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Effect of Implant Design on Knee Flexion

Douglas A. Dennis MD [a], R. David Heekin MD [b], Charles R. Clark MD [c], Jeffrey A. Murphy MS [d], Tammy L. O'Dell CCRC, CCRA [d], Kimberly A. Dwyer PhD, CCRA [d]

[a] Colorado Joint Replacement, Denver, Colorado
[b] Heekin Orthopaedics, Jacksonville, Florida
[c] University of Iowa Hospitals & Clinics, Orthopaedic Surgery 01075-JPP, Iowa City, Iowa
[d] DePuy Orthopaedics, Warsaw, Indiana

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ABSTRACT

From March 2006 to August 2008, 93 subjects (186 knees) underwent simultaneous bilateral total knee arthroplasty performed by eight surgeons at North American centers. This randomized study was conducted to determine whether non-weight-bearing passive flexion was superior for knees receiving a posterior stabilized high flexion device compared to a posterior stabilized standard device in the contra-lateral knee. Weight-bearing single leg active flexion was one secondary endpoint. Follow-up compliance was 92.5%. Results show small, but significant superiority in the motion metrics for the high flexion device compared to the standard device 12 months after surgery, especially for a subgroup of patients with pre-operative flexion less than 120° in both knees. Thus, the ideal candidate for the high flexion device may be one with lesser pre-operative flexion.

Orthopaedic surgeons are replacing knees in younger, more active subjects who have elevated expectations of implant performance. Expectations include restoration of joint function, including greater knee flexion [1–3]. To address these heightened expectations, many orthopaedic companies have enhanced their total knee arthroplasty (TKA) portfolios by including devices specifically designed to provide high flexion (HF) [4].

Early published results comparing flexion of HF to standard (STD) devices are mixed. Two randomized, controlled trials [5,6] comparing STD to HF knees of fixed tibial bearing, posterior stabilized designs found no significant differences in knee flexion between the groups, although Nutton et al. [6] admitted their unilateral study was underpowered. A third study [4], which was a matched-pair study comparing rotating platform, posterior stabilized STD to HF devices (of the same design as those used in this study) demonstrated enhanced flexion in those subjects implanted with the HF design, particularly in those subjects whose pre-operative knee flexion was less than 120°.

Knee flexion after TKA is affected by multiple variables including implant design, surgical technique, physical therapy regimen, post-operative pain management protocol, and subject factors such as pre-operative flexion, body habitus, and subject motivation [1,2,7,8]. Therefore, we designed this simultaneous bilateral study in which each subject would receive both devices and therefore, eliminate most of these variables, that is surgical technique, physical therapy regimen, post-operative pain management protocol, body habitus, and subject motivation, from interfering with any flexion differences that may exist between the HF and STD knee designs. Both the HF and STD designs were from the same knee implant family (P.F.C. Sigma Rotating Platform and P.F.C. Sigma Rotating Platform High Flexion, DePuy Orthopaedics, Warsaw, Indiana). We defined 'simultaneous' bilateral as implanted during the same bilateral TKA procedure. Consequently, the HF feature of the implant could be evaluated without confounding variables present in non-bilateral studies [9,10].

The primary objective of this study was to determine whether the HF design provided superior non-weight-bearing passive flexion (PF) compared to the STD design 6 and 12 months after surgery. Twelve months was chosen as the maximum time for endpoint comparison because most studies show no change in motion beyond the first year [5,7,11–14]. Secondary study objectives included identification of pre-operative factors, such as body mass index (BMI), gender, age, thigh girth, and skin-fold thickness, which may be associated with improved flexion with this HF design.

Materials and Methods

Each subject received a standard (STD) device in one knee and a high flexion (HF) device in the other, eliminating most confounding variables present in non-bilateral studies [9,10]. From March 2006 to August 2008, data were collected prospectively for 93 subjects (186 knees) who underwent simultaneous bilateral total knee

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Reprint requests: Douglas A. Dennis, MD, Colorado Joint Replacement, 2535 S. Downing Street, #100, Denver, CO 80210.

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arthroplasty (TKA) performed during the same operative procedure from eight experienced joint replacement specialists across eight North American centers. Allocation of subjects for enrollment was evenly distributed amongst the eight centers; however, there were varying degrees of enrollment attained at each center (see Fig. 1).

Criteria for inclusion included males and females age 40–70, inclusive, subjects willing to return for all post-operative follow-ups, suitable bilateral candidates for the devices specified in the protocol, and voluntary, written informed consent. Subjects were excluded if they had a diagnosis of inflammatory arthritis, flexion contracture greater than 20°, involved in litigation or worker's compensation claims, known drug, alcohol or psychological disorders that could affect follow-up care, participation in a clinical investigation with an investigational product in the last three months, previous revision, and pregnant or lactating females.

