**Paper #7**

**Comparing the Incidence of Patellofemoral Complications in a New Total Knee Arthroplasty System vs. Currently Available Products in Two, World-Wide, Multi-Center Prospective Clinical Studies**

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**Introduction:** Patellofemoral complications in TKA include crepitus and clunk (PCCs), which are associated more commonly with posterior stabilized (PS) components. The cumulative incidence rate (CIR) of PCCs and CIR of symptomatic patellofemoral crepitus excluding clunk (SC) at both 1-year and 2-year post-op using a new knee implant system (NEW-TKA) were compared to currently available products (CA-TKA).

**Methods:** From October 2011-March 2015, 22 investigators (from US, UK, Australia, New Zealand) prospectively enrolled 845 patients with CA-TKA. 422 (50%) received a PS-configuration. From November 2012-May 2015, 23 investigators (19 from CA-TKA study) enrolled 1,138 patients in the NEW-TKA study. 584 (51%) received a PS-configuration. PCCs were compared and a focused comparison of SC excluding clunk was analyzed. CIR was estimated with Kaplan-Meier time-to-event methodology. The time variable was time to first observation of the event, or last clinical follow-up or death if there was no event. The CIR was 100% minus Kaplan-Meier event-free survivorship.

**Results:** Demographics and length of follow-up were similar. In CA-TKA, 29-PCCs (27 Crepitus, 2 Clunk) were reported with a CIR of 5.14% at 1-year and 6.74% at 2-years. For NEW-TKA, there were 16-PCCs (14 Crepitus, 2 Clunk). CIR was 2.96% at 1-year and 4.78% at 2-years. In CA-TKA there were 13-SCs (11 PSRP, 2 PSFB), of which 11 occurred prior to 2-years post-op, with a CIR of 2.97%, whereas for NEW-TKA, there were 5-SCs (4 PSRP, 1 PSFB) of which all occurred prior to 2-years post op with a CIR of 1.69%. A log-rank test showed that differences in the point-wise estimates of PCC and SC among PS knees were not statistically significant through 2-years post-op with these interim data (p-value for PCC=0.262; p-value for SC=0.207).

**Conclusions:** At 1-year, incidence of SC in NEW-TKA was half of that for CA-TKA; while not statistically significant, this trend is promising. Longer follow-up is ongoing. The time to event methodology is useful for comparing adverse events with cohorts of varying follow-up times.