

Clinical and Patient-Reported Outcomes after Customized Individually Made Total Knee Arthroplasty

Raphael Kaelin, Nicole Vogel, Markus P. Arnold

Praxis LEONARDO, Hirslanden Klinik Birshof, CH-4142 Münchenstein, Switzerland

Introduction

Classical total knee arthroplasty (TKA) is subject to different problems that can negatively influence clinical and patient-reported outcome. In literature several causes are discussed. Rotational and coronal malalignment, implant overhang and non-anatomic implant design with altered knee kinematic are only some of these. The idea behind customized individually made (CIM) TKA is to avoid such problems and improve outcome. The purpose of this study was to assess clinical and patient-reported outcome measures (PROMs) of patients with CIM TKA.

Methods

Since 2015, CIM TKA are available at our clinic. In 2017, we started to prospectively collect PROMs from patients scheduled for a knee arthroplasty¹. For this study, we included patients with primary cruciate-retaining CIM TKA (iTTotal CR G2, ConforMIS, Inc., Bedford, US; Figure 1) who agreed to complete PROMs. Between January 2017 and June 2020, the senior author (MA) implanted 97 CIM TKA, for 75% of them PROMs were available and included in this study. We excluded patients with major re-operation or revision surgery.

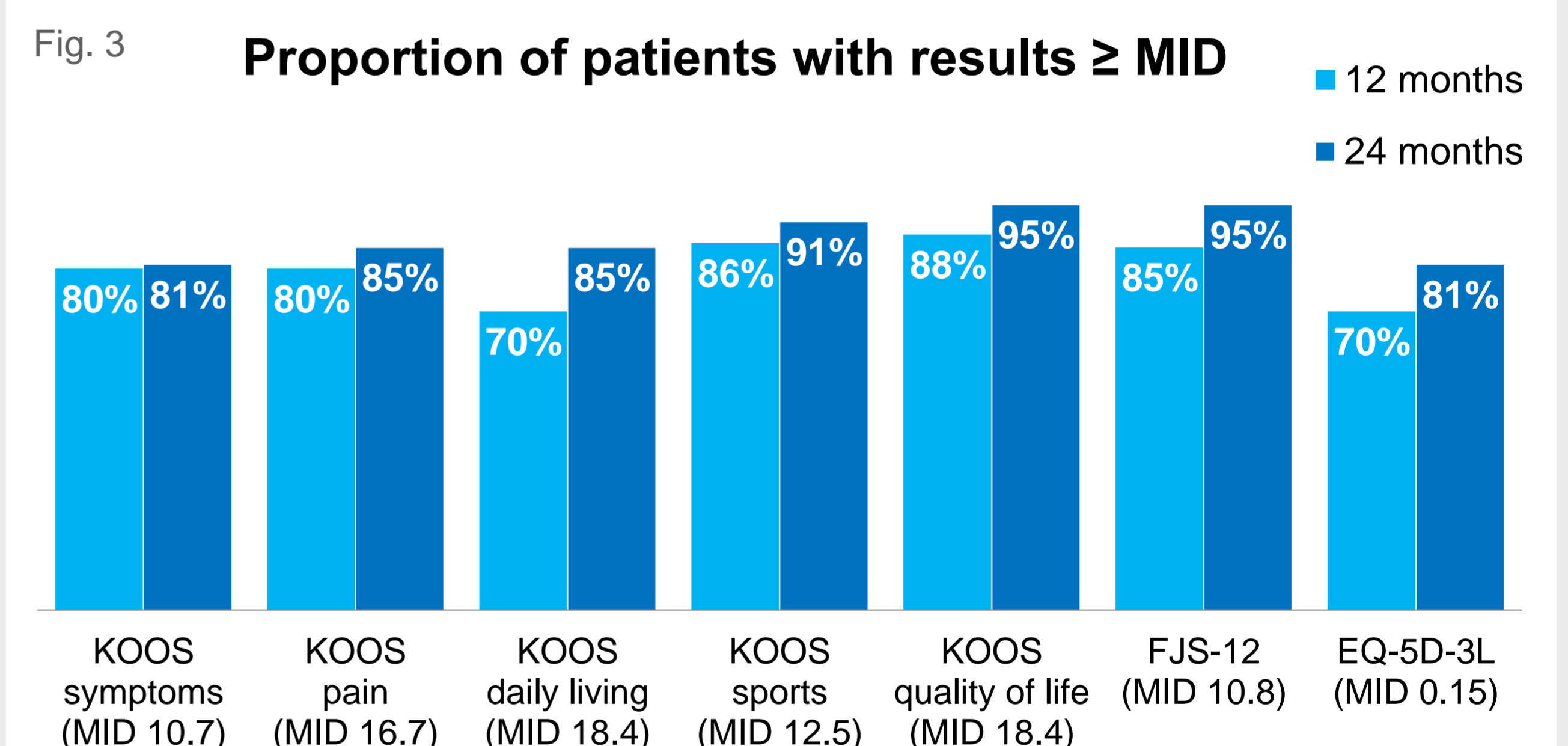
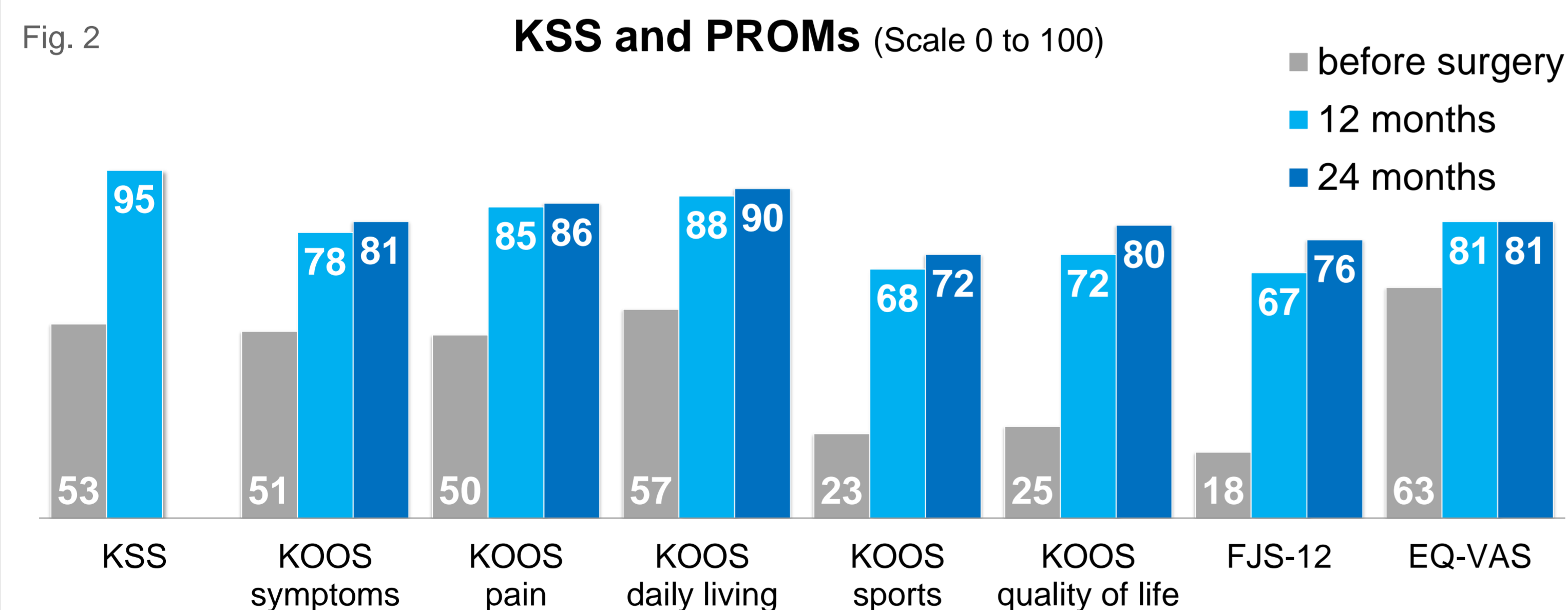
Data was collected preoperatively, and after 12 and 24 months. Outcome measures included the objective Knee Society Score (KSS; not after 24 months) and the following PROMs: Knee injury and Osteoarthritis Outcome Score (KOOS), Forgotten Joint Score (FJS-12), EQ-5D-3L and patient satisfaction. We analyzed pre-post data with paired t-tests and calculated the proportion of patients with an improvement above the minimal important difference (MID)²⁻⁴. The MID is defined as the smallest difference in a score that patients perceive as important.



