Clinical and Patient-Reported Short-Term Results after Customized Individually Made Total Knee Arthroplasty

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Introduction

Conventional knee arthroplasty is subject to different problems that can negatively influence the clinical outcome. In the 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 is, that customized individually made total knee arthroplasty (CIM TKA) can avoid such problems and improve clinical outcome. The purpose of this study was to assess the clinical and patient-reported outcome measures of CIM TKA.

Methods

Since January 2017, we prospectively collected clinical and patient-reported outcome measures from all patients scheduled for CIM TKA (iTotal, ConforMIS, Inc., Bedford, MA; Figure 1). Consistent with the indications for total knee arthroplasty, we excluded patients with compromised collateral ligaments or a varus/valgus deformity > 15°. All surgeries were done by the senior author (MA) who started to implement CIM TKA. Thus, results might reflect a learning curve.

We collected data before the surgery and 12 months postoperatively. Outcome measures included the objective Knee Society Score (oKSS) and patient reported scores: the Knee injury and Osteoarthritis Outcome Score (KOOS), the Forgotten Joint Score (FJS), the generic instrument EQ-5D for general health and patient satisfaction. We analyzed pre-post data with paired t-tests and calculated the proportion of patients whose results improved at least by the minimal important difference (MID)1-3.

Results

We analyzed 12 months follow-up data for 24 prostheses (21 patients, 12 male). Mean patient age was 66.5 years (standard deviation [SD] 9.4, range 48 to 82), mean range of motion (ROM) for extension-flexion was 108° (SD 15.3, range 70 to 130). Anatomic alignment before the surgery was neutral (n = 4), varus (n = 12) and valgus (n = 8), Kellgren-Lawrence classification of osteoarthritis was grade 2 (n = 1), grade 3 (n = 10) and grade 4 (n = 13), respectively.

Twelve months after the surgery all patients had a neutral alignment. Mean ROM was 126° (SD 12.7, range 90 to 145, p = 0.001). All knee scores improved significantly (p < 0.001, Figure 2), EQ-5D improved from 0.580 to 0.881 (Scale 0 to 1, p < 0.001). The proportion of patients whose results improved at least by the MID are shown in Figure 3. Mostly, patients were very satisfied (59 %) or satisfied (23 %) with the result of the surgery, only some were neutral (9 %) or unsatisfied (9 %). There were no complications, besides one patient who required an arthrolysis following an arthrofibrosis due to a meanwhile healed complex regional pain syndrome.

Conclusion

The 12 months follow-up data collected on CIM TKA showed good clinical and patient-reported results, which are comparable to those reported for off-the-shelf implants4. 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