary PROMs will be analysed by use of linear regression analysis or mixed model analysis and adjusted for potential confounders where necessary. Chi-squared tests will be performed in case of dichotomous variables (e.g. as complications). Additionally, revision rates will be calculated at 5 and 10 year follow up by use of Kaplan Meier (KM) analysis and compared by use of Log Rank tests. Cox proportional Hazard analysis will be performed to calculate Hazard Ratio's with 95%CI, crude as well as adjusted for potential confounders (when necessary). Proportional Hazard assumption will be checked visually by use of Log minus Log plots.

For all secondary analyses a p-value of 0.05 is considered statistically significant.

The idea of initiating the randomization process perioperatively, upon confirming a participant's fitness for inclusion, was explored. However, this approach is deemed to lack meaningfulness and effectiveness. Being on standby for perioperative randomization would be necessary. Moreover, it is probable that the participant's unsuitability for randomization would be known before the surgery.

## **9. ETHICAL CONSIDERATIONS**

### **9.1 Regulation statement**

Ethical approval is necessary because of the randomized design of this study. This approval is to be obtained by the Medical Ethical committee of the Amsterdam UMC. The study will be conducted according to the principles of the Declaration of Helsinki and in accordance with the Medical Research Involving Human Subjects Act (WMO).

### **9.2 Recruitment and consent**

The patients are recruited for the study in all participating hospitals. When a patient is diagnosed with symptomatic osteoarthritis and after the decision is made to proceed with placement on the waiting list for an anatomic shoulder arthroplasty, the patient will be assessed for eligibility for the study using the inclusion and exclusion criteria. If criteria are met, the treating physician will briefly inform the patient about the trial. The Coordinating Investigator will then inform the patient more thoroughly about the trial and explain the procedure for consent. The patient will receive both verbal and written information and will be given the time to consider participation.

After one week the patient will be contacted by an independent research nurse and asked whether they wish to participate or not. After signing the informed consent, the patients will be randomly allocated to one of the two treatment groups using Research Manager (Nova Business Software).

### **9.3 Benefits and risks assessment, group relatedness**

The burden associated with participation is an increased number of subjective scores to fillout, an increased number of (non-invasive) measurements of the function of the shoulder. In addition to the normal treatment and after-treatment pattern, supplementary mid- and long-term radiographs will be made to monitor the both implants. The risks associated are not

increased, for both methods are widely used and none is so far proven superior.

#### **9.4 Compensation for injury**

There will be no separate insurance for subjects participating in this study. The risks associated are not increased, for both methods are widely used and none is so far proven superior. A request for dispensation from the statutory obligation to provide insurance will be made. An exemption from the insurance for the subjects participating in the study was requested in accordance with the WMO. The investigator has a liability insurance which is in accordance with article 7 of the WMO.

#### **9.5 Incentives (if applicable)**

There will be no special incentives, compensation or treatment that subjects will receive through participation in the study. The only exception is financial compensation for travelling and/or parking costs in case of extra visits to the hospital for the subject (e.g. (S)AE's)

## ADMINISTRATIVE ASPECTS, MONITORING AND PUBLICATION

### 9.6 Handling and storage of data and documents

Personal patient files are used and the data obtained in this study will be added to the encoded data files in Research Manager (Cloud 9 software, Deventer, Netherlands). Besides clinical data, demographic characteristics are collected. Authorized users can obtain an account and insert relevant data for their respective participating center. Independent observers will review data that is coded by the principal investigator of the study. Every patient will be given a random alphanumeric code. All data will be treated confidentially. The data will be securely stored on the site of the principal investigator, and the research assistant is the only one that has access on a day-to-day basis. From each site, encoded data files will be shared with Lima Corporate once a specific follow up period is reached for publication purposes.

Internal monitoring will be provided by the sponsor (Spaarne Gasthuis). All data will be handled and stored in accordance with the AVG (Algemene Verordening Gegevensbescherming). The encoded data will be stored for a period of 15 years on an encrypted server.

### 9.7 Amendments

Amendments are changes made to the research after a favourable opinion by the accredited METC has been given. All amendments will be submitted to the METC that approved the original protocol.

A ‘substantial amendment’ is defined as an amendment to the terms of the METC application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree:

- the safety or physical or mental integrity of the subjects of the trial;
- the scientific value of the trial;

- the conduct or management of the trial or;
- the quality or safety of any intervention used in the trial.

All substantial amendments will be submitted to the METC and to the competent authority.

