Supplementary data

Table 3. Characteristics of patients with deviation in allocated randomization group

| Case | Patient | Reason for deviation | Outcome |
|------|------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------|
| #1: | Female, 55 y, osteoarthritis, BMI 35, HKA 179°, lateral plate from valgus- producing HTO (2001) in situ | Ligament balancing difficulties, additional bone-cuts needed, and inferior lateral compartment after plate-removal | Migration pattern stable. Functionally satisfied with high KSS scores |
| #5: | Female, 72 y, osteoarthritis, BMI 38, HKA 174°, previously valgus-producing HTO (1994) and staple removal (2005) | Difficulties with ligament balancing, exposure, and mobilization of tibia due to previous surgical procedures | Migration pattern stable. Functionally satisfied, high KSS Knee Scores, KSS Function Score compromised due to ataxia |
| #16: | Female, 72 y, osteoarthritis, BMI 26, HKA 171° | Tight soft tissue requiring undesirable additional releases around fragile soft bone | Migration pattern stable. Functionally satisfied with high KSS scores |
| #32: | Female, 78 y, rheumatoid arthritis, BMI 20, HKA 191° | Minimal releases and exposure possible due to soft bone and fragile soft tissue affected by rheumatoid arthritis | Migration pattern stable. Medium to high KSS scores until 4 years. Patient died after 4 years due to respiratory health problems |
| #35: | Female, 52 y, osteoarthritis, BMI 34, HKA 168° | Bilateral procedure, first knee was an uncomplicated mobile-bearing design, second knee was tight with difficult releases while the epidural block wore off | Continuous migration after three years, progressive varus alignment with low to medium KSS scores. Revision due to aseptic loosening after 6 years |

Table 4. RSA migration analysis of mean maximum total point motion (MTPM) with lower and upper limits of 95% CI (log values are back-transformed in the original scale in mm)

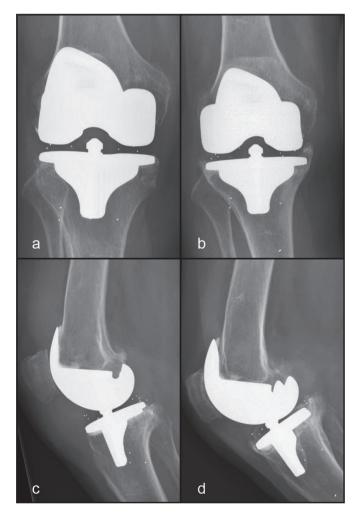
| Factor | Fixed bearing | Mobile bearing | p-value | | | | | | |
|--------------------|------------------|------------------|---------|--|--|--|--|--|--|
| Intention-to-treat | | | | | | | | | |
| 6 months | 0.61 (0.32-0.95) | 0.69 (0.39-1.06) | | | | | | | |
| 1 year | 0.69 (0.41–1.02) | 0.75 (0.46–1.09) | | | | | | | |
| 2 years | 0.77 (0.45–1.16) | 0.90 (0.56–1.33) | | | | | | | |
| 3 years | 0.92 (0.52-1.42) | 0.91 (0.51–1.41) | | | | | | | |
| 4 years | 0.84 (0.48-1.29) | 1.08 (0.67-1.59) | | | | | | | |
| 5 years | 0.90 (0.53-1.37) | 1.25 (0.81-1.80) | | | | | | | |
| 6 years | 0.90 (0.49-1.41) | 1.22 (0.75–1.80) | 0.3 | | | | | | |
| As-treated | | | | | | | | | |
| 6 months | 0.65 (0.38-0.97) | 0.64 (0.31-1.05) | | | | | | | |
| 1 year | 0.71 (0.45–1.01) | 0.73 (0.41-1.12) | | | | | | | |
| 2 years | 0.80 (0.50-1.16) | 0.89 (0.51-1.38) | | | | | | | |
| 3 years | 0.93 (0.56-1.38) | 0.88 (0.44-1.46) | | | | | | | |
| 4 years | 0.89 (0.55-1.31) | 1.06 (0.61-1.65) | | | | | | | |
| 5 years | 1.00 (0.64–1.44) | 1.18 (0.70-1.80) | | | | | | | |
| 6 years | 1.04 (0.64–1.53) | 1.08 (0.59–1.72) | 0.9 | | | | | | |

