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Intra-and inter-rater reliability of the knee society knee score, post total knee arthroplasty at Johannesburg Hospital.

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METHOD

CHAPTER 3

METHOD

3.1 Introduction

This chapter explains the methodology and the design used in this study.

3.2 Study Design

The design used in the study was a correlational study design

3.3 Ethical Considerations

Ethical clearance for this study was obtained from the Human Research Ethics Committee (Medical) of the University of the Witwatersrand [Protocol number: M060310]. Information about the study was given to the patients without prejudice. All patients signed an informed consent and were allowed to withdraw at any stage from the study. Patients' confidentiality was maintained throughout the study by allocating codes to each patient.

3.4 Examiners

Two physiotherapists were selected for data collection, to prove their reliability in using the KSKS. They are referred to as Examiner 1 and Examiner 2. Examiner 1 was the principle researcher of this reliability study and Examiner 2 was another physiotherapist who is the principle researcher of a randomised controlled trial, which is to be conducted at Johannesburg Hospital in which the KSKS is used as an outcome measure.

3.5 Patient Population

3.5.1 Sample selection

The study was conducted at the Arthroplasty Clinic, in Johannesburg Hospital. The Knee Society Knee Score was administered on all post TKA who met the inclusion criteria and gave consent for participation.

Inclusion criteria:

- Patients attending the clinic for their postoperative follow up visit who were aged between 45 – 75 years
- Patients attending clinic after six weeks and prior to one year post operative

Exclusion criteria:

- Subjects who were not walking (independently or without walking aids) prior to surgery / severe pain
- Preexisting septic arthritis or condition that may compromise TKA outcome (Charcot's joint, Paget's disease, severe osteoporosis)
- Patients with neurological disorder that may affect the outcome of TKA
- Patients with infectious diseases
- Metastatic diseases
- Lack of willingness to participate

3.5.2 Sample size

The sample size required was taken as 30 based on the assumptions of normality that a minimum sample size of n = 30, is essential to be able to assess agreement. Consultation with Prof. Piet Becker, Statistician- Medical Research Council, was done prior to the study.

3.6 Procedure

The principle researcher (Examiner 1) and another physiotherapist (Examiner 2) evaluated the patients independently of one another. On arrival of the patient at the orthopaedic clinic Examiner 1 introduced himself to the patient, explained the study and handed over an information form (refer appendix D) in a language that the patient understood. Patients who agreed to take part in the study signed the consent form (refer appendix D) and were assigned numerical codes on the data sheet used to record their measurements. Each patient was allotted four data sheets by an independent observer.

3.6.1 Measurements

The patients were greeted and taken into a room with a firm couch and a chair with back support along with the researcher (examiner 1) and observer. The same room, chair, couch and goniometer were used for all measurements and for full duration of the study.

Examiner 1 took all measurements, immediately followed by examiner 2. The patients then collected their x-rays and finished their consultation with the surgeon. The

procedures were repeated by examiner 1 and examiner 2 with a stipulated time interval not less than 45 minutes between their first and second measurements. The examiners did not record the measure directly but, gave the actual measures (eg. degrees of ROM) to the independent observer who noted it down in the data entry sheet, and hence the examiner bias was prevented. The researcher completed the scoring after data collection was complete.

Procedures followed for measuring each component of the score-

3.6.2 Pain

The patient was requested to lie-down on the plinth with their head rested on a pillow comfortably to ensure relaxation. The patients were asked, “Do you have any pain in your operated knee?” If they answered “yes” they were asked, “Is your pain mild, moderate or severe”. If they had mild pain, they were asked whether they had pain while using stairs and walking. If they had moderate pain they were asked whether the pain was continuous or occasional. The information was recorded by the independent observer.

3.6.3 Range of motion (ROM)

A Universal goniometer was used to measure the range of motion at the knee joint. The patient was in supine lying. The head will be supported by a pillow, with the hip in the anatomical position and the knee extended (Clarkson and Gilewhich 1989). The goniometer axis was placed over the lateral condyle of the femur with its stationary arm parallel to the longitudinal axis of the femur pointing towards greater trochanter

and movable arm parallel to longitudinal axis of fibula pointing to the lateral malleolus. The measurement was noted down as initial ROM. If the initial ROM was not 0° the reading was taken as degree of flexion contracture. The patient was instructed to take their heel towards their buttock and the examiner assisted the movement to feel the end range and measured range of motion. The patient was instructed to inform the examiner if they felt any pain or discomfort in their knee and the movement was stopped at that point. The measurement was recorded in the data sheet by the observer.

3.6.4 Stability

The Lachman's test (Petty and Moore 1998) and Valgus-Varus stress test (Magee 1997) was used to assess the anteroposterior and mediolateral stability respectively. The amount of translation of the tibia over the femur during the Lachman's, and the amount of angulation at the knee joint during the Valgus-Varus test experienced by the examiner were conveyed to the observer and noted down on the data sheet. These were the amounts of movement felt by the examiners during the tests and hence it becomes essential to show the reliability of the examiners in using this component.

Anteroposterior stability

The patient was positioned in supine lying with knee flexed to 0˚- 30˚. The examiner stabilised the patient's femur with one hand and encircling the proximal tibia with other hand applied a posteroanterior force to the tibia. The amount of movement felt

when the tibia moves over the femur, which is a clinical measurement, was recorded in millimetres.

Mediolateral stability

The patient was positioned in supine lying with knees extended and the leg grasped between examiner's hands, one at the distal femur and other at the ankle.

Valgus stress – (medial stability) a lateral force directed medially was applied over the lateral aspect of the knee and the degree of angulation felt between the tibia and the femur, which is a clinical measurement, was recorded in degrees.

Varus stress - (lateral stability) a medial force directed laterally was applied from the medial side of the knee and degree of angulation felt between the tibia and the femur, which is a clinical measurement, was recorded in degrees.

3.6.5 Extension lag

The patient was positioned supine at the end of the couch, with the leg hanging down, with a towel roll underneath the distal thigh. The patient was asked to actively extend the knee and range was measured using the goniometer as active extension ROM. The difference between active extension ROM and the passive extension ROM was recorded as the degree of extension lag (Stillman 2004) by the observer.

3.6.6 Alignment

Measurements calculated by the surgeon using x-ray and a computerised programme will be used to record the degree of valgus and varus at the knee joint. The alignment score was given at the end of data collection.

The final score was allocated for the measurements obtained from the data entry sheets when the data collection was over.

3.7 Statiscal Analysis

Reliability was assessed by making use of Intraclass Correlation Coefficient (ICC) (John 2004). ICC (h) is the number we obtained from the statistical analysis which ranges from zero to positive or negative one. The closer the value of ICC is to one, the closer the relationship between the two variables (Hicks 1995). The closer the figure to zero, the wider the variation between variables.