SCORPIO PS Vs SCORPIO NRG PS TOTAL KNEE ARTHROPLASTY

Comparative Investigation of Function

Date: 08thJune 2010
Version: 4
Reference: ScorpioPS_NRG 20100506

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This document is an amendment of the protocol (Reference: ScorpioPS_NRG 20051122) version 3, prepared by C. Arts from 10th July 2007

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SCORPIO PS Vs SCORPIO NRG PS
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STUDY DESIGN SUMMARY

- **Surveillance design**: Single-centre, prospective, randomized comparative study.
- **Objectives:** To compare the average Range of Motion and Chair Raise achievement ratios. All complications will be documented.
- **Regulatory status:** Scorpio PS: CE Number: 0050

  Scorpio PS NRG: CE Number :0086
- **Number of subjects to be enrolled**: All consecutive Scorpio patients are included until a group size of 88 is reached.
- **Clinical evaluations:** Chair raise test, Stair climb test, WOMAC patient self-evaluation, EQ-5D patient questionnaire. Standard clinical, functional and pain parameters (Knee Society Score), pre-operatively and post-operatively. All per- and post-op complications.

SCORPIO PS Vs SCORPIO NRG PS
Comparative Investigation of Function

1 INTRODUCTION

The Scorpio TKA family offers a complete range of Fixed Bearing, Mobile Bearing and revision components, all of which share a single design philosophy. Central to this philosophy is one idea incorporating a single M/L and A/P axis design, supported by a single instrument platform. In an otherwise satisfactory total knee arthroplasty (TKA) (well aligned, well fixed, stable, and with good flexion), symptoms related to extensor mechanism function and the patellofemoral articulation., including anterior knee pain, are the prevalent issues after TKA [1,3,13] Many factors influence the outcome of TKA, including prosthetic design. Classic kinematics theory teaches that knee flexion and extension occurs around changing instant centers of rotation. Several reports indicate that TKA's with a multiradius sagittal profile do not restore extensor mechanism moment arms to normal, with the greatest reduction occurring in the last 30 degrees of extension [5,9] The validity of the anatomic observations that are the foundation for the changing instant centers of rotation has been challenged. [11] Other anatomic studies [4]indicate that knee motion occurs around a single, fixed flexion-extension axis located in the posterior condyles. This single flexion extension axis is approximated by the transepicondylar axis. [2]The relatively anterior axis of rotation in multiradius TKA's may account, at least in part, for why extensor mechanism moment arms are shorter after TKA. All other factors being equal, a relatively posterior flexion-extension axis would lengthen the extensor mechanism moment arms and improve extensor mechanism function. Several studies have proved the functional benefit from this improved moment arm. The Scorpio NRG has a redesigned tibial insert, and improved Post and Cam design. Also the posterior condyle height of the femoral component is reduced. These improvements should reduce the operation time, decrease the post operative ventral knee pain, improve rotation in deep flexion and increase maximum flexion. The Standard procedure at the academic hospital Maastricht consists of implantation of the Scorpio PS knee prosthesis, the same prosthesis that will be used in the control group of this study. If a patient's anatomy or specific lifestyle functions require a non scorpio prosthesis, it is possible to implant a NEXgen total knee prosthesis. This category of patients will not be asked to participate in this study.

The purpose of this investigation is to primarily compare the post-op function recovery of and complications of patients who received a Scorpio PS or Scorpio NRG PS design. A secondary purpose is to compare anterior knee pain, patella tracking and patella tilting between these two groups.

2 STUDY DESIGN

This is a prospective single-centre post market randomized comparative study.

2.1 Pre-operative inclusion

Patients on the waiting list for a total knee prosthesis who fulfil the inclusion and exclusion criteria will be asked to participate in this study. Oral and written information (appendix 1)

about the study will be given to the patient at the first hospital visit, related to the TKP. Oral information will be given again at a pre-operative information meeting one week before surgery. All study information will be given by the scientific researcher and orthopaedic surgeon. When a patient wants to participate the informed consent (appendix 1) will be signed and all pre-operative study information will be completed. This consists of demographics, medical history, a knee society score evaluation (KSS) (appendix 2), a stair climb and chair raise test combined with a VAS (visual analogue scale, appendix 3) score to measure pain. The VAS score is a 10 point scale with zero as no pain and 10 as the worst possible pain. A WOMAC patient questionnaire (appendix 3) and EQ-5D patient questionnaire on health status (appendix 3) will be done and additional X-rays will be made to measure pre-operative patella tracking and tilting.