The 93 subjects enrolled in the study were considered the Safety Dataset and underwent adverse event analysis. Twelve of these 93 subjects did not complete the primary endpoint, non-weight-bearing passive flexion (PF), 12 months after surgery (see Fig. 1). One subject withdrew consent 10 months after the bilateral surgeries; the withdrawal was unrelated to either implant. There were two protocol violations in which the STD components (femurs with lugs) were not listed in the study protocol, but the appropriate HF devices were implanted on the contra-lateral side. One of the two subjects with a protocol violation had their eligible HF knee complete the primary endpoint; therefore, that knee was used in unpaired analyses. There were two revision TKA procedures, one HF device and one STD device. The HF device was revised 6 months after the index surgery and the STD at 7 months; both revisions were secondary to deep infection, and were performed at different centers. The remaining seven subjects were lost to follow-up, leaving 81 bilateral subjects available for the Primary Efficacy Dataset and respective analyses (Fig. 1), and provides a 92.5% (86 of 93) subject follow-up compliance rate.

There were two protocol deviations in which 71- and 73-year old subjects were inadvertently enrolled when the study maximum specified age was 70. This age criterion was set to help ensure strong subjects were enrolled because of the invasive nature of this bilateral

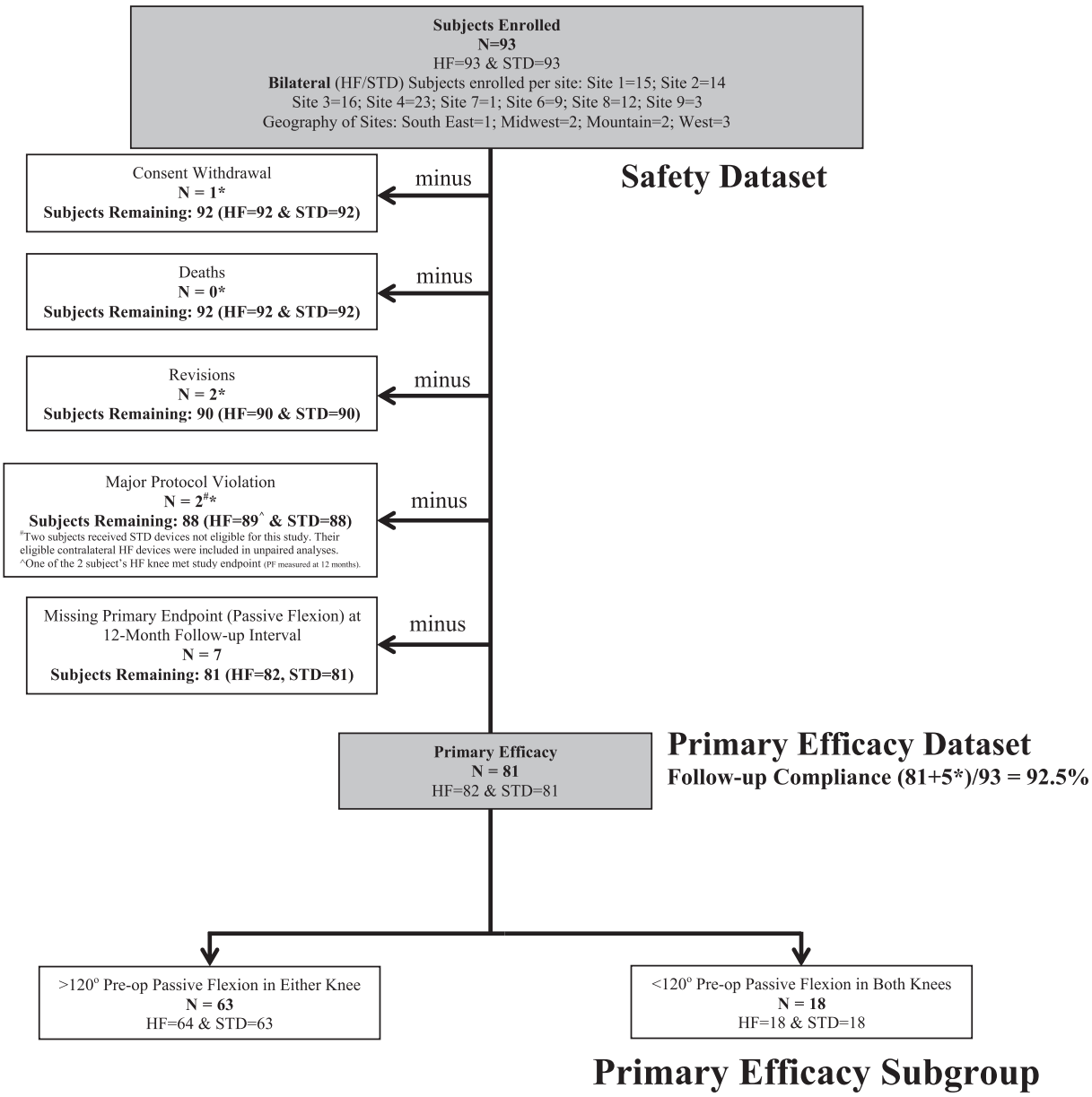

Fig. 1. Subject accountability flowchart demonstrating two main datasets for analysis: Safety Dataset and Primary Efficacy Dataset.