

SECTION VII - SUMMARY OF UNPUBLISHED DATA

This section contains summaries of mobile bearing knee information obtained from seven ongoing IDE studies and two international clinical outcomes studies. A summary table of 1 and 2 year global knee rating scale data and brief summaries of each study are presented in this section. Complete data from each study is presented in Appendix 2.

**Table 1: IDE Study - Summary Table, Global Knee-Rating Scale Data
% Good To Excellent At 1 And 2 Years**

Knee	Manufacturer	% Good to Excellent*	
		1 year	2 year
TRAC PS Mobile Bearing Knee	Biomet Orthopedics, Inc.	77.4	83.7
Oxford Meniscal Bearing Unicompartmental Knee - Phase 2	Biomet Orthopedics, Inc.	----	95.2
Genesis II Mobile Bearing Knee	Smith & Nephew Orthopaedics	89	----
Profix Mobile Bearing Knee	Smith & Nephew Orthopaedics	92	----
MBK Mobile Bearing Knee	Zimmer, Inc.	89.7	89.3
NexGen LPS-Flex Mobile Knee	Zimmer, Inc.	84	----

The Scorpio[®] + PS Mobile Bearing Knee (Stryker Howmedica Osteonics) IDE has data less than 1 year and is, therefore, not included in this table.

* Global knee-rating scale, KSS or HSS

**Table 2: International Clinical Outcomes Studies - Summary Table,
Global Knee-Rating Scale Data
% Good To Excellent At 1 And 2 Years**

Knee	Manufacturer	% Good to Excellent*	
		1 year	2 year
MBK Mobile Bearing Knee	Zimmer, Inc.	A: 81**	A: 86
		B: 87	B: 84
		C: 67	C: 74
NexGen LPS-Flex Mobile Knee	Zimmer, Inc.	A: 93	A: 100
		B: 79	B: 67
		C: 91	C: 100

* Global knee rating scale, KSS or HSS

** Patient categories: A - Unilateral or bilateral knees, opposite knee successfully replaced; B - Unilateral knee, opposite knee symptomatic; C - Multiple arthritis or medical infirmity (Insall, 1989)

IDE Study Summaries

Biomet Orthopedics, Inc.

1. TRAC PS Mobile Bearing Knee



This IDE study was performed as a clinical prospective multicenter trial that enrolled 130 patients with an average mean follow-up of 2.2 years. A global knee-rating scale (KSS) was used to assess effectiveness. A total of 102 patients were available for follow-up at one year. Good to excellent results were reported among 77.4% of patients. At two years, 86 patients were available for follow-up and good to excellent results were reported for 83.7% of patients. At three years of follow-up, 33 patients were available for follow-up and good to excellent results were reported for 84.9% of patients. At four years, good to excellent results were reported for 100% of patients (N=6). A total of 7 revisions have occurred in the study: 5 due to polyethylene dislocation, 1 for insert sublaxation, and 1 for patient dislike (noise). Overall, the revision rate was 5.4%.

2. Oxford Meniscal Bearing Unicompartmental Knee - Phase 2



This IDE study was performed as a clinical prospective multicenter trial that enrolled 104 patients with an average mean follow-up of 4.8 years. The Hospital for Special Surgery scale was used to assess effectiveness. Good to excellent results were reported at 95.2% for the 104 patients (2 year +). A total of 16 revisions occurred during the conduct of the study for a revision rate of 15.4%. Reasons for revision were as follows: 4 for lateral compartment degeneration (continuing OA), 3 for aseptic loosening of the femur, 2 for polyethylene dislocation, 1 for deep infection, 1 for aseptic loosening of the tibial component, 1 for polyethylene wear (caused by an osteophyte), 1 for patellar complications, 1 for rheumatoid arthritis on-set, 1 due to automobile accident, and 1 for improper alignment.

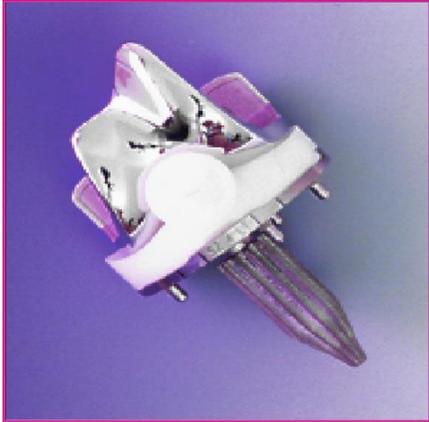
Smith & Nephew Orthopedics

3. Genesis II Mobile Bearing Knee



This IDE study was designed as a prospective, multicenter, randomized study. Enrollment is continuing and a total of 109 patients (119 knees) have been enrolled thus far and the average follow-up is 1 year (range: 3 months to 2 years). The mean KSS score at one year is 89 and 2 revisions have occurred (revision rate 1.7%). Reasons for revision were deep infection and polyethylene subluxation.

