Safety of orthopedic implants: implant migration analysis a must

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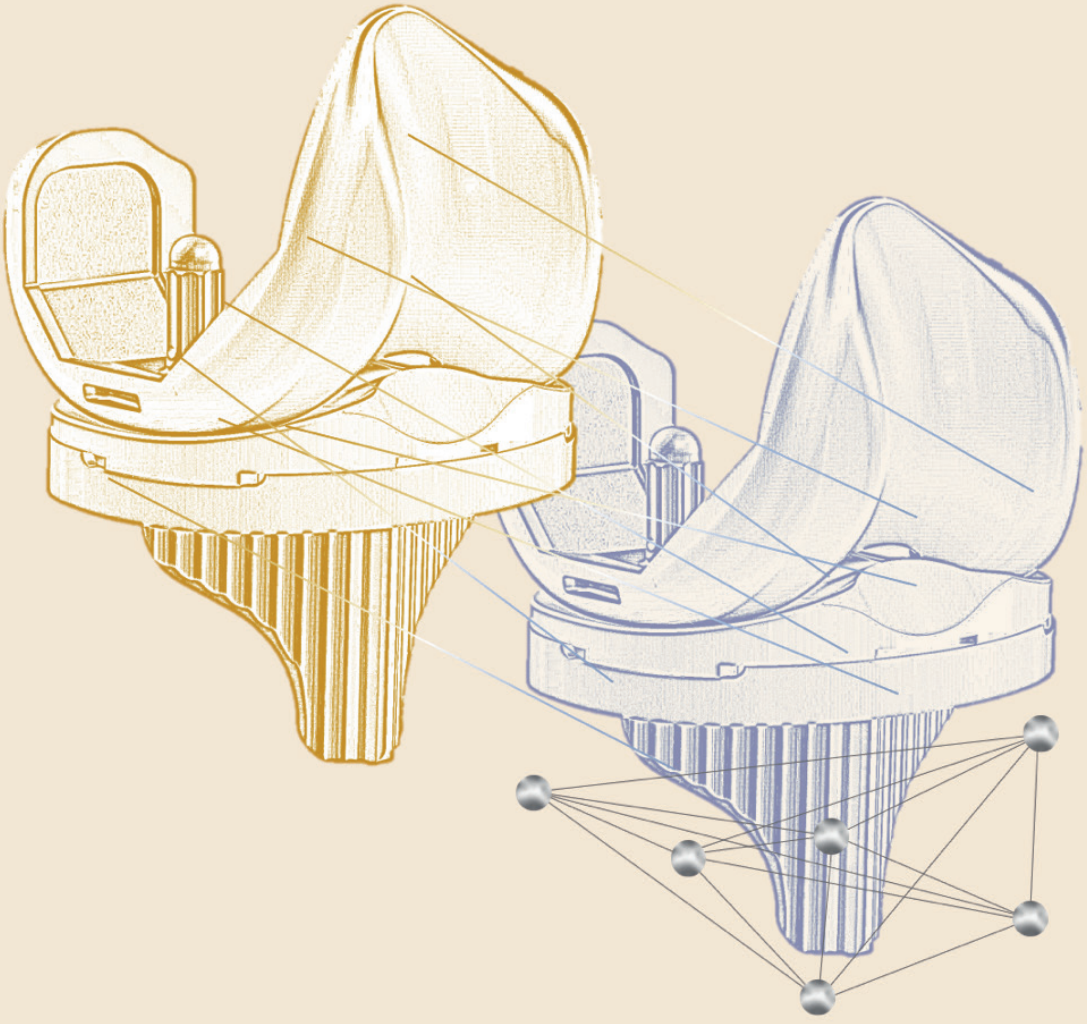

Chapter X

Summary

The aim of the present thesis was to contribute to better understand the influence of differences in implant design and surgical techniques on migration of TKA, and more broadly on the effect of using RSA and other markers to detect loosening early.

In Chapter II, we compared revision rates of RSA-tested TKA designs with non-RSA-tested TKA designs using national and regional arthroplasty registries. Seven registries comprising of 339 TKA designs were included. These TKA designs were compared to TKA designs used in RSA studies on three characteristics: prosthesis model, fixation method and insert type. TKA designs from registries matching a design used in an RSA study were classified as RSA-tested. All remaining TKA designs were classified as non-RSA-tested. The RSA-tested and non-RSA-tested groups included 236 and 103 TKA designs, respectively. The pooled revision rate of RSA-tested TKAs at five years was 2.9% and at ten years was 4.4%. The pooled revision rate of non-RSA-tested TKAs at five years was 3.6% and was 5.5% at ten years. Revision rates were 0.6% and 0.9% lower at five and ten years in favor of RSA-tested TKAs. This absolute reduction of revision risk could translate in a relative reduction of approximately 20% at ten years.

