APEX Knee™ System Survivorship

INTRODUCTION

Survival analysis is an important tool for assessing the outcome of total joint replacement. Registries from Australia, Sweden, and the UK provide survival data for products listed in the registries that can be used to benchmark similar devices. This paper provides a review of the APEX Knee System survival estimate based on the information known to OMNIlife science (OMNI). Survival of the APEX Knee System is based on reports of revisions provided by any source but generally from physicians, hospitals and sales professionals. Although all devices implanted in the US are included, all revisions may not be reported to OMNI.

PRODUCT

The APEX Knee System is a primary or revision total knee replacement and is intended for use with or without bone cement. The APEX total knee replacement system consists of a range of sizes of cobalt chrome femoral components with a deep patellar groove, dome shaped UHMWPE patella resurfacing components, UHMWPE tibial inserts, Cobalt Chrome tibial baseplates with or without a Titanium-Hydroxylapatite porous coating, and a titanium alloy locking bolt. A range of non-irradiated, ETO sterilized, UHMWPE inserts are available. The modular configuration allows the surgeon user to choose a combination of femoral and tibial baseplate component sizes to appropriately fit the anatomy of the patient, and to use a tibial insert with a size-for-size match to the femoral component.

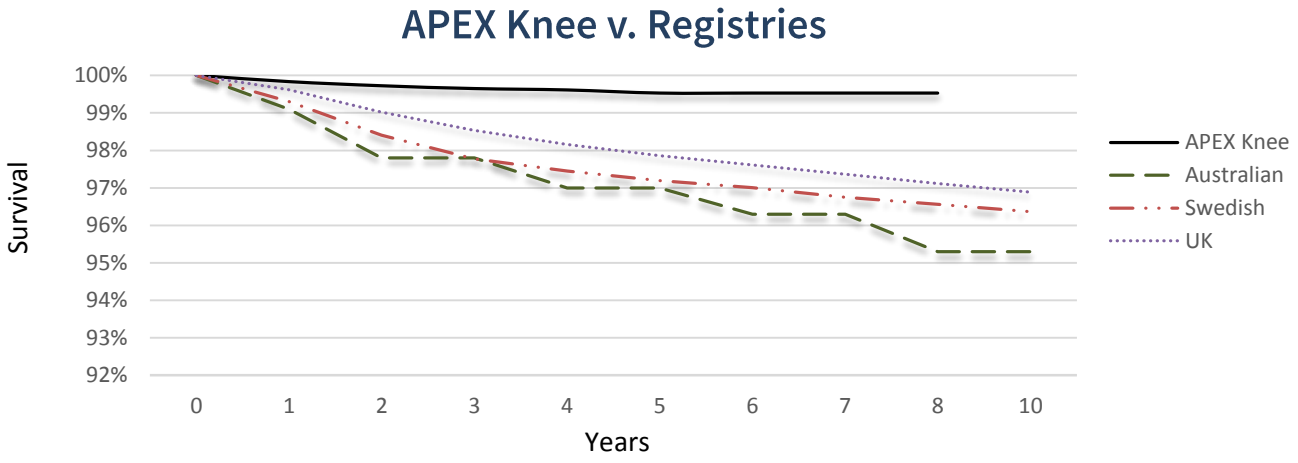
MARKET HISTORY

The APEX Knee System is available in APEX CR™ or APEX PS™ femoral designs. Cruciate retaining "Congruent" or cruciate substituting "Ultra" tibial inserts are available for use with the APEX CR femoral component. The APEX PS is a posterior stabilized post and cam design. The APEX CR Knee, and both Congruent and Ultra inserts, received US FDA clearance in 2006, the APEX PS Knee was cleared in 2011. The European CE Mark was obtained in 2010.

KAPLAN-MEIER SURVIVAL ESTIMATE

The Kaplan-Meier (K-M) survival estimate is used in this report to provide the probability of the APEX Knee System surviving a given length of time based on the number of patients implanted with each type of device and the length of time to reported revisions. The K-M estimate is frequently reported in the literature and registries.