2.2 Randomisation procedure

The randomisation procedure will be executed by the scientific researcher with the computer programme randomizer. After defining group size and the amount of subgroups, a list will be given with patient inclusion number and the prosthesis that has to be used. The scientific researcher will make envelopes with a form inside which mentions the patient inclusion number and type of prosthesis that has to be implanted. On the day of surgery a randomisation envelope will be opened.

If the surgeon notices during the operation that the study prosthesis is not suitable for the patient's anatomy, he will exclude the patient from the study and will place a suitable prosthesis.

The following criteria determine deviation from the randomisation procedure:

- Bone stock quality far less than expected by X-ray (patient will receive long stem revision prosthesis and will be excluded from the study)
- Fracture or fissure in tibial plateau threatening prosthesis stability (patient will receive long stem revision prosthesis and will be excluded from the study)

This will be mentioned in the CRF as a complication and the patient will be excluded from further participation.

The patient will not be informed which prosthesis he/she has received.

All study related operations will be performed under computer navigation.

2.3 post-operative evaluations

After surgery the patient will be evaluated at fixed follow up moments (Table 2 page 8). At each follow up moment a KSS evaluation, a chair raise and stair climb test combined with VAS pain score will be done. Also patient questionnaires (WOMAC, EQ-5D) will be done and X-rays will be taken.

The KSS score consists of a knee score (pain, range of motion en function of the prosthesis) and a function score (walking, stair climbing, use of support). To compare this KSS between

the different follow up moments the improvement can be measured. The stair climb and chair raise test will be executed in the same way at every follow up. The pain during these two activities measured with a VAS will be compared between the follow up moments.

All clinical measurements will be done by the clinical researcher. Specific knee clinical evaluations have to be done by a knee specialist to make sure that everything is done correctly.

3 OBJECTIVES

The primary objective is to compare the maximum flexion, both passive and active at every clinical follow-up time point up till 5 years postoperative, measured with a large goniometer. Our primary hypothesis is that the Scorpio NRG PS knee prosthesis has an average flexion of at least 7 degrees higher than the Scorpio PS knee prosthesis. Secondary objectives are to assess the complications, Chair raise test outcomes, knee pain (VAS) and surgery time. The secondary hypothesis is that there is no difference in complications and pain during the stair climb and chair raise test between the Scorpio NRG PS and the Scorpio PS. So more flexion does not result in more anterior knee pain. Also, the validity of computer navigated measurements and the relation between patella tilting and post-operative pain will be evaluated.

4 METHODS

Performance will be clinically measured using the Knee Society Score (Ewald, 1989; appendix 2). As part of the KSS flexion will be measured, both passive and active. The measurement will be done by a physiotherapist. Like the patient the physiotherapist will be blinded for the treatment.

The Chair Raise test(standing up from a firm straight-backed chair keeping the arms folded across the chest) and stair climb test(ascending a flight of eleven 17.8 cm tall steps with an 30 cm tread depth, use of one hand rail is allowed) is combined with a 10 point VAS measurement of anterior knee pain(McCormack et al., 1988). This consists of a pain scale from 0 to 10 on which the patient can point to the amount of pain (0 means no pain, 10 means the worst possible pain) Recording of the nature and incidence of all intra-operative and post-operative complications will be the method to assess safety. The difference between computer navigation measurements of leg axis and range of motion and clinical and X-ray measurements of these parameters will be evaluated. For this evaluation the pre-op standard X-rays and the per-operative computer navigation data will be used.

The relation between patella tilting and post-operative pain will be measured during functional tests Stair climb and chair raise according to a Visual analog scale (VAS) .

Patellar tilting will also be assessed on consecutive X-rays by the orthopaedic surgeon.