In Chapter III, we conducted a systematic review to identify serum and urine markers which could discriminate between aseptic loosened and stable hip and knee implants. Twenty-eight studies assessing these biomarkers were included. Serum and urine markers were studied in 22 and in ten studies, respectively. Serum tumor necrosis factor α, interleukin-1b and osteocalcin as well as urinary N-terminal telopeptide were significantly elevated in loosened implants compared to stable implants. These biomarkers should be studied further as they potentially could open strategies to not only prevent severe implant loosening by acting as a therapeutic target, but also have the potential to monitor disease progression.

In Chapter IV, migration and patient reported outcome scores (PROMs) of two implant designs were compared in a randomized controlled trial (RCT) conducted in Hässleholm, Sweden. Sixty patients were randomized to either a cemented metal-

backed tibial (MBT) posterior-stabilizing (PS) TKA or an all-polyethylene tibial (APT) PS TKA. Primary outcome was migration measured with RSA and secondary outcomes were the knee society score (KSS), knee osteoarthritis outcome score (KOOS) and the forgotten joint score (FJS). Patient follow-up was at three months, one year and two years postoperative. No differences in migration between MBT and APT TKAs was found. Further, no significant differences were found in KSS, KOOS or FJS scores between both implant designs. These findings suggest that the risk of aseptic loosening is comparable for MBT and APT TKAs.

In Chapter V, two different fixation methods were compared using migration measured with RSA and PROMS. This RCT was conducted in Hässleholm, Sweden. Seventy-two patients were randomized to either a cemented or an uncemented, 3D-printed TKA. RSA radiographs were taken within two-three days postoperative, at three months, at one year and at two years. Secondary outcome measures were the KSS, KOOS and FJS. The 3D-printed, uncemented TKAs migrated more over the two-year period than their cemented counterparts. The difference was due to higher migration of the uncemented TKAs in the first three months. After three months, cemented and 3D-printed, uncemented TKAs showed comparable migration. No differences were found in KSS, KOOS and FJS between both fixation methods. These findings suggest that 3D-printed, uncemented TKAs are as stable as cemented TKAs after an initial period of settling.

In Chapter VI, two RCTs were pooled and migration of MBT and APT TKAs were compared up to five years. In this study, MBT cruciate-stabilizing (CS) TKAs were compared with APT CS TKAs, and MBT PS TKAs were compared with APT PS TKAs. Further, migration profiles of continuously migrating implants were evaluated beyond two years. Sixty patients were randomized in each study, but five patients were excluded due to various reasons, leaving 115 patients to be analysed. No differences in migration between MBT-CS and APT-CS nor between MBT-PS and APT-PS TKAs was found. However, the surgeon had a significant influence on implant migration in the CS-study. Further, nine TKAs showed continuously

migration in both studies combined. Of these TKAs, one was revised for instability, four stabilized, and four had missing five-year data. These findings suggest that the risk of aseptic loosening is comparable between MBT and APT TKAs using data up to five years. Further, the surgeon seems to influence migration in particular implant designs. Last, the finding that four TKAs showed late stabilization stresses the need for mid- and long-term RSA studies to determine whether predictions at two years are correct.

In Chapter VII, we conducted a meta-analysis to evaluate migration patterns of tibial components of unicondylar knee arthroplasties (UKAs). Ten studies comprising of 13 study groups and 381 UKAs were included. We found that the majority of migration occurred in the first 6 months postoperatively followed by a period of very little migration, similar to what is reported for TKAs. However, migration at one year and two years was higher for UKAs than for TKAs. These findings suggest that migration profiles of UKAs are comparable to TKA migration.

In Chapter VIII, ten RCTs conducted in Hässleholm, Sweden or Leiden, The Netherlands were pooled to compare migration of in-range TKAs with out-of-range TKAs in patients with a preoperative varus or valgus knee. In-range was classified as a hip-knee-ankle angle (HKA) of 0 ±3° and out-of-range as a HKA of <-3° or >3°. The in-range group consisted of 290 TKAs and 186 TKAs were included in the out-of-range group. We found no difference in migration up to two years between in-range and out-of-range TKAs. However, the fixation method (i.e., cemented, uncemented-coated, or uncemented-uncoated) had a significant influence on migration with uncemented-uncoated implants showing the highest migration. Thus, failing to achieve an in-range TKA in patients with a preoperative varus or valgus knee did not increase migration up to two years, suggesting that leaving residual varus or valgus has no impact on TKA migration.