

Low Early Complication Rate and High 4-year Survivorship Following Implantation of a New Femoral Stem Design: A Multi-center Registry Review

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BACKGROUND

Many successful modern stem designs have embraced the philosophy of achieving fit and fill in the femoral metaphysis to avoid rotational instability and prevent subsidence. Recently, the ACTIS Total Hip System™ stem was introduced as a medially collared, triple-tapered, proximally coated hip stem for use with the direct anterior and other minimally invasive approaches.

OBJECTIVES

A retrospective, multi-center outcome review was conducted to provide further data on the use of this femoral stem in primary total hip arthroplasty (THA).

DESIGN AND METHODS

Clinical assessments were summarized. It is recognized that sites within the registry have different standard of care regarding clinical follow-up visits, therefore, standardized registry visit windows were established, which were back-to-back to include all follow-up data. Kaplan-Meier (KM) survivorship was performed with revision of the femoral component and revision of any component as endpoints. For each endpoint two survivorship analyses were performed with differing censoring assumptions. First, unrevised subjects were censored at the last clinical follow-up [clinical assumption (CA)], and second at the date of database extract [registry assumption (RA)]. In all cases survival estimates and graphs were truncated at 40 hips remaining at risk. For the survivorship of the femoral component, subjects were censored at the time of removal of other components.

RESULTS

A total of 4,388 stems were implanted at several institutions. Primary diagnosis was osteoarthritis in 91% of cases. The mean age was 64.5 years (range 21 to 93), 47% were female and BMI averaged 28.1 (range 16 to 74). Approach was direct anterior in 90% of cases. There were a total of 18 revisions, 15 occurred in the first-year post op. Reasons for revision are listed in Table 1. There was 1 intraoperative femoral perforation and two femoral fractures (1 calcar, 1 unicortical lateral). There were 9 revisions of the stem, 8 secondary to infection, 1 due to dislocation. No revisions were reported for stem subsidence or stem loosening. One subject presented with a Vancouver Type B2 fracture one month after THA which was treated with ORIF. KM survivorship estimates (95% CI; N with further follow-up) for CA and RA are listed in Table 2, with survivorship defined as no revision of any component for any reason and revision of the stem. Plots of the KM survivorship of the THA construct with 95% confidence interval (shaded) is provided in Figure 1, and for the stem in Figure 2. Mean Harris Hip Scores are presented in Table 3.



CONCLUSION

In an observational registry data setting it is believed that RA tends to overestimate survivorship estimates, whereas CA has the potential to underestimate survivorship; this report included both analysis methods to improve transparency of the data analysis. In this cohort of over 4000 total hip arthroplasty procedures using this femoral stem, the complication profile related to this femoral component is extremely low and early to mid-term survivorship is promising. The authors believe that this data predicts the high likelihood of long-term fixation and clinical success of this implant and supports the use of a collared, triple tapered femoral component in less invasive total hip arthroplasty procedures, including the anterior approach.

| Revision Reason | N |
|-------------------------|-----------|
| Dislocation | 5 |
| Infection | 11 |
| Liner Dissociation | 1 |
| Periprosthetic Fracture | 1 |
| Total | 18 |