A WOMAC patient questionnaire (appendix 3) will be done to evaluate the patient's opinion on recovery, post-operative pain, and function(Bellamy et al., 1988).

An EQ-5D patient questionnaire (appendix 3) will be done to evaluate the patient's opinion of their health status (mobility, self-care, usual activities, pain/discomfort, anxiety/depression and a visual analog scale (VAS) to measure the patient's self-rated health outcome).

All evaluations will be conducted on the follow up moments mentioned in the follow up table

at page 8.

The prostheses used in this study both have a CE mark. All information concerning these prostheses is attached as appendix 4

5 INVESTIGATIONAL SITES

This study will be conducted at the Academic Hospital in Maastricht, the Netherlands.

6 SELECTION OF PATIENTS

6.1 Number of patients

The number of patients is based on average postoperative flexion as the primary endpoint. According to Morawa[10] Scorpio patients showed a maximum post-operative flexion of 104 degrees. An increase in maximum flexion of 5 degrees is already noticeable for the patient, so clinically important. According to pre marketing results the Scorpio NRG PS knee prosthesis can reach a flexion of more than ten degrees extra compared to the Scorpio PS. For the primary endpoint we want to aim at an increase in maximum flexion of 7 degrees. According to Schouten[12] a sample size of 40 patients in each group is needed with a difference in flexion of 7 degrees, a standard deviation of 11 [7,8] a 80% power with a significance level (alpha) of 0.05 (two-tailed). When we take into account a lost of FU of 10% a total groupsize of 88 is anticipated.

6.2 Patient selection criteria

All patients on the waiting list for a total knee prosthesis at the department of orthopaedics at the AZM will be checked for suitability for this study. Patients will be verbally and in writing informed about the study during the first visit related to the TKP, and will be provided with the patient information. One week before surgery during a pre-operative visit the patients will be orally informed again, All questions about the study will be answered and the patient will be asked to participate in this study. If a completely informed patient wants to participate, the informed consent will be signed.

If a patient doesn't want to participate it is very likely that he will receive the Scorpio PS prosthesis since this is the standard used knee prosthesis at the AZM. If a patient does or doesn't want to participate has no effect on day of surgery or further medical care.

The confidentiality of the subject will be maintained at all times. The patient will be told that he/she is free to refuse the collection of his/her clinical data or to withdraw from the Investigation at any time without compromising future medical care.

TABLE 1. Patient Inclusion and Exclusion Criteria

Inclusions

- Patients requiring a primary TKA
- Male and nonpregnant female patients
- Between 18 and 80 years of age at time of surgery
- Patients with a diagnosis of osteoarthritis (OA), avascular necrosis (AVN), and not severe posttraumatic arthritis
- No previous osteosynthesis of the involved knee during the last 12 months
- Patients who understand the conditions of the study and are wiling to participate for the length of the described follow up
- Patients who are capable of, and have given, informed consent for participation in the study

Exclusion

- Patients requiring revision surgery of a previous implanted total knee system
- Patients with a diagnosis of severe posttraumatic arthritis (TA) and rheumatoid arthritis (RA)
- Patients with active infection
- Patients with malignancy
- Patients with an immobile hip or ankle arthrodesis
- Severe obese patients (BMI > 35)
- Patients with a neurological deficit
- Previous history of unicompartemental knee arthroplasty or patellar prosthesis
- Patients with concurrent illnesses which are likely to affect their outcome

7 LENGTH OF SURVEILLANCE

The study has a follow up of 5 years. An inclusion period of 1,5 years is anticipated, so the study will run for 1,5 plus 5 years. When the inclusions start in June 2010, the study will end March 2016.The table below gives us an overview of the time window per visit.

VISIT	TIME WINDOW
Pre-op.	Date of or any time post the date of written informed consent up to the date of surgery.
Operation	N/A
PTD	N/A
6 weeks post-op.	± 1 week
12 weeks post-op	± 2 weeks
26 weeks post-op	± 2 weeks
1 year post-op	± 2 months
2 year post-op	± 2 months
5 years post-op	± 2 months

8 DESCRIPTION OF THE DEVICES

All components of the Scorpio systems used in this study obtained the CE mark and have been approved for sale and use throughout Europe. The devices are described in the product information (appendix 4 and 5).

