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Similar early migration when comparing CR and PS in Triathlon™ TKA: A prospective randomised RSA trial

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ABSTRACT

Objectives: The objective of this study was to compare the early migration of the cruciate retaining and posterior stabilising versions of the recently introduced Triathlon™ total knee system, with a view to predicting long term fixation performance.
Methods: Sixty patients were prospectively randomised to receive either Triathlon™ posterior stabilised cemented knee prosthesis or Triathlon™ cruciate retaining cemented knee prosthesis. Tibial component migration was measured by radiostereometric analysis postoperatively and at three months, one year and two years. Clinical outcome was measured by the American Knee Society Score and Knee Osteoarthritis and Injury Outcome Score.
Results: There were no differences in rotation around the three coordinal axes or in the maximum total point motion (MTPM) during the two year follow-up. The posterior stabilised prosthesis had more posterior–anterior translation at three months and one year and more caudal–cranial translation at one year and two years. There were no differences in functional outcome between the groups.
Conclusion: The tibial tray of the Triathlon™ cemented knee prosthesis showed similar early stability.
Level of evidence: Level I.
Article summary: Article focus:
This was a prospective randomised trial aiming to compare the single radius posterior stabilised (PS) Triathlon™ total knee arthroplasty (TKA) to the cruciate retaining Triathlon™ TKA system with regard to fixation.
Strengths and limitations of this study:
Strength of this study was that it is a randomised prospective trial using an objective measuring tool. The sample size of 25–30 patients was reportedly sufficient for the screening of implants using RSA [1].
Trial registration:
ClinicalTrials.gov Identifier: NCT00436982.

1. Introduction

In the healthy knee, the posterior cruciate ligament (PCL) causes posterior translation of the femur onto the tibia or "roll back" during knee flexion [2,3]. At high flexion the anterolateral bundle of the PCL is thought to constrain the mediolateral translation of the tibia, whilst the posteromedial bundle constrains the anteroposterior translation of the tibia [4]. In patients having a total knee replacement (TKA), the stabilising action of an intact PCL can assist in maintaining the natural knee movements [5,6] and therefore there is some controversy over whether it is best to retain the PCL and use a cruciate retaining (CR) prosthesis or to remove it and use a posterior stabilising (PS) prosthesis during TKA. Currently there is limited scientific evidence to assist surgeons in deciding whether to use a CR or a PS design and the main factors influencing this choice are the degenerative status of the ligament, the type of implant available and the preference of the surgeon [7].

The presence of micromotion, as measured by radiostereometric analysis (RSA) of prostheses within the first two years, can serve as a predictor of late mechanical loosening and long-term failure [1]. In a study comparing a PS design with a mobile bearing (MB) design, a higher variability in subsidence and rotation about the transverse axis was found for the PS group [8]. An increase in varus–valgus tilting of the tibial component has also been reported for PS designs [9]. There is little data available in the literature describing difference in micromotion between the CR and PS concepts.

The purpose of this study was to compare the amount of short-term three-dimensional micromotion of the tibial component between the