Non-substantial amendments will not be submitted to the accredited METC and the competent authority, but will be recorded and filed by the sponsor.

### **9.8 Annual progress report**

The investigator will submit a summary of the progress of the trial to the accredited METC once a year. Information will be provided on the date of inclusion of the first subject, numbers of subjects included and numbers of subjects that have completed the trial, serious adverse events/ serious adverse reactions and amendments.

### **9.9 End of study report**

The investigator will notify the accredited METC of the end of the study within a period of 8 weeks. The end of the study is defined as the last patient's last visit. In case the study is ended prematurely, the investigator will notify the accredited METC within 15 days, including the reasons for the premature termination. Within one year after the end of the study, the investigator/sponsor will submit a final study report with the results of the study, including any publications/abstracts of the study, to the accredited METC. Before the study reaches its end at the 10 year follow up, intermediate results will be published after 2, 5 and 10-year follow-up.

### **9.10 Public disclosure and publication policy**

Publication of the research data will be in a journal in the field of research. Whenever possible, results of the data will be presented on symposia or annual meetings of related instances.

**10. REFERENCES**

1. **Gonzalez JF, Alami GB, Baque F, Walch G, Boileau P.** Complications of unconstrained shoulder prostheses. *J Shoulder Elb Surg.* 2011 Jun;20(4):666–82.
2. **Bohsali KI, Bois AJ, Wirth MA.** Complications of shoulder arthroplasty. *J Bone Jt Surg - Am Vol.* 2017;99(3):256–69.
3. **Kim DM, Aldeghaither M, Alabdullatif F, Shin MJ, Kholinne E, Kim H, et al.** Loosening and revision rates after total shoulder arthroplasty: A systematic review of cemented all-polyethylene glenoid and three modern designs of metal-backed glenoid. *BMC Musculoskelet Disord.* 2020;21(1):1–16.
4. **Boileau P, Moineau G, Morin-Salvo N, Avidor C, Godenèche A, Lévine C, et al.** Metal-backed glenoid implant with polyethylene insert is not a viable long-term therapeutic option. *J Shoulder Elb Surg.* 2015;24(10):1534–43.
5. **Papadonikolakis A, Matsen FA.** Metal-backed glenoid components have a higher rate of failure and fail by different modes in comparison with all-polyethylene components: A systematic review. *J Bone Jt Surg - Am Vol.* 2014;96(12):1041–7.
6. **Page RS, Pai V, Eng K, Bain G, Graves S, Lorimer M.** Cementless versus cemented glenoid components in conventional total shoulder joint arthroplasty: analysis from the Australian Orthopaedic Association National Joint Replacement Registry. *J Shoulder Elb Surg.* 2018;27(10):1859–65.
7. **Sharplin PK, Frampton CMA, Hirner M.** Cemented vs. uncemented glenoid fixation in total shoulder arthroplasty for osteoarthritis: a New Zealand Joint Registry study. *J Shoulder Elb Surg.* 2020;29(10):2097–103.
8. **Haleem A, Sedrak P, Gohal C, Athwal GS, Khan M, Alolabi B.** Hybrid Glenoid Designs in Anatomic Total Shoulder Arthroplasty: A Systematic Review. *HSS J.* 2022;18(2):219–28.
9. **Malahias MA, Kostretzis L, Gkias I, Chronopoulos E, Brilakis E, Antonogiannakis E.** Total shoulder arthroplasty with hybrid fixation of glenoid components consisting of cementless porous metal pegs or cage along with cemented backside polyethylene surface: a systematic review. *Musculoskelet Surg.* 2020;104(3):229–36.
10. **Simovitch R, Flurin PH, Wright T, Zuckerman JD, Roche CP.** Quantifying success after total shoulder arthroplasty: the minimal clinically important difference. *J Shoulder Elb Surg.* 2018 Feb 1;27(2):298–305.
11. **Churchill RS, Chuinard C, Wiater JM, Friedman R, Freehill M, Jacobson S, et al.** Clinical and radiographic outcomes of the simpliciti canal-sparing shoulder arthroplasty system. *J Bone Jt Surg - Am Vol.* 2016 Apr;98(7):552–60.
12. **Habermeyer P, Lichtenberg S, Tauber M, Magosch P.** Midterm results of stemless shoulder arthroplasty: A prospective study. *J Shoulder Elb Surg.* 2015 Sep;24(9):1463–72.
13. **Antuna SA, Sperling JW, Cofield RH, Rowland CM.** Glenoid revision surgery after total shoulder arthroplasty. *J Shoulder Elb Surg.* 2001;10(3):217–24.
14. **Constant CR, Murley AHG.** A clinical method of functional assessment of the shoulder. *Clin Orthop Relat Res.* 1987 Jan;No. 214(214):160–4.
15. **Katolik LI, Romeo AA, Cole BJ, Verma NN, Hayden JK, Bach BR.** Normalization of the Constant score. *J Shoulder Elb Surg.* 2005;14(3):279–85.
16. **Dawson J, Fitzpatrick R, Carr A.** Questionnaire on the perceptions of patients about shoulder surgery. *J Bone Jt Surg - Ser B.* 1996;78(4):593–600.

