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Does Insert Type Affect Clinical and Functional Outcome in Total Knee Arthroplasty? A Randomised Controlled Clinical Trial With 5-Year Follow-Up

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ABSTRACT

New insert types have been developed to improve clinical and functional outcome in mobile bearing (MB-TKA) and fixed bearing total knee arthroplasty (FB-TKA). A prospective single blinded randomised controlled clinical trial was performed to evaluate 2 types of MB-TKA inserts and 2 types of FB-TKA inserts of the Genesis II prosthesis (Smith & Nephew) in 146 patients with 5-years follow-up. A significant difference ($P = .042$) between the MB-TKA inserts was found in KSS function scores, but clinical significance is expected to be limited. Goniometry, temporal gait parameters and QoL were similar in all groups. Survival was significantly better ($P = .047$) for FB-TKA. The comparable outcome and higher revision rate in MB-TKA indicate that FB-TKA may be preferential for the Genesis II implant system.

Total knee arthroplasty (TKA) has been increasingly performed to treat patients with osteoarthritis of the knee. The number of TKA procedures is expected to rise more as patients become older and remain active longer [1,2]. The original total knee prostheses were developed with an insert fixed to the tibial component (*fixed bearing* (FB)) and allowed only minimal tibial axial rotation, which is normally present in knee motion during flexion and extension [3]. In the 1980's *mobile bearing* (MB) TKA was developed to allow more axial rotation of the insert relative to the tibia [4]. MB-TKA is assumed to cause less wear of the insert, associated with less loosening and revisions, and provide a more natural movement of the knee joint [3–5]. So far, studies have not been able to prove these theoretical advantages, with similar results in FB-TKA and MB-TKA when looking at in vivo kinematics [3,5,6], clinical function [7–10], quality of life (QoL) [7], radiological outcome [6,11] and gait parameters [12,13].

To further improve MB-TKA, inserts have been developed with anterior-posterior translation as well as axial rotation. These rotating & translating inserts are hypothesised to allow more femoral condylar rollback [14]. For the FB-TKA, a new deep dish insert was developed to reduce the need for resection of the femoral bone compared to the normal dish insert [15–17]. To our knowledge, there have been no comparative studies with medium to long term follow-up of the outcome of both FB-TKA and MB-TKA in general and insert type more specifically. The aim of this study was to compare clinical and functional outcomes up to 5 years after FB-TKA and MB-TKA, in a randomized controlled clinical trial in a population of patients with osteoarthritis of the knee who were scheduled to undergo total knee replacement. In addition, to explore the effect of insert type, outcomes of Normal Dish (ND) and Deep Dish (DD) inserts for FB-TKA were compared in a randomized design as well as Rotating (R) and Rotating/Translating (R/T) inserts for MB-TKA.

Patients and Methods

Study Design

A multicenter, prospective, randomised, single blinded parallel-group clinical study was conducted in 2 large teaching hospitals in the Netherlands with an allocation ratio of 1:1:1:1. After inclusion, patients were first randomly assigned to either the fixed bearing (FB) or the mobile bearing (MB) group. Further randomisation was done within each group to either a normal dish (ND) insert or deep dish (DD) insert in the FB group, or to either a rotating (R) or rotating/translating (R/T) insert in the MB group. This study was performed in accordance with the

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Table 1
Inclusion and Exclusion Criteria.

Inclusion criteria
- Diagnosis of osteoarthritis of the involved knee
- Patients of either gender requiring cemented total knee replacement surgery
- Adults ranging in age from 50–75 years inclusive at moment of inclusion
- Patients have to be free of or treated for cardiac, pulmonary, haematological or other conditions that would pose excessive operative risk
- Adults able to understand their role as participants in a clinical study, who agree to return for follow-up, are willing to follow instructions and who agree to provide Informed Consent in accordance with the Medical Ethical Review Committee Requirements
Exclusion criteria
- Diagnosis of rheumatoid arthritis
- Insufficient quantity or quality of bone support, resulting from conditions such as cancer, distal femoral/proximal tibial osteotomy, osteoporosis or metabolic disorders of calcified tissues
- Revision of previous knee arthroplasty or arthrodesis
- Pre-existing local knee sepsis
- Pre-existing neurologic disorder
- Patients unable or unwilling to comply with all the aspects of the study, return for scheduled follow-up through at least five years, or adhere to all applicable conditions of the study protocol
- Genu varus >25 degrees
- Genu valgus >10 degrees
- Collateral ligament or PCL insufficiency

guidelines on Good Clinical Practice of the International Conference on Harmonisation [18], and the Declaration of Helsinki [19]. The study protocol was approved by the Medical Ethical Committee at Zwolle, The Netherlands and registered under number 01.0319.