Table 1 – Revisions

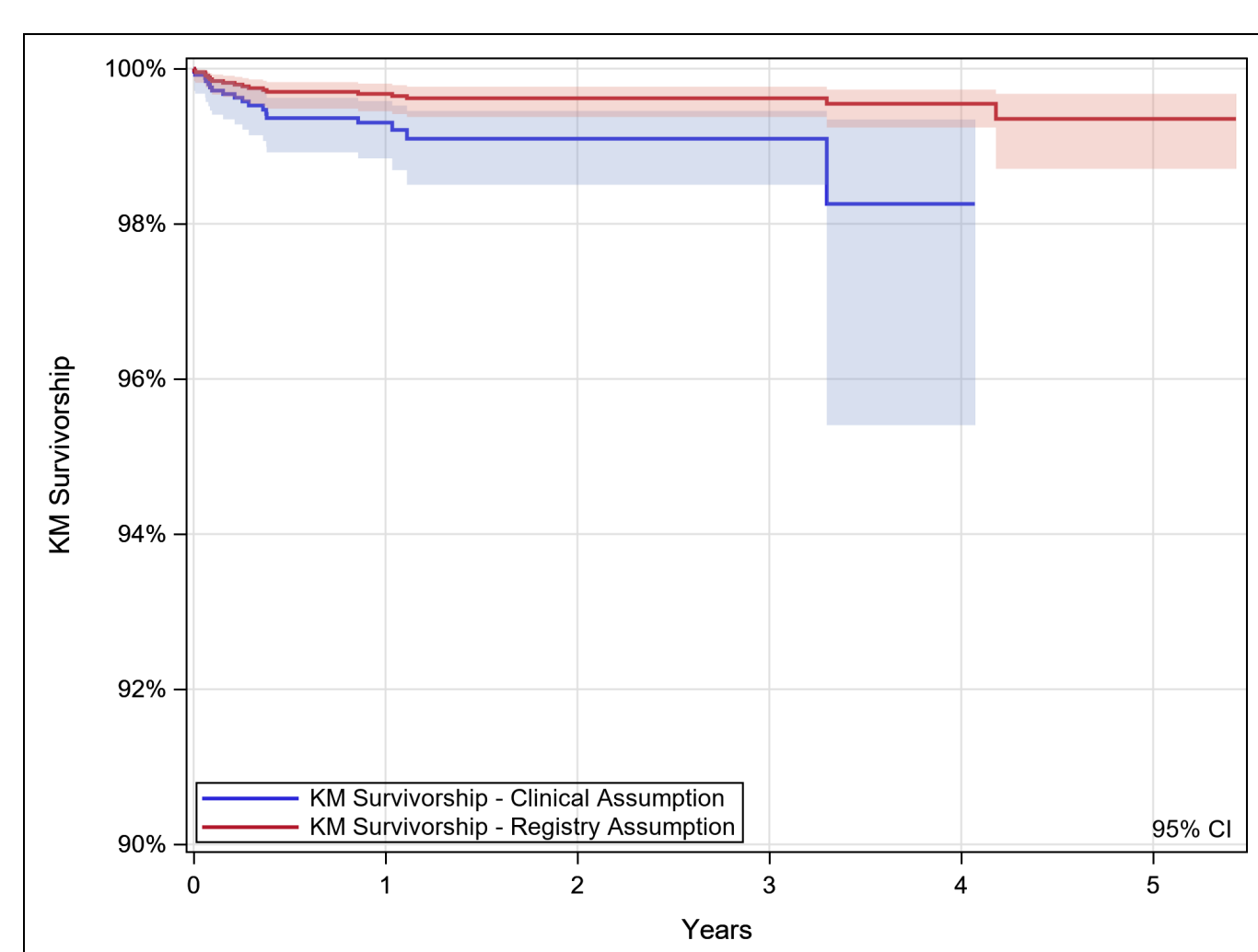


Figure 1 – Any Component Kaplan-Meier Survivorship and 95% CI

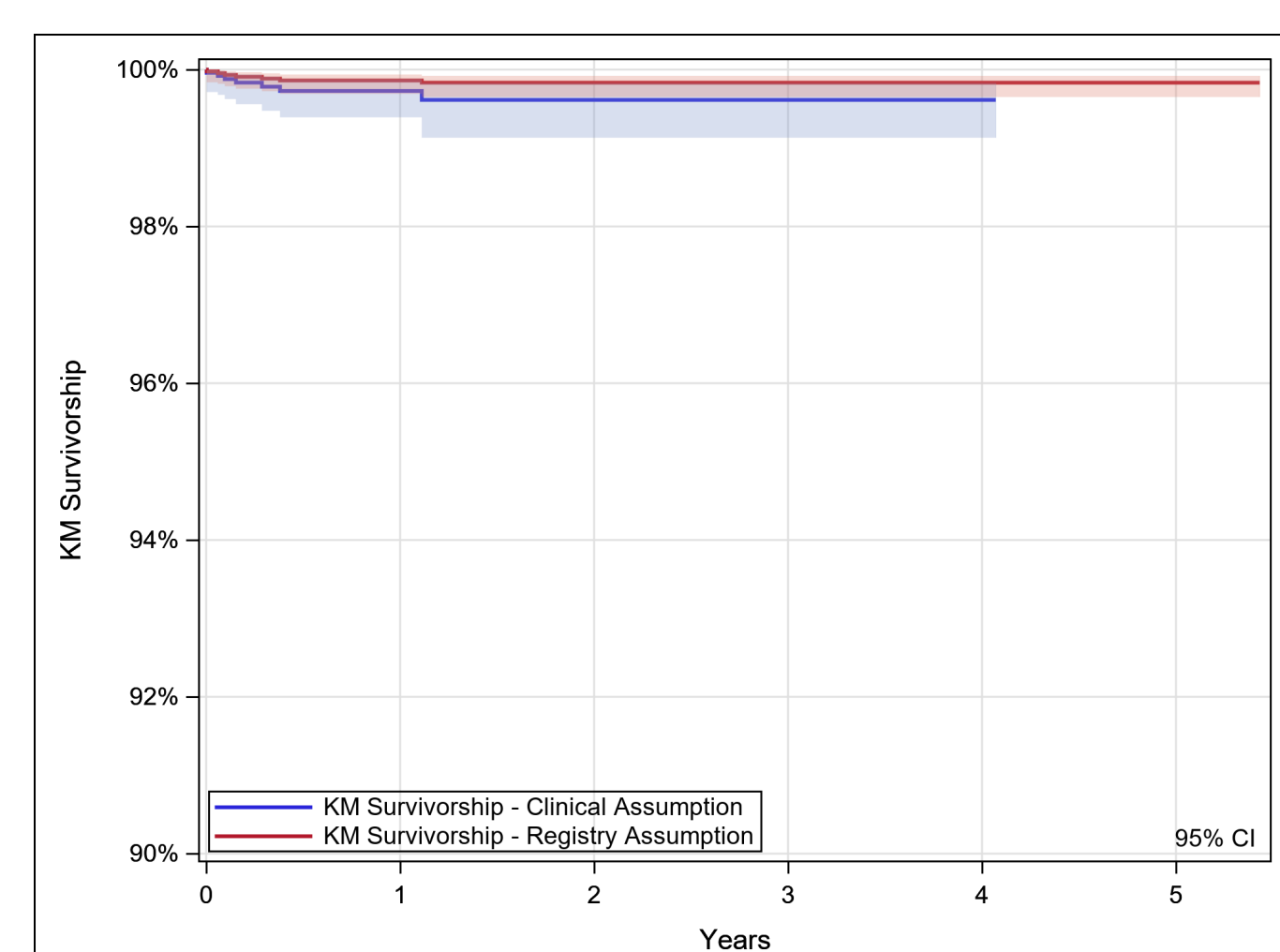


Figure 2 – Stem Only Kaplan-Meier Survivorship and 95% CI

| All Hips (N=4,388) | 1 Year KM Survivorship | 2 Year KM Survivorship | 3 Year KM Survivorship | 4 Year KM Survivorship |
|-------------------------|----------------------------------|----------------------------------|----------------------------------|--------------------------------|
| | (95% CI) N with Later Follow-up | | | |
| All Cause Revision - CA | 99.3% (98.8%,99.6%) N = 1,300 | 99.1% (98.5%,99.5%) N = 504 | 99.1% (98.5%,99.5%) N = 174 | 98.3% (95.4%,99.3%) N = 60 |
