Personalization in Total Knee Replacement Surgery (PNP-trial): A Prospective, Randomized, Controlled Trial Comparing a Novel, Personalized Total Knee Replacement Design with Two Conventional Knee Replacements

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INTRODUCTION:
The longevity of contemporary total knee replacement (TKR) designs is excellent as survival rate for modern TKR design exceeds 95% during the first decade of implant lifetime. Nevertheless, the patient-reported functional outcome and patient satisfaction still leave room for improvement. Functional outcome after TKR is the result of complex interplay, where the implant design is only one factor, and both patient characteristics as well as the surgical technique play major roles as well. Recently, a variety of personalized TKR implant designs have been developed and introduced to the market. Personalizing means more anatomically shaped and accurate implants, finer sizing increments, and a continuum of bearing constraints in comparison to previous generation of modern TKRs.

The aim of this randomized controlled trial (RCT) was to investigate the results of a novel, personalized TKR implant design in comparison to two conventional TKR designs. Primary outcome was Oxford Knee Score (OKS) at 24 months.
METHODS:
We conducted a parallel group design RCT with a 1:1:1 allocation ratio. Patients were randomized into the intervention group involved personalized TKR implant design; and the two control groups involved conventional TKR designs. The study protocol was reviewed and approved by the Regional Ethics Committee and was registered in the ClinicalTrials Registry. The study was designed and conducted following the SPIRIT and CONSORT guidelines and the study protocol has been published previously.

All patients with primary knee OA who were referred to the outpatient clinic at our hospital between September 2015 and August 2018 and who met our criteria for primary TKR, were assessed for eligibility by a participating orthopaedic surgeon alongside their routine outpatient work. Patients meeting one or more of the following criteria were excluded from participation: unwilling to provide informed consent, >15 degrees varus or valgus, or >15 degrees fixed flexion deformity, predominantly patellofemoral OA, physical, emotional, or neurologic conditions that would compromise rehabilitation and follow up (e.g., drug or alcohol abuse, serious mental illness, general neurological conditions, such as Parkinson, MS, etc.). If a patient was eligible and willing to participate, informed, written consent was obtained.

Patients were blinded to the implant design used in their operation. Also the physiotherapists conducting the follow-up visits (at 2–3 months, 1 year, and 2 years, i.e., the outcome assessors) were blinded to the allocation. The patients have not received information on the specific implant design used in their operation until all patients have completed the 2-year follow-up visit. Primary outcome measure was the OKS and the FJS secondary outcome at 24 months. Based on power calculations the total number of patients was 240. Other measures were the Forgotten Joint Score (FJS), the 15D, the UCLA activity score, and the visual analogue scale (VAS) pain score. Complications, revisions, and adverse events were recorded.
RESULTS:
Between September 2015 and August 2018, we randomized 240 patients to undergo TKR with personalized TKR implant design (80 patients) or with two conventional TKR designs (80 patients each). The majority of patients were female (67.5%) at the mean age of 61.8 years (range 49–71). The final 24-month assessments were completed in 2021 with delay due to COVID-19. Of the 240 patients who underwent randomization, 224 were included in the final analyses. Sixteen patients withdrew from the study since they were unwilling to undergo surgery (post randomization exclusion). The baseline characteristics were similar in the three treatment groups.

The OKS improved clinically significantly from baseline to 2 years in all 3 treatment groups (figure 1). At the final follow up, OKS was equivalent between the group as 95% CI excluded between-group differences larger than 3 points. At the final follow up FJS was 5 and 6 points worse in the intervention group compared to conventional implant groups. This estimate was however imprecise and zero difference could not be excluded based on the CIs. Similarly, no clear evidence was found to support the hypothesis that 15D was better in the intervention group.

The prevalence of adverse events was highest in the conventional implant group B but we did not observe statistically significant differences between the groups.
DISCUSSION AND CONCLUSION:

This randomized controlled trial demonstrated that we were unable to find clinically relevant differences in functional outcomes measured either with OKS or with FJS between two conventional TKR designs and the novel TKR design at the time of the 2-year follow up. The marketed features of personalization in the novel TKR design did not meet the expectations they raised, as older TKR designs with proven track records of survivorship and function were able offer the same patient-reported and functional outcome as the novel design.

Figure 1. Primary outcome (Oxford Knee Score) in the conventional implant design A group,

intervention group, novel design and the conventional B group. Values are means with 95% CIs.