4. Profix Mobile Bearing Knee



This IDE study was designed as a prospective, multicenter, randomized study. Enrollment is continuing and a total of 59 patients have been enrolled thus far and the average follow-up is 9 months (range: 3 months to 2 years). The mean KSS score at one year is 92 and no revisions have occurred.

Stryker Howmedica Osteonics

5. Scorpio[®]+ PS Mobile Bearing Knee



This study is a prospective, randomized, single blind multicenter clinical trial. Enrollment is currently ongoing and a total of 62 patients have been enrolled thus far. The average mean follow-up is 3 months. Good to excellent results at the 6 month interval have been reported for 12 patients as 75%. There have been no revisions in the study.

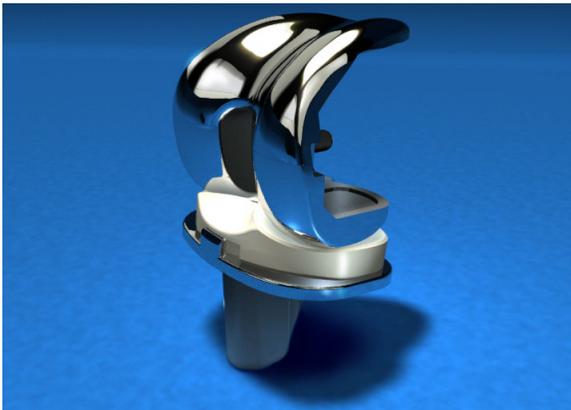
Zimmer, Inc.

6. MBK Mobile Bearing Knee



This study was performed using a clinical prospective multicenter design. A total of 179 patients have been enrolled. The average mean follow-up is 1.5 years. KSS good to excellent results were 89.7% at 1 year with 145 patients reporting. Two year results for 65 patients reporting were 89.3%. Three revisions (revision rate: 1.7%) have occurred during the conduct of the study. Reasons for revision were: 1 for deep infection, 1 for pain, and 1 for PCL insufficiency (polyethylene exchange required).

7. NexGen LPS-Flex Mobile Knee



This study is a prospective, randomized, single blind multicenter clinical trial. Enrollment is currently ongoing and a total of 61 mobile bearing patients have been enrolled thus far. Enrollment is still continuing and patient follow-up is as follows: 100% at 6 weeks, 85% at 6 months, and 72% at 1 year. KSS good to excellent results were 84% at 1 year for the mobile bearing group (N=18). There have been no revisions in the study.

International Clinical Outcome Study Summaries

Two international clinical outcomes studies are currently underway. A total of more than 1,600 patients have been enrolled, with 2 year follow-up data available for 132 patients. These studies feature open enrollment, with no patient selection criteria beyond those described in standard product labeling. Surgeon participation is open and includes surgeons in Europe, Asia, and the Middle East. Information from these studies therefore may be more widely generalizable than from more limited IDE-type studies.

Zimmer, Inc.

1. MBK Mobile Bearing Knee

In an international outcomes study of the MBK Mobile Bearing Knee design, there were 1,254 cases implanted by 22 surgeons from 7 countries (Australia, Canada, France, Germany, Italy, Spain, and the United Kingdom). At one year, among patients who had a unilateral or bilateral replacement (Insall Category A) KSS good to excellent results were found for 81% of patients (N=447). At two years, 85.7% of patients (N=223) reported good to excellent results. For patients who had one knee replaced but the other remained symptomatic (Insall Category B) at 1 year, good to excellent KSS scores were reported for 87% of patients (N=223). At two years, 83.8 % of patients (N=117) had good to excellent results. For patients with multiple arthritis or medical infirmity (Insall Category C), at one year 67% had good to excellent results (N=143), and at 2 years, 74% had good to excellent results (N=74). A total of 8 revisions have occurred (revision rate: 0.6%) for the following reasons: 2 for patellar complications, 4 for fixed flexion deformity or stiffness, and 2 for some other unspecified reason.

2. NexGen LPS-Flex Mobile Knee

In an international outcomes study initiated in 1999, using the NexGen LPS Flex Mobile Knee design, there have been 390 implantations by 19 surgeons from 17 centers from Europe, the United Arab Emirates, and Japan. At 1 year, among patients who had a unilateral or bilateral replacement (Insall Category A) KSS good to excellent results were found for 93% of patients (N=80). At two years, these patients (N=15) reported good to excellent results of 100%. For patients who had one knee replaced but the other remained symptomatic (Insall Category B), good to excellent results were reported at 1 year for 79% of patients (N=24). At two years, 67% of these patients had good to excellent results (N=3). For patients with multiple arthritis or medical infirmity (Insall Category C), at one year 91% had good to excellent results (N=55), and at 2 years, 100% had good to excellent results (N=4). Two revisions (revision rate: 0.5%) have occurred: 1 for deep infection and 1 for instability.