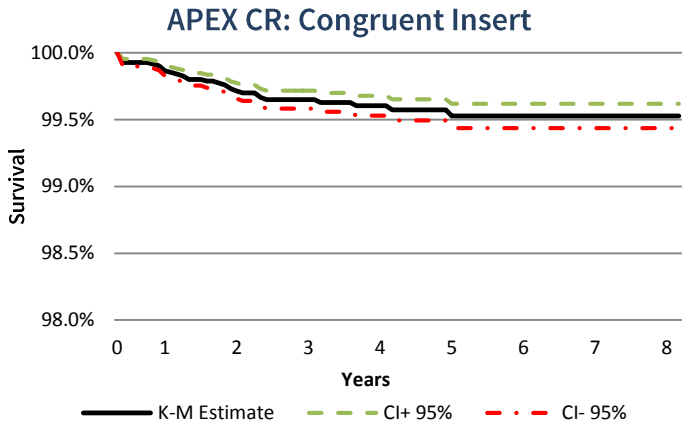
The survival estimates for the APEX Knee System are based on all units implanted in the United States and revisions reported for any reason. This report relies on doctors, hospitals and sales representatives to report revisions and it is likely that not all revisions are reported. The primary reasons for revision are similar to those reported in the registries including infection, instability, loosening, pain and fracture.

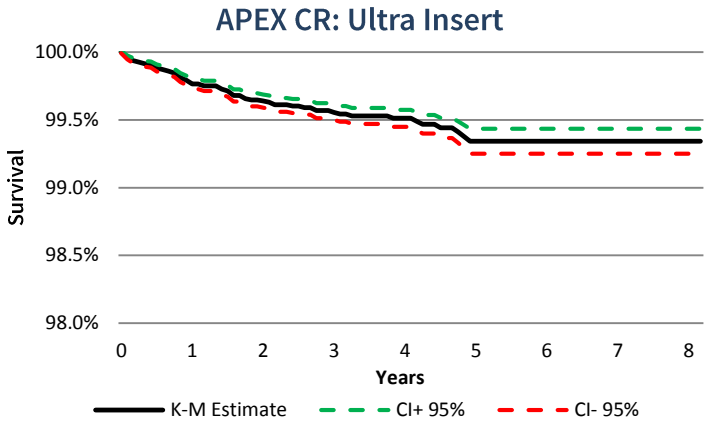


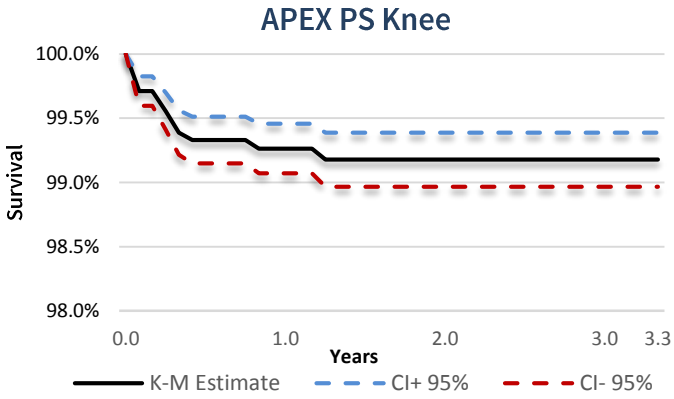
The survival estimate for the APEX Knee System (all types combined) is compared below to data published in the Australian, Swedish and UK national registries [1,2,3] for primary knee arthroplasty. The APEX Knee System has not been distributed in the geographic areas covered by the registries in sufficient quantities to be included in registry data.

SURVIVAL BY PRODUCT

The Kaplan-Meier Survival Estimate has been calculated separately for the APEX CR™ (Congruent & Ultra) and APEX PS™ and plotted below. The plots include a 95% confidence interval (CI) using Greenwood's method. [4]







DISCUSSION

The purpose of this review was to compare APEX Knee™ System survival to similar products. The Kaplan-Meier method is used to estimate the incidence of revision over the time the products have been on the market. The survival estimate for the APEX Knee is above 99%. The reasons for revisions are similar to the primary reasons reported in the registries. This report does not account for non-reporting or competing events that preclude revision such as death. It should be noted that the survivor function at the far right of the K-M survival curve should be interpreted cautiously since there are fewer patients remaining in the study group and the survival estimates are not as accurate. [5]

The APEX Knee System has been shown to have an excellent survival record when compared to registry data for knee systems. Although it cannot be assured that all APEX Knee System revisions are reported to OMNI, reports from all sources are investigated and included in this report.

REFERENCES

1. Australian Orthopaedic Association Hip and Knee Arthroplasty, Annual Report 2014
2. National Joint Registry of England and Wales, 9th Annual Report 2014
3. Swedish Knee Arthroplasty Register Annual Report 2013
4. Kaplan EL, Meier P, Nonparametric estimation from incomplete observations. J Am Stat Assoc 1958;53:457-81.
5. Jason T. Rich, MD et al., A practical guide to understanding Kaplan-Meier curves, Otolaryngology-Head and Neck Surgery (2010) 143, 331-336.

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