9 PATIENT EVALUATIONS

Patients will be assessed pre-operatively, per-operatively and post-operatively. Appropriate data will be recorded both in their hospital notes and case report forms. The follow-up intervals are described in the following table.

Table 2: follow up intervals

Evaluation	**Pre-op**	**Per-op**	**Post-operatively**						
			Prior to Discharge	**6 wks**	**12 wks**	**26 wks**	**1 Year**	**2 Years**	**5 Years**
Medical History	√								
Clinical + KSS	√			√	√	√	√	√	√
Operative Data		√							
Chair Raise test **Stair climb test**	√			√	√	√	√	√	√
X-rays **A/P en lateral**	√		√	√	√	√	√	√	√
X-rays **Long leg**	√				√				
X-rays **Patella defile**	√				√	√	√	√	√
WOMAC, **EQ-5D** **Patient evaluation**	√				√	√	√	√	√

9.1 Evaluations at each assessment

9.1.1 Pre-operative Evaluation

- Clinical History*(clinical researcher)*

- Date informed consent obtained
- Patient initials, study number
- Date of birth, weight, height, and gender
- Knee for surgery
- Primary diagnosis
- Previous knee surgery

- Clinical Evaluation*(physiotherapist)*

- Knee Society Score Evaluation
  - Pain
  - Walking
  - Stairs
  - Support
  - Flexion Contracture
    Extension Lag
  - Range of Motion (active / passive)
- Stability-Anteroposterior
- Mediolateral stability
- Patella tracking
- Chair raise test and stair climb test
- WOMAC, EQ-5D patient evaluation questionnaires

- Radiographic Evaluation*(clinical researcher)*

- Date of graphs taken
- Leg axis
- Femoral tibial angle
- Patella tilting

9.1.2 Intra-operative Evaluation

- Surgical details*(surgeon)*

- Date of surgery
- Scorpio implant and component fixation
- Surgical approach
- Type of anaesthesia

- Anaesthesia class
- Systemic prophylactic therapy
- Gaps
- Implant sizes
- Valgus angle
- Passive range of motion
- Computer navigation details

9.1.3 At Discharge(clinical researcher)

- Date of discharge
- Mobilisation figures (date out of bed and date mobilisation)
- Complications
- Active Range of Motion
- X-graph post-op evaluation

9.1.4 Post-operative Evaluation

Patients will be assessed at post operative intervals at 6 weeks 3 months, 6 months 1, 2 and 5 years.

Post-operatively

- **Clinical Evaluation*(physiotherapist)***
  - Date of assessment
  - Complications
  - Knee Society Score Evaluation
    - Pain
    - Walking
    - Stairs
    - Support
    - Flexion Contracture
    - Extension Lag
    - Range of Motion (active and passive)
    - Stability-anterposterior
    - Mediolateral stability
    - Patella tracking
    - Chair raise test, stair climb test
    - WOMAC, EQ-5D patient evaluation questionnaires

- **Radiographic Evaluation*(clinical researcher)***
  - Date of graphs taken
  - AP and Lateral view
  - Radiolucencies
  - Patella tilt

9.2 Adverse event/ Complications (surgeon)

- Intra-operative and post-operative complications
- Date of event/complication
  - Local complications
  - Mechanical complications
  - Revision required
- General complications
- Outcome complication

10 ADVERSE EVENTS

The investigator is required to document in the adverse event/complication section of the CRF all operative site and general medical complications, including date of occurrence, date diagnosed, type of complication and treatment.

10.1 Definitions[6]

An **adverse event** is "any untoward medical occurrence in a subject (this definition does not imply that there is a relationship between the adverse event and the device under investigation)".

A **serious adverse event** is an adverse event which

a) led to a death

b) led to a serious deterioration in the health of a subject that

1. resulted in a life-threatening illness or injury,
2. resulted in a permanent impairment of a body structure or a body function,
3. required in-patient hospitalization or prolongation of existing hospitalisation,
4. resulted in medical or surgical intervention to prevent permanent impairment to body structure or a body function.

c) led to foetal distress, foetal death or a congenital abnormality or birth defect.

