

## **Patient-Specific Instruments Do Not Show Advantage Over Conventional Instruments In Unicompartmental Knee Arthroplasty At Two Years Follow Up: A Prospective, Two-Centre, Randomised, Double Blind, Controlled Trial**

Orthopaedics / Knee & Lower Leg / Joint Replacement - Primary

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### **Background**

Unicompartmental knee arthroplasty (UKA) has been used in the treatment of unicompartmental knee osteoarthritis for several decades. Advantages of UKA over total knee arthroplasty (TKA) include faster return to work and a lower rate of adverse events (AEs). Joint registries have demonstrated a lower survival rate, compared to TKA. Achieving the correct alignment in UKA is technically demanding and associated with a significant learning curve.

An instrumentation method that has now been available for 10 years is the patient-specific instrumentation (PSI). With this instrumentation method, it is theoretically possible to accurately plan the position and size of the implants, prior to surgery, based on magnetic resonance imaging (MRI) or computed tomography (CT). As correct component positioning is critical to the success and survival of UKA, technologies to improve alignment accuracy may therefore greatly benefit UKA and need to be thoroughly investigated. This is the first independent multi-centre RCT, assessing the radiological and functional outcome, as well the rate of AEs of PSI in UKA in a study population of 120 patients.

### **Objectives**

The aim of this two-centre RCT was to compare post-operative radiological outcomes, clinical and functional outcomes between patient-specific instrumentated (PSI) and conventional instrumented (CI) unicompartmental knee arthroplasty (UKA). It was hypothesised that both alignment methods would have comparable post-operative radiological, clinical and functional outcomes.

### **Study Design & Methods**

120 patients were included in 2 different teaching hospitals, and randomly allocated to the PSI or the CI group. Outcome measures were peri-operative outcomes (operation time, length of hospital stay and intra-operative changes of implant size) and post-operative radiological outcomes including the alignment of the tibial and femoral component in the sagittal and frontal plane and the hip-knee-ankle-axis (HKA-axis), rate of adverse events (AEs) and patient-reported outcome measures (PROMs) pre-operatively and at 3, 12 and 24 months post-operatively.

### **Results**

There was a statistically significant difference ( $p < 0.05$ ) in alignment of the femoral component in the

frontal plane in favor of the CI method. No statistical significant differences were found for the peri-operative data, nor in the functional outcome at two years follow up. In the PSI group, the approved implant size of the femoral component was correct in 98.2% of the cases and the tibial component was correct in 60.7% of the cases. There was a comparable rate of AEs; 5.1% in the CI and 5.4% in the PSI group.

### **Conclusions**

The PSI method did not show improvement of component positioning in comparison to CI, nor in functional outcome or prosthesis survival at short term follow up. We conclude that the possible advantages of PSI do not outweigh the costs of the MRI scan and the manufacturing of the PSI.