Results

After 12 months we analyzed data for 70 CIM TKA (61 patients, 49% female) and after 24 months for 41 CIM TKA (34 patients, 56% female). Mean patient age at surgery was 67 years (SD 8.7, range 48 to 83), mean KSS was 52 points (SD 11.6). Anatomic alignment before the surgery was neutral (n = 11), varus (n = 42) and valgus (n = 17). Kellgren-Lawrence classification of osteoarthritis was grade 2 (n = 1), grade 3 (n = 22) and grade 4 (n = 47).

After 12 months anatomic alignment was neutral (n = 68), varus (n = 1) and valgus (n = 1), the mean KSS improved to 95 points (SD 6.3, p < 0.001). All PROMs improved after 12 and 24 months compared to baseline (p < 0.001, Figure 2), EQ-5D-3L improved from 0.607 to 0.876 (12 months, p < 0.001) and to 0.934 (24 months, p < 0.001). The proportion of patients whose results improved at least by the MID is shown in Figure 3. Satisfaction rate was 86% after 12 months and 88% after 24 months. Complications occurred in three patients: an arthrolysis due to arthrofibrosis (13 months), a quadriceps tendon rupture (18 months), and one patient needed complete revision (18 months).



Conclusion

The 12 and 24 months follow-up data collected on CIM TKA showed very good clinical and patient-reported results, which are comparable to those reported for off-the-shelf implants⁵. Future studies have to confirm those results in a larger patient collective and in long-term. Likewise, case-control studies are needed to show a clinically relevant difference compared to off-the-shelf implants.

References

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