Customized, Individually Made Unicondylar Knee Replacement: A Prospective, Multicenter Study of 2-Year Clinical Outcomes

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INTRODUCTION

Over the past decade, the number of unicompartmental knee arthroplasties (UKA) performed has increased by 30%.[1] Patients tend to prefer this treatment option as it is shown to provide better function and range-of-motion (ROM).[2] While they do offer benefits, UKAs often have to be revised. To address this, a customized, individually-made (CIM) UKA offers patient-specific fit and positioning, reducing the incidence of underhang and component malpositioning, common causes of tibial loosening and subsidence. The purpose of this study was to assess clinical and patient-reported outcomes utilizing this CIM unicondylar knee replacement (UKR) prostheses.

METHODS

A prospectively recruited cohort of 118 patients were implanted with 120 CIM UKR (110 medial and 10 lateral) at 8 centers (Table 1). Patients who were diagnosed with unicompartmental osteoarthritis of the medial or lateral compartment and consented to take part in the study were included. Patients with a BMI>35, compromised cruciate or collateral ligaments, or who had a varus/valgus deformity >15° were excluded from the study. Using the Knee Society Knee and Function Scores, WOMAC and VAS Pain scales as well as ROM tests, patients were assessed pre-operatively, at 6-months post-op, 1 year post-op and 2 years post-op. Patients were also asked about their satisfaction level and if the movement of their implanted knee felt natural.

Table 1: Patient demographics of the study population

Knees / Patients (N)	120 / 118
Patient Gender (Male/Female)	78 / 40
Mean Age at Surgery (years)	65 [33 - 84]
Mean Body Mass Index (BMI)	28 [18 - 38]

RESULTS

Range-of-motion was improved by an average of 11° from 120° pre-operatively to 131° at 2 years post-op (116° at 6 weeks, 129° at 6 months, and 129° at 1 year) (Figure 1). Patients demonstrated marked improvements from baseline scores across all measured domains. A total of 88 patients have reached their 2-year follow-up visit to date. Average scores at the 2-year interval are as follows: KSS Knee Score - 94, KSS Function - 91, scaled WOMAC - 90, and VAS Pain - 1.3 (Figure 2). Additionally, 99% of patients said they were satisfied with their UKR (89% reporting they were very or extremely satisfied) and 89% stated that the movement of their knee felt natural (Figure 3). To date, 2 patients have undergone revision for tibial loosening and 2 additional patients were revised for disease progression yielding a cumulative revision rate of 3.3% at an average follow-up of 2 years.

1. Riddle DL, Jiranek WA, McGlynn FJ. Yearly incidence of unicompartmental knee arthroplasty in the United States. J Arthroplasty 2008;23(3):408.
2. Rougraff B, et al.; A comparison of tricompartmental and unicompartmental arthroplasty for the treatment of gonarthrosis; Clin Orthop Relat Res; Dec 1991; Vol. 273: pp. 157–164

Figure 1: Mean range of motion pre-operatively, at 6 weeks, 6 months, 1 year, and 2 year follow-up.
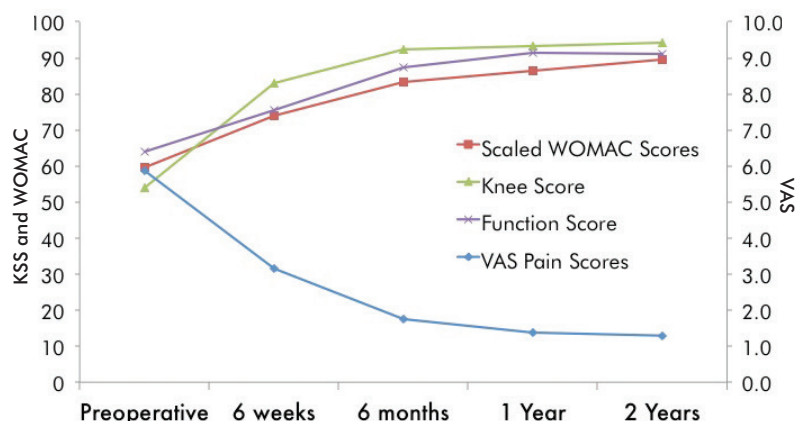

Figure 2: Average KSS Knee, KSS Function, Scaled WOMAC, and VAS Pain scores for all patients that reached 2-year follow-up.
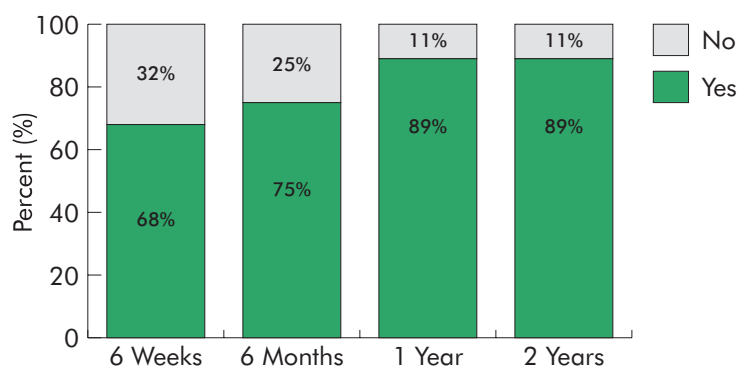

Figure 3: Patient responses when asked, "Does the movement of your treated knee feel natural," at various timepoints of follow-up.

Discussion

As the number of UKAs performed each year increases, ensuring patient satisfaction is critical. The 2-year follow up data collected on this CIM UKR is promising as 99% of patients reported that they were satisfied with their CIM UKR and 89% reported that the movement of their knee felt natural. Additionally, this data compares favorably to published scores for traditional, off-the-shelf unicompartmental implants.