Table 5. Secondary outcomes. Values are mean (standard error) unless otherwise specified.

| | Intention-to-treat | | | As-treated | | | | |
|--------------------|--------------------|-------------------|---------------------------------------------------------|----------------------|---------------|-------------------|---------------------------------------------------------|----------------------|
| Factor | Fixed bearing | Mobile bearing | Difference in progression between groups (95% CI) | p-value ^a | Fixed bearing | Mobile bearing | Difference in progression between groups (95% CI) | p-value ^a |
| Flexion (°) | | | | | | | | |
| Preoperative | 111 (3) | 112 (3) | | | 111 (3) | 112 (4) | | |
| 1 year | 114 (2) | 117 (2) | | | 113 (2) | 119 (̀3)́ | | |
| 6 years | 111 (3) | 119 (3) | 7 (-4 to 18) | 0.2 | 113 (3) | 119 (̀3)́ | 5 (-6 to 16) | 0.4 |
| Extension (°) b | ` , | ` , | ` ' | | ` ' | ` , | , | |
| Preoperative | -4 (1) | -3 (1) | | | -4 (1) | -3 (1) | | |
| 1 year | -0 (1) | -0 (1) | | | -0 (1) | 0 (1) | | |
| 6 years | -0 (1) | -1 (1) | -2 (-6 to 1) | 0.2 | 0 (1) | -3 (2) | -4 (-8 to 1) | 0.1 |
| KSS Knee Score | | | | | | | | |
| Preoperative | 49 (2) | 47 (4) | | | 48 (2) | 49 (4) | | |
| 1 year | 86 (3) | 89 (2) | | | 86 (3) | 90 (3) | | |
| 6 years | 92 (5) | 93 (2) | 3 (-11 to 17) | 0.7 | 91 (4) | 95 (2) | 3 (-11 to 16) | 0.7 |
| KSS Function Score | | | | | | | | |
| Preoperative | 46 (7) | 36 (7) | | | 44 (6) | 35 (8) | | |
| 1 year | 69 (6) | 57 (6) | | | 67 (5) | 58 (6) | | |
| 6 years | 54 (7) | 43 (6) | -2 (-21 to 18) | 0.9 | 54 (6) | 39 (7) | -6 (-26 to 13) | 0.5 |

^a p-values indicate testing the mean between-group differences of improvement after 6 years of follow-up derived with a linear mixed-effects model analysis (data on all follow-up measurements are used to test for differences).

^b Negative extension means no full extension possible.



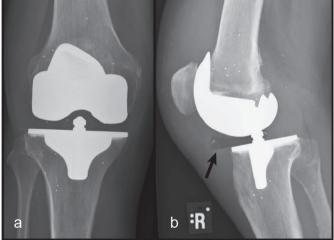


Figure 5. Insert dislocation of the mobile-bearing insert in a 66-year-old man with osteoarthritis. The anteroposterior radiograph (a) shows no abnormalities, the lateral radiograph (b) shows anterior displacement of the insert (black arrow).

Figure 4. Mobile-bearing TKP suspected for aseptic loosening in a 72-year-old woman with rheumatoid arthritis. Revision surgery was postponed due to refractory stasis dermatitis around the knee. Anteroposterior radiographs (a) 3 months and (b) 6 years follow-up, lateral radiographs (c) 3 months and (d) 6 years follow-up. Note the varus tilt of 3.5° (b), anterior translation of 3.5 mm (d) and subsidence of 9.2 mm (both b and d) of the tibial component.