| All Cause Revision - RA | 99.7% (99.5%,99.8%) N = 3,670 | 99.6% (99.4%,99.8%) N = 2,678 | 99.6% (99.4%,99.8%) N = 1,669 | 99.5% (99.2%,99.7%) N = 670 |
| Stem Revision - CA | 99.7% (99.4%,99.9%) N = 1,300 | 99.6% (99.1%,99.8%) N = 504 | 99.6% (99.1%,99.8%) N = 174 | 99.6% (99.1%,99.8%) N = 60 |
| Stem Revision - RA | 99.9% (99.7%,99.9%) N = 3,670 | 99.8% (99.7%,99.9%) N = 2,678 | 99.8% (99.7%,99.9%) N = 1,669 | 99.8% (99.7%,99.9%) N = 670 |

Table 2 – Kaplan-Meier Survivorship Estimates

| | Mean Pre-op HHS (SD; N) | Mean 1 Year HHS (SD; N) | Mean 2 Year HHS (SD; N) | Mean 3 Year HHS (SD; N) | Mean 4 Year HHS (SD; N) |
|--------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| All Hips (N=4,388) | 53.1 (14.0; 3,532) | 95.5 (7.9; 1,562) | 95.4 (7.8; 538) | 95.3 (7.4; 116) | 96.6 (4.8; 85) |

Table 3 – Mean Harris Hip Scores