An **adverse device effect** is “any untoward and unintended response to a medical device (this definition includes any event resulting from insufficiencies or inadequacies in the instructions for use or the deployment of the device. This definition includes any event that is a result of a user error)”.

A **serious adverse device effect** is “an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event or that might have led to any of these consequences if suitable action had not been taken or intervention had not been made or if circumstances had been less opportune”.

All **serious adverse device effects** must be reported to Stryker by telephone, or in writing, ideally within 24 hours after the investigator first learns of the event. This can be either to the Surveillance project manager (details mentioned on page 10) or the local country product manager. The investigator also has to inform his Ethics Committee about any **serious adverse device effects**.

11 PATIENT WITHDRAWALS

Every attempt must be made to ensure that all the patients return for all of the post-operative assessments. However, patients are free to withdraw from the Investigation at any time and are under no obligation to provide a reason for doing so. Patients who withdraw from the Investigation should have the reason for their withdrawal recorded on the case report forms (CRF’s), if at all possible. All attempts should be made to ascertain whether any patient apparently lost to follow up has actually chosen not to return or is deceased.

12 REPORTING OF RESULTS

All the above-mentioned pre-operative patient assessments, per-operative details and post-operative follow-up assessments will be recorded on the CRFs (Case Record Forms), which will be provided, and also in a database.

A case record form will be completed for each patient.

All data recorded in the CRFs should be in agreement with the information reported in the patient’s hospital records and other primary sources of data.

In order to maintain patient confidentiality, the patient’s name or address will not be recorded on the form. Only the patient’s study number will be recorded on the CRF For means of tracing the patient the scientific researcher has a code list on which patient study number and his name, date of birth and patient hospital number is mentioned.

These case record forms must be completed, checked for accuracy and signed by the investigator.

13 INVESTIGATION MONITORING

During the course of the Surveillance and thereafter until the centre has been closed, the monitor(s) possibly visit the Surveillance centre(s) by prior arrangement. The clinical Surveillance project manager or Surveillance monitor can also be contacted concerning any problems or queries regarding the clinical Surveillance.

CRA: Annemarieke vanDam
Clinical Research Associate
Telephone: +31 622741602 (direct)
E-Mail: annemarieke.vandam@stryker.com

Upon completion of the CRF, the Monitor will send a copy of the CRF to Stryker Data Management for data entry.

The monitor shall be given unhindered access to Surveillance relevant source documents (including medical records) to enable complete data verification, but with respect to the patient's integrity as described in section 17.4.

14 ANALYSIS OF RESULTS

Results obtained from the Surveillance will be tabulated and statistically analysed by Stryker's Clinical Research Department using an appropriate statistical software package.

14.1 Statistical Analysis

There will be summaries and comparisons presented according to:

- Demographic and pre-operative assessments
- Operative assessments
- Post-operative pain and function assessments
- Chair raise and stair climb assessment
- Patella-tracking assessment
- Adverse events
- General complications
- Local complications
- Device-related complications
- Revisions/removals

Descriptive statistics will be used like frequency and percent distributions and will be presented in tabular form for categorical variables. The mean, standard deviation, minimum and maximum values will be presented for quantitative variables. Students T-test will be used to compare variables between groups and various time points.

15 PUBLICATION OF RESULTS

For this study, as a single-centre Stryker Initiated Study, the following shall apply:

Ownership of data

- Study data owned, managed and analysed by Stryker SA

Publication plan

- Collectively defined and agreed by Stryker and Principle Investigator before study start
- Analysis timelines
- Covers Journals, Congresses and according timelines

- **2 year after completion of follow-up we plan to submit an abstract with preliminary findings to ORS and EFORT and the National Dutch Orthopaedic Association meeting.**

- **We plan to submit a two year data paper to either JBJS Br or Acta Orthopaedica depending on the data outcome and its relevance to the orthopaedic research community.**

- **We will submit a 5 year follow-up paper to either JBJS Br or Acta Orthopaedica depending on the data outcome and its relevance to the orthopaedic research community. This data will also be presented at orthopaedic conferences such as EFORT, ORS and the National Dutch Orthopaedic Association meeting.**

Authorship

- Number and Order to be agreed by Stryker and Principle investigator (according to requirements of intended Journals)
- If required by the intended Journal, the study will be registered publicly on the required internet site. (Release of information is limited to serve the aforementioned purpose, taking into consideration that scientific methods and protection of intellectual property of the sponsor and the Investigators).