17. **Berendes T, Pilot P, Willems J, Verburg H, te Slaa R.** Validation of the Dutch version of the Oxford Shoulder Score. *J Shoulder Elb Surg.* 2010;19(6):829–36.
18. **Jost B, Pfirrmann CWA, Gerber C.** Clinical outcome after structural failure of rotator cuff repairs. *J Bone Jt Surg - Ser A.* 2000 Mar;82(3):304–14.
19. **Freyd M.** The Graphic Rating Scale. *J Educ Psychol.* 1923;14(2):83–102.
20. **The Euroqol Group.** EuroQol - a new facility for the measurement of health-related quality of life. *Health Policy (New York).* 1990;16(3):199–208.
21. **Zigmond AS, Snaith RP.** The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand.* 1983;67(6):361–70.
22. **Aerts BR, Kuijer PP, Beumer A, Eygendaal D, Frings-Dresen MH.** Work-Related Questionnaire for Upper extremity disorders (WORQ-UP): Factor Analysis and Internal Consistency. *Arch Phys Med Rehabil.* 2018;99(9):1818–26.
23. **Ilmarinen J, Tuomi K.** Work ability of aging workers. *Scand J Work Environ Heal.* 1992;18(SUPPL. 2):8–10.
24. **El Fassi M, Bocquet V, Majery N, Lair ML, Couffignal S, Mairiaux P.** Work ability assessment in a worker population: Comparison and determinants of Work Ability Index and Work Ability score. *BMC Public Health.* 2013;13(1):1–10.
25. **Sluiter JK, Frings-Dresen MHW.** Quality of life and illness perception in working and sick-listed chronic RSI patients. *Int Arch Occup Environ Health.* 2008;81(4):495–501.
26. **Levin JM, Rodriguez K, Polascik BA, Zeng S, Warren EJ, Rechenmacher A, et al.** Simple preoperative radiographic and computed tomography measurements predict adequate bone quality for stemless total shoulder arthroplasty. *J shoulder Elb Surg.* 2022 Jun;
27. **Walch G, Badet R, Boulahia A, Khoury A.** Morphologic study of the glenoid in primary glenohumeral osteoarthritis. *J Arthroplasty.* 1999;14(6):756–60.
28. **Bercik MJ, Kruse K, Yalozis M, Gauci MO, Chaoui J, Walch G.** A modification to the Walch classification of the glenoid in primary glenohumeral osteoarthritis using three-dimensional imaging. *J Shoulder Elb Surg.* 2016;25(10):1601–6.
29. **Goutallier D, Bernageau J, Patte D.** Assessment of the trophicity of the muscles of the ruptured rotator cuff by CT scan. In: Post M, Morrey B, Hawkins R, editors. *Surgery of the Shoulder.* St. Louis: Mosby Inc.; 1990. p. 11–3.
30. **Beck S, Martin RJ, Patsalis T, Burggraf M, Busch A, Landgraeber S, et al.** Determination of humeral inclination in stemless shoulder arthroplasty using plain radiographs. *Orthop Rev (Pavia).* 2019 Dec 2;11(4):197–200.
31. **Youderian AR, Ricchetti ET, Drews M, Iannotti JP.** Determination of humeral head size in anatomic shoulder replacement for glenohumeral osteoarthritis. *J Shoulder Elb Surg.* 2014;23(7):955–63.
32. **Lazarus MD, Jensen KL, Southworth C, Matsen FA.** The Radiographic Evaluation of Keeled and Pegged Glenoid Component Insertion. *J Bone Jt Surg.* 2002 Jul;84(7):1174–82.
33. **Sheikhzadeh A, Wertli MM, Weiner SS, Rasmussen-Barr E, Weiser S.** Do psychological factors affect outcomes in musculoskeletal shoulder disorders? A systematic review. *BMC musculoskeletal disorders.* 2021 Jun 19;22(1):560.