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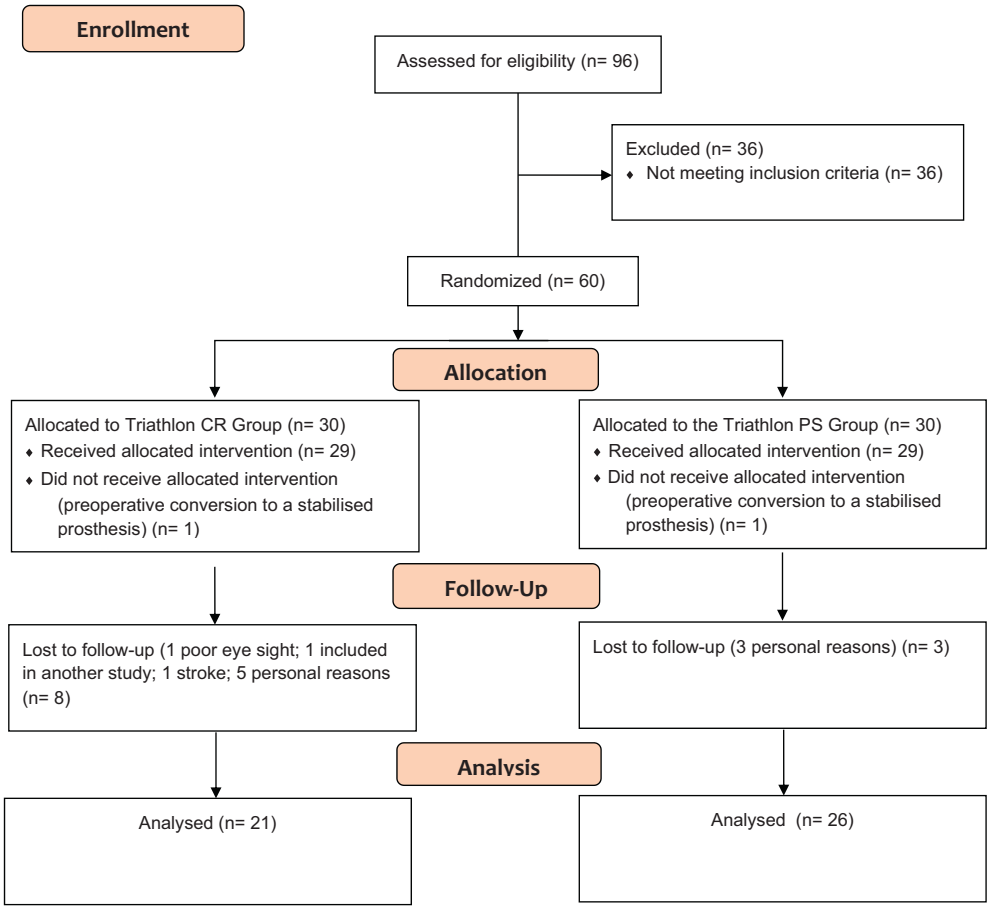

Fig. 1. CONSORT recruitment and follow-up chart.

PS and CR variants of a recently introduced total knee system using RSA. This study provides data for a new TKA design for which there is currently very limited information on function and likely long-term prosthetic fixation.

2. Patients and methods

2.1. Design

This study was a prospective randomised study of patients receiving a TKA for treatment of osteoarthritis of the knee. Patients were recruited from a single centre and were prospectively randomised to receive either a Triathlon™ PS or Triathlon™ CR (Stryker, Mahwah, New Jersey, USA) total knee system.

2.2. Participants

Randomisation was achieved using a sealed envelope technique. Three surgeons (MM, CFN and STL) were involved in both the selection and operation of the patients. During the period of trial 96 total knee replacements were performed in 96 patients using either the Triathlon™ PS or Triathlon™ CR total knee system; of these, 36 patients were excluded from the study due to long travelling time for follow up or for not having met the inclusion criteria. Therefore, 60 patients (24 men and 36 women) were included in the study, with 30 patients randomised to each group (Fig. 1).

Patients were blinded to the treatment allocated. Ethics Committee approval was obtained from the local medical ethics committee prior to initiation of the study. Patients were considered for enrolment according to their clinical findings and subject to gaining their written informed consent according to International Conference on Harmonisation Good Clinical Practice (ICH GCP) requirements. The inclusion criteria for selection to participate in the study are provided in Table 1. The exclusion criteria are provided in Table 2.

At two years, 26 patients were available for RSA follow-up in the Triathlon™ PS group and 21 patients were available for follow-up in the Triathlon™ CR (Fig. 1). In the Triathlon™ PS group one patient left the study due to perioperative conversion to a stabilised prosthesis; and three patients left the study due to personal reasons. In the Triathlon™ CR group, one patient left the study prior to the three month follow-up due to poor eyesight; one patient was excluded because they were already included in another study; one patient left the study due to perioperative conversion to a stabilised prosthesis; one patient left the study prior to the second year follow-up due to a stroke; and five patients left the study due to personal reasons (Fig. 1).

Table 1
Inclusion criteria.

Inclusion criteria
1. Patient suffering exclusively from OA; stages II–V (Ahlback 1968)
2. Patient requiring knee prosthesis is suitable for the use of either the Duracon or Triathlon Knee System.
3. Patient understands the conditions of the study and is willing and able to comply with the scheduled post-operative clinical and radiographic evaluations and the prescribed rehabilitation.
4. Patient has signed the Ethics Committee approved Informed Consent Form prior to surgery.