Later publications

- Any publication proposals containing study data (including presentation of the data at any public event) after the general publication has been published in a peer review journal, shall be submitted to Stryker for review and acknowledgement, min. 30 days in advance.

16 RISK BENEFIT ANALYSIS

16.1 Risk

The Scorpio PS knee prosthesis is standard used for total knee arthroplasties in the AZM. During the 10 years experience with the Scorpio PS no additional complications have been seen. The Scorpio NRG PS has evolved from the the Scorpio PS. In basis both prostheses are

the same, only the tibial insert has changed and the femoral component has a slightly different shape. No additional risks for the use of the Scorpio NRG knee prosthesis are expected but still need to be proven.As in any surgical procedure, certain risks are associated with total knee arthroplasty. These risks include but are not limited to: anaesthetic and post-anaesthetic reactions (such as hyperaemia), allergic reactions to prophylactic antibiotics or blood transfusions, damage to blood vessels or nerves, patella, femoral or tibial fractures during implantation, perforation of the cortical wall, or death. Post-operatively, a patient may experience thrombophlebitis, pulmonary embolus, dislocation, pain, limp, component loosening, or the need for additional surgery.

16.2 Minimization of Risks

Pre-clinical, clinical, and mechanical testing of the Stryker Scorpio TKA designs indicate that the above mentioned risks should not occur at a rate greater than that for any other type of TKA systems reported in the literature.

16.3 Benefit

Patient benefits should include relief of pain and therefore increase in functional capabilities, in addition to better assessment of the effect of the implant design and materials on functional and radiographic performance and bone remodelling around the implant. This will increase the current scientific body of knowledge concerning TKA and possibly leading to improved implant designs.

17 ETHICAL CONSIDERATIONS

Informed Consent

Prior to entry into the Surveillance the investigator (or nominated representative) will give the patient written (in native language of the patient) and verbal explanation of the nature of the study to an appropriate level of detail. The patient must give a written consent to participate in the study. Patients are invited to sign and date the consent form, indicating their consent for enrolment (Investigators may not date the consent form on the patient's behalf).

The investigator (or nominated representative) will also sign and date the Consent Form to indicate that the purpose, risks and benefits of the study were explained to the patient and their signature witnessed. The original signed Consent Form will be filed at the Investigational site.

Patients are free to withdraw from the Investigation at any time and are under no obligation to provide a reason for doing so. A clinical trial insurance and a liability insurance is arranged. An independent orthopaedic surgeon is appointed who is fully informed about this study but does not participate in the study.

Patients can, at any time, receive information about his/ her results.

The study will be performed according to the declaration of Helsinki, wet medisch-wetenschappelijk onderzoek met mensen and guidelines CCMO.

Stryker's local CRA will provide the MEC azM/UM with the following reports:

- An annual progress report
- An end-report,sent within 8 weeks after completion of the study
- An end-report containing the results and conclusions, sent within 1 year after completion of the study

Personal data protection

Stryker Europe affirms and upholds the principle of the patient rights to protection against invasion of privacy. All data recorded in the CRFs or used for further evaluation are coded by patient study number. Identification is restricted to authorized persons. In all data analyses the identity of patients will remain anonymous. Anonymous patient data may be stored and electronically processed by Stryker Europe for the purpose of scientific evaluation and may be forwarded to a company and/or an authority located in- and outside Europe for registration and/or marketing purposes. Only authorized representatives of Stryker Europe and health authorities will have allowed access to personal medical records for the sole purpose of checking the accuracy of data collected in the trial.

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