Study Population

The study took place in two Dutch high volume general teaching hospitals between January 2002 and December 2011. Patients aged 50–75 years with osteoarthritis for whom a cemented TKA was indicated were eligible for inclusion. Inclusion and exclusion criteria are detailed in Table 1. Recruitment took place at the orthopaedic outpatient clinic in both hospitals and was done by the attending orthopaedic surgeons.

Intervention

All patients received a cruciate retaining Genesis II Total Knee Replacement prosthesis with cemented tibial and femoral components with a standard polyethylene insert (Smith & Nephew, London, United Kingdom) [17,20–22]. The bearing and insert as allocated through randomisation were implanted. Eight orthopaedic surgeons were involved in the study. All eight surgeons implanted all four insert types using the surgical technique for TKA with which they were most comfortable. No minimal invasive incisions were used. A patellar component was placed when the operating surgeon deemed this necessary. No patients underwent a bilateral TKA in a single session. Mobilisation after surgery was identical for all groups and consisted of walking with 2 crutches for 6 weeks, followed by 1 crutch for another 4 weeks. During this time all patients received physical therapy by a blinded therapist. Study follow-up visits were at 1 year and 5 years after surgery.

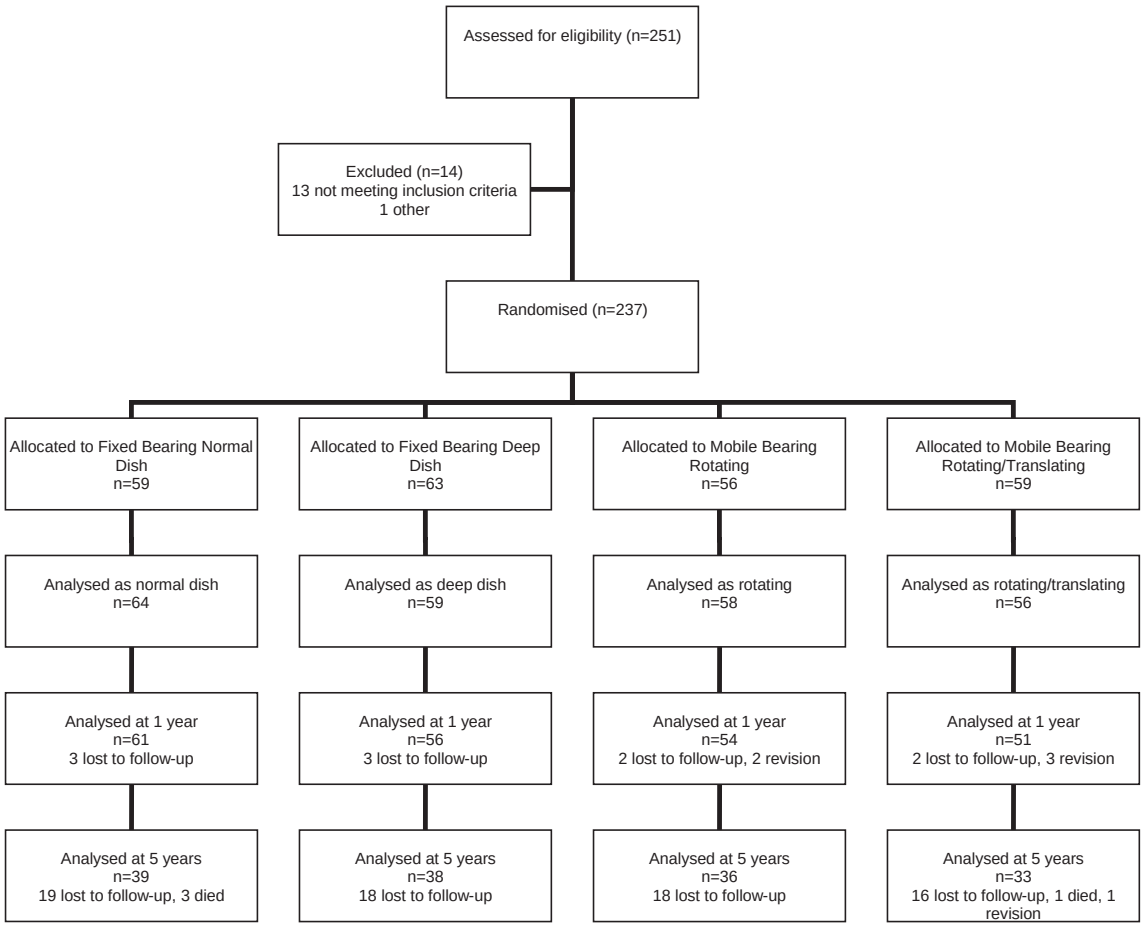

Fig. 1. CONSORT diagram with participant flow [35]. Patients that had a randomisation violation were analysed according to the